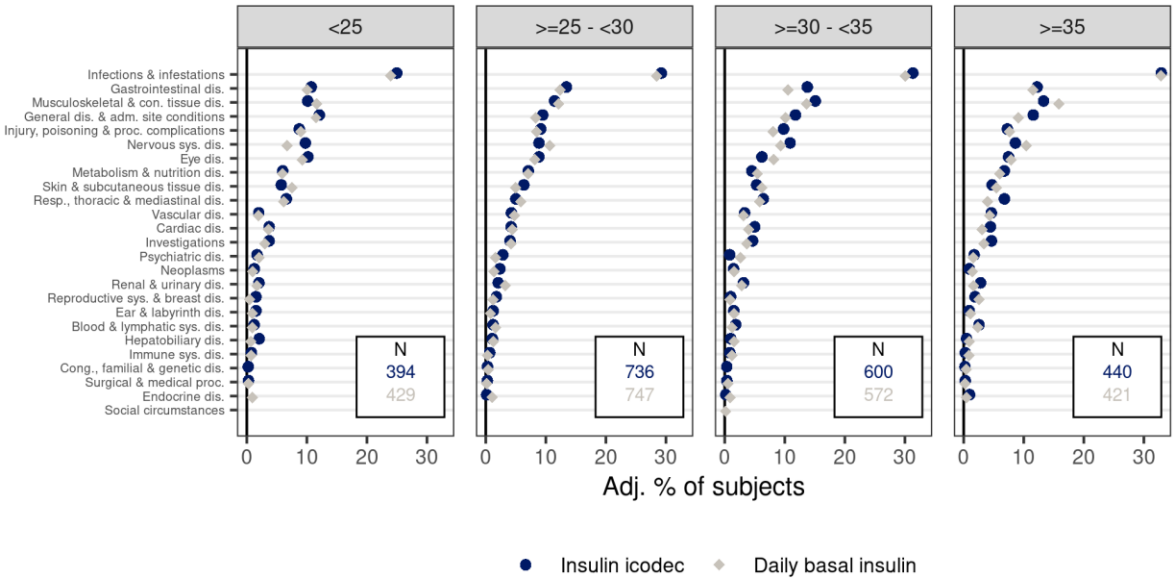
7.7.61 Adverse events by baseline BMI group and system organ class - on-treatment/main-on-treatment - dot plot - safety analysis set - phase 3a pool

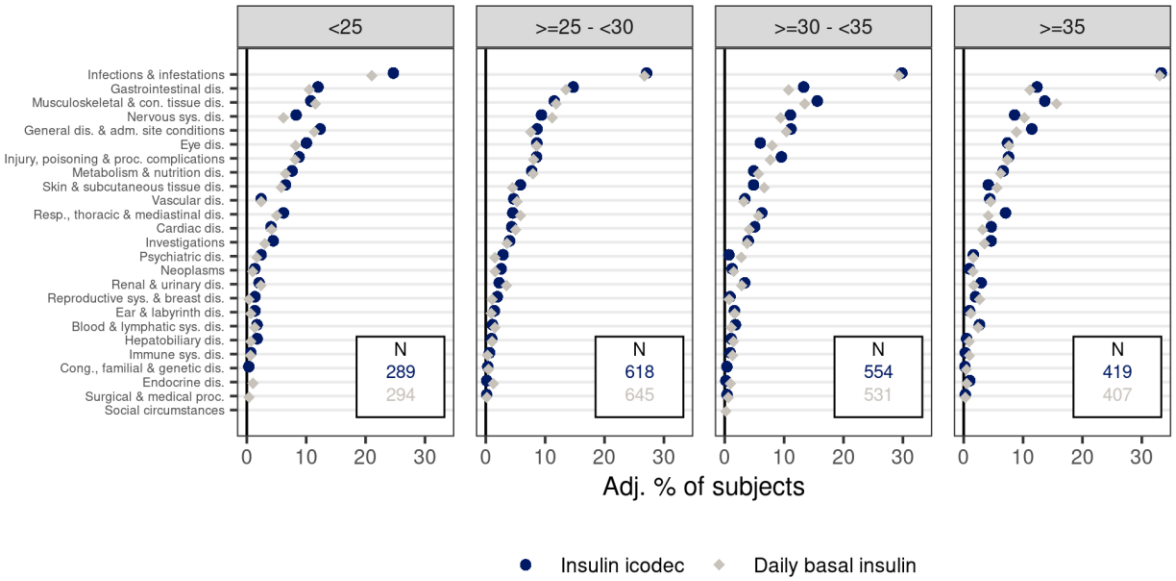


% of subjects: Percentage of subjects with one or more events, BMI: Body mass index (kg/m$^{2)}$, N: Number of subjects, dis.: disorders, adm.: administration, con.: connective, proc.: procedural/procedures, sys.: system, resp.: respiratory, cong.: congenital. Adj.: Adjusted percentages were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. Safety analysis set. MedDRA version 24.1. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adsl.xpt; variable(s): BMIG1BL; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS BMIG1BL; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:59:32 - faedotgrp/faesocgrpbmidotontp3asas.png

7.7.62 Adverse events by baseline BMI group and system organ class - on-treatment/main-on-treatment - dot plot - safety analysis set - T2D pool

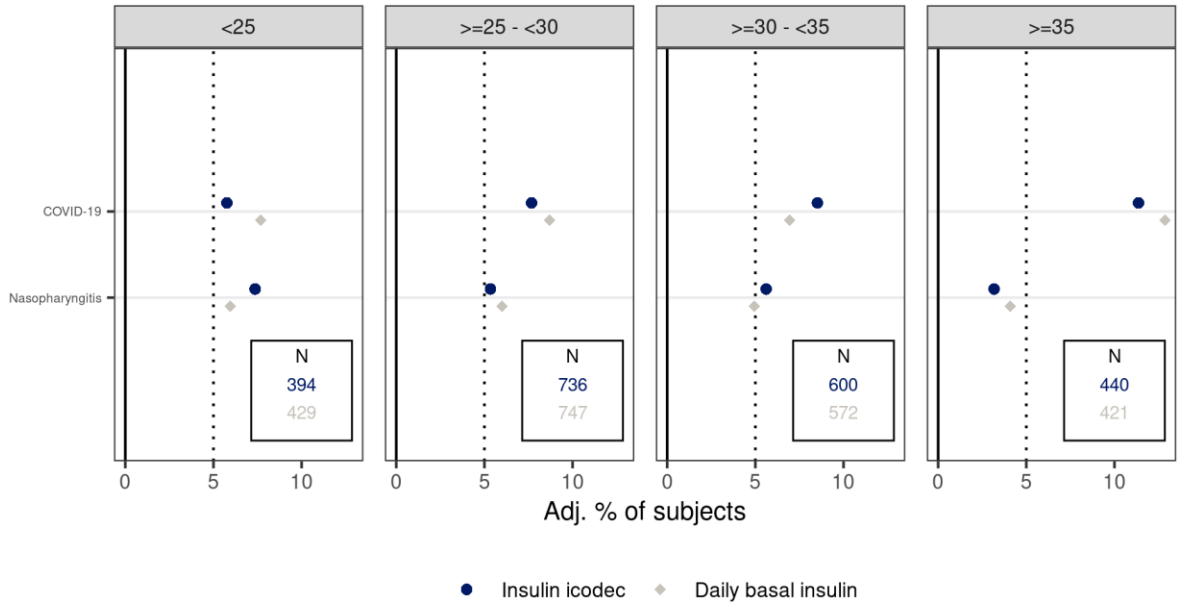


% of subjects: Percentage of subjects with one or more events, BMI: Body mass index (kg/m$^{2)}$, N: Number of subjects, dis.: disorders, adm.: administration, con.: connective, proc.: procedural/procedures, sys.: system, resp.: respiratory, cong.: congenital, Adj.: Adjusted percentages were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. Safety analysis set. MedDRA version 24.1. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): BMIG1BL; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS BMIG1BL; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:59:36 - faedotgrp/faesocgrpbmidotontt2dsas.png

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

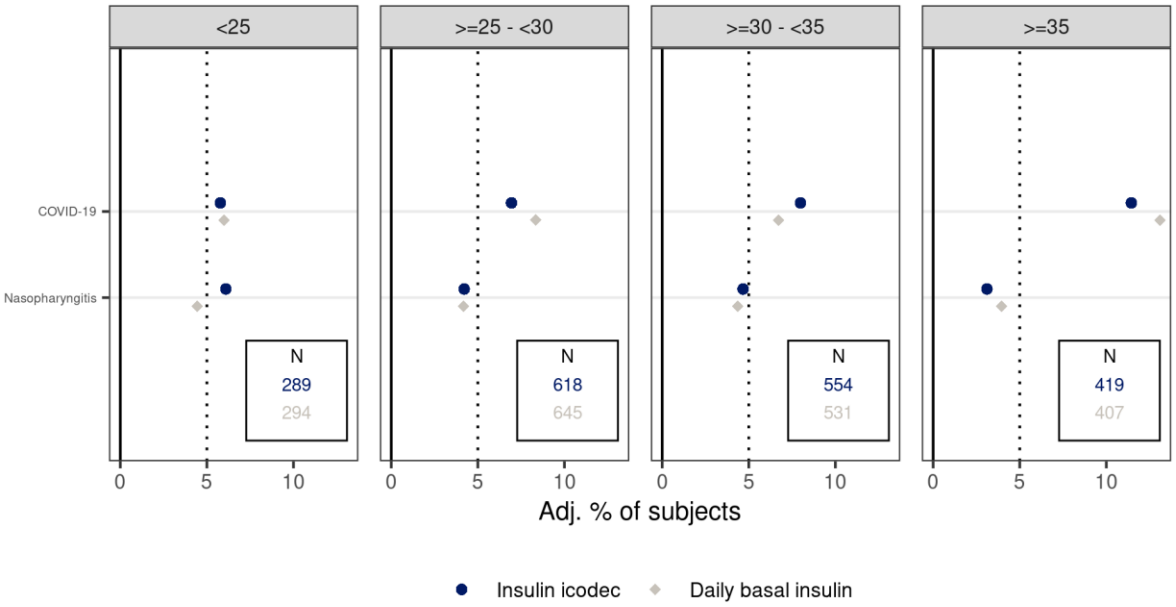


% of subjects: Percentage of subjects with one or more events, BMI: Body mass index ($kg/m^{2)}$, N: Number of subjects. Adj.: Adjusted percentages were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. Safety analysis set. MedDRA version 24.1. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adsl.xpt; variable(s): BMIG1BL; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEDECOD BMIG1BL; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:59:41 - faedotgrp/faept5pctgrpbmidotontp3asas.png

7.7.64 Adverse events by baseline BMI group 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, BMI: Body mass index (kg/m$^{2)}$, 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. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): BMIG1BL; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEDECOD BMIG1BL; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:59:47 - faedotgrp/faept5pctgrpbmidotontt2dsas.png

7.7.65 Adverse events by baseline renal function - on-treatment/main-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								
Normal	1121				1137			
Mild impairment	837				791			
Moderate or severe impairment	211				241			
Missing	1				1			
PYE (years)								
Normal	868.19				876.95			
Mild impairment	649.05				615.74			
Moderate or severe impairment	163.41				187.56			
Missing	0.58				0.33			
Events								
Normal	663	(59.2)	1934	241.66	641	(56.5)	1870	233.04
Mild impairment	534	(63.9)	1693	279.10	481	(60.7)	1513	267.73
Moderate or severe impairment	131	(62.2)	358	229.64	141	(58.5)	495	274.89
Missing	0				0			
Serious								
Yes								
Normal	65	(5.8)	101	11.84	70	(6.2)	100	11.51
Mild impairment	72	(8.6)	100	15.85	61	(7.7)	75	11.36
Moderate or severe impairment	29	(13.8)	44	27.39	38	(16.0)	63	32.49
Missing	0				0			
No								
Normal	646	(57.7)	1833	229.83	630	(55.5)	1770	221.53
Mild impairment	517	(61.8)	1593	263.25	463	(58.4)	1438	256.37
Moderate or severe impairment	124	(58.9)	314	202.25	130	(53.8)	432	242.41
Missing	0				0			
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. 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 renal function - on-treatment/main-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								
Normal	40	(3.6)	52	6.84	39	(3.4)	55	5.82
Mild impairment	34	(4.1)	45	7.08	29	(3.7)	34	5.02
Moderate or severe impairment	18	(8.6)	24	15.86	21	(8.8)	44	22.54
Missing	0				0			
Moderate								
Normal	256	(22.9)	467	56.32	256	(22.5)	452	54.73
Mild impairment	205	(24.5)	371	58.53	164	(20.7)	295	47.96
Moderate or severe impairment	51	(24.3)	93	56.77	58	(24.1)	109	57.68
Missing	0				0			
Mild								
Normal	547	(48.8)	1415	178.50	547	(48.2)	1363	172.49
Mild impairment	463	(55.4)	1277	213.49	410	(51.7)	1184	214.76
Moderate or severe impairment	103	(48.8)	241	157.01	116	(48.0)	342	194.67
Missing	0				0			
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. 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 renal function - on-treatment/main-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								
Normal	39	(3.5)	60	8.82	39	(3.4)	75	8.55
Mild impairment	38	(4.6)	54	8.95	31	(3.9)	48	8.15
Moderate or severe impairment	5	(2.4)	6	3.58	6	(2.5)	10	5.24
Missing	0				0			
Possible								
Normal	47	(4.2)	61	8.47	46	(4.0)	55	7.23
Mild impairment	70	(8.4)	102	18.13	47	(5.9)	96	18.17
Moderate or severe impairment	8	(3.7)	16	10.32	12	(4.9)	27	18.17
Missing	0				0			
Unlikely								
Normal	638	(56.9)	1807	223.55	621	(54.7)	1738	217.03
Mild impairment	511	(61.1)	1532	251.10	468	(59.0)	1366	240.92
Moderate or severe impairment	127	(60.3)	335	214.85	137	(57.0)	457	250.82
Missing	0				0			
Missing								
Normal	4	(0.4)	6	0.82	2	(0.2)	2	0.23
Mild impairment	3	(0.3)	5	0.92	3	(0.4)	3	0.48
Moderate or severe impairment	1	(0.5)	1	0.88	1	(0.4)	1	0.66
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. 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 renal function - on-treatment/main-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								
Normal	4	(0.4)	4	0.63	4	(0.3)	5	0.74
Mild impairment	6	(0.7)	6	1.20	0			
Moderate or severe impairment	1	(0.4)	1	0.77	3	(1.3)	3	2.35
Missing	0				0			
No								
Normal	661	(59.0)	1924	240.22	638	(56.2)	1861	231.77
Mild impairment	534	(63.9)	1682	276.98	480	(60.5)	1510	267.25
Moderate or severe impairment	130	(61.6)	355	227.11	140	(58.1)	491	271.89
Missing	0				0			
NA								
Normal	0				1	(0.1)	1	0.14
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.88	0			
Missing	0				0			
Missing								
Normal	4	(0.4)	6	0.82	3	(0.3)	3	0.38
Mild impairment	3	(0.3)	5	0.92	3	(0.4)	3	0.48
Moderate or severe impairment	1	(0.5)	1	0.88	1	(0.4)	1	0.66
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. 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 renal function - on-treatment/main-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								
Normal	4	(0.4)	6	0.73	5	(0.4)	6	0.64
Mild impairment	4	(0.5)	5	0.84	4	(0.5)	5	0.73
Moderate or severe impairment	6	(2.9)	7	5.21	4	(1.6)	4	1.88
Missing	0				0			
Not recovered/not resolved								
Normal	274	(24.4)	508	60.96	278	(24.5)	513	61.65
Mild impairment	260	(31.3)	483	79.91	227	(28.5)	396	69.08
Moderate or severe impairment	55	(26.0)	96	59.72	65	(26.8)	133	68.85
Missing	0				0			
Recovered/resolved with sequelae								
Normal	2	(0.2)	2	0.17	6	(0.5)	6	0.68
Mild impairment	6	(0.7)	6	0.88	6	(0.7)	7	1.11
Moderate or severe impairment	2	(1.0)	2	1.03	4	(1.7)	5	3.16
Missing	0				0			
Recovering/resolving								
Normal	44	(4.0)	73	9.92	39	(3.4)	48	5.95
Mild impairment	42	(4.9)	52	8.36	35	(4.4)	43	7.85
Moderate or severe impairment	10	(4.6)	11	6.75	18	(7.3)	20	11.66
Missing	0				0			
Recovered/resolved								
Normal	557	(49.7)	1345	169.88	537	(47.3)	1296	164.04
Mild impairment	453	(54.2)	1147	189.12	388	(48.9)	1061	188.84
Moderate or severe impairment	112	(53.3)	241	156.47	114	(47.3)	333	189.34
Missing	0				0			
Unknown								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Missing	0				0			
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. 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.

7.7.66 Adverse events by baseline renal function - on-treatment/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								
Normal	924				947			
Mild impairment	749				698			
Moderate or severe impairment	206				232			
Missing	1				1			
PYE (years)								
Normal	770.83				783.47			
Mild impairment	606.63				569.62			
Moderate or severe impairment	160.88				183.05			
Missing	0.58				0.33			
Events								
Normal	539	(58.4)	1615	223.87	523	(55.3)	1545	209.32
Mild impairment	472	(63.0)	1511	260.31	416	(59.5)	1232	224.95
Moderate or severe impairment	128	(62.2)	352	229.43	134	(57.9)	482	274.49
Missing	0				0			
Serious								
Yes								
Normal	59	(6.4)	93	12.59	65	(6.9)	93	12.34
Mild impairment	67	(9.0)	93	15.77	59	(8.4)	73	12.24
Moderate or severe impairment	29	(14.2)	44	28.21	38	(16.5)	63	33.45
Missing	0				0			
No								
Normal	525	(56.9)	1522	211.28	514	(54.3)	1452	196.98
Mild impairment	456	(60.9)	1418	244.55	399	(57.1)	1159	212.71
Moderate or severe impairment	121	(58.8)	308	201.23	123	(53.1)	419	241.05
Missing	0				0			
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. 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 renal function - on-treatment/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								
Normal	34	(3.7)	46	6.98	36	(3.8)	51	6.14
Mild impairment	31	(4.2)	41	6.79	28	(4.0)	33	5.37
Moderate or severe impairment	18	(8.8)	24	16.33	21	(9.1)	44	23.20
Missing	0				0			
Moderate								
Normal	223	(24.1)	408	55.44	221	(23.4)	390	52.33
Mild impairment	187	(25.0)	340	56.71	151	(21.6)	272	47.72
Moderate or severe impairment	51	(25.0)	93	58.45	55	(23.8)	105	56.76
Missing	0				0			
Mild								
Normal	438	(47.5)	1161	161.45	440	(46.5)	1104	150.85
Mild impairment	406	(54.2)	1130	196.82	353	(50.5)	927	171.86
Moderate or severe impairment	100	(48.4)	235	154.65	110	(47.4)	333	194.53
Missing	0				0			
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. 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 renal function - on-treatment/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								
Normal	28	(3.1)	49	8.31	34	(3.6)	70	9.21
Mild impairment	32	(4.3)	45	7.42	29	(4.1)	45	8.36
Moderate or severe impairment	5	(2.4)	6	3.69	6	(2.6)	10	5.40
Missing	0				0			
Possible								
Normal	36	(3.9)	48	7.46	39	(4.1)	47	6.96
Mild impairment	59	(7.9)	89	16.56	38	(5.4)	64	11.76
Moderate or severe impairment	8	(3.8)	16	10.63	11	(4.7)	26	18.05
Missing	0				0			
Unlikely								
Normal	521	(56.4)	1512	207.10	503	(53.2)	1426	192.88
Mild impairment	453	(60.5)	1372	235.30	403	(57.7)	1120	204.29
Moderate or severe impairment	124	(60.3)	329	214.21	131	(56.7)	445	250.37
Missing	0				0			
Missing								
Normal	4	(0.4)	6	0.99	2	(0.2)	2	0.27
Mild impairment	3	(0.4)	5	1.04	3	(0.4)	3	0.54
Moderate or severe impairment	1	(0.5)	1	0.91	1	(0.4)	1	0.67
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. 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 renal function - on-treatment/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								
Normal	4	(0.4)	4	0.76	4	(0.4)	5	0.90
Mild impairment	6	(0.8)	6	1.36	0			
Moderate or severe impairment	1	(0.4)	1	0.79	3	(1.3)	3	2.42
Missing	0				0			
No								
Normal	537	(58.2)	1605	222.12	520	(55.0)	1536	207.79
Mild impairment	472	(63.0)	1500	257.92	415	(59.4)	1229	224.41
Moderate or severe impairment	127	(61.7)	349	226.83	133	(57.5)	478	271.40
Missing	0				0			
NA								
Normal	0				1	(0.1)	1	0.17
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.91	0			
Missing	0				0			
Missing								
Normal	4	(0.4)	6	0.99	3	(0.3)	3	0.46
Mild impairment	3	(0.4)	5	1.04	3	(0.4)	3	0.54
Moderate or severe impairment	1	(0.5)	1	0.91	1	(0.4)	1	0.67
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. 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 renal function - on-treatment/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								
Normal	4	(0.4)	6	0.88	5	(0.5)	6	0.77
Mild impairment	3	(0.4)	4	0.65	4	(0.6)	5	0.82
Moderate or severe impairment	6	(3.0)	7	5.36	4	(1.7)	4	1.94
Missing	0				0			
Not recovered/not resolved								
Normal	225	(24.3)	444	59.98	235	(24.9)	438	57.80
Mild impairment	223	(29.9)	413	69.25	189	(27.0)	329	59.54
Moderate or severe impairment	55	(26.8)	96	61.49	63	(27.0)	131	69.58
Missing	0				0			
Recovered/resolved with sequelae								
Normal	2	(0.2)	2	0.21	5	(0.5)	5	0.60
Mild impairment	6	(0.8)	6	0.99	4	(0.6)	5	0.71
Moderate or severe impairment	2	(1.0)	2	1.06	4	(1.8)	5	3.25
Missing	0				0			
Recovering/resolving								
Normal	38	(4.2)	67	10.70	37	(3.9)	46	6.74
Mild impairment	42	(5.5)	52	9.40	32	(4.6)	37	7.20
Moderate or severe impairment	10	(4.7)	11	6.95	18	(7.6)	20	12.00
Missing	0				0			
Recovered/resolved								
Normal	449	(48.6)	1096	152.10	433	(45.8)	1049	143.30
Mild impairment	404	(54.0)	1036	180.03	338	(48.3)	855	156.54
Moderate or severe impairment	109	(53.1)	235	154.10	107	(46.4)	322	187.72
Missing	0				0			
Unknown								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Missing	0				0			
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. 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.

7.7.67 Adverse events by baseline renal function, system organ class and preferred term - on-treatment/ main-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								
Normal	1121				1137			
Mild impairment	837				791			
Moderate or severe impairment	211				241			
Missing	1				1			
PYE (years)								
Normal	868.19				876.95			
Mild impairment	649.05				615.74			
Moderate or severe impairment	163.41				187.56			
Missing	0.58				0.33			
Events								
Normal	663	(59.2)	1934	241.66	641	(56.5)	1870	233.04
Mild impairment	534	(63.9)	1693	279.10	481	(60.7)	1513	267.73
Moderate or severe impairment	131	(62.2)	358	229.64	141	(58.5)	495	274.89
Missing	0				0			
Infections and infestations								
All								
Normal	333	(29.6)	510	64.30	339	(30.0)	498	61.79
Mild impairment	254	(30.3)	334	57.33	222	(28.0)	325	56.00
Moderate or severe impairment	61	(28.7)	76	49.62	63	(26.1)	82	46.81
COVID-19								
Normal	110	(9.8)	112	13.76	121	(10.8)	126	15.37
Mild impairment	54	(6.5)	56	9.54	55	(6.9)	57	8.95
Moderate or severe impairment	17	(8.0)	17	11.39	16	(6.8)	16	9.16
Nasopharyngitis								
Normal	61	(5.4)	76	10.72	54	(4.8)	62	9.00
Mild impairment	49	(5.8)	58	10.21	49	(6.2)	58	10.87
Moderate or severe impairment	7	(3.3)	7	5.15	12	(4.9)	15	9.49
Upper respiratory tract infection								
Normal	43	(3.8)	52	5.66	29	(2.5)	32	4.07
Mild impairment	22	(2.6)	25	4.27	17	(2.1)	18	2.84
Moderate or severe impairment	3	(1.4)	4	2.30	6	(2.4)	6	3.16
Urinary tract infection								
Normal	21	(1.9)	22	2.97	24	(2.1)	24	2.57
Mild impairment	16	(1.9)	17	2.94	18	(2.3)	23	3.96
Moderate or severe impairment	6	(2.9)	7	4.44	8	(3.3)	9	5.27

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Gastroenteritis								
Normal	17	(1.5)	18	2.33	10	(0.9)	10	1.34
Mild impairment	11	(1.3)	11	2.44	6	(0.8)	7	1.37
Moderate or severe impairment	4	(1.8)	4	3.17	2	(0.9)	2	1.27
Influenza								
Normal	15	(1.4)	16	2.32	23	(2.0)	26	3.58
Mild impairment	11	(1.3)	13	2.42	9	(1.1)	9	1.92
Moderate or severe impairment	3	(1.3)	3	2.00	1	(0.5)	1	0.85
Bronchitis								
Normal	15	(1.3)	15	1.84	12	(1.1)	12	1.51
Mild impairment	11	(1.3)	12	2.21	4	(0.5)	4	0.70
Moderate or severe impairment	4	(1.8)	4	2.50	3	(1.2)	3	1.23
Pharyngitis								
Normal	15	(1.3)	17	1.98	13	(1.1)	15	1.71
Mild impairment	6	(0.7)	6	1.09	3	(0.4)	4	0.71
Moderate or severe impairment	0				2	(0.9)	2	1.27
Sinusitis								
Normal	11	(1.0)	13	1.78	10	(0.9)	13	1.36
Mild impairment	7	(0.8)	7	1.14	9	(1.2)	9	1.73
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Respiratory tract infection viral								
Normal	8	(0.7)	9	1.40	6	(0.5)	7	1.13
Mild impairment	4	(0.5)	4	0.67	3	(0.4)	3	0.48
Moderate or severe impairment	0				1	(0.5)	1	0.85
Herpes zoster								
Normal	7	(0.6)	7	0.77	4	(0.4)	4	0.40
Mild impairment	4	(0.5)	4	0.57	11	(1.4)	12	1.94
Moderate or severe impairment	0				2	(0.9)	2	1.27
Pneumonia								
Normal	6	(0.5)	6	0.83	2	(0.2)	2	0.29
Mild impairment	6	(0.7)	6	0.98	2	(0.2)	2	0.24
Moderate or severe impairment	3	(1.5)	3	1.86	2	(0.9)	2	1.27
Vaginal infection								
Normal	5	(0.5)	6	0.91	1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.23
Moderate or severe impairment	0				1	(0.4)	1	0.42
Cystitis								
Normal	5	(0.5)	5	0.80	8	(0.7)	9	1.04
Mild impairment	9	(1.1)	10	1.64	7	(0.9)	8	1.34
Moderate or severe impairment	1	(0.5)	1	0.47	2	(0.9)	2	1.27

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-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								
Normal	5	(0.4)	7	0.84	5	(0.4)	5	0.61
Mild impairment	4	(0.5)	4	0.65	2	(0.3)	2	0.44
Moderate or severe impairment	0				1	(0.4)	1	0.66
Rhinitis								
Normal	5	(0.4)	5	0.45	7	(0.6)	7	0.93
Mild impairment	4	(0.5)	4	0.85	4	(0.5)	7	1.55
Moderate or severe impairment	0				0			
COVID-19 pneumonia								
Normal	5	(0.4)	5	0.59	7	(0.6)	7	0.89
Mild impairment	8	(0.9)	8	1.28	3	(0.4)	3	0.38
Moderate or severe impairment	2	(0.9)	2	1.23	1	(0.4)	1	0.40
Conjunctivitis								
Normal	5	(0.4)	5	0.62	4	(0.4)	4	0.47
Mild impairment	6	(0.7)	6	1.16	2	(0.3)	2	0.35
Moderate or severe impairment	1	(0.5)	1	0.51	1	(0.4)	1	0.42
Fungal infection								
Normal	4	(0.4)	5	0.58	2	(0.2)	2	0.24
Mild impairment	3	(0.4)	3	0.52	0			
Moderate or severe impairment	0				0			
Tooth abscess								
Normal	4	(0.4)	4	0.60	3	(0.3)	3	0.26
Mild impairment	4	(0.5)	4	0.75	3	(0.4)	4	0.68
Moderate or severe impairment	1	(0.5)	1	0.51	1	(0.5)	1	0.85
Respiratory tract infection								
Normal	4	(0.4)	4	0.51	3	(0.3)	3	0.40
Mild impairment	3	(0.4)	3	0.45	3	(0.4)	3	0.38
Moderate or severe impairment	2	(0.9)	2	1.27	0			
Gastroenteritis viral								
Normal	4	(0.4)	4	0.44	3	(0.3)	3	0.42
Mild impairment	2	(0.2)	2	0.33	3	(0.4)	3	0.49
Moderate or severe impairment	0				0			
Lower respiratory tract infection								
Normal	4	(0.4)	4	0.44	1	(0.1)	3	0.27
Mild impairment	2	(0.2)	2	0.24	1	(0.1)	1	0.24
Moderate or severe impairment	0				1	(0.4)	1	0.42
Gastrointestinal infection								
Normal	3	(0.3)	3	0.50	2	(0.2)	2	0.27
Mild impairment	0				3	(0.4)	5	0.85
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-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								
Normal	3	(0.3)	4	0.43	4	(0.4)	4	0.36
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Fungal skin infection								
Normal	3	(0.3)	3	0.42	1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Laryngitis								
Normal	3	(0.3)	3	0.26	5	(0.4)	5	0.66
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Viral infection								
Normal	3	(0.3)	3	0.35	10	(0.9)	13	1.42
Mild impairment	3	(0.4)	3	0.53	3	(0.4)	3	0.59
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Coronavirus infection								
Normal	3	(0.3)	3	0.26	3	(0.3)	4	0.58
Mild impairment	1	(0.1)	1	0.12	2	(0.3)	3	0.38
Moderate or severe impairment	0				0			
Otitis media								
Normal	2	(0.2)	2	0.32	3	(0.3)	3	0.43
Mild impairment	4	(0.5)	4	0.69	2	(0.3)	2	0.35
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Furuncle								
Normal	2	(0.2)	3	0.34	2	(0.2)	2	0.17
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Erysipelas								
Normal	2	(0.2)	2	0.24	2	(0.2)	3	0.38
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Ear infection								
Normal	2	(0.2)	2	0.18	3	(0.3)	3	0.32
Mild impairment	2	(0.2)	2	0.30	1	(0.1)	1	0.23
Moderate or severe impairment	0				1	(0.4)	1	0.40
Acute sinusitis								
Normal	2	(0.2)	2	0.17	4	(0.4)	4	0.60
Mild impairment	3	(0.4)	3	0.43	2	(0.2)	2	0.36
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-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 syncytial virus infection								
Normal	2	(0.2)	2	0.17	0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.76	0			
Gingivitis								
Normal	2	(0.2)	2	0.27	2	(0.2)	2	0.33
Mild impairment	1	(0.1)	2	0.24	3	(0.4)	3	0.57
Moderate or severe impairment	0				0			
Tonsillitis								
Normal	2	(0.2)	2	0.26	1	(0.1)	1	0.09
Mild impairment	2	(0.2)	2	0.31	1	(0.1)	1	0.23
Moderate or severe impairment	0				0			
Abscess limb								
Normal	1	(0.1)	1	0.16	2	(0.2)	3	0.51
Mild impairment	1	(0.1)	1	0.26	0			
Moderate or severe impairment	0				0			
Cellulitis								
Normal	1	(0.1)	1	0.16	2	(0.2)	3	0.38
Mild impairment	2	(0.2)	2	0.24	4	(0.5)	4	0.68
Moderate or severe impairment	1	(0.5)	1	0.47	2	(0.9)	2	1.23
Paraspinal abscess								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pulpitis dental								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.15
Mild impairment	0				3	(0.4)	3	0.57
Moderate or severe impairment	0				0			
Genital infection								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.15
Mild impairment	2	(0.2)	2	0.24	0			
Moderate or severe impairment	0				0			
Injection site abscess								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Skin infection								
Normal	1	(0.1)	1	0.16	2	(0.2)	2	0.33
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.24
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-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								
Normal	1	(0.1)	2	0.31	1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.20	1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Osteomyelitis								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Periodontitis								
Normal	1	(0.1)	1	0.16	3	(0.3)	3	0.38
Mild impairment	1	(0.1)	1	0.26	4	(0.5)	4	0.72
Moderate or severe impairment	3	(1.4)	3	1.79	0			
Pneumonia viral								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pulmonary tuberculoma								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Sepsis								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.77	0			
Viral tracheitis								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Vulvovaginal mycotic infection								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Asymptomatic COVID-19								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	0				1	(0.4)	1	0.42
Balanitis candida								
Normal	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-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								
Normal	1	(0.1)	1	0.09	1	(0.1)	1	0.15
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Chlamydial infection								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Chronic tonsillitis								
Normal	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Escherichia urinary tract infection								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Helicobacter gastritis								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Herpes simplex								
Normal	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Infected bite								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Laryngopharyngitis								
Normal	1	(0.1)	1	0.09	1	(0.1)	2	0.17
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Localised infection								
Normal	1	(0.1)	1	0.09	1	(0.1)	1	0.18
Mild impairment	2	(0.2)	2	0.33	1	(0.1)	1	0.12
Moderate or severe impairment	0				1	(0.4)	1	0.66
Mastitis								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Oropharyngeal candidiasis								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Otitis media chronic								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Tinea infection								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	1	(0.1)	1	0.20	0			
Moderate or severe impairment	0				0			
Tracheitis								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Urethritis								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Viral upper respiratory tract infection								
Normal	1	(0.1)	1	0.09	3	(0.3)	3	0.27
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Acarodermatitis								
Normal	1	(0.1)	1	0.08	3	(0.3)	3	0.26
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Appendicitis								
Normal	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Chronic sinusitis								
Normal	1	(0.1)	1	0.08	2	(0.2)	2	0.18
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Clostridium difficile colitis								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Ear infection fungal								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Helicobacter infection								
Normal	1	(0.1)	1	0.08	1	(0.1)	1	0.15
Mild impairment	1	(0.1)	1	0.18	1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Nail infection								
Normal	1	(0.1)	2	0.17	1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Paronychia								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				2	(0.3)	3	0.64
Moderate or severe impairment	1	(0.4)	1	0.76	0			
Peritonsillar abscess								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				1	(0.1)	1	0.23
Moderate or severe impairment	0				0			
Post-acute COVID-19 syndrome								
Normal	1	(0.1)	2	0.17	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Viral pharyngitis								
Normal	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Breast abscess								
Normal	1	(0.1)	1	0.18	3	(0.3)	3	0.33
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Eye infection								
Normal	1	(0.1)	1	0.18	1	(0.1)	1	0.14
Mild impairment	0				2	(0.2)	2	0.42
Moderate or severe impairment	0				0			
Genital infection fungal								
Normal	1	(0.1)	2	0.35	2	(0.2)	2	0.17
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hordeolum								
Normal	1	(0.1)	1	0.18	2	(0.2)	2	0.23
Mild impairment	2	(0.2)	2	0.24	2	(0.2)	2	0.46
Moderate or severe impairment	0				0			
Norovirus infection								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Severe acute respiratory syndrome								
Normal	1	(0.1)	1	0.18	1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Tinea cruris								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Tinea pedis								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	1	(0.1)	1	0.20	2	(0.3)	2	0.47
Moderate or severe impairment	0				0			
Vulvovaginitis								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Abdominal abscess								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Abscess								
Normal	0				1	(0.1)	1	0.09
Mild impairment	2	(0.2)	2	0.33	0			
Moderate or severe impairment	0				0			
Anal abscess								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.18	1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Bacteraemia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-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								
Normal	0				1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Bartholinitis								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Body tinea								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Breast cellulitis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Campylobacter gastroenteritis								
Normal	0				1	(0.1)	1	0.14
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cholecystitis infective								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Chronic hepatitis C								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Clostridium difficile infection								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Cystitis escherichia								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Dermatophytosis of nail								
Normal	0				1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.13
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Diabetic foot infection								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	1	(0.4)	1	0.76	0			
Diverticulitis								
Normal	0				2	(0.2)	2	0.17
Mild impairment	0				2	(0.3)	2	0.25
Moderate or severe impairment	0				1	(0.4)	1	0.42
Empyema								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Endophthalmitis								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Enteritis infectious								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.18	0			
Moderate or severe impairment	0				0			
Epididymitis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Escherichia bacteraemia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.20	0			
Moderate or severe impairment	0				0			
Eye infection bacterial								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Folliculitis								
Normal	0				1	(0.1)	1	0.14
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Fungal balanitis								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Gangrene								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Gastric infection								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gastroenteritis norovirus								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Genital candidiasis								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.20	0			
Moderate or severe impairment	0				0			
Giardiasis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Herpes dermatitis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Herpes virus infection								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Herpes zoster infection neurological								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Infected cyst								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Infected dermal cyst								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.76	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Infective iritis								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Kidney infection								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.18	0			
Moderate or severe impairment	0				0			
Labyrinthitis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Lyme disease								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Onychomycosis								
Normal	0				1	(0.1)	1	0.09
Mild impairment	2	(0.2)	2	0.31	3	(0.4)	3	0.36
Moderate or severe impairment	0				0			
Oophoritis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Oral candidiasis								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.20	0			
Moderate or severe impairment	0				0			
Otitis externa								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.20	5	(0.6)	5	0.85
Moderate or severe impairment	1	(0.5)	1	0.47	1	(0.3)	1	0.64
Otitis media acute								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				2	(0.3)	2	0.25
Moderate or severe impairment	0				0			
Parotitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Peri-implantitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Pericoronitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Pharyngotonsillitis								
Normal	0				1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.21	1	(0.1)	2	0.25
Moderate or severe impairment	0				0			
Post procedural infection								
Normal	0				0			
Mild impairment	0				2	(0.2)	2	0.34
Moderate or severe impairment	0				0			
Postoperative wound infection								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.20	1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Purulence								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Pustule								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.88	0			
Pyelonephritis								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Rotavirus infection								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Salpingitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-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 bacterial								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Skin bacterial infection								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Skin candida								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.22
Moderate or severe impairment	0				0			
Soft tissue infection								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.66
Subcutaneous abscess								
Normal	0				1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	2	0.25
Moderate or severe impairment	1	(0.5)	1	0.88	0			
Suspected COVID-19								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.20	0			
Moderate or severe impairment	0				0			
Sweat gland infection								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Tinea versicolour								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.18	0			
Moderate or severe impairment	0				0			
Urosepsis								
Normal	0				2	(0.2)	2	0.23
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Varicella								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Varicella zoster virus infection								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.88	0			
Viral rhinitis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	0				0			
Vulvitis								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.45	0			
Moderate or severe impairment	0				0			
Wound infection								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.30	1	(0.1)	1	0.22
Moderate or severe impairment	1	(0.4)	1	0.77	0			
Gastrointestinal disorders								
All								
Normal	138	(12.3)	212	25.45	127	(11.1)	166	20.96
Mild impairment	109	(13.0)	161	26.12	92	(11.6)	132	22.55
Moderate or severe impairment	30	(14.5)	45	27.33	26	(10.5)	45	23.67
Diarrhoea								
Normal	37	(3.3)	44	5.21	26	(2.3)	26	3.29
Mild impairment	39	(4.6)	48	7.72	20	(2.5)	21	3.77
Moderate or severe impairment	13	(6.4)	16	10.01	9	(3.6)	10	5.07
Nausea								
Normal	23	(2.1)	24	2.93	22	(1.9)	22	2.84
Mild impairment	14	(1.7)	14	2.27	7	(0.9)	8	1.47
Moderate or severe impairment	4	(2.0)	4	2.01	6	(2.4)	7	3.62
Vomiting								
Normal	20	(1.8)	24	3.61	11	(1.0)	11	1.54
Mild impairment	9	(1.1)	9	1.62	7	(0.9)	8	1.34
Moderate or severe impairment	2	(0.9)	6	3.10	3	(1.2)	5	2.33
Abdominal pain								
Normal	11	(1.0)	11	1.34	7	(0.6)	8	1.02
Mild impairment	6	(0.7)	6	0.87	8	(1.0)	8	1.18
Moderate or severe impairment	0				3	(1.3)	3	2.09
Gastrooesophageal reflux disease								
Normal	9	(0.8)	9	1.00	8	(0.7)	8	1.04

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	4	(0.5)	4	0.62	4	(0.5)	4	0.69
Moderate or severe impairment	1	(0.5)	1	0.88	3	(1.2)	3	1.25
Abdominal pain upper								
Normal	8	(0.7)	10	1.26	10	(0.9)	10	1.11
Mild impairment	7	(0.8)	7	1.23	6	(0.8)	7	1.10
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Toothache								
Normal	8	(0.7)	8	0.80	6	(0.5)	10	1.64
Mild impairment	7	(0.8)	7	1.14	6	(0.8)	7	1.34
Moderate or severe impairment	0				1	(0.4)	1	0.66
Constipation								
Normal	7	(0.6)	7	0.84	8	(0.7)	8	1.00
Mild impairment	6	(0.7)	9	1.47	7	(0.9)	7	1.23
Moderate or severe impairment	4	(1.9)	4	2.58	1	(0.4)	1	0.42
Haemorrhoids								
Normal	6	(0.5)	6	0.67	1	(0.1)	1	0.14
Mild impairment	1	(0.1)	1	0.12	2	(0.3)	2	0.47
Moderate or severe impairment	0				1	(0.4)	1	0.42
Dental caries								
Normal	6	(0.5)	7	0.69	4	(0.4)	4	0.41
Mild impairment	4	(0.5)	5	0.60	4	(0.5)	4	0.76
Moderate or severe impairment	2	(1.0)	2	1.03	2	(0.8)	2	1.31
Chronic gastritis								
Normal	5	(0.4)	5	0.58	1	(0.1)	1	0.15
Mild impairment	2	(0.2)	2	0.38	3	(0.4)	3	0.61
Moderate or severe impairment	2	(0.9)	2	1.64	2	(0.8)	2	0.84
Gastritis								
Normal	4	(0.4)	4	0.56	6	(0.5)	6	0.69
Mild impairment	4	(0.5)	4	0.70	2	(0.2)	2	0.24
Moderate or severe impairment	0				1	(0.5)	1	0.83
Dyspepsia								
Normal	4	(0.4)	4	0.58	6	(0.5)	6	0.63
Mild impairment	4	(0.5)	4	0.62	3	(0.4)	3	0.59
Moderate or severe impairment	0				0			
Abdominal distension								
Normal	4	(0.4)	4	0.51	3	(0.3)	3	0.42
Mild impairment	4	(0.5)	4	0.48	1	(0.1)	1	0.13
Moderate or severe impairment	0				1	(0.5)	1	0.85
Flatulence								
Normal	3	(0.3)	3	0.34	1	(0.1)	1	0.15

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				1	(0.1)	1	0.22
Moderate or severe impairment	1	(0.5)	1	0.88	0			
Food poisoning								
Normal	3	(0.3)	3	0.33	1	(0.1)	2	0.29
Mild impairment	0				3	(0.4)	3	0.56
Moderate or severe impairment	2	(1.0)	2	1.35	0			
Diverticulum intestinal								
Normal	3	(0.3)	3	0.26	0			
Mild impairment	1	(0.1)	1	0.26	1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Large intestine polyp								
Normal	3	(0.3)	3	0.26	3	(0.3)	3	0.31
Mild impairment	1	(0.1)	1	0.18	3	(0.4)	4	0.50
Moderate or severe impairment	0				0			
Abdominal pain lower								
Normal	2	(0.2)	2	0.25	1	(0.1)	1	0.09
Mild impairment	2	(0.2)	2	0.31	1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Aphthous ulcer								
Normal	2	(0.2)	2	0.17	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Inguinal hernia								
Normal	2	(0.2)	2	0.17	0			
Mild impairment	0				1	(0.1)	2	0.25
Moderate or severe impairment	0				0			
Anal fissure								
Normal	2	(0.2)	2	0.26	0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				1	(0.4)	1	0.40
Diverticulum								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.09
Mild impairment	0				2	(0.3)	2	0.35
Moderate or severe impairment	0				0			
Gastrointestinal angiodysplasia								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Tongue rough								
Normal	1	(0.1)	1	0.16	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gastric dilatation								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gastric polyps								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.14
Mild impairment	1	(0.1)	1	0.12	3	(0.4)	3	0.61
Moderate or severe impairment	0				0			
Vomiting projectile								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pancreatitis chronic								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Dry mouth								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Enterocolitis								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	2	(0.2)	3	0.36	0			
Moderate or severe impairment	0				0			
Hyperaesthesia teeth								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	1	(0.1)	1	0.18	0			
Moderate or severe impairment	0				0			
Loose tooth								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Oral discomfort								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pancreatitis								
Normal	1	(0.1)	1	0.09	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Tooth impacted								
Normal	1	(0.1)	1	0.09	1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Diabetic gastropathy								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Eosinophilic oesophagitis								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Eructation								
Normal	1	(0.1)	1	0.08	1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gastric ulcer								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gastrointestinal haemorrhage								
Normal	1	(0.1)	1	0.08	2	(0.2)	2	0.24
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Haemorrhoidal haemorrhage								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Hiatus hernia								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	1	(0.1)	1	0.18	2	(0.2)	2	0.37
Moderate or severe impairment	0				0			
Hypoaesthesia oral								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	1	(0.1)	3	0.64	0			
Moderate or severe impairment	1	(0.4)	1	0.76	0			
Rectal polyp								
Normal	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, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Abdominal discomfort								
Normal	1	(0.1)	1	0.18	2	(0.2)	2	0.17
Mild impairment	2	(0.2)	2	0.24	4	(0.5)	5	1.01
Moderate or severe impairment	1	(0.4)	1	0.76	0			
Pancreatic failure								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Abdominal wall disorder								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Acid peptic disease								
Normal	0				2	(0.2)	2	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Anal pruritus								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Colitis								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				2	(0.8)	2	0.84
Colitis ischaemic								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Colitis microscopic								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Crohn's disease								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Duodenitis								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Enteritis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Epigastric discomfort								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Faeces pale								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.85
Faeces soft								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.26	0			
Moderate or severe impairment	0				0			
Frequent bowel movements								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Gastric disorder								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gastric dysplasia								
Normal	0				1	(0.1)	1	0.14
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gastric mucosal hypertrophy								
Normal	0				1	(0.1)	1	0.14
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gastritis erosive								
Normal	0				0			
Mild impairment	0				2	(0.2)	2	0.48
Moderate or severe impairment	0				0			
Gastrointestinal disorder								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	0				0			
Gastrointestinal inflammation								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Gastrointestinal sounds abnormal								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gingival bleeding								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.18	0			
Moderate or severe impairment	0				0			
Gingival disorder								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	0				0			
Gingival recession								
Normal	0				1	(0.1)	2	0.37
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Haematochezia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Hyperchlorhydria								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Ileus								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Impaired gastric emptying								
Normal	0				0			
Mild impairment	1	(0.1)	2	0.52	0			
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Intestinal dilatation								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Intra-abdominal haematoma								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.18	1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Irritable bowel syndrome								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.26	1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Lip swelling								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Lumbar hernia								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Melaena								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Mesenteric panniculitis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Noninfective gingivitis								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.20	0			
Moderate or severe impairment	0				0			
Odynophagia								
Normal	0				2	(0.2)	2	0.33
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Oesophageal pain								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Oesophagitis								
Normal	0				1	(0.1)	1	0.15

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Oral pain								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.20	0			
Moderate or severe impairment	0				0			
Pancreatic duct dilatation								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Pancreatic pseudocyst								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.66
Pancreatitis acute								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Peptic ulcer								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Periodontal disease								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	2	(0.3)	2	0.44
Moderate or severe impairment	0				0			
Periodontal inflammation								
Normal	0				1	(0.1)	2	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pneumatosis intestinalis								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Proctalgia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Rectal prolapse								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Small intestinal obstruction								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Stomatitis								
Normal	0				0			
Mild impairment	0				2	(0.3)	2	0.25
Moderate or severe impairment	0				0			
Tooth disorder								
Normal	0				1	(0.1)	1	0.15
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Ulcerative gastritis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Umbilical hernia								
Normal	0				1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Upper gastrointestinal haemorrhage								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Musculoskeletal and connective tissue disorders								
All								
Normal	135	(12.1)	202	23.61	138	(12.1)	203	25.98
Mild impairment	117	(13.9)	170	27.24	113	(14.2)	154	26.60
Moderate or severe impairment	21	(9.9)	28	17.62	33	(13.4)	44	22.42
Back pain								
Normal	33	(3.0)	35	4.46	31	(2.7)	47	6.86
Mild impairment	27	(3.2)	29	4.22	33	(4.2)	33	5.92
Moderate or severe impairment	5	(2.4)	5	2.72	8	(3.1)	9	4.92
Arthralgia								
Normal	21	(1.9)	24	2.76	28	(2.4)	30	4.00
Mild impairment	24	(2.9)	28	4.70	16	(2.0)	19	3.45

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	6	(2.9)	7	4.59	13	(5.3)	14	7.09
Pain in extremity								
Normal	19	(1.7)	20	2.30	21	(1.8)	22	2.90
Mild impairment	15	(1.8)	16	2.59	15	(1.9)	20	3.55
Moderate or severe impairment	3	(1.5)	3	1.50	1	(0.5)	1	0.83
Osteoarthritis								
Normal	13	(1.1)	15	1.80	16	(1.4)	19	2.14
Mild impairment	10	(1.2)	10	1.54	9	(1.1)	9	1.62
Moderate or severe impairment	1	(0.5)	1	0.47	1	(0.4)	1	0.40
Muscle spasms								
Normal	9	(0.8)	9	1.11	2	(0.2)	2	0.17
Mild impairment	13	(1.5)	15	2.47	7	(0.9)	7	1.16
Moderate or severe impairment	3	(1.4)	3	2.15	0			
Myalgia								
Normal	8	(0.7)	8	1.00	10	(0.9)	10	1.49
Mild impairment	8	(0.9)	8	1.45	6	(0.7)	7	1.43
Moderate or severe impairment	0				0			
Neck pain								
Normal	8	(0.7)	8	0.94	5	(0.4)	5	0.45
Mild impairment	6	(0.7)	6	0.97	3	(0.4)	3	0.56
Moderate or severe impairment	2	(0.9)	2	1.53	0			
Arthritis								
Normal	5	(0.5)	5	0.58	1	(0.1)	1	0.15
Mild impairment	2	(0.2)	2	0.38	4	(0.5)	4	0.70
Moderate or severe impairment	0				1	(0.4)	1	0.66
Rotator cuff syndrome								
Normal	4	(0.4)	4	0.50	2	(0.2)	2	0.17
Mild impairment	1	(0.1)	1	0.12	2	(0.2)	2	0.24
Moderate or severe impairment	0				0			
Tendonitis								
Normal	4	(0.4)	4	0.42	3	(0.3)	3	0.36
Mild impairment	4	(0.5)	6	0.91	2	(0.3)	2	0.43
Moderate or severe impairment	0				0			
Trigger finger								
Normal	4	(0.4)	4	0.59	3	(0.3)	3	0.41
Mild impairment	4	(0.5)	4	0.73	3	(0.4)	5	0.63
Moderate or severe impairment	1	(0.4)	1	0.76	0			
Intervertebral disc disorder								
Normal	3	(0.3)	3	0.34	1	(0.1)	1	0.09
Mild impairment	0				1	(0.1)	1	0.22

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Intervertebral disc protrusion								
Normal	3	(0.3)	6	0.58	4	(0.3)	5	0.56
Mild impairment	5	(0.6)	6	0.82	2	(0.3)	2	0.25
Moderate or severe impairment	0				0			
Musculoskeletal stiffness								
Normal	3	(0.3)	3	0.42	0			
Mild impairment	2	(0.2)	2	0.31	2	(0.2)	2	0.37
Moderate or severe impairment	0				0			
Foot deformity								
Normal	3	(0.3)	5	0.49	2	(0.2)	2	0.30
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Periarthritis								
Normal	3	(0.3)	3	0.27	3	(0.3)	3	0.45
Mild impairment	4	(0.5)	4	0.64	4	(0.5)	4	0.71
Moderate or severe impairment	1	(0.5)	1	0.51	2	(0.8)	2	0.84
Exostosis								
Normal	3	(0.3)	3	0.26	1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Spinal osteoarthritis								
Normal	3	(0.3)	3	0.26	2	(0.2)	2	0.17
Mild impairment	3	(0.4)	3	0.55	2	(0.3)	2	0.25
Moderate or severe impairment	0				1	(0.4)	2	0.81
Plantar fasciitis								
Normal	2	(0.2)	3	0.34	3	(0.3)	3	0.26
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Bursitis								
Normal	2	(0.2)	2	0.25	3	(0.3)	3	0.36
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.13
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Muscular weakness								
Normal	2	(0.2)	2	0.33	2	(0.2)	2	0.24
Mild impairment	2	(0.2)	2	0.32	1	(0.1)	1	0.22
Moderate or severe impairment	0				0			
Back disorder								
Normal	2	(0.2)	2	0.25	0			
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Osteochondrosis								
Normal	2	(0.2)	2	0.24	3	(0.3)	3	0.39
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Groin pain								
Normal	2	(0.2)	2	0.18	0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				1	(0.4)	1	0.42
Musculoskeletal chest pain								
Normal	2	(0.2)	2	0.18	0			
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.13
Moderate or severe impairment	0				1	(0.4)	1	0.40
Chondropathy								
Normal	2	(0.2)	2	0.17	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Soft tissue swelling								
Normal	1	(0.1)	3	0.48	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Spinal stenosis								
Normal	1	(0.1)	2	0.32	1	(0.1)	1	0.09
Mild impairment	3	(0.4)	4	0.61	0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Musculoskeletal pain								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Pain in jaw								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Bone cyst								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	0				0			
Coccydynia								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	1	(0.1)	1	0.21	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				1	(0.4)	1	0.40
Costochondritis								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.83
Fibromyalgia								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Myositis								
Normal	1	(0.1)	1	0.09	1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Polyarthritis								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Spinal pain								
Normal	1	(0.1)	1	0.09	2	(0.2)	2	0.24
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				1	(0.4)	1	0.42
Tenosynovitis								
Normal	1	(0.1)	1	0.09	3	(0.3)	3	0.26
Mild impairment	1	(0.1)	1	0.26	4	(0.5)	5	0.72
Moderate or severe impairment	0				2	(0.8)	2	1.07
Acquired claw toe								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Facet joint syndrome								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Joint effusion								
Normal	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Mild impairment	1	(0.1)	2	0.40	1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Meniscopathy								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Psoriatic arthropathy								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Sacroiliitis								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Tendon disorder								
Normal	1	(0.1)	1	0.08	1	(0.1)	1	0.15
Mild impairment	2	(0.2)	2	0.40	0			
Moderate or severe impairment	0				0			
Limb discomfort								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Arthropathy								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.20	0			
Moderate or severe impairment	0				0			
Axillary mass								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.18	1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Bone pain								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cervical spinal stenosis								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Chondromalacia								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Diastasis recti abdominis								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Dupuytren's contracture								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Fistula								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Flank pain								
Normal	0				3	(0.3)	4	0.40
Mild impairment	0				3	(0.4)	3	0.56
Moderate or severe impairment	1	(0.5)	1	0.88	0			
Haemarthrosis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Intervertebral disc degeneration								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Intervertebral disc space narrowing								
Normal	0				0			
Mild impairment	0				1	(0.1)	2	0.24
Moderate or severe impairment	0				0			
Jaw disorder								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Joint swelling								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				1	(0.1)	1	0.22
Moderate or severe impairment	0				1	(0.4)	1	0.42
Limb deformity								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Limb mass								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Lumbar spinal stenosis								
Normal	0				1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Mastication disorder								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	2	0.84
Muscle contracture								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.77	0			
Muscle twitching								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Neuropathic arthropathy								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nodal osteoarthritis								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Osteochondritis								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Osteopenia								
Normal	0				1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Osteoporosis								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.37	0			
Moderate or severe impairment	0				0			
Periostitis								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Polymyalgia rheumatica								
Normal	0				1	(0.1)	3	0.43
Mild impairment	1	(0.1)	1	0.18	0			
Moderate or severe impairment	0				0			
Rheumatoid arthritis								
Normal	0				2	(0.2)	2	0.33
Mild impairment	0				2	(0.2)	2	0.36
Moderate or severe impairment	0				0			
Scoliosis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Spinal retrolisthesis								
Normal	0				0			
Mild impairment	0				1	(0.1)	2	0.24
Moderate or severe impairment	0				0			
Synovial cyst								
Normal	0				0			
Mild impairment	3	(0.4)	3	0.51	0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Tenosynovitis stenosans								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Torticollis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.77	1	(0.5)	1	0.85
Vertebral osteophyte								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
General disorders and administration site conditions								
All								
Normal	103	(9.2)	158	21.81	92	(8.1)	143	16.72
Mild impairment	116	(13.9)	182	30.48	92	(11.6)	170	32.20
Moderate or severe impairment	21	(10.0)	23	14.71	24	(9.9)	31	16.77

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Fatigue								
Normal	16	(1.4)	17	2.32	9	(0.8)	9	1.06
Mild impairment	14	(1.7)	17	2.58	5	(0.6)	5	0.72
Moderate or severe impairment	2	(1.1)	2	1.65	2	(0.8)	2	0.82
Pyrexia								
Normal	13	(1.1)	14	1.90	15	(1.3)	16	2.01
Mild impairment	26	(3.1)	27	4.49	24	(3.0)	25	4.15
Moderate or severe impairment	2	(1.0)	2	1.40	4	(1.6)	4	2.34
Injection site reaction								
Normal	9	(0.8)	18	2.77	2	(0.2)	4	0.35
Mild impairment	6	(0.7)	11	2.12	3	(0.4)	3	0.56
Moderate or severe impairment	0				1	(0.4)	1	0.66
Oedema peripheral								
Normal	7	(0.6)	7	1.06	5	(0.4)	6	0.63
Mild impairment	7	(0.8)	7	1.22	4	(0.5)	4	0.58
Moderate or severe impairment	5	(2.4)	5	2.48	1	(0.5)	1	0.85
Chest pain								
Normal	6	(0.5)	6	0.66	4	(0.4)	4	0.45
Mild impairment	5	(0.6)	5	0.66	2	(0.2)	2	0.24
Moderate or severe impairment	3	(1.3)	3	1.98	1	(0.3)	1	0.64
Pain								
Normal	6	(0.5)	6	0.93	7	(0.6)	7	0.85
Mild impairment	6	(0.7)	7	1.15	4	(0.5)	4	0.50
Moderate or severe impairment	1	(0.4)	1	0.76	3	(1.3)	4	2.48
Influenza like illness								
Normal	5	(0.5)	5	0.83	3	(0.3)	3	0.36
Mild impairment	2	(0.2)	3	0.50	1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Medical device site pruritus								
Normal	5	(0.4)	5	0.61	2	(0.2)	2	0.37
Mild impairment	0				2	(0.2)	2	0.37
Moderate or severe impairment	0				0			
Malaise								
Normal	5	(0.4)	6	0.77	3	(0.3)	5	0.55
Mild impairment	10	(1.2)	11	1.62	11	(1.4)	54	12.17
Moderate or severe impairment	1	(0.4)	1	0.76	1	(0.4)	1	0.42
Chest discomfort								
Normal	4	(0.4)	4	0.49	0			
Mild impairment	4	(0.5)	4	0.63	2	(0.3)	2	0.35
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asthenia								
Normal	4	(0.4)	4	0.49	5	(0.4)	5	0.69
Mild impairment	6	(0.7)	6	0.97	5	(0.6)	5	0.80
Moderate or severe impairment	0				0			
Medical device site bruise								
Normal	3	(0.3)	5	0.59	1	(0.1)	1	0.09
Mild impairment	4	(0.5)	4	0.77	0			
Moderate or severe impairment	0				0			
Peripheral swelling								
Normal	3	(0.3)	4	0.48	3	(0.3)	3	0.33
Mild impairment	2	(0.2)	2	0.24	0			
Moderate or severe impairment	0				1	(0.5)	1	0.85
Medical device site reaction								
Normal	3	(0.3)	3	0.51	0			
Mild impairment	3	(0.4)	5	0.81	1	(0.1)	1	0.13
Moderate or severe impairment	1	(0.4)	1	0.76	0			
Medical device site erythema								
Normal	2	(0.2)	2	0.32	3	(0.3)	4	0.64
Mild impairment	0				2	(0.2)	2	0.45
Moderate or severe impairment	0				0			
Injection site pruritus								
Normal	2	(0.2)	17	2.68	1	(0.1)	1	0.15
Mild impairment	2	(0.2)	2	0.24	0			
Moderate or severe impairment	0				0			
Injection site erythema								
Normal	2	(0.2)	2	0.25	1	(0.1)	1	0.09
Mild impairment	1	(0.1)	3	0.60	2	(0.3)	2	0.25
Moderate or severe impairment	0				1	(0.4)	1	0.42
Thirst								
Normal	2	(0.2)	2	0.25	1	(0.1)	1	0.15
Mild impairment	1	(0.1)	1	0.20	0			
Moderate or severe impairment	0				0			
Injection site mass								
Normal	2	(0.2)	2	0.17	1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Medical device site pain								
Normal	2	(0.2)	2	0.27	2	(0.2)	2	0.24
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-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								
Normal	2	(0.2)	2	0.35	3	(0.3)	3	0.55
Mild impairment	4	(0.5)	4	1.05	5	(0.6)	5	1.20
Moderate or severe impairment	0				0			
Inflammation								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.26	1	(0.1)	1	0.21
Moderate or severe impairment	0				1	(0.4)	1	0.42
Injection site haemorrhage								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	1	(0.1)	1	0.20	2	(0.3)	2	0.35
Moderate or severe impairment	0				0			
Injection site pain								
Normal	1	(0.1)	1	0.16	8	(0.7)	26	2.56
Mild impairment	2	(0.2)	2	0.40	5	(0.6)	5	0.90
Moderate or severe impairment	0				0			
Injection site swelling								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	1	(0.1)	1	0.18	1	(0.1)	1	0.22
Moderate or severe impairment	0				0			
Multiple organ dysfunction syndrome								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Vaccination site inflammation								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Vaccination site pruritus								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Xerosis								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Discomfort								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	1	(0.1)	1	0.20	1	(0.1)	8	1.69
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Drug intolerance								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	2	(0.2)	2	0.24	0			
Moderate or severe impairment	0				0			
Feeling hot								
Normal	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gait disturbance								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	1	(0.5)	1	0.47	1	(0.4)	1	0.40
Hunger								
Normal	1	(0.1)	2	0.18	0			
Mild impairment	5	(0.6)	5	0.81	3	(0.4)	4	0.84
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Injection site dermatitis								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Injection site hypersensitivity								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Medical device site eczema								
Normal	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Medical device site haemorrhage								
Normal	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.24
Moderate or severe impairment	2	(1.0)	2	1.03	1	(0.4)	1	0.42
Medical device site hypersensitivity								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Injection site bruising								
Normal	1	(0.1)	1	0.08	2	(0.2)	2	0.17
Mild impairment	1	(0.1)	1	0.20	3	(0.4)	3	0.47
Moderate or severe impairment	1	(0.4)	1	0.77	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Localised oedema								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Injection site urticaria								
Normal	1	(0.1)	2	0.35	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Medical device site dermatitis								
Normal	1	(0.1)	1	0.18	2	(0.2)	2	0.27
Mild impairment	6	(0.7)	9	1.53	7	(0.9)	14	2.12
Moderate or severe impairment	0				2	(0.8)	2	0.84
Swelling face								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.22
Moderate or severe impairment	0				1	(0.4)	1	0.40
Application site bruise								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.20	0			
Moderate or severe impairment	0				0			
Application site pruritus								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.20	0			
Moderate or severe impairment	0				0			
Axillary pain								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.85
Chills								
Normal	0				1	(0.1)	1	0.09
Mild impairment	4	(0.5)	4	0.55	0			
Moderate or severe impairment	0				0			
Condition aggravated								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.23
Moderate or severe impairment	0				0			
Cyst								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	0				1	(0.4)	1	0.40

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Death								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				1	(0.4)	1	0.42
Early satiety								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Facial pain								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Feeling abnormal								
Normal	0				0			
Mild impairment	3	(0.4)	5	0.79	0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Hernia								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hyperthermia								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Implant site pruritus								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Injection site haematoma								
Normal	0				3	(0.3)	8	1.17
Mild impairment	2	(0.2)	6	1.19	0			
Moderate or severe impairment	0				0			
Injection site hypertrophy								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Injection site induration								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.40

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Injection site oedema								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Injection site rash								
Normal	0				1	(0.1)	1	0.15
Mild impairment	1	(0.1)	1	0.20	0			
Moderate or severe impairment	0				0			
Medical device site haematoma								
Normal	0				1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.26	0			
Moderate or severe impairment	0				0			
Medical device site inflammation								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Medical device site irritation								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.26	0			
Moderate or severe impairment	0				0			
Non-cardiac chest pain								
Normal	0				3	(0.3)	5	0.43
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Oedema								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				2	(0.2)	2	0.34
Moderate or severe impairment	1	(0.4)	1	0.76	0			
Oedema due to renal disease								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Procedural failure								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Swelling								
Normal	0				1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-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								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Vaccination site erythema								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Vaccination site pain								
Normal	0				4	(0.4)	4	0.45
Mild impairment	9	(1.1)	11	1.80	3	(0.4)	3	0.68
Moderate or severe impairment	1	(0.5)	1	0.88	2	(0.8)	2	1.50
Vaccination site reaction								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Vessel puncture site bruise								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Nervous system disorders								
All								
Normal	101	(9.0)	139	18.09	83	(7.3)	111	13.30
Mild impairment	87	(10.4)	134	22.19	92	(11.6)	172	33.58
Moderate or severe impairment	19	(9.1)	25	17.79	32	(13.2)	43	26.37
Headache								
Normal	40	(3.6)	52	7.41	26	(2.3)	31	3.93
Mild impairment	25	(3.0)	33	5.65	31	(3.9)	40	6.94
Moderate or severe impairment	5	(2.3)	7	4.55	7	(2.9)	9	5.98
Dizziness								
Normal	15	(1.3)	18	2.07	15	(1.3)	17	2.02
Mild impairment	21	(2.5)	28	4.52	16	(2.0)	21	3.79
Moderate or severe impairment	4	(1.9)	5	3.69	8	(3.1)	9	5.18
Carpal tunnel syndrome								
Normal	8	(0.7)	8	0.98	3	(0.3)	3	0.39
Mild impairment	3	(0.4)	3	0.36	5	(0.6)	5	0.92
Moderate or severe impairment	0				0			
Hypoaesthesia								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	6	(0.5)	9	1.14	2	(0.2)	2	0.24
Mild impairment	2	(0.2)	2	0.24	6	(0.8)	6	1.17
Moderate or severe impairment	1	(0.5)	1	0.51	2	(0.8)	3	1.25
Sciatica								
Normal	6	(0.5)	6	0.73	5	(0.4)	6	0.53
Mild impairment	7	(0.8)	7	1.15	6	(0.8)	6	1.05
Moderate or severe impairment	0				1	(0.4)	1	0.66
Migraine								
Normal	5	(0.5)	6	0.85	2	(0.2)	2	0.33
Mild impairment	3	(0.4)	3	0.56	2	(0.2)	2	0.37
Moderate or severe impairment	0				1	(0.5)	1	0.85
Syncope								
Normal	5	(0.4)	5	0.53	1	(0.1)	1	0.09
Mild impairment	2	(0.2)	2	0.31	0			
Moderate or severe impairment	0				0			
Paraesthesia								
Normal	3	(0.3)	3	0.34	6	(0.5)	6	0.77
Mild impairment	5	(0.6)	6	0.72	4	(0.5)	4	0.67
Moderate or severe impairment	0				2	(0.9)	2	1.25
Tremor								
Normal	3	(0.3)	3	0.26	3	(0.3)	3	0.48
Mild impairment	7	(0.8)	8	1.18	6	(0.8)	56	13.15
Moderate or severe impairment	2	(0.9)	2	1.23	1	(0.5)	2	1.70
Autonomic nervous system imbalance								
Normal	2	(0.2)	2	0.34	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Diabetic neuropathy								
Normal	2	(0.2)	2	0.31	6	(0.5)	6	0.64
Mild impairment	3	(0.4)	3	0.50	3	(0.4)	3	0.56
Moderate or severe impairment	1	(0.4)	1	0.76	3	(1.2)	3	1.92
Transient ischaemic attack								
Normal	2	(0.2)	2	0.17	1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.20	2	(0.2)	2	0.34
Moderate or severe impairment	0				0			
Carotid artery aneurysm								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Facial paralysis								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Piriformis syndrome								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Thalamic infarction								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Neuropathy peripheral								
Normal	1	(0.1)	2	0.32	2	(0.2)	2	0.23
Mild impairment	4	(0.5)	4	0.57	5	(0.6)	5	0.83
Moderate or severe impairment	1	(0.4)	1	0.77	3	(1.2)	3	1.48
Vascular headache								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Ageusia								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Anosmia								
Normal	1	(0.1)	1	0.09	1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cerebrovascular disorder								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Cervical radiculopathy								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Neuroglycopenia								
Normal	1	(0.1)	1	0.09	1	(0.1)	3	0.27
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Presyncope								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				2	(0.8)	2	0.84
Carotid artery stenosis								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Cluster headache								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Disturbance in attention								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	1	(0.1)	9	2.36	0			
Moderate or severe impairment	0				0			
Dysgeusia								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	2	(0.2)	2	0.33	0			
Moderate or severe impairment	0				0			
Intracranial pressure increased								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cervicobrachial syndrome								
Normal	1	(0.1)	1	0.18	1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.18	0			
Moderate or severe impairment	0				0			
Hypoglycaemic seizure								
Normal	1	(0.1)	1	0.18	1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Loss of consciousness								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				1	(0.4)	1	0.40
Sinus headache								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Speech disorder								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	1	(0.1)	1	0.18	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Amnesia								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.32	0			
Moderate or severe impairment	0				0			
Balance disorder								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Basilar migraine								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Brain injury								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Burning sensation								
Normal	0				3	(0.3)	3	0.32
Mild impairment	2	(0.2)	2	0.24	0			
Moderate or severe impairment	1	(0.6)	1	1.13	0			
Carotid arteriosclerosis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Cerebral arteriosclerosis								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Cerebral artery embolism								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cerebral atrophy								
Normal	0				1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Cerebral haemorrhage								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Cerebral infarction								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.23
Moderate or severe impairment	0				0			
Cerebrovascular accident								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				1	(0.5)	1	0.85
Cognitive disorder								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				1	(0.5)	1	0.85
Dementia Alzheimer's type								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Dizziness postural								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	2	(0.2)	2	0.45
Moderate or severe impairment	0				0			
Encephalopathy								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Essential tremor								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Facial nerve disorder								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	0				0			
Haemorrhage intracranial								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.26	0			
Moderate or severe impairment	0				0			
Hemiparesis								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hypoglycaemic coma								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.85
Hypoglycaemic unconsciousness								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hyporeflexia								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	0				0			
Hypotonia								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Ischaemic stroke								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Lethargy								
Normal	0				0			
Mild impairment	0				2	(0.3)	2	0.25
Moderate or severe impairment	0				0			
Lumbar radiculopathy								
Normal	0				3	(0.3)	4	0.35
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Memory impairment								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	2	(0.9)	2	1.27	0			
Mental impairment								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Meralgia paraesthetica								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Morton's neuralgia								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Myelopathy								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Neuralgia								
Normal	0				1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.18	0			
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Ophthalmic migraine								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Orthostatic tremor								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Parkinsonian gait								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Peripheral paralysis								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.18	0			
Moderate or severe impairment	0				0			
Post herpetic neuralgia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.24
Moderate or severe impairment	1	(0.5)	1	0.88	0			
Radiculopathy								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Restless legs syndrome								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.23
Moderate or severe impairment	0				0			
Sleep deficit								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.85
Somnolence								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.18	1	(0.1)	1	0.13
Moderate or severe impairment	1	(0.6)	1	1.13	0			
Tension headache								
Normal	0				0			
Mild impairment	1	(0.1)	2	0.24	0			
Moderate or severe impairment	2	(1.0)	2	1.40	0			
Thrombotic stroke								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				1	(0.4)	1	0.66
Trigeminal neuralgia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Vascular encephalopathy								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Vertebral artery occlusion								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
White matter lesion								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Injury, poisoning and procedural complications								
All								
Normal	85	(7.5)	105	13.40	90	(7.9)	108	14.75

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	92	(11.0)	114	18.72	65	(8.2)	72	12.94
Moderate or severe impairment	17	(8.2)	22	14.70	25	(10.3)	37	20.88
Fall								
Normal	11	(1.0)	11	1.19	5	(0.4)	6	0.61
Mild impairment	9	(1.0)	9	1.33	3	(0.4)	3	0.57
Moderate or severe impairment	0				3	(1.3)	3	1.89
Vaccination complication								
Normal	10	(0.9)	11	1.63	12	(1.1)	17	2.58
Mild impairment	9	(1.1)	12	1.79	10	(1.3)	12	1.91
Moderate or severe impairment	1	(0.5)	1	0.88	7	(2.8)	9	4.66
Accidental overdose								
Normal	6	(0.5)	6	0.95	4	(0.4)	5	0.79
Mild impairment	7	(0.8)	8	1.72	0			
Moderate or severe impairment	1	(0.5)	1	0.88	0			
Contusion								
Normal	5	(0.5)	6	0.67	1	(0.1)	1	0.09
Mild impairment	8	(1.0)	8	1.26	6	(0.7)	6	0.96
Moderate or severe impairment	2	(0.9)	2	1.23	2	(0.7)	2	1.06
Ligament sprain								
Normal	5	(0.4)	5	0.82	6	(0.5)	6	0.76
Mild impairment	7	(0.8)	7	1.11	2	(0.2)	2	0.34
Moderate or severe impairment	0				0			
Limb injury								
Normal	5	(0.4)	5	0.60	1	(0.1)	1	0.15
Mild impairment	1	(0.1)	1	0.20	3	(0.4)	3	0.54
Moderate or severe impairment	0				2	(0.8)	3	1.71
Incorrect dose administered								
Normal	4	(0.4)	4	0.67	3	(0.3)	4	0.52
Mild impairment	1	(0.1)	1	0.26	2	(0.3)	3	0.64
Moderate or severe impairment	1	(0.4)	1	0.76	0			
Road traffic accident								
Normal	3	(0.3)	4	0.59	1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	1	(0.5)	1	0.88	0			
Skin laceration								
Normal	3	(0.3)	3	0.26	1	(0.1)	1	0.18
Mild impairment	3	(0.4)	3	0.52	0			
Moderate or severe impairment	1	(0.5)	1	0.88	0			
Ankle fracture								
Normal	3	(0.3)	3	0.26	1	(0.1)	1	0.09

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.12
Moderate or severe impairment	0				1	(0.4)	1	0.40
Hand fracture								
Normal	3	(0.3)	3	0.35	1	(0.1)	1	0.09
Mild impairment	4	(0.5)	4	0.70	0			
Moderate or severe impairment	0				0			
Skin abrasion								
Normal	3	(0.3)	6	0.69	0			
Mild impairment	5	(0.6)	5	0.84	4	(0.5)	4	0.81
Moderate or severe impairment	1	(0.5)	1	0.88	1	(0.5)	1	0.85
Prescribed overdose								
Normal	3	(0.3)	3	0.53	0			
Mild impairment	2	(0.3)	2	0.52	0			
Moderate or severe impairment	0				0			
Thermal burn								
Normal	2	(0.2)	2	0.25	0			
Mild impairment	1	(0.1)	1	0.18	0			
Moderate or severe impairment	0				2	(0.9)	2	1.27
Tendon rupture								
Normal	2	(0.2)	2	0.24	0			
Mild impairment	0				1	(0.1)	1	0.23
Moderate or severe impairment	0				0			
Joint injury								
Normal	2	(0.2)	2	0.25	4	(0.4)	4	0.40
Mild impairment	3	(0.3)	3	0.50	1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Fibula fracture								
Normal	2	(0.2)	2	0.18	1	(0.1)	1	0.18
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Upper limb fracture								
Normal	2	(0.2)	2	0.17	0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Procedural pain								
Normal	2	(0.2)	2	0.26	1	(0.1)	1	0.15
Mild impairment	2	(0.2)	2	0.40	0			
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Facial bones fracture								
Normal	1	(0.1)	1	0.16	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Overdose								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.15
Mild impairment	2	(0.2)	2	0.31	0			
Moderate or severe impairment	1	(0.4)	1	0.76	2	(0.9)	2	1.25
Procedural complication								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Rib fracture								
Normal	1	(0.1)	1	0.16	2	(0.2)	2	0.29
Mild impairment	2	(0.2)	2	0.31	1	(0.1)	1	0.13
Moderate or severe impairment	1	(0.5)	1	0.47	2	(0.8)	2	0.81
Extra dose administered								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Subdural haematoma								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Wrong product administered								
Normal	1	(0.1)	2	0.31	4	(0.4)	4	0.73
Mild impairment	0				2	(0.3)	2	0.43
Moderate or severe impairment	0				0			
Injury								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Muscle strain								
Normal	1	(0.1)	1	0.09	4	(0.4)	4	0.51
Mild impairment	0				1	(0.1)	1	0.22
Moderate or severe impairment	0				0			
Post procedural fistula								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Post procedural hypothyroidism								
Normal	1	(0.1)	1	0.09	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Radius fracture								
Normal	1	(0.1)	1	0.09	1	(0.1)	1	0.18
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Wound								
Normal	1	(0.1)	1	0.09	5	(0.4)	5	0.71
Mild impairment	2	(0.2)	2	0.33	1	(0.1)	1	0.23
Moderate or severe impairment	0				0			
Animal bite								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	0				2	(0.8)	2	0.82
Back injury								
Normal	1	(0.1)	1	0.08	2	(0.2)	2	0.27
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Injury of conjunctiva								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Neck injury								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Spinal compression fracture								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	0				0			
Tooth fracture								
Normal	1	(0.1)	1	0.08	2	(0.2)	2	0.27
Mild impairment	2	(0.2)	2	0.33	0			
Moderate or severe impairment	1	(0.4)	1	0.76	1	(0.5)	1	0.85
Face injury								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	1	(0.1)	1	0.18	1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Product administration error								
Normal	1	(0.1)	1	0.18	2	(0.2)	2	0.24

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Product dispensing error								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Accidental underdose								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Anaemia postoperative								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Animal scratch								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Arthropod bite								
Normal	0				3	(0.3)	3	0.48
Mild impairment	3	(0.4)	3	0.61	1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Arthropod sting								
Normal	0				0			
Mild impairment	3	(0.4)	3	0.45	0			
Moderate or severe impairment	0				1	(0.4)	1	0.66
Bone contusion								
Normal	0				2	(0.2)	2	0.23
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Burn oral cavity								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Burns first degree								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Cervical vertebral fracture								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Chillblains								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	1	(0.4)	1	0.76	0			
Clavicle fracture								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Concussion								
Normal	0				2	(0.2)	2	0.31
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Corneal abrasion								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Craniocerebral injury								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.18	0			
Moderate or severe impairment	0				0			
Crush injury								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.85
Deafness traumatic								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Endotracheal intubation complication								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Epicondylitis								
Normal	0				1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.26	0			
Moderate or severe impairment	0				0			
Exposure to SARS-CoV-2								
Normal	0				1	(0.1)	1	0.15

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Eye injury								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Femoral neck fracture								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Foot fracture								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.33	3	(0.4)	3	0.49
Moderate or severe impairment	1	(0.4)	1	0.76	0			
Gun shot wound								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.20	0			
Moderate or severe impairment	0				0			
Head injury								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Heat illness								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	2	(0.3)	2	0.36
Moderate or severe impairment	0				1	(0.4)	2	0.84
Heat stroke								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Hip fracture								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Humerus fracture								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Inflammation of wound								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Intentional overdose								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.66
Intentional product use issue								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Ligament rupture								
Normal	0				0			
Mild impairment	1	(0.1)	2	0.40	0			
Moderate or severe impairment	0				0			
Lower limb fracture								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Medication error								
Normal	0				2	(0.2)	2	0.33
Mild impairment	2	(0.2)	2	0.40	0			
Moderate or severe impairment	0				1	(0.5)	1	0.85
Meniscus injury								
Normal	0				2	(0.2)	2	0.17
Mild impairment	2	(0.2)	2	0.24	3	(0.4)	3	0.45
Moderate or severe impairment	0				0			
Multiple injuries								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Muscle contusion								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.23
Moderate or severe impairment	0				0			
Muscle injury								
Normal	0				1	(0.1)	1	0.15
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.23
Moderate or severe impairment	0				0			
Nerve injury								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Penile contusion								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Periprocedural myocardial infarction								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Post procedural complication								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Post procedural haematuria								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Post procedural haemorrhage								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Post procedural inflammation								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Post procedural stroke								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Post procedural swelling								
Normal	0				1	(0.1)	2	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Post-traumatic neck syndrome								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Radiation skin injury								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Scar								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Scratch								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Seroma								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Soft tissue injury								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Spinal column injury								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Stab wound								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.23
Moderate or severe impairment	0				0			
Subcutaneous haematoma								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.18	1	(0.1)	1	0.21
Moderate or severe impairment	0				0			
Sunburn								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Tendon injury								
Normal	0				1	(0.1)	1	0.14
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Tibia fracture								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				1	(0.1)	1	0.23
Moderate or severe impairment	0				0			
Traumatic haematoma								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Underdose								
Normal	0				2	(0.2)	2	0.29
Mild impairment	1	(0.1)	1	0.18	1	(0.1)	1	0.23
Moderate or severe impairment	0				2	(0.8)	2	1.07
Wound dehiscence								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Wrist fracture								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	1	(0.5)	1	0.88	0			
Wrong dose								
Normal	0				2	(0.2)	2	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Respiratory, thoracic and mediastinal disorders								
All								
Normal	69	(6.1)	90	11.11	64	(5.6)	80	10.92
Mild impairment	52	(6.2)	72	12.28	45	(5.7)	57	9.45
Moderate or severe impairment	11	(5.4)	15	10.76	13	(5.3)	16	8.38
Cough								
Normal	15	(1.3)	16	1.76	16	(1.4)	17	2.60
Mild impairment	10	(1.2)	12	2.39	12	(1.5)	13	1.89
Moderate or severe impairment	1	(0.4)	1	0.76	0			
Oropharyngeal pain								
Normal	15	(1.3)	15	1.82	10	(0.9)	10	1.41
Mild impairment	5	(0.6)	6	0.88	8	(1.0)	10	1.75
Moderate or severe impairment	4	(1.9)	5	3.13	1	(0.4)	1	0.42
Rhinorrhoea								
Normal	7	(0.6)	7	0.94	6	(0.5)	6	1.01
Mild impairment	5	(0.6)	8	1.28	5	(0.6)	5	0.82

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				2	(0.8)	2	1.07
Respiratory disorder								
Normal	6	(0.5)	6	1.02	3	(0.3)	3	0.46
Mild impairment	2	(0.2)	2	0.33	3	(0.4)	3	0.47
Moderate or severe impairment	0				1	(0.5)	1	0.85
Dyspnoea								
Normal	5	(0.5)	5	0.64	6	(0.5)	7	0.81
Mild impairment	3	(0.4)	3	0.43	3	(0.4)	3	0.46
Moderate or severe impairment	1	(0.4)	1	0.76	4	(1.7)	4	2.52
Asthma								
Normal	5	(0.4)	6	0.73	0			
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	0				0			
Sleep apnoea syndrome								
Normal	4	(0.4)	4	0.42	0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	2	(1.0)	2	1.40	0			
Nasal congestion								
Normal	4	(0.4)	4	0.35	3	(0.3)	3	0.36
Mild impairment	5	(0.6)	5	0.76	2	(0.3)	2	0.25
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Epistaxis								
Normal	3	(0.3)	3	0.48	0			
Mild impairment	3	(0.4)	7	1.40	2	(0.2)	4	0.68
Moderate or severe impairment	0				0			
Productive cough								
Normal	2	(0.2)	2	0.25	1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.18	3	(0.4)	3	0.60
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Emphysema								
Normal	2	(0.2)	2	0.25	2	(0.2)	2	0.24
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pulmonary fibrosis								
Normal	2	(0.2)	3	0.34	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nasal obstruction								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				1	(0.4)	1	0.40
Chronic obstructive pulmonary disease								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.09
Mild impairment	2	(0.2)	2	0.31	0			
Moderate or severe impairment	1	(0.5)	1	0.88	0			
Pleurisy								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.3)	1	0.64
Pulmonary hypertension								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Sinus pain								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.15
Mild impairment	1	(0.1)	2	0.24	0			
Moderate or severe impairment	0				0			
Acquired diaphragmatic eventration								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Acute respiratory failure								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	1	(0.5)	1	0.88	1	(0.4)	1	0.42
Bronchiectasis								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Laryngeal cyst								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nasal turbinate hypertrophy								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Sneezing								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	2	(0.2)	2	0.45	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Increased viscosity of upper respiratory secretion								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Rhinitis allergic								
Normal	1	(0.1)	1	0.08	6	(0.5)	10	1.22
Mild impairment	1	(0.1)	1	0.26	0			
Moderate or severe impairment	0				0			
Upper respiratory tract inflammation								
Normal	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Bronchial hyperreactivity								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Sinus congestion								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	4	(0.5)	5	0.77	2	(0.2)	2	0.37
Moderate or severe impairment	1	(0.6)	1	1.13	0			
Upper-airway cough syndrome								
Normal	1	(0.1)	1	0.18	1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Acute pulmonary oedema								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Allergic bronchitis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Allergic cough								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Aphonia								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Bronchitis chronic								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Bronchospasm								
Normal	0				1	(0.1)	1	0.15
Mild impairment	1	(0.1)	1	0.20	0			
Moderate or severe impairment	0				0			
Dry throat								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Dysphonia								
Normal	0				0			
Mild impairment	0				1	(0.1)	2	0.44
Moderate or severe impairment	0				0			
Dyspnoea exertional								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.38	1	(0.1)	1	0.13
Moderate or severe impairment	0				1	(0.4)	1	0.40
Haemoptysis								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hiccups								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.26	0			
Moderate or severe impairment	0				0			
Interstitial lung disease								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.24	0			
Moderate or severe impairment	0				0			
Lung disorder								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nasal dryness								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Nasal septum deviation								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.40	1	(0.1)	1	0.21
Moderate or severe impairment	0				0			
Paranasal cyst								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	0				0			
Paranasal sinus discomfort								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pleural disorder								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.22
Moderate or severe impairment	0				0			
Pleural effusion								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				2	(0.8)	2	0.82
Pleuritic pain								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Pulmonary congestion								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.26	0			
Moderate or severe impairment	0				0			
Pulmonary embolism								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Pulmonary mass								
Normal	0				3	(0.3)	3	0.38
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Respiratory failure								
Normal	0				2	(0.2)	2	0.17

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.88	0			
Respiratory tract inflammation								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Throat irritation								
Normal	0				2	(0.2)	2	0.33
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Metabolism and nutrition disorders								
All								
Normal	68	(6.1)	86	10.19	66	(5.8)	78	9.09
Mild impairment	47	(5.7)	57	8.43	50	(6.3)	67	11.56
Moderate or severe impairment	17	(8.0)	20	12.25	18	(7.6)	24	12.99
Hypoglycaemia								
Normal	14	(1.3)	20	2.86	7	(0.6)	10	1.25
Mild impairment	3	(0.4)	5	1.17	12	(1.5)	22	3.94
Moderate or severe impairment	1	(0.4)	1	0.76	4	(1.7)	8	4.00
Dyslipidaemia								
Normal	13	(1.2)	14	1.65	9	(0.8)	9	1.10
Mild impairment	6	(0.7)	6	0.97	8	(1.0)	8	1.56
Moderate or severe impairment	2	(0.9)	2	1.28	0			
Vitamin D deficiency								
Normal	9	(0.8)	9	0.92	11	(1.0)	11	1.20
Mild impairment	7	(0.8)	7	0.84	2	(0.3)	2	0.25
Moderate or severe impairment	1	(0.5)	1	0.47	1	(0.5)	1	0.85
Hyperlipidaemia								
Normal	7	(0.6)	7	0.82	10	(0.9)	10	1.04
Mild impairment	5	(0.6)	5	0.68	2	(0.3)	2	0.35
Moderate or severe impairment	2	(0.9)	2	1.24	1	(0.4)	1	0.42
Hypertriglyceridaemia								
Normal	6	(0.5)	6	0.67	6	(0.5)	6	0.78
Mild impairment	4	(0.5)	4	0.58	2	(0.3)	2	0.25
Moderate or severe impairment	0				0			
Vitamin B12 deficiency								
Normal	5	(0.4)	5	0.42	1	(0.1)	1	0.09
Mild impairment	5	(0.6)	5	0.59	0			
Moderate or severe impairment	1	(0.5)	1	0.47	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hyperuricaemia								
Normal	4	(0.4)	4	0.51	0			
Mild impairment	0				2	(0.3)	2	0.25
Moderate or severe impairment	0				1	(0.4)	1	0.40
Iron deficiency								
Normal	4	(0.4)	4	0.34	3	(0.3)	3	0.26
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Hypercholesterolaemia								
Normal	3	(0.3)	3	0.40	2	(0.2)	2	0.34
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				1	(0.4)	1	0.66
Hyponatraemia								
Normal	2	(0.2)	2	0.33	0			
Mild impairment	1	(0.1)	1	0.21	1	(0.1)	1	0.21
Moderate or severe impairment	0				0			
Decreased appetite								
Normal	2	(0.2)	2	0.18	2	(0.2)	2	0.17
Mild impairment	2	(0.2)	2	0.32	2	(0.2)	2	0.33
Moderate or severe impairment	0				1	(0.4)	1	0.40
Abnormal weight gain								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hyperglycaemia								
Normal	1	(0.1)	1	0.16	9	(0.8)	9	1.04
Mild impairment	3	(0.4)	3	0.42	3	(0.4)	3	0.57
Moderate or severe impairment	2	(0.9)	3	2.42	2	(0.9)	2	1.70
Hyperkalaemia								
Normal	1	(0.1)	1	0.16	2	(0.2)	2	0.31
Mild impairment	4	(0.5)	4	0.57	4	(0.5)	4	0.70
Moderate or severe impairment	3	(1.5)	4	2.42	4	(1.7)	4	2.08
Fluid retention								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.76	0			
Increased appetite								
Normal	1	(0.1)	1	0.09	3	(0.3)	3	0.38
Mild impairment	2	(0.2)	2	0.24	2	(0.3)	3	0.56
Moderate or severe impairment	0				1	(0.5)	1	0.85

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Dehydration								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	1	(0.1)	1	0.21	2	(0.2)	3	0.61
Moderate or severe impairment	0				0			
Diabetes mellitus inadequate control								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Folate deficiency								
Normal	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Vitamin B complex deficiency								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Zinc deficiency								
Normal	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Appetite disorder								
Normal	0				0			
Mild impairment	0				1	(0.1)	2	0.25
Moderate or severe impairment	0				0			
Diabetes mellitus								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.13
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Electrolyte imbalance								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Food craving								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.22
Moderate or severe impairment	0				0			
Gout								
Normal	0				0			
Mild impairment	3	(0.4)	4	0.48	2	(0.3)	3	0.37
Moderate or severe impairment	1	(0.5)	1	0.47	4	(1.6)	4	1.65

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hyperammonaemia								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.23
Moderate or severe impairment	0				0			
Hypercalcaemia								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hypernatraemia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Hypoalbuminaemia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Hypokalaemia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	1	(0.1)	1	0.13
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Insulin resistance								
Normal	0				2	(0.2)	2	0.27
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Lactic acidosis								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Lipomatosis								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Magnesium deficiency								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Malnutrition								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.13
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Metabolic acidosis								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Metabolic disorder								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Obesity								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Eye disorders								
All								
Normal	63	(5.7)	78	10.72	85	(7.4)	106	14.01
Mild impairment	96	(11.5)	128	22.49	69	(8.7)	92	17.44
Moderate or severe impairment	17	(8.0)	19	12.34	26	(10.9)	38	23.75
Diabetic retinopathy								
Normal	27	(2.4)	31	4.50	41	(3.6)	43	5.95
Mild impairment	31	(3.7)	33	6.37	24	(3.0)	26	5.05
Moderate or severe impairment	6	(2.8)	6	4.23	7	(2.9)	7	4.00
Cataract								
Normal	7	(0.6)	8	1.00	9	(0.8)	9	1.17
Mild impairment	19	(2.3)	23	3.60	12	(1.5)	15	2.41
Moderate or severe impairment	2	(1.0)	2	0.98	6	(2.5)	6	2.69
Macular oedema								
Normal	4	(0.4)	4	0.58	3	(0.3)	3	0.35
Mild impairment	8	(1.0)	9	1.85	1	(0.1)	1	0.12
Moderate or severe impairment	0				1	(0.5)	1	0.85
Retinopathy hypertensive								
Normal	4	(0.4)	5	0.68	3	(0.3)	3	0.39
Mild impairment	3	(0.4)	3	0.53	2	(0.2)	2	0.42
Moderate or severe impairment	1	(0.4)	1	0.77	0			
Diabetic retinal oedema								
Normal	3	(0.3)	3	0.49	4	(0.3)	5	0.62
Mild impairment	3	(0.4)	3	0.66	4	(0.5)	4	0.67
Moderate or severe impairment	0				2	(0.7)	2	1.29
Eye pain								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	3	(0.3)	3	0.33	2	(0.2)	2	0.24
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Retinal haemorrhage								
Normal	2	(0.2)	2	0.32	0			
Mild impairment	2	(0.2)	2	0.33	0			
Moderate or severe impairment	0				0			
Cataract nuclear								
Normal	2	(0.2)	2	0.34	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Epiretinal membrane								
Normal	2	(0.2)	2	0.34	1	(0.1)	1	0.18
Mild impairment	0				1	(0.1)	1	0.22
Moderate or severe impairment	0				1	(0.4)	1	0.40
Blepharitis								
Normal	2	(0.2)	2	0.24	0			
Mild impairment	2	(0.2)	2	0.24	0			
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Vision blurred								
Normal	2	(0.2)	2	0.24	2	(0.2)	2	0.24
Mild impairment	4	(0.5)	4	0.85	1	(0.1)	1	0.13
Moderate or severe impairment	0				2	(0.8)	2	1.07
Vitreous detachment								
Normal	2	(0.2)	2	0.24	0			
Mild impairment	1	(0.1)	1	0.12	2	(0.2)	2	0.48
Moderate or severe impairment	0				0			
Retinal exudates								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.85
Non-proliferative retinopathy								
Normal	1	(0.1)	2	0.32	2	(0.2)	2	0.33
Mild impairment	2	(0.3)	2	0.52	2	(0.3)	2	0.47
Moderate or severe impairment	0				0			
Conjunctival erosion								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Conjunctival haemorrhage								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	1	(0.1)	1	0.09	0			
Mild impairment	2	(0.2)	2	0.45	0			
Moderate or severe impairment	0				0			
Retinal aneurysm								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.83
Dry eye								
Normal	1	(0.1)	1	0.08	2	(0.2)	2	0.33
Mild impairment	5	(0.6)	5	0.80	5	(0.6)	5	0.64
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Glaucoma								
Normal	1	(0.1)	1	0.08	2	(0.2)	2	0.23
Mild impairment	2	(0.2)	2	0.38	3	(0.4)	3	0.72
Moderate or severe impairment	1	(0.5)	1	0.47	1	(0.4)	1	0.40
Maculopathy								
Normal	1	(0.1)	1	0.08	1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Retinal degeneration								
Normal	1	(0.1)	1	0.08	1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Arteriosclerotic retinopathy								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Retinal vascular disorder								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	0				0			
Acquired epiblepharon								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Age-related macular degeneration								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.33	0			
Moderate or severe impairment	0				0			
Amaurosis fugax								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Angle closure glaucoma								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Asthenopia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Astigmatism								
Normal	0				4	(0.4)	4	0.51
Mild impairment	1	(0.1)	2	0.24	1	(0.1)	1	0.23
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Chorioretinal atrophy								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Conjunctival hyperaemia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Conjunctival suffusion								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Conjunctivitis allergic								
Normal	0				0			
Mild impairment	2	(0.2)	3	0.44	0			
Moderate or severe impairment	0				0			
Corneal bleeding								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.83
Corneal erosion								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.26	1	(0.1)	1	0.21
Moderate or severe impairment	0				0			
Cystoid macular oedema								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Dacryoadenitis acquired								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Diplopia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.21
Moderate or severe impairment	1	(0.4)	1	0.76	0			
Dry age-related macular degeneration								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.18	0			
Moderate or severe impairment	0				0			
Eye discharge								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	0				1	(0.4)	1	0.42
Eye inflammation								
Normal	0				1	(0.1)	1	0.15
Mild impairment	2	(0.2)	2	0.32	0			
Moderate or severe impairment	0				1	(0.5)	1	0.85
Eye irritation								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.18	0			
Moderate or severe impairment	0				0			
Eye pruritus								
Normal	0				0			
Mild impairment	0				1	(0.1)	2	0.44
Moderate or severe impairment	0				0			
Eyelid oedema								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hypermetropia								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Lacrimation increased								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				1	(0.1)	1	0.15
Mild impairment	1	(0.1)	1	0.18	0			
Moderate or severe impairment	0				0			
Macular degeneration								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	0				1	(0.4)	1	0.40
Macular hole								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.22
Moderate or severe impairment	0				0			
Meibomianitis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	0				0			
Myopia								
Normal	0				3	(0.3)	3	0.35
Mild impairment	1	(0.1)	1	0.18	0			
Moderate or severe impairment	0				0			
Normal tension glaucoma								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Ocular hyperaemia								
Normal	0				0			
Mild impairment	0				1	(0.1)	2	0.44
Moderate or severe impairment	2	(0.9)	3	2.42	0			
Ocular hypertension								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.30	2	(0.2)	3	0.61
Moderate or severe impairment	0				0			
Ocular ischaemic syndrome								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Open angle glaucoma								
Normal	0				0			
Mild impairment	0				1	(0.1)	2	0.42
Moderate or severe impairment	0				0			
Ophthalmic vein thrombosis								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Optic disc haemorrhage								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Optic disc vascular disorder								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Photophobia								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Photopsia								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Post thrombotic retinopathy								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Posterior capsule opacification								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.38	0			
Moderate or severe impairment	0				0			
Presbyopia								
Normal	0				1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.21	2	(0.3)	2	0.47
Moderate or severe impairment	0				0			
Pterygium								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Retinal artery occlusion								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Retinal deposits								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Retinal detachment								
Normal	0				2	(0.2)	2	0.24
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Retinal drusen								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	1	(0.1)	1	0.21
Moderate or severe impairment	0				0			
Retinal scar								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.76	0			
Retinal tear								
Normal	0				1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Retinal vein occlusion								
Normal	0				1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.18	0			
Moderate or severe impairment	0				0			
Retinopathy								
Normal	0				2	(0.2)	2	0.33
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Scintillating scotoma								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Uveitis								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Visual acuity reduced								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.23
Moderate or severe impairment	0				0			
Visual impairment								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				1	(0.5)	9	7.63
Vitreous degeneration								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.22
Moderate or severe impairment	0				0			
Vitreous floaters								
Normal	0				2	(0.2)	2	0.33
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Vitreous haemorrhage								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.40	2	(0.2)	2	0.34
Moderate or severe impairment	0				0			
Vitreous opacities								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Skin and subcutaneous tissue disorders								
All								
Normal	52	(4.6)	53	6.83	62	(5.5)	69	8.78
Mild impairment	60	(7.2)	66	10.80	49	(6.1)	65	11.15
Moderate or severe impairment	11	(5.4)	12	7.81	17	(6.9)	21	10.95
Eczema								
Normal	5	(0.5)	5	0.58	4	(0.4)	4	0.57
Mild impairment	5	(0.6)	5	0.70	1	(0.1)	1	0.21
Moderate or severe impairment	0				2	(0.8)	2	1.07
Rash								
Normal	5	(0.4)	5	0.68	4	(0.4)	4	0.42
Mild impairment	9	(1.1)	9	1.51	6	(0.8)	7	0.87
Moderate or severe impairment	0				1	(0.4)	1	0.66
Alopecia								
Normal	4	(0.4)	4	0.53	1	(0.1)	1	0.09
Mild impairment	4	(0.5)	4	0.78	2	(0.3)	2	0.35
Moderate or severe impairment	0				0			
Dermatitis contact								
Normal	4	(0.4)	4	0.53	4	(0.4)	4	0.51
Mild impairment	2	(0.2)	3	0.36	8	(1.0)	8	1.59

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	1	(0.5)	1	0.51	2	(0.9)	2	1.27
Dermatitis								
Normal	4	(0.3)	4	0.53	3	(0.3)	4	0.47
Mild impairment	2	(0.3)	2	0.52	3	(0.4)	3	0.50
Moderate or severe impairment	1	(0.4)	1	0.77	1	(0.4)	1	0.66
Hyperhidrosis								
Normal	3	(0.3)	3	0.33	4	(0.3)	4	0.47
Mild impairment	4	(0.5)	4	0.64	1	(0.1)	1	0.13
Moderate or severe impairment	1	(0.4)	1	0.76	0			
Pruritus								
Normal	3	(0.3)	3	0.33	8	(0.7)	8	1.04
Mild impairment	5	(0.6)	5	0.76	1	(0.1)	1	0.12
Moderate or severe impairment	0				3	(1.3)	3	1.68
Blister								
Normal	2	(0.2)	2	0.34	0			
Mild impairment	0				2	(0.2)	2	0.34
Moderate or severe impairment	0				0			
Acne								
Normal	2	(0.2)	2	0.24	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Rash erythematous								
Normal	2	(0.2)	2	0.33	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Ingrowing nail								
Normal	2	(0.2)	2	0.17	1	(0.1)	1	0.09
Mild impairment	0				2	(0.3)	2	0.25
Moderate or severe impairment	0				0			
Urticaria								
Normal	1	(0.1)	1	0.16	5	(0.4)	5	0.69
Mild impairment	6	(0.7)	6	0.93	6	(0.7)	6	0.86
Moderate or severe impairment	0				1	(0.4)	1	0.42
Skin ulcer								
Normal	1	(0.1)	1	0.16	3	(0.3)	3	0.45
Mild impairment	3	(0.4)	3	0.45	1	(0.1)	1	0.21
Moderate or severe impairment	0				1	(0.4)	1	0.40
Umbilical haematoma								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Dermatitis allergic								
Normal	1	(0.1)	1	0.09	1	(0.1)	1	0.15
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Dry skin								
Normal	1	(0.1)	1	0.09	4	(0.4)	4	0.40
Mild impairment	3	(0.4)	3	0.51	1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Granuloma annulare								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Myxoid cyst								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Skin exfoliation								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Skin lesion								
Normal	1	(0.1)	1	0.09	1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.26	0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Urticaria contact								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nail bed inflammation								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Dermal cyst								
Normal	1	(0.1)	1	0.18	1	(0.1)	1	0.09
Mild impairment	0				3	(0.4)	3	0.60
Moderate or severe impairment	0				0			
Hidradenitis								
Normal	1	(0.1)	1	0.18	1	(0.1)	1	0.09
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Ingrown hair								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Lichen sclerosus								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Macule								
Normal	1	(0.1)	1	0.18	1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Skin irritation								
Normal	1	(0.1)	1	0.18	3	(0.3)	3	0.35
Mild impairment	2	(0.2)	3	0.36	0			
Moderate or severe impairment	1	(0.6)	1	1.13	0			
Actinic keratosis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Alopecia areata								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Angioedema								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				2	(0.3)	2	0.25
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Asteatosis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Chronic spontaneous urticaria								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cold sweat								
Normal	0				0			
Mild impairment	3	(0.4)	3	0.46	6	(0.7)	10	2.27

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	1	(0.4)	1	0.76	2	(0.7)	2	1.06
Cold urticaria								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Decubitus ulcer								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.20	0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Dermatitis atopic								
Normal	0				2	(0.2)	2	0.37
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Diabetic foot								
Normal	0				2	(0.2)	2	0.17
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Drug eruption								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Ecchymosis								
Normal	0				2	(0.2)	2	0.18
Mild impairment	1	(0.1)	1	0.20	0			
Moderate or severe impairment	0				0			
Erythema								
Normal	0				2	(0.2)	2	0.27
Mild impairment	0				2	(0.3)	2	0.34
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Haemorrhage subcutaneous								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Hyperkeratosis								
Normal	0				1	(0.1)	1	0.18
Mild impairment	2	(0.2)	2	0.32	1	(0.1)	1	0.21
Moderate or severe impairment	0				0			
Intertrigo								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Lentigo								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Leukoplakia								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Lipodystrophy acquired								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Lipohypertrophy								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Livedo reticularis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Miliaria								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.37	2	(0.3)	2	0.25
Moderate or severe impairment	0				2	(0.8)	2	0.84
Neurodermatitis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.23
Moderate or severe impairment	0				0			
Night sweats								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.32	0			
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Pruritus allergic								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.22
Moderate or severe impairment	0				0			
Psoriasis								
Normal	0				1	(0.1)	1	0.09
Mild impairment	2	(0.2)	2	0.24	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				1	(0.5)	1	0.83
Purpura								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Rash maculo-papular								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Rash papular								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.88	0			
Seborrhoea								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Skin discolouration								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Skin fissures								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Skin odour abnormal								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.20	0			
Moderate or severe impairment	0				0			
Skin reaction								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	0				0			
Telangiectasia								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Urticaria thermal								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Xeroderma								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.26	0			
Moderate or severe impairment	0				0			
Investigations								
All								
Normal	45	(4.0)	53	6.64	48	(4.3)	55	7.03
Mild impairment	38	(4.6)	44	7.21	24	(3.0)	25	4.40
Moderate or severe impairment	11	(5.2)	12	8.42	7	(3.0)	8	5.00
Weight increased								
Normal	8	(0.7)	8	0.97	11	(1.0)	11	1.22
Mild impairment	10	(1.2)	10	1.59	7	(0.9)	7	1.15
Moderate or severe impairment	2	(0.9)	2	1.27	0			
SARS-CoV-2 test positive								
Normal	4	(0.4)	4	0.49	4	(0.4)	4	0.73
Mild impairment	2	(0.2)	2	0.41	0			
Moderate or severe impairment	1	(0.5)	1	0.88	0			
Blood triglycerides increased								
Normal	3	(0.3)	3	0.42	2	(0.2)	2	0.17
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Blood pressure increased								
Normal	3	(0.3)	3	0.44	0			
Mild impairment	1	(0.1)	1	0.12	2	(0.2)	2	0.34
Moderate or severe impairment	1	(0.4)	1	0.77	2	(0.8)	2	0.82
Blood creatinine increased								
Normal	2	(0.2)	2	0.25	0			
Mild impairment	1	(0.1)	1	0.20	0			
Moderate or severe impairment	5	(2.4)	5	3.76	0			
Occult blood								
Normal	2	(0.2)	2	0.24	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Liver function test increased								
Normal	2	(0.2)	2	0.24	1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-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 cholesterol increased								
Normal	2	(0.2)	2	0.18	1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.26	0			
Moderate or severe impairment	0				0			
Blood immunoglobulin E increased								
Normal	2	(0.2)	2	0.17	3	(0.3)	3	0.26
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Alanine aminotransferase increased								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	3	(0.4)	3	0.52	0			
Moderate or severe impairment	0				0			
Arthroscopy								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Blood glucose fluctuation								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Monocyte count decreased								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.83
Monofilament pressure perception test								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Blood alkaline phosphatase increased								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	2	(0.2)	2	0.40	0			
Moderate or severe impairment	0				0			
Catheterisation cardiac								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Liver function test abnormal								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				1	(0.1)	2	0.47
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Glycosylated haemoglobin increased								
Normal	1	(0.1)	1	0.09	2	(0.2)	3	0.26
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Blood urine present								
Normal	1	(0.1)	3	0.25	1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Bone density decreased								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Electrocardiogram abnormal								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	1	(0.1)	1	0.26	2	(0.2)	2	0.33
Moderate or severe impairment	0				0			
Electrocardiogram ST segment abnormal								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Electrocardiogram T wave inversion								
Normal	1	(0.1)	1	0.08	1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Low density lipoprotein increased								
Normal	1	(0.1)	1	0.08	1	(0.1)	1	0.15
Mild impairment	1	(0.1)	1	0.26	1	(0.1)	1	0.22
Moderate or severe impairment	0				0			
QRS axis abnormal								
Normal	1	(0.1)	1	0.08	1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Transaminases increased								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	0				0			
Angiogram								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Aspartate aminotransferase increased								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	1	(0.1)	1	0.20	1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Blood testosterone decreased								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Heart rate increased								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hepatic enzyme increased								
Normal	1	(0.1)	1	0.18	2	(0.2)	2	0.27
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Mycobacterium tuberculosis complex test positive								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Amylase increased								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.85
Antinuclear antibody positive								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Blood creatine increased								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Blood creatine phosphokinase increased								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Blood glucose decreased								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-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 glucose increased								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Blood potassium increased								
Normal	0				1	(0.1)	1	0.14
Mild impairment	1	(0.1)	1	0.20	0			
Moderate or severe impairment	0				0			
Blood pressure decreased								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Blood uric acid increased								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Body temperature increased								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Breath sounds abnormal								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Carbohydrate antigen 19-9 increased								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cardiac murmur								
Normal	0				2	(0.2)	2	0.27
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cardiac stress test abnormal								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Ejection fraction decreased								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Electrocardiogram P wave biphasic								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Electrocardiogram repolarisation abnormality								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Electrocardiogram ST segment depression								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Eosinophil count increased								
Normal	0				1	(0.1)	2	0.37
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.76	0			
Free fatty acids increased								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.83
Glomerular filtration rate decreased								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.85
Grip strength decreased								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Haematocrit increased								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Haemoglobin decreased								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Haemoglobin increased								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-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								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.26	0			
Moderate or severe impairment	0				0			
International normalised ratio abnormal								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
International normalised ratio decreased								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
International normalised ratio increased								
Normal	0				0			
Mild impairment	1	(0.1)	2	0.24	0			
Moderate or severe impairment	0				0			
Intraocular pressure increased								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.23
Moderate or severe impairment	0				0			
Lipase increased								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Lipids abnormal								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Lipids increased								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Occult blood positive								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.26	0			
Moderate or severe impairment	0				0			
Platelet count decreased								
Normal	0				2	(0.2)	2	0.29
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Prostatic specific antigen increased								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.24	0			
Moderate or severe impairment	0				0			
Red blood cell count decreased								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Thyroid function test abnormal								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Transferrin saturation decreased								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Vitamin D decreased								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Weight decreased								
Normal	0				2	(0.2)	2	0.27
Mild impairment	4	(0.5)	4	0.48	0			
Moderate or severe impairment	0				0			
White blood cell count decreased								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cardiac disorders								
All								
Normal	40	(3.6)	55	5.98	37	(3.3)	54	5.89
Mild impairment	40	(4.8)	57	8.53	30	(3.8)	35	5.35
Moderate or severe impairment	15	(7.2)	21	11.31	17	(7.1)	26	14.46
Coronary artery disease								
Normal	5	(0.4)	5	0.43	5	(0.4)	5	0.49
Mild impairment	5	(0.6)	5	0.76	2	(0.3)	2	0.25
Moderate or severe impairment	2	(1.0)	2	0.98	3	(1.3)	3	1.67
Atrial fibrillation								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	4	(0.4)	4	0.42	0			
Mild impairment	6	(0.7)	6	0.87	3	(0.4)	3	0.38
Moderate or severe impairment	3	(1.5)	4	2.01	3	(1.3)	3	1.68
Angina pectoris								
Normal	4	(0.4)	4	0.43	3	(0.3)	3	0.32
Mild impairment	2	(0.2)	2	0.24	1	(0.1)	1	0.13
Moderate or severe impairment	1	(0.4)	1	0.76	0			
Myocardial ischaemia								
Normal	3	(0.3)	3	0.40	3	(0.3)	3	0.36
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Angina unstable								
Normal	3	(0.3)	3	0.27	2	(0.2)	2	0.27
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Myocardial infarction								
Normal	3	(0.3)	3	0.27	2	(0.2)	2	0.17
Mild impairment	3	(0.4)	3	0.61	1	(0.1)	1	0.12
Moderate or severe impairment	0				1	(0.4)	1	0.42
Ventricular extrasystoles								
Normal	3	(0.3)	3	0.35	1	(0.1)	2	0.17
Mild impairment	5	(0.6)	5	0.89	1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Acute coronary syndrome								
Normal	3	(0.3)	3	0.26	0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Supraventricular extrasystoles								
Normal	2	(0.2)	2	0.32	0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	1	(0.5)	1	0.51	1	(0.4)	1	0.40
Supraventricular tachycardia								
Normal	2	(0.2)	2	0.25	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cardiac failure chronic								
Normal	2	(0.2)	2	0.18	1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Palpitations								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	2	(0.2)	2	0.17	2	(0.2)	2	0.27
Mild impairment	4	(0.5)	4	0.70	3	(0.4)	3	0.58
Moderate or severe impairment	1	(0.5)	1	0.51	2	(0.8)	2	0.82
Acute myocardial infarction								
Normal	2	(0.2)	2	0.17	3	(0.3)	3	0.32
Mild impairment	5	(0.6)	5	0.83	3	(0.4)	3	0.47
Moderate or severe impairment	2	(1.0)	2	0.98	2	(0.8)	2	1.07
Arrhythmia								
Normal	2	(0.2)	2	0.17	0			
Mild impairment	0				3	(0.4)	3	0.48
Moderate or severe impairment	0				0			
Cardiac failure								
Normal	2	(0.2)	2	0.17	1	(0.1)	1	0.09
Mild impairment	4	(0.5)	4	0.56	1	(0.1)	1	0.24
Moderate or severe impairment	2	(1.0)	2	0.98	1	(0.5)	2	1.70
Tachycardia								
Normal	2	(0.2)	2	0.17	4	(0.4)	4	0.40
Mild impairment	0				2	(0.3)	2	0.35
Moderate or severe impairment	1	(0.5)	1	0.47	1	(0.5)	1	0.85
Cardiac flutter								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Bundle branch block left								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.15
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Left ventricular dysfunction								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.15
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Mitral valve incompetence								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	2	(0.2)	2	0.24	2	(0.2)	2	0.24
Moderate or severe impairment	0				0			
Aortic valve sclerosis								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Left atrial enlargement								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	1	(0.1)	1	0.16	2	(0.2)	2	0.23
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Coronary artery occlusion								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Arteriosclerosis coronary artery								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Left ventricular hypertrophy								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	2	(0.2)	2	0.24	1	(0.1)	1	0.21
Moderate or severe impairment	0				1	(0.4)	1	0.42
Bundle branch block right								
Normal	1	(0.1)	1	0.18	3	(0.3)	3	0.42
Mild impairment	1	(0.1)	1	0.12	4	(0.5)	5	0.71
Moderate or severe impairment	0				0			
Cardiovascular disorder								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Aortic valve calcification								
Normal	0				2	(0.2)	2	0.24
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Aortic valve incompetence								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Atrial enlargement								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Atrial flutter								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Atrial thrombosis								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Atrioventricular block complete								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Atrioventricular block first degree								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.32	0			
Moderate or severe impairment	0				0			
Bradycardia								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.23
Moderate or severe impairment	1	(0.5)	1	0.51	1	(0.4)	1	0.42
Cardiac arrest								
Normal	0				2	(0.2)	2	0.17
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cardiac dysfunction								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Cardiac failure acute								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Cardiac failure congestive								
Normal	0				0			
Mild impairment	3	(0.4)	3	0.42	0			
Moderate or severe impairment	1	(0.5)	1	0.51	2	(0.9)	3	2.54
Cardiac perfusion defect								
Normal	0				1	(0.1)	2	0.31
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cardiac ventricular thrombosis								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Cardio-respiratory arrest								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.77	0			
Cardiomegaly								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.26	0			
Moderate or severe impairment	0				0			
Chronic coronary syndrome								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Coronary artery stenosis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Diastolic dysfunction								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Left atrial dilatation								
Normal	0				1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Mitral valve stenosis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.77	0			
Pericardial effusion								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Pericarditis								
Normal	0				1	(0.1)	1	0.15
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Sinus arrhythmia								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Sinus bradycardia								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				2	(0.2)	2	0.17
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	0				0			
Sinus tachycardia								
Normal	0				3	(0.3)	3	0.26
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Subendocardial ischaemia								
Normal	0				2	(0.2)	2	0.17
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Tricuspid valve incompetence								
Normal	0				1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.12	2	(0.3)	2	0.25
Moderate or severe impairment	0				0			
Ventricular arrhythmia								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Ventricular tachycardia								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Vascular disorders								
All								
Normal	38	(3.4)	44	5.01	34	(3.0)	48	5.69
Mild impairment	36	(4.3)	39	6.39	35	(4.4)	37	6.22
Moderate or severe impairment	5	(2.4)	5	2.81	11	(4.7)	14	7.47
Hypertension								
Normal	17	(1.5)	17	2.08	15	(1.3)	19	2.22
Mild impairment	18	(2.2)	18	3.20	17	(2.2)	17	3.23
Moderate or severe impairment	2	(1.0)	2	1.03	6	(2.5)	7	3.32
Arteriosclerosis								
Normal	4	(0.4)	4	0.43	4	(0.3)	4	0.53
Mild impairment	0				3	(0.4)	3	0.38
Moderate or severe impairment	0				0			
Peripheral arterial occlusive disease								
Normal	3	(0.3)	4	0.42	1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.20	1	(0.1)	1	0.13

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Hypotension								
Normal	3	(0.3)	3	0.27	1	(0.1)	1	0.09
Mild impairment	3	(0.4)	3	0.51	0			
Moderate or severe impairment	0				2	(0.9)	2	1.27
Peripheral artery stenosis								
Normal	2	(0.2)	5	0.65	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Blood pressure inadequately controlled								
Normal	2	(0.2)	2	0.17	1	(0.1)	1	0.09
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Varicose ulceration								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Haematoma								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				2	(0.9)	2	1.68
Hypertensive crisis								
Normal	1	(0.1)	1	0.16	1	(0.1)	3	0.46
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Aortic arteriosclerosis								
Normal	1	(0.1)	1	0.09	3	(0.3)	3	0.40
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.22
Moderate or severe impairment	0				0			
Brachiocephalic arteriosclerosis								
Normal	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Mild impairment	0				2	(0.3)	2	0.25
Moderate or severe impairment	0				0			
Flushing								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hot flush								
Normal	1	(0.1)	1	0.08	1	(0.1)	1	0.15
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Superficial vein thrombosis								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	2	(0.2)	2	0.24	0			
Moderate or severe impairment	0				0			
Venous stenosis								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Aneurysm								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Aortic aneurysm								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Aortic dilatation								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Aortic stenosis								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Arterial insufficiency								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.20	0			
Moderate or severe impairment	0				0			
Blood pressure fluctuation								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Deep vein thrombosis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.76	0			
Diabetic vascular disorder								
Normal	0				1	(0.1)	1	0.15
Mild impairment	1	(0.1)	1	0.21	1	(0.1)	1	0.21

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Hypertensive urgency								
Normal	0				2	(0.2)	3	0.32
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Iliac artery stenosis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Intermittent claudication								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Macroangiopathy								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Neovascularisation								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	0				0			
Orthostatic hypotension								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.40	0			
Moderate or severe impairment	0				0			
Peripheral artery aneurysm								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.22
Moderate or severe impairment	0				0			
Peripheral artery occlusion								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Peripheral coldness								
Normal	0				0			
Mild impairment	3	(0.4)	3	0.36	1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Peripheral ischaemia								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Peripheral vascular disorder								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Peripheral venous disease								
Normal	0				1	(0.1)	1	0.15
Mild impairment	1	(0.1)	1	0.21	1	(0.1)	1	0.13
Moderate or severe impairment	1	(0.5)	1	0.51	1	(0.4)	1	0.40
Phlebitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Thrombophlebitis								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Thrombosis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Varicose vein								
Normal	0				1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.12	2	(0.2)	2	0.37
Moderate or severe impairment	0				0			
Renal and urinary disorders								
All								
Normal	24	(2.1)	28	3.25	17	(1.5)	22	2.26
Mild impairment	21	(2.5)	28	4.63	22	(2.8)	27	4.66
Moderate or severe impairment	9	(4.3)	9	5.75	15	(6.4)	21	10.79
Renal cyst								
Normal	5	(0.4)	5	0.58	2	(0.2)	2	0.17
Mild impairment	2	(0.2)	2	0.40	2	(0.2)	2	0.36
Moderate or severe impairment	0				1	(0.5)	1	0.85
Renal pain								
Normal	3	(0.3)	3	0.44	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-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								
Normal	2	(0.2)	2	0.25	1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nephrolithiasis								
Normal	2	(0.2)	2	0.17	2	(0.2)	2	0.24
Mild impairment	2	(0.2)	2	0.24	1	(0.1)	2	0.44
Moderate or severe impairment	1	(0.5)	1	0.51	1	(0.4)	2	0.81
Dysuria								
Normal	2	(0.2)	3	0.25	1	(0.1)	1	0.09
Mild impairment	2	(0.2)	2	0.33	3	(0.4)	3	0.47
Moderate or severe impairment	0				0			
Urethral stenosis								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Chromaturia								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pollakiuria								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	4	(0.5)	4	0.70	1	(0.1)	1	0.13
Moderate or severe impairment	0				1	(0.4)	1	0.42
Ureterolithiasis								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	2	(0.2)	2	0.24	2	(0.3)	2	0.25
Moderate or severe impairment	0				1	(0.4)	1	0.40
Acute kidney injury								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.09
Mild impairment	2	(0.2)	2	0.32	0			
Moderate or severe impairment	0				4	(1.7)	4	1.63
Chronic kidney disease								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.09
Mild impairment	2	(0.2)	2	0.32	1	(0.1)	1	0.24
Moderate or severe impairment	1	(0.4)	1	0.76	4	(1.7)	4	2.09
Microalbuminuria								
Normal	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.26	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Pyelocaliectasis								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Renal colic								
Normal	1	(0.1)	1	0.09	2	(0.2)	2	0.24
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.83
Nocturia								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				2	(0.3)	2	0.25
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Urinary incontinence								
Normal	1	(0.1)	1	0.08	3	(0.3)	3	0.26
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Urinary retention								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				1	(0.4)	1	0.42
Urinary tract disorder								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Bladder mass								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Bladder prolapse								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.18	0			
Moderate or severe impairment	0				0			
Calculus urinary								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Cystitis haemorrhagic								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Diabetic nephropathy								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	4	(0.5)	4	0.93
Moderate or severe impairment	2	(1.0)	2	1.40	0			
Haematuria								
Normal	0				1	(0.1)	1	0.09
Mild impairment	1	(0.1)	2	0.43	4	(0.5)	4	0.60
Moderate or severe impairment	0				0			
Hydrocalyx								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				1	(0.5)	1	0.85
Hydronephrosis								
Normal	0				1	(0.1)	1	0.15
Mild impairment	1	(0.1)	1	0.18	0			
Moderate or severe impairment	0				0			
Hypertensive nephropathy								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Hypertonic bladder								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Micturition urgency								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nephropathy								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.85
Nephrotic syndrome								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.18	0			
Moderate or severe impairment	0				0			
Polyuria								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.18	0			
Moderate or severe impairment	0				1	(0.4)	1	0.40

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Proteinuria								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Renal failure								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.77	0			
Renal impairment								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.18	2	(0.3)	2	0.25
Moderate or severe impairment	3	(1.4)	3	1.80	1	(0.4)	1	0.42
Renal mass								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Strangury								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Stress urinary incontinence								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Urinary tract inflammation								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Urinary tract obstruction								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Psychiatric disorders								
All								
Normal	22	(2.0)	24	3.10	29	(2.6)	31	3.95
Mild impairment	16	(1.9)	18	2.39	11	(1.4)	11	2.17
Moderate or severe impairment	3	(1.5)	3	1.91	3	(1.3)	4	2.51
Insomnia								
Normal	4	(0.4)	4	0.58	3	(0.3)	4	0.47

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	6	(0.7)	6	0.85	2	(0.2)	2	0.34
Moderate or severe impairment	1	(0.5)	1	0.51	1	(0.4)	1	0.40
Depression								
Normal	4	(0.4)	4	0.42	9	(0.8)	9	1.14
Mild impairment	4	(0.5)	4	0.57	2	(0.3)	2	0.47
Moderate or severe impairment	0				1	(0.5)	1	0.85
Anxiety								
Normal	2	(0.2)	2	0.33	7	(0.6)	7	1.00
Mild impairment	4	(0.5)	4	0.48	2	(0.2)	2	0.24
Moderate or severe impairment	0				1	(0.4)	1	0.40
Depressed mood								
Normal	2	(0.2)	2	0.27	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Sleep disorder								
Normal	2	(0.2)	2	0.26	3	(0.3)	3	0.44
Mild impairment	2	(0.2)	2	0.24	1	(0.1)	1	0.23
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Agitation								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Drug abuse								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Irritability								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Mental status changes								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nightmare								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Adjustment disorder with mixed anxiety and depressed mood								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Disorientation								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Post-traumatic stress disorder								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Stress								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Attention deficit hyperactivity disorder								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Adjustment disorder								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.88	0			
Adjustment disorder with depressed mood								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.22
Moderate or severe impairment	0				0			
Affect lability								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.85
Anxiety disorder								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Bruxism								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Drug dependence								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Emotional distress								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.22
Moderate or severe impairment	0				0			
Fear								
Normal	0				2	(0.2)	2	0.31
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Listless								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Major depression								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.23
Moderate or severe impairment	0				0			
Mixed anxiety and depressive disorder								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	0				0			
Mood swings								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Persistent depressive disorder								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Phobia								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Blood and lymphatic system disorders								
All								
Normal	20	(1.8)	22	2.85	19	(1.7)	19	2.12
Mild impairment	13	(1.6)	13	2.11	8	(1.0)	8	1.35

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	3	(1.4)	3	1.79	6	(2.6)	6	3.73
Anaemia								
Normal	12	(1.1)	14	1.86	5	(0.4)	5	0.44
Mild impairment	6	(0.7)	6	1.04	5	(0.6)	5	0.80
Moderate or severe impairment	2	(1.0)	2	1.03	4	(1.8)	4	2.91
Leukopenia								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Blood loss anaemia								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Lymphadenopathy mediastinal								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Iron deficiency anaemia								
Normal	1	(0.1)	1	0.09	2	(0.2)	2	0.27
Mild impairment	1	(0.1)	1	0.21	1	(0.1)	1	0.21
Moderate or severe impairment	0				1	(0.4)	1	0.40
Lymphadenopathy								
Normal	1	(0.1)	1	0.09	1	(0.1)	1	0.18
Mild impairment	2	(0.2)	2	0.38	1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Leukocytosis								
Normal	1	(0.1)	1	0.08	3	(0.3)	3	0.26
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Splenomegaly								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Lymphadenitis								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Eosinophilia								
Normal	0				1	(0.1)	1	0.09
Mild impairment	2	(0.2)	2	0.24	1	(0.1)	1	0.21

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	1	(0.4)	1	0.76	0			
Hypochromic anaemia								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Normocytic anaemia								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pancytopenia								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Polycythaemia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Thrombocytopenia								
Normal	0				1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Thrombocytosis								
Normal	0				1	(0.1)	1	0.14
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Reproductive system and breast disorders								
All								
Normal	13	(1.2)	13	1.66	15	(1.3)	17	2.22
Mild impairment	17	(2.0)	17	2.69	9	(1.1)	11	1.54
Moderate or severe impairment	3	(1.5)	3	1.54	3	(1.3)	5	2.47
Intermenstrual bleeding								
Normal	2	(0.2)	2	0.32	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Erectile dysfunction								
Normal	2	(0.2)	2	0.17	0			
Mild impairment	2	(0.2)	2	0.30	0			
Moderate or severe impairment	1	(0.5)	1	0.51	1	(0.5)	1	0.83

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Prostatitis								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.14
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Breast pain								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Prostatic calcification								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Uterine prolapse								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Ejaculation failure								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Menstruation irregular								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pelvic discomfort								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Dysmenorrhoea								
Normal	1	(0.1)	1	0.18	2	(0.2)	2	0.27
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Premenstrual syndrome								
Normal	1	(0.1)	1	0.18	1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Atrophic vulvovaginitis								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				1	(0.4)	1	0.42

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-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 prostatic hyperplasia								
Normal	0				1	(0.1)	1	0.09
Mild impairment	6	(0.7)	6	1.02	2	(0.2)	2	0.34
Moderate or severe impairment	0				0			
Breast mass								
Normal	0				1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Cervical polyp								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.18	0			
Moderate or severe impairment	0				0			
Colpocele								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Ectropion of cervix								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Fibrocystic breast disease								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Galactorrhoea								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Genital prolapse								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Menopausal disorder								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	0				0			
Menopausal symptoms								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Menstruation delayed								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.20	0			
Moderate or severe impairment	0				0			
Ovarian cyst								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Ovarian disorder								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Penile pain								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Penile rash								
Normal	0				0			
Mild impairment	0				1	(0.1)	2	0.25
Moderate or severe impairment	0				0			
Prostatomegaly								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.26	0			
Moderate or severe impairment	0				0			
Pruritus genital								
Normal	0				1	(0.1)	1	0.14
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Testicular cyst								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Uterine enlargement								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Uterine polyp								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.24	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Vaginal discharge								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Vaginal haemorrhage								
Normal	0				0			
Mild impairment	0				2	(0.2)	2	0.24
Moderate or severe impairment	0				0			
Vulvovaginal dryness								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Vulvovaginal pruritus								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	1	(0.5)	1	0.51	1	(0.4)	1	0.40
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
Normal	13	(1.2)	14	1.68	9	(0.8)	11	1.37
Mild impairment	16	(1.9)	21	3.21	14	(1.8)	21	3.45
Moderate or severe impairment	6	(2.8)	8	5.15	6	(2.4)	11	4.73
Colon adenoma								
Normal	3	(0.3)	3	0.40	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Osteoma								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Small cell lung cancer								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Acrochordon								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Basal cell carcinoma								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				2	(0.3)	2	0.25
Moderate or severe impairment	0				1	(0.4)	1	0.42
Salivary gland neoplasm								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Seborrhoeic keratosis								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	1	(0.1)	2	0.24	0			
Moderate or severe impairment	0				0			
Metastases to liver								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Pancreatic carcinoma								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Squamous cell carcinoma of skin								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Benign neoplasm of thyroid gland								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Melanocytic naevus								
Normal	1	(0.1)	1	0.18	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Adenocarcinoma of colon								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Adenocarcinoma pancreas								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.32	0			
Moderate or severe impairment	0				0			
Adrenal adenoma								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				1	(0.1)	1	0.22
Moderate or severe impairment	0				0			
Benign renal neoplasm								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				1	(0.4)	1	0.40
Bladder cancer								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Bladder papilloma								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.77	0			
Bowen's disease								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Breast cancer								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.66
Breast cancer metastatic								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Chronic myeloid leukaemia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.18	0			
Moderate or severe impairment	0				0			
Colon cancer								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Colon cancer stage II								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.23
Moderate or severe impairment	0				0			
Colorectal cancer								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	1	(0.4)	1	0.77	0			
Dysplastic naevus								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Endometrial adenocarcinoma								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Eye naevus								
Normal	0				0			
Mild impairment	3	(0.4)	4	0.71	0			
Moderate or severe impairment	0				0			
Gastric cancer								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.88	0			
Gastrointestinal tract adenoma								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Glioblastoma multiforme								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Haemangioma of liver								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.38	0			
Moderate or severe impairment	0				0			
Hepatocellular carcinoma								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Invasive breast carcinoma								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Invasive ductal breast carcinoma								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Invasive lobular breast carcinoma								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Lipoma								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Lung adenocarcinoma								
Normal	0				0			
Mild impairment	0				2	(0.3)	2	0.43
Moderate or severe impairment	0				0			
Lung cancer metastatic								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.77	0			
Lymphangioma								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.23
Moderate or severe impairment	0				0			
Malignant melanoma								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Malignant melanoma in situ								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Malignant peritoneal neoplasm								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Metastases to bone marrow								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Metastases to lymph nodes								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Myxoma								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Neoplasm skin								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Oral fibroma								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Ovarian cancer metastatic								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Pancreatic carcinoma metastatic								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.23
Moderate or severe impairment	0				0			
Pancreatic neoplasm								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.33	0			
Moderate or severe impairment	0				0			
Prostate cancer								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.51	0			
Prostatic adenoma								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Renal cell carcinoma								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Renal hamartoma								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Renal neoplasm								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Skin papilloma								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.20	0			
Moderate or severe impairment	0				0			
Small intestine neuroendocrine tumour								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Uterine cancer								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Uterine leiomyoma								
Normal	0				3	(0.3)	3	0.42
Mild impairment	0				2	(0.2)	2	0.37
Moderate or severe impairment	0				0			
Hepatobiliary disorders								
All								
Normal	13	(1.2)	19	2.28	13	(1.1)	13	1.53
Mild impairment	9	(1.1)	10	1.79	8	(1.0)	11	2.09
Moderate or severe impairment	2	(1.0)	2	1.35	4	(1.7)	5	2.48
Hepatic steatosis								
Normal	7	(0.6)	7	0.86	6	(0.5)	6	0.63
Mild impairment	4	(0.5)	4	0.63	4	(0.5)	4	0.71
Moderate or severe impairment	0				0			
Hepatomegaly								
Normal	2	(0.2)	2	0.24	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hypertransaminasaemia								
Normal	2	(0.2)	3	0.35	0			
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Cholecystitis								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hepatic function abnormal								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				2	(0.2)	2	0.34
Moderate or severe impairment	0				0			
Cholecystitis chronic								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gallbladder cholesterolosis								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Non-alcoholic steatohepatitis								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cholelithiasis								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	1	(0.5)	1	0.47	1	(0.4)	1	0.40
Hepatic mass								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Alcoholic liver disease								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.88	0			
Bile duct stone								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	2	0.81
Biliary colic								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.22

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Biliary dyskinesia								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gallbladder disorder								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Gallbladder polyp								
Normal	0				1	(0.1)	1	0.18
Mild impairment	2	(0.2)	2	0.45	2	(0.2)	2	0.45
Moderate or severe impairment	0				0			
Hepatic calcification								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.26	0			
Moderate or severe impairment	0				0			
Hepatic cirrhosis								
Normal	0				2	(0.2)	2	0.23
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hepatic cyst								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Hyperplastic cholecystopathy								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Liver disorder								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				1	(0.5)	1	0.85
Nonalcoholic fatty liver disease								
Normal	0				2	(0.2)	2	0.17
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Steatohepatitis								
Normal	0				0			
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				1	(0.4)	1	0.42
Ear and labyrinth disorders								
All								
Normal	10	(0.9)	10	1.19	9	(0.8)	9	1.25
Mild impairment	13	(1.6)	16	2.20	10	(1.3)	10	1.57
Moderate or severe impairment	5	(2.4)	5	3.46	5	(2.1)	6	3.16
Ear pain								
Normal	3	(0.3)	3	0.43	2	(0.2)	2	0.33
Mild impairment	2	(0.2)	2	0.32	0			
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Vertigo								
Normal	2	(0.2)	2	0.25	1	(0.1)	1	0.15
Mild impairment	6	(0.7)	7	0.92	6	(0.8)	6	0.98
Moderate or severe impairment	2	(1.0)	2	1.76	2	(0.9)	3	1.68
Tinnitus								
Normal	2	(0.2)	2	0.17	0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				1	(0.4)	1	0.66
Hypoacusis								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.12	1	(0.1)	1	0.12
Moderate or severe impairment	0				1	(0.4)	1	0.42
Ear inflammation								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Eustachian tube dysfunction								
Normal	1	(0.1)	1	0.09	1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cerumen impaction								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.21
Moderate or severe impairment	1	(0.4)	1	0.76	0			
Deafness bilateral								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.24	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Deafness neurosensory								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.26	0			
Moderate or severe impairment	0				0			
Deafness unilateral								
Normal	0				1	(0.1)	1	0.14
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Ear discomfort								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
External ear pain								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Meniere's disease								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Middle ear inflammation								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Motion sickness								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Presbyacusis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Vertigo positional								
Normal	0				1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	1	(0.5)	1	0.47	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-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								
Normal	7	(0.6)	8	1.09	11	(1.0)	12	1.50
Mild impairment	5	(0.6)	5	0.66	3	(0.4)	3	0.47
Moderate or severe impairment	2	(0.9)	2	1.23	2	(0.8)	2	1.31
Seasonal allergy								
Normal	4	(0.4)	4	0.49	6	(0.5)	6	0.80
Mild impairment	4	(0.5)	4	0.48	3	(0.4)	3	0.47
Moderate or severe impairment	0				0			
Hypersensitivity								
Normal	2	(0.2)	2	0.35	1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.76	0			
Drug hypersensitivity								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Allergy to arthropod bite								
Normal	1	(0.1)	1	0.09	1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.66
Allergy to arthropod sting								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.66
Anaphylactic reaction								
Normal	0				1	(0.1)	1	0.14
Mild impairment	1	(0.1)	1	0.18	0			
Moderate or severe impairment	0				0			
Food allergy								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.47	0			
Immunisation reaction								
Normal	0				1	(0.1)	2	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-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								
Normal	4	(0.4)	4	0.56	3	(0.3)	3	0.32
Mild impairment	2	(0.2)	2	0.32	2	(0.2)	2	0.24
Moderate or severe impairment	0				0			
Type V hyperlipidaemia								
Normal	3	(0.3)	3	0.40	1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Corneal dystrophy								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Atrial septal defect								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Congenital syphilitic osteochondritis								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cystic fibrosis lung								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.20	0			
Moderate or severe impairment	0				0			
Hydrocele								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				0			
Hypertrophic cardiomyopathy								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Myotonic dystrophy								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Endocrine disorders								
All								
Normal	4	(0.4)	4	0.48	11	(1.0)	11	1.29
Mild impairment	2	(0.2)	2	0.24	4	(0.5)	4	0.50
Moderate or severe impairment	0				4	(1.7)	4	2.29
Hypothyroidism								
Normal	2	(0.2)	2	0.24	1	(0.1)	1	0.18
Mild impairment	0				2	(0.3)	2	0.25
Moderate or severe impairment	0				2	(0.8)	2	1.06
Hypogonadism								
Normal	1	(0.1)	1	0.16	1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Autoimmune thyroiditis								
Normal	1	(0.1)	1	0.08	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Adrenal mass								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.40
Adrenocortical insufficiency acute								
Normal	0				2	(0.2)	2	0.30
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Goitre								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Hyperplasia adrenal								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Hyperprolactinaemia								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hyperthyroidism								
Normal	0				2	(0.2)	2	0.17
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Inappropriate antidiuretic hormone secretion								
Normal	0				1	(0.1)	1	0.14
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Secondary hypogonadism								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.83
Thyroid mass								
Normal	0				2	(0.2)	2	0.23
Mild impairment	2	(0.2)	2	0.24	0			
Moderate or severe impairment	0				0			
Surgical and medical procedures								
All								
Normal	3	(0.3)	3	0.40	2	(0.2)	2	0.17
Mild impairment	3	(0.4)	3	0.64	2	(0.3)	2	0.25
Moderate or severe impairment	0				2	(0.8)	2	1.50
Shoulder operation								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Tooth extraction								
Normal	1	(0.1)	1	0.16	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Knee operation								
Normal	1	(0.1)	1	0.09	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cardiac ablation								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.26	0			
Moderate or severe impairment	0				0			
Cardiac pacemaker replacement								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	1	(0.1)	1	0.12	0			
Moderate or severe impairment	0				1	(0.5)	1	0.85
Large intestinal polypectomy								
Normal	0				1	(0.1)	1	0.09
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Removal of foreign body								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.13
Moderate or severe impairment	0				0			
Skin neoplasm excision								
Normal	0				1	(0.1)	1	0.09
Mild impairment	1	(0.1)	1	0.26	0			
Moderate or severe impairment	0				0			
Spinal operation								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.12
Moderate or severe impairment	0				0			
Toe amputation								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.66
Social circumstances								
All								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Menopause								
Normal	0				1	(0.1)	1	0.15
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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.

7.7.68 Adverse events by baseline renal function, system organ class and preferred term - on-treatment/ 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								
Normal	924				947			
Mild impairment	749				698			
Moderate or severe impairment	206				232			
Missing	1				1			
PYE (years)								
Normal	770.83				783.47			
Mild impairment	606.63				569.62			
Moderate or severe impairment	160.88				183.05			
Missing	0.58				0.33			
Events								
Normal	539	(58.4)	1615	223.87	523	(55.3)	1545	209.32
Mild impairment	472	(63.0)	1511	260.31	416	(59.5)	1232	224.95
Moderate or severe impairment	128	(62.2)	352	229.43	134	(57.9)	482	274.49
Missing	0				0			
Infections and infestations								
All								
Normal	261	(28.2)	403	54.86	269	(28.5)	399	52.67
Mild impairment	223	(29.7)	295	53.00	195	(27.9)	282	51.33
Moderate or severe impairment	60	(29.0)	75	49.92	59	(25.6)	76	44.26
COVID-19								
Normal	88	(9.5)	89	11.72	93	(9.9)	96	11.90
Mild impairment	47	(6.3)	49	8.67	52	(7.4)	54	9.26
Moderate or severe impairment	17	(8.2)	17	11.72	15	(6.6)	15	8.78
Upper respiratory tract infection								
Normal	39	(4.2)	48	5.98	24	(2.5)	26	3.58
Mild impairment	20	(2.6)	23	4.22	15	(2.1)	16	2.65
Moderate or severe impairment	3	(1.5)	4	2.37	6	(2.5)	6	3.25
Nasopharyngitis								
Normal	36	(3.9)	44	6.14	28	(3.0)	31	4.00
Mild impairment	41	(5.4)	49	8.83	41	(5.9)	48	9.51
Moderate or severe impairment	6	(2.8)	6	4.13	10	(4.4)	13	8.46
Urinary tract infection								
Normal	18	(2.0)	19	2.94	21	(2.3)	21	2.44
Mild impairment	13	(1.8)	14	2.43	16	(2.3)	20	3.65
Moderate or severe impairment	6	(3.0)	7	4.57	7	(3.0)	7	4.11

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Gastroenteritis								
Normal	15	(1.6)	15	2.18	9	(0.9)	9	1.40
Mild impairment	7	(0.9)	7	1.56	5	(0.7)	6	1.27
Moderate or severe impairment	4	(1.9)	4	3.26	2	(0.9)	2	1.30
Influenza								
Normal	14	(1.5)	15	2.58	20	(2.1)	23	3.66
Mild impairment	11	(1.5)	13	2.72	7	(1.0)	7	1.62
Moderate or severe impairment	3	(1.4)	3	2.05	1	(0.5)	1	0.87
Bronchitis								
Normal	13	(1.4)	13	1.79	11	(1.2)	11	1.60
Mild impairment	9	(1.2)	10	1.89	3	(0.4)	3	0.52
Moderate or severe impairment	4	(1.9)	4	2.57	3	(1.3)	3	1.26
Pharyngitis								
Normal	12	(1.3)	14	1.75	13	(1.4)	15	2.06
Mild impairment	4	(0.5)	4	0.63	2	(0.3)	3	0.52
Moderate or severe impairment	0				2	(0.9)	2	1.30
Sinusitis								
Normal	7	(0.8)	9	1.29	9	(1.0)	12	1.42
Mild impairment	6	(0.8)	6	0.99	8	(1.2)	8	1.68
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Herpes zoster								
Normal	6	(0.6)	6	0.72	4	(0.4)	4	0.49
Mild impairment	4	(0.5)	4	0.65	9	(1.3)	10	1.64
Moderate or severe impairment	0				2	(0.9)	2	1.30
Pneumonia								
Normal	5	(0.5)	5	0.78	2	(0.2)	2	0.35
Mild impairment	6	(0.8)	6	1.11	2	(0.3)	2	0.27
Moderate or severe impairment	3	(1.5)	3	1.92	2	(0.9)	2	1.30
Respiratory tract infection viral								
Normal	5	(0.5)	6	1.05	4	(0.4)	5	0.92
Mild impairment	4	(0.5)	4	0.75	3	(0.4)	3	0.54
Moderate or severe impairment	0				1	(0.5)	1	0.87
Rhinitis								
Normal	5	(0.5)	5	0.54	5	(0.5)	5	0.68
Mild impairment	2	(0.3)	2	0.36	2	(0.3)	4	0.93
Moderate or severe impairment	0				0			
Vaginal infection								
Normal	4	(0.4)	4	0.68	1	(0.1)	1	0.10
Mild impairment	1	(0.1)	1	0.13	1	(0.2)	1	0.26
Moderate or severe impairment	0				1	(0.4)	1	0.43

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ 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								
Normal	4	(0.4)	4	0.76	8	(0.8)	9	1.25
Mild impairment	7	(0.9)	8	1.25	6	(0.9)	7	1.23
Moderate or severe impairment	1	(0.5)	1	0.48	2	(0.9)	2	1.30
Fungal infection								
Normal	4	(0.4)	5	0.70	2	(0.2)	2	0.29
Mild impairment	3	(0.4)	3	0.58	0			
Moderate or severe impairment	0				0			
Tooth infection								
Normal	4	(0.4)	6	0.80	5	(0.5)	5	0.74
Mild impairment	4	(0.5)	4	0.73	2	(0.3)	2	0.50
Moderate or severe impairment	0				1	(0.4)	1	0.67
COVID-19 pneumonia								
Normal	4	(0.4)	4	0.50	6	(0.6)	6	0.85
Mild impairment	8	(1.1)	8	1.44	3	(0.4)	3	0.42
Moderate or severe impairment	2	(0.9)	2	1.26	1	(0.4)	1	0.42
Vulvovaginal candidiasis								
Normal	3	(0.3)	4	0.52	4	(0.4)	4	0.43
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Respiratory tract infection								
Normal	3	(0.3)	3	0.40	3	(0.3)	3	0.48
Mild impairment	3	(0.4)	3	0.51	3	(0.4)	3	0.43
Moderate or severe impairment	2	(1.0)	2	1.31	0			
Gastroenteritis viral								
Normal	3	(0.3)	3	0.32	2	(0.2)	2	0.29
Mild impairment	2	(0.3)	2	0.38	2	(0.3)	2	0.28
Moderate or severe impairment	0				0			
Lower respiratory tract infection								
Normal	3	(0.3)	3	0.32	1	(0.1)	3	0.33
Mild impairment	2	(0.3)	2	0.27	0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Conjunctivitis								
Normal	3	(0.3)	3	0.32	4	(0.4)	4	0.57
Mild impairment	4	(0.5)	4	0.72	2	(0.3)	2	0.39
Moderate or severe impairment	1	(0.5)	1	0.53	1	(0.4)	1	0.43
Laryngitis								
Normal	3	(0.3)	3	0.32	4	(0.4)	4	0.58
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Coronavirus infection								
Normal	3	(0.3)	3	0.31	2	(0.2)	3	0.48
Mild impairment	1	(0.1)	1	0.14	2	(0.3)	3	0.43
Moderate or severe impairment	0				0			
Gastrointestinal infection								
Normal	2	(0.2)	2	0.39	1	(0.1)	1	0.10
Mild impairment	0				2	(0.3)	3	0.42
Moderate or severe impairment	0				0			
Otitis media								
Normal	2	(0.2)	2	0.38	2	(0.2)	2	0.29
Mild impairment	4	(0.5)	4	0.77	2	(0.3)	2	0.40
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Tooth abscess								
Normal	2	(0.2)	2	0.30	3	(0.3)	3	0.31
Mild impairment	4	(0.5)	4	0.84	3	(0.4)	4	0.76
Moderate or severe impairment	1	(0.5)	1	0.53	1	(0.5)	1	0.87
Fungal skin infection								
Normal	2	(0.2)	2	0.30	1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Furuncle								
Normal	2	(0.2)	3	0.41	2	(0.2)	2	0.21
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Erysipelas								
Normal	2	(0.2)	2	0.29	2	(0.2)	3	0.46
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Ear infection								
Normal	2	(0.2)	2	0.22	3	(0.3)	3	0.39
Mild impairment	2	(0.3)	2	0.34	1	(0.2)	1	0.26
Moderate or severe impairment	0				1	(0.4)	1	0.42
Viral infection								
Normal	2	(0.2)	2	0.22	7	(0.8)	10	1.04
Mild impairment	3	(0.4)	3	0.60	2	(0.3)	2	0.39
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Acute sinusitis								
Normal	2	(0.2)	2	0.21	2	(0.2)	2	0.28
Mild impairment	3	(0.4)	3	0.49	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ 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 syncytial virus infection								
Normal	2	(0.2)	2	0.21	0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.78	0			
Abscess limb								
Normal	1	(0.1)	1	0.20	1	(0.1)	1	0.17
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cellulitis								
Normal	1	(0.1)	1	0.20	2	(0.2)	3	0.45
Mild impairment	2	(0.3)	2	0.27	4	(0.6)	4	0.77
Moderate or severe impairment	1	(0.5)	1	0.48	2	(0.9)	2	1.27
Paraspinal abscess								
Normal	1	(0.1)	1	0.20	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pulpitis dental								
Normal	1	(0.1)	1	0.20	1	(0.1)	1	0.18
Mild impairment	0				3	(0.4)	3	0.64
Moderate or severe impairment	0				0			
Genital infection								
Normal	1	(0.1)	1	0.19	1	(0.1)	1	0.18
Mild impairment	2	(0.3)	2	0.27	0			
Moderate or severe impairment	0				0			
Injection site abscess								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Skin infection								
Normal	1	(0.1)	1	0.19	1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Oral herpes								
Normal	1	(0.1)	2	0.38	1	(0.1)	1	0.11
Mild impairment	1	(0.1)	1	0.22	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Osteomyelitis								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Periodontitis								
Normal	1	(0.1)	1	0.19	3	(0.3)	3	0.46
Mild impairment	0				3	(0.4)	3	0.54
Moderate or severe impairment	3	(1.5)	3	1.84	0			
Pneumonia viral								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pulmonary tuberculoma								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Sepsis								
Normal	1	(0.1)	1	0.19	1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.79	0			
Viral tracheitis								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Vulvovaginal mycotic infection								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Asymptomatic COVID-19								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				1	(0.4)	1	0.43
Balanitis candida								
Normal	1	(0.1)	1	0.11	1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Candida infection								
Normal	1	(0.1)	1	0.11	1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Chlamydial infection								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ 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								
Normal	1	(0.1)	1	0.11	1	(0.1)	1	0.11
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Escherichia urinary tract infection								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gingivitis								
Normal	1	(0.1)	1	0.11	1	(0.1)	1	0.18
Mild impairment	1	(0.1)	2	0.27	3	(0.4)	3	0.64
Moderate or severe impairment	0				0			
Helicobacter gastritis								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Herpes simplex								
Normal	1	(0.1)	1	0.11	1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Infected bite								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Laryngopharyngitis								
Normal	1	(0.1)	1	0.11	1	(0.1)	2	0.21
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Localised infection								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	2	(0.3)	2	0.38	1	(0.1)	1	0.14
Moderate or severe impairment	0				1	(0.4)	1	0.67
Mastitis								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Oropharyngeal candidiasis								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ 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 media chronic								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Tinea infection								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	1	(0.1)	1	0.22	0			
Moderate or severe impairment	0				0			
Tracheitis								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Urethritis								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Viral upper respiratory tract infection								
Normal	1	(0.1)	1	0.11	3	(0.3)	3	0.33
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Acarodermatitis								
Normal	1	(0.1)	1	0.10	3	(0.3)	3	0.31
Mild impairment	1	(0.1)	1	0.13	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Appendicitis								
Normal	1	(0.1)	1	0.10	1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Chronic sinusitis								
Normal	1	(0.1)	1	0.10	2	(0.2)	2	0.22
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Clostridium difficile colitis								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Ear infection fungal								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Helicobacter infection								
Normal	1	(0.1)	1	0.10	1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.21	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Nail infection								
Normal	1	(0.1)	2	0.20	1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Paronychia								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				2	(0.3)	3	0.72
Moderate or severe impairment	1	(0.4)	1	0.78	0			
Peritonsillar abscess								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				1	(0.2)	1	0.26
Moderate or severe impairment	0				0			
Post-acute COVID-19 syndrome								
Normal	1	(0.1)	2	0.20	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Tonsillitis								
Normal	1	(0.1)	1	0.10	1	(0.1)	1	0.11
Mild impairment	2	(0.3)	2	0.34	1	(0.2)	1	0.26
Moderate or severe impairment	0				0			
Viral pharyngitis								
Normal	1	(0.1)	1	0.10	1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Abdominal abscess								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Abscess								
Normal	0				1	(0.1)	1	0.10
Mild impairment	2	(0.3)	2	0.38	0			
Moderate or severe impairment	0				0			
Anal abscess								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Bacteraemia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.24	0			
Moderate or severe impairment	0				0			
Bacterial infection								
Normal	0				1	(0.1)	1	0.11
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Bartholinitis								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Body tinea								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Breast abscess								
Normal	0				3	(0.3)	3	0.40
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Breast cellulitis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Campylobacter gastroenteritis								
Normal	0				1	(0.1)	1	0.17
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cholecystitis infective								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.24	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Chronic hepatitis C								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Clostridium difficile infection								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				1	(0.4)	1	0.43

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Dermatophytosis of nail								
Normal	0				1	(0.1)	1	0.10
Mild impairment	1	(0.1)	1	0.14	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Diabetic foot infection								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	1	(0.4)	1	0.78	0			
Diverticulitis								
Normal	0				2	(0.2)	2	0.21
Mild impairment	0				2	(0.3)	2	0.29
Moderate or severe impairment	0				1	(0.4)	1	0.43
Empyema								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Endophthalmitis								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Enteritis infectious								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Epididymitis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Escherichia bacteraemia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.22	0			
Moderate or severe impairment	0				0			
Eye infection								
Normal	0				1	(0.1)	1	0.17
Mild impairment	0				2	(0.3)	2	0.48
Moderate or severe impairment	0				0			
Eye infection bacterial								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Folliculitis								
Normal	0				1	(0.1)	1	0.17
Mild impairment	1	(0.1)	1	0.14	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Fungal balanitis								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gangrene								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Gastroenteritis norovirus								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Genital candidiasis								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.22	0			
Moderate or severe impairment	0				0			
Genital infection fungal								
Normal	0				2	(0.2)	2	0.21
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Giardiasis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Herpes dermatitis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Herpes virus infection								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Herpes zoster infection neurological								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hordeolum								
Normal	0				2	(0.2)	2	0.28
Mild impairment	2	(0.3)	2	0.27	1	(0.1)	1	0.25
Moderate or severe impairment	0				0			
Infected dermal cyst								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.78	0			
Infective iritis								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Kidney infection								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Labyrinthitis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Lyme disease								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Onychomycosis								
Normal	0				1	(0.1)	1	0.10
Mild impairment	2	(0.3)	2	0.34	3	(0.4)	3	0.41
Moderate or severe impairment	0				0			
Oophoritis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Oral candidiasis								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.22	0			
Moderate or severe impairment	0				0			
Otitis externa								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.22	3	(0.4)	3	0.42
Moderate or severe impairment	1	(0.5)	1	0.48	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ 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 media acute								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				2	(0.3)	2	0.28
Moderate or severe impairment	0				0			
Parotitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Peri-implantitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Pericoronitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Pharyngotonsillitis								
Normal	0				1	(0.1)	1	0.11
Mild impairment	1	(0.1)	1	0.24	1	(0.1)	2	0.29
Moderate or severe impairment	0				0			
Post procedural infection								
Normal	0				0			
Mild impairment	0				2	(0.3)	2	0.38
Moderate or severe impairment	0				0			
Postoperative wound infection								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.22	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Purulence								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Pustule								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.91	0			
Pyelonephritis								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Rotavirus infection								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Salpingitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Sinusitis bacterial								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Skin bacterial infection								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Skin candida								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	1	(0.1)	1	0.25
Moderate or severe impairment	0				0			
Soft tissue infection								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.67
Subcutaneous abscess								
Normal	0				1	(0.1)	1	0.10
Mild impairment	1	(0.1)	1	0.13	1	(0.1)	2	0.29
Moderate or severe impairment	1	(0.5)	1	0.91	0			
Suspected COVID-19								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.22	0			
Moderate or severe impairment	0				0			
Sweat gland infection								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Tinea cruris								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ 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 pedis								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.22	1	(0.2)	1	0.26
Moderate or severe impairment	0				0			
Tinea versicolour								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Urosepsis								
Normal	0				2	(0.2)	2	0.28
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Varicella								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Varicella zoster virus infection								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.91	0			
Viral rhinitis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Vulvitis								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Wound infection								
Normal	0				0			
Mild impairment	2	(0.3)	2	0.34	1	(0.1)	1	0.25
Moderate or severe impairment	1	(0.4)	1	0.79	0			
Gastrointestinal disorders								
All								
Normal	121	(13.1)	187	25.40	115	(12.1)	145	20.65
Mild impairment	100	(13.4)	148	25.55	80	(11.4)	112	19.94
Moderate or severe impairment	30	(14.9)	45	28.14	26	(10.8)	45	24.37
Diarrhoea								
Normal	33	(3.6)	39	5.22	25	(2.6)	25	3.75

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	38	(5.1)	47	8.39	17	(2.4)	17	3.16
Moderate or severe impairment	13	(6.6)	16	10.30	9	(3.7)	10	5.22
Nausea								
Normal	20	(2.2)	21	2.90	18	(1.9)	18	2.54
Mild impairment	13	(1.7)	13	2.26	3	(0.4)	4	0.57
Moderate or severe impairment	4	(2.0)	4	2.07	6	(2.4)	7	3.73
Vomiting								
Normal	14	(1.5)	18	3.08	7	(0.7)	7	0.97
Mild impairment	8	(1.1)	8	1.52	6	(0.9)	7	1.23
Moderate or severe impairment	2	(0.9)	6	3.19	3	(1.2)	5	2.39
Abdominal pain								
Normal	10	(1.1)	10	1.40	7	(0.7)	8	1.23
Mild impairment	6	(0.8)	6	0.98	8	(1.1)	8	1.33
Moderate or severe impairment	0				3	(1.4)	3	2.15
Gastrooesophageal reflux disease								
Normal	9	(1.0)	9	1.20	7	(0.7)	7	1.03
Mild impairment	3	(0.4)	3	0.41	4	(0.6)	4	0.78
Moderate or severe impairment	1	(0.5)	1	0.91	3	(1.2)	3	1.29
Toothache								
Normal	7	(0.7)	7	0.75	3	(0.3)	5	0.88
Mild impairment	6	(0.8)	6	0.99	6	(0.9)	7	1.51
Moderate or severe impairment	0				1	(0.4)	1	0.67
Haemorrhoids								
Normal	6	(0.7)	6	0.80	1	(0.1)	1	0.17
Mild impairment	1	(0.1)	1	0.14	1	(0.2)	1	0.26
Moderate or severe impairment	0				1	(0.4)	1	0.43
Constipation								
Normal	6	(0.6)	6	0.80	8	(0.8)	8	1.20
Mild impairment	6	(0.8)	9	1.65	7	(1.0)	7	1.39
Moderate or severe impairment	4	(1.9)	4	2.65	1	(0.4)	1	0.43
Abdominal pain upper								
Normal	6	(0.6)	8	1.09	10	(1.1)	10	1.34
Mild impairment	6	(0.8)	6	1.09	5	(0.7)	6	0.97
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Chronic gastritis								
Normal	5	(0.5)	5	0.70	1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.14	1	(0.1)	1	0.14
Moderate or severe impairment	2	(1.0)	2	1.69	2	(0.8)	2	0.86
Dental caries								
Normal	5	(0.5)	6	0.62	4	(0.4)	4	0.49

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	4	(0.5)	5	0.68	4	(0.6)	4	0.86
Moderate or severe impairment	2	(1.0)	2	1.06	2	(0.8)	2	1.35
Gastritis								
Normal	4	(0.4)	4	0.68	6	(0.6)	6	0.83
Mild impairment	3	(0.4)	3	0.49	2	(0.3)	2	0.27
Moderate or severe impairment	0				1	(0.5)	1	0.85
Dyspepsia								
Normal	3	(0.3)	3	0.49	6	(0.6)	6	0.77
Mild impairment	4	(0.5)	4	0.70	2	(0.3)	2	0.39
Moderate or severe impairment	0				0			
Abdominal distension								
Normal	3	(0.3)	3	0.41	2	(0.2)	2	0.29
Mild impairment	4	(0.5)	4	0.54	1	(0.1)	1	0.14
Moderate or severe impairment	0				1	(0.5)	1	0.87
Flatulence								
Normal	3	(0.3)	3	0.41	1	(0.1)	1	0.18
Mild impairment	0				1	(0.1)	1	0.25
Moderate or severe impairment	1	(0.5)	1	0.91	0			
Food poisoning								
Normal	3	(0.3)	3	0.40	1	(0.1)	2	0.34
Mild impairment	0				3	(0.4)	3	0.63
Moderate or severe impairment	2	(1.0)	2	1.39	0			
Diverticulum intestinal								
Normal	3	(0.3)	3	0.31	0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Large intestine polyp								
Normal	3	(0.3)	3	0.31	3	(0.3)	3	0.38
Mild impairment	1	(0.1)	1	0.21	3	(0.4)	4	0.57
Moderate or severe impairment	0				0			
Abdominal pain lower								
Normal	2	(0.2)	2	0.30	1	(0.1)	1	0.10
Mild impairment	2	(0.3)	2	0.34	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Aphthous ulcer								
Normal	2	(0.2)	2	0.20	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Inguinal hernia								
Normal	2	(0.2)	2	0.20	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				1	(0.1)	2	0.29
Moderate or severe impairment	0				0			
Diverticulum								
Normal	1	(0.1)	1	0.20	1	(0.1)	1	0.11
Mild impairment	0				2	(0.3)	2	0.39
Moderate or severe impairment	0				0			
Gastrointestinal angiodysplasia								
Normal	1	(0.1)	1	0.20	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Tongue rough								
Normal	1	(0.1)	1	0.20	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gastric dilatation								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gastric polyps								
Normal	1	(0.1)	1	0.19	1	(0.1)	1	0.17
Mild impairment	1	(0.1)	1	0.14	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Vomiting projectile								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pancreatitis chronic								
Normal	1	(0.1)	1	0.19	1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Dry mouth								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Enterocolitis								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	2	(0.3)	3	0.41	0			
Moderate or severe impairment	0				0			
Hyperaesthesia teeth								
Normal	1	(0.1)	1	0.11	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Loose tooth								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Oral discomfort								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pancreatitis								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Tooth impacted								
Normal	1	(0.1)	1	0.11	1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Anal fissure								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				1	(0.4)	1	0.42
Diabetic gastropathy								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Eosinophilic oesophagitis								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Eructation								
Normal	1	(0.1)	1	0.10	1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gastric ulcer								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gastrointestinal haemorrhage								
Normal	1	(0.1)	1	0.10	2	(0.2)	2	0.29

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Haemorrhoidal haemorrhage								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Hiatus hernia								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	1	(0.1)	1	0.21	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Hypoaesthesia oral								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	1	(0.1)	3	0.72	0			
Moderate or severe impairment	1	(0.4)	1	0.78	0			
Rectal polyp								
Normal	1	(0.1)	1	0.10	1	(0.1)	1	0.11
Mild impairment	1	(0.1)	1	0.14	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Abdominal discomfort								
Normal	0				2	(0.2)	2	0.21
Mild impairment	2	(0.3)	2	0.27	3	(0.4)	4	0.87
Moderate or severe impairment	1	(0.4)	1	0.78	0			
Abdominal wall disorder								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Acid peptic disease								
Normal	0				2	(0.2)	2	0.22
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Anal pruritus								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Colitis								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				2	(0.8)	2	0.86
Colitis ischaemic								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Colitis microscopic								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Crohn's disease								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Duodenitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Enteritis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Epigastric discomfort								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Faeces pale								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.87
Frequent bowel movements								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Gastric disorder								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gastric dysplasia								
Normal	0				1	(0.1)	1	0.17
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gastric mucosal hypertrophy								
Normal	0				1	(0.1)	1	0.17

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gastrointestinal disorder								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Gastrointestinal inflammation								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Gastrointestinal sounds abnormal								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gingival bleeding								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Gingival disorder								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Haematochezia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Hyperchlorhydria								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Ileus								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Impaired gastric emptying								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Intestinal dilatation								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Intra-abdominal haematoma								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Irritable bowel syndrome								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Lip swelling								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Melaena								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Mesenteric panniculitis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Noninfective gingivitis								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.22	0			
Moderate or severe impairment	0				0			
Odynophagia								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Oesophageal pain								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Oesophagitis								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Oral pain								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	1	(0.1)	1	0.22	0			
Moderate or severe impairment	0				0			
Pancreatic duct dilatation								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.24	0			
Moderate or severe impairment	0				0			
Pancreatic failure								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.24	0			
Moderate or severe impairment	0				0			
Pancreatic pseudocyst								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.67
Pancreatitis acute								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Peptic ulcer								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Periodontal disease								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	2	(0.3)	2	0.50
Moderate or severe impairment	0				0			
Periodontal inflammation								
Normal	0				1	(0.1)	2	0.22
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Proctalgia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.24	0			
Moderate or severe impairment	0				0			
Rectal prolapse								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Small intestinal obstruction								
Normal	0				1	(0.1)	1	0.10

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Stomatitis								
Normal	0				0			
Mild impairment	0				2	(0.3)	2	0.29
Moderate or severe impairment	0				0			
Tooth disorder								
Normal	0				1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Ulcerative gastritis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Umbilical hernia								
Normal	0				1	(0.1)	1	0.11
Mild impairment	1	(0.1)	1	0.13	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Upper gastrointestinal haemorrhage								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Musculoskeletal and connective tissue disorders								
All								
Normal	116	(12.6)	180	23.81	118	(12.5)	162	22.28
Mild impairment	109	(14.5)	161	28.00	96	(13.7)	134	24.51
Moderate or severe impairment	21	(10.2)	28	18.15	31	(13.2)	42	21.77
Back pain								
Normal	30	(3.3)	32	4.75	24	(2.5)	26	3.63
Mild impairment	27	(3.6)	29	4.75	30	(4.3)	30	5.85
Moderate or severe impairment	5	(2.4)	5	2.80	7	(2.8)	8	4.40
Arthralgia								
Normal	17	(1.8)	20	2.48	23	(2.4)	25	3.72
Mild impairment	22	(2.9)	26	4.70	13	(1.9)	16	3.06
Moderate or severe impairment	6	(3.0)	7	4.72	12	(5.1)	13	6.65
Pain in extremity								
Normal	16	(1.7)	17	2.14	17	(1.8)	18	2.61
Mild impairment	12	(1.6)	13	2.03	13	(1.9)	18	3.45

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	3	(1.5)	3	1.54	1	(0.5)	1	0.85
Osteoarthritis								
Normal	10	(1.1)	12	1.53	15	(1.6)	18	2.36
Mild impairment	10	(1.3)	10	1.73	8	(1.1)	8	1.55
Moderate or severe impairment	1	(0.5)	1	0.48	1	(0.4)	1	0.42
Myalgia								
Normal	7	(0.8)	7	0.99	6	(0.6)	6	0.91
Mild impairment	7	(0.9)	7	1.34	3	(0.4)	3	0.52
Moderate or severe impairment	0				0			
Muscle spasms								
Normal	7	(0.8)	7	0.91	2	(0.2)	2	0.21
Mild impairment	13	(1.7)	15	2.78	7	(1.0)	7	1.30
Moderate or severe impairment	3	(1.5)	3	2.22	0			
Neck pain								
Normal	7	(0.8)	7	0.92	5	(0.5)	5	0.54
Mild impairment	6	(0.8)	6	1.09	3	(0.4)	3	0.63
Moderate or severe impairment	2	(0.9)	2	1.57	0			
Arthritis								
Normal	5	(0.5)	5	0.70	1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.13	4	(0.6)	4	0.79
Moderate or severe impairment	0				1	(0.4)	1	0.67
Rotator cuff syndrome								
Normal	4	(0.4)	4	0.60	2	(0.2)	2	0.21
Mild impairment	1	(0.1)	1	0.14	2	(0.3)	2	0.27
Moderate or severe impairment	0				0			
Tendonitis								
Normal	4	(0.4)	4	0.51	2	(0.2)	2	0.22
Mild impairment	4	(0.5)	6	1.02	2	(0.3)	2	0.49
Moderate or severe impairment	0				0			
Intervertebral disc disorder								
Normal	3	(0.3)	3	0.41	1	(0.1)	1	0.11
Mild impairment	0				1	(0.1)	1	0.25
Moderate or severe impairment	0				0			
Intervertebral disc protrusion								
Normal	3	(0.3)	6	0.70	4	(0.4)	5	0.68
Mild impairment	5	(0.7)	6	0.92	2	(0.3)	2	0.28
Moderate or severe impairment	0				0			
Foot deformity								
Normal	3	(0.3)	5	0.60	2	(0.2)	2	0.36
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				1	(0.4)	1	0.42
Periarthritis								
Normal	3	(0.3)	3	0.32	1	(0.1)	1	0.10
Mild impairment	4	(0.5)	4	0.72	3	(0.4)	3	0.52
Moderate or severe impairment	1	(0.5)	1	0.53	2	(0.8)	2	0.86
Exostosis								
Normal	3	(0.3)	3	0.31	1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Spinal osteoarthritis								
Normal	3	(0.3)	3	0.31	2	(0.2)	2	0.21
Mild impairment	3	(0.4)	3	0.62	2	(0.3)	2	0.28
Moderate or severe impairment	0				1	(0.4)	2	0.83
Plantar fasciitis								
Normal	2	(0.2)	3	0.41	3	(0.3)	3	0.31
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Bursitis								
Normal	2	(0.2)	2	0.30	2	(0.2)	2	0.22
Mild impairment	1	(0.1)	1	0.14	1	(0.1)	1	0.14
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Musculoskeletal stiffness								
Normal	2	(0.2)	2	0.30	0			
Mild impairment	2	(0.3)	2	0.34	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Back disorder								
Normal	2	(0.2)	2	0.30	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Osteochondrosis								
Normal	2	(0.2)	2	0.29	3	(0.3)	3	0.47
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Trigger finger								
Normal	2	(0.2)	2	0.29	2	(0.2)	2	0.27
Mild impairment	4	(0.5)	4	0.82	3	(0.4)	5	0.71
Moderate or severe impairment	1	(0.4)	1	0.78	0			
Groin pain								
Normal	2	(0.2)	2	0.22	0			
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				1	(0.4)	1	0.43
Musculoskeletal chest pain								
Normal	2	(0.2)	2	0.22	0			
Mild impairment	1	(0.1)	1	0.13	1	(0.1)	1	0.14
Moderate or severe impairment	0				1	(0.4)	1	0.42
Chondropathy								
Normal	2	(0.2)	2	0.21	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Soft tissue swelling								
Normal	1	(0.1)	3	0.59	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Spinal stenosis								
Normal	1	(0.1)	2	0.39	1	(0.1)	1	0.10
Mild impairment	3	(0.4)	4	0.69	0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Muscular weakness								
Normal	1	(0.1)	1	0.19	2	(0.2)	2	0.29
Mild impairment	2	(0.3)	2	0.36	1	(0.1)	1	0.25
Moderate or severe impairment	0				0			
Musculoskeletal pain								
Normal	1	(0.1)	1	0.19	1	(0.1)	1	0.11
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Pain in jaw								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Bone cyst								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Coccydynia								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	1	(0.1)	1	0.24	0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Costochondritis								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				1	(0.5)	1	0.85
Fibromyalgia								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Myositis								
Normal	1	(0.1)	1	0.11	1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Polyarthritis								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Spinal pain								
Normal	1	(0.1)	1	0.11	2	(0.2)	2	0.29
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				1	(0.4)	1	0.43
Tenosynovitis								
Normal	1	(0.1)	1	0.11	3	(0.3)	3	0.31
Mild impairment	0				4	(0.6)	5	0.81
Moderate or severe impairment	0				2	(0.8)	2	1.10
Acquired claw toe								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Facet joint syndrome								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Joint effusion								
Normal	1	(0.1)	1	0.10	1	(0.1)	1	0.10
Mild impairment	1	(0.1)	2	0.45	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Meniscopathy								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Psoriatic arthropathy								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Sacroiliitis								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Tendon disorder								
Normal	1	(0.1)	1	0.10	1	(0.1)	1	0.18
Mild impairment	2	(0.3)	2	0.45	0			
Moderate or severe impairment	0				0			
Arthropathy								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.22	0			
Moderate or severe impairment	0				0			
Axillary mass								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Bone pain								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cervical spinal stenosis								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Diastasis recti abdominis								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Dupuytren's contracture								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Fistula								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Flank pain								
Normal	0				3	(0.3)	4	0.49
Mild impairment	0				3	(0.4)	3	0.63

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	1	(0.5)	1	0.91	0			
Haemarthrosis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Intervertebral disc degeneration								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Intervertebral disc space narrowing								
Normal	0				0			
Mild impairment	0				1	(0.1)	2	0.27
Moderate or severe impairment	0				0			
Jaw disorder								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Joint swelling								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				1	(0.1)	1	0.25
Moderate or severe impairment	0				1	(0.4)	1	0.43
Limb deformity								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Lumbar spinal stenosis								
Normal	0				1	(0.1)	1	0.10
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Mastication disorder								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	2	0.86
Muscle contracture								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.79	0			
Muscle twitching								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Neuropathic arthropathy								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nodal osteoarthritis								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Osteochondritis								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Osteopenia								
Normal	0				1	(0.1)	1	0.10
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Osteoporosis								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.41	0			
Moderate or severe impairment	0				0			
Periostitis								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Polymyalgia rheumatica								
Normal	0				1	(0.1)	3	0.52
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Rheumatoid arthritis								
Normal	0				1	(0.1)	1	0.17
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Scoliosis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Spinal retrolisthesis								
Normal	0				0			
Mild impairment	0				1	(0.1)	2	0.27

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Synovial cyst								
Normal	0				0			
Mild impairment	2	(0.3)	2	0.27	0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Tenosynovitis stenosans								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Torticollis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.79	1	(0.5)	1	0.87
Vertebral osteophyte								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nervous system disorders								
All								
Normal	83	(9.0)	112	16.10	75	(7.9)	100	13.61
Mild impairment	80	(10.7)	117	19.95	76	(10.8)	105	19.59
Moderate or severe impairment	17	(8.2)	23	15.98	32	(13.5)	43	27.15
Headache								
Normal	29	(3.2)	35	5.33	22	(2.3)	25	3.42
Mild impairment	23	(3.0)	31	5.77	25	(3.6)	33	5.91
Moderate or severe impairment	5	(2.4)	7	4.68	7	(2.9)	9	6.16
Dizziness								
Normal	14	(1.5)	17	2.28	15	(1.6)	17	2.44
Mild impairment	20	(2.7)	26	4.49	14	(2.0)	18	3.45
Moderate or severe impairment	4	(1.9)	5	3.80	8	(3.2)	9	5.34
Carpal tunnel syndrome								
Normal	8	(0.9)	8	1.18	3	(0.3)	3	0.47
Mild impairment	3	(0.4)	3	0.41	4	(0.6)	4	0.76
Moderate or severe impairment	0				0			
Hypoaesthesia								
Normal	6	(0.7)	9	1.38	2	(0.2)	2	0.29
Mild impairment	2	(0.3)	2	0.27	5	(0.7)	5	1.04
Moderate or severe impairment	1	(0.5)	1	0.53	2	(0.8)	3	1.29

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Sciatica								
Normal	6	(0.7)	6	0.89	5	(0.5)	6	0.64
Mild impairment	7	(0.9)	7	1.30	6	(0.9)	6	1.18
Moderate or severe impairment	0				1	(0.4)	1	0.67
Migraine								
Normal	4	(0.4)	4	0.59	1	(0.1)	1	0.18
Mild impairment	2	(0.3)	2	0.34	1	(0.1)	1	0.14
Moderate or severe impairment	0				1	(0.5)	1	0.87
Syncope								
Normal	4	(0.4)	4	0.43	1	(0.1)	1	0.11
Mild impairment	2	(0.3)	2	0.34	0			
Moderate or severe impairment	0				0			
Paraesthesia								
Normal	3	(0.3)	3	0.41	6	(0.6)	6	0.92
Mild impairment	5	(0.7)	6	0.80	4	(0.6)	4	0.76
Moderate or severe impairment	0				2	(0.9)	2	1.29
Tremor								
Normal	3	(0.3)	3	0.32	2	(0.2)	2	0.35
Mild impairment	6	(0.8)	7	1.04	5	(0.7)	8	1.75
Moderate or severe impairment	2	(0.9)	2	1.26	1	(0.5)	2	1.75
Diabetic neuropathy								
Normal	2	(0.2)	2	0.38	6	(0.6)	6	0.77
Mild impairment	2	(0.3)	2	0.27	3	(0.4)	3	0.63
Moderate or severe impairment	1	(0.4)	1	0.78	3	(1.3)	3	1.98
Transient ischaemic attack								
Normal	2	(0.2)	2	0.21	1	(0.1)	1	0.11
Mild impairment	1	(0.1)	1	0.22	2	(0.3)	2	0.38
Moderate or severe impairment	0				0			
Autonomic nervous system imbalance								
Normal	1	(0.1)	1	0.20	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Carotid artery aneurysm								
Normal	1	(0.1)	1	0.20	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Facial paralysis								
Normal	1	(0.1)	1	0.20	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Piriformis syndrome								
Normal	1	(0.1)	1	0.20	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Thalamic infarction								
Normal	1	(0.1)	1	0.20	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Neuropathy peripheral								
Normal	1	(0.1)	2	0.38	2	(0.2)	2	0.28
Mild impairment	4	(0.5)	4	0.65	4	(0.6)	4	0.67
Moderate or severe impairment	1	(0.4)	1	0.79	3	(1.2)	3	1.52
Vascular headache								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Ageusia								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Anosmia								
Normal	1	(0.1)	1	0.11	1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cerebrovascular disorder								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	1	(0.1)	1	0.24	0			
Moderate or severe impairment	0				0			
Cervical radiculopathy								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Neuroglycopenia								
Normal	1	(0.1)	1	0.11	1	(0.1)	3	0.33
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Presyncope								
Normal	1	(0.1)	1	0.11	1	(0.1)	1	0.10
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				2	(0.8)	2	0.86

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Carotid artery stenosis								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	1	(0.1)	1	0.13	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Cluster headache								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Disturbance in attention								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Dysgeusia								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	2	(0.3)	2	0.38	0			
Moderate or severe impairment	0				0			
Intracranial pressure increased								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Amnesia								
Normal	0				0			
Mild impairment	2	(0.3)	2	0.36	0			
Moderate or severe impairment	0				0			
Balance disorder								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Basilar migraine								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Brain injury								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Burning sensation								
Normal	0				3	(0.3)	3	0.38
Mild impairment	2	(0.3)	2	0.27	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Carotid arteriosclerosis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Cerebral arteriosclerosis								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.24	0			
Moderate or severe impairment	0				0			
Cerebral artery embolism								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cerebral atrophy								
Normal	0				1	(0.1)	1	0.11
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Cerebral haemorrhage								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Cerebral infarction								
Normal	0				0			
Mild impairment	0				1	(0.2)	1	0.26
Moderate or severe impairment	0				0			
Cerebrovascular accident								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				1	(0.5)	1	0.87
Cervicobrachial syndrome								
Normal	0				1	(0.1)	1	0.10
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Cognitive disorder								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				1	(0.5)	1	0.87
Dementia Alzheimer's type								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ 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 postural								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Essential tremor								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Facial nerve disorder								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Hemiparesis								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hypoglycaemic coma								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.87
Hyporeflexia								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Ischaemic stroke								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Lethargy								
Normal	0				0			
Mild impairment	0				2	(0.3)	2	0.29
Moderate or severe impairment	0				0			
Loss of consciousness								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Lumbar radiculopathy								
Normal	0				3	(0.3)	4	0.42
Mild impairment	1	(0.1)	1	0.14	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Memory impairment								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	2	(1.0)	2	1.31	0			
Mental impairment								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Meralgia paraesthetica								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Morton's neuralgia								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Myelopathy								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Neuralgia								
Normal	0				1	(0.1)	1	0.11
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Ophthalmic migraine								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Orthostatic tremor								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Parkinsonian gait								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Peripheral paralysis								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ 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 herpetic neuralgia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	1	(0.5)	1	0.91	0			
Radiculopathy								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Restless legs syndrome								
Normal	0				0			
Mild impairment	0				1	(0.2)	1	0.26
Moderate or severe impairment	0				0			
Sleep deficit								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.87
Somnolence								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Tension headache								
Normal	0				0			
Mild impairment	1	(0.1)	2	0.27	0			
Moderate or severe impairment	2	(1.0)	2	1.44	0			
Thrombotic stroke								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				1	(0.4)	1	0.67
Trigeminal neuralgia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Vascular encephalopathy								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.24	0			
Moderate or severe impairment	0				0			
Vertebral artery occlusion								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
White matter lesion								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
General disorders and administration site conditions								
All								
Normal	81	(8.8)	131	20.58	74	(7.8)	122	15.53
Mild impairment	98	(13.1)	160	27.80	77	(11.0)	109	19.67
Moderate or severe impairment	20	(9.7)	22	13.98	23	(9.9)	30	16.61
Fatigue								
Normal	13	(1.4)	14	2.16	8	(0.8)	8	1.06
Mild impairment	13	(1.8)	15	2.32	5	(0.7)	5	0.81
Moderate or severe impairment	1	(0.5)	1	0.53	2	(0.8)	2	0.85
Injection site reaction								
Normal	9	(1.0)	18	3.35	2	(0.2)	4	0.42
Mild impairment	6	(0.8)	11	2.38	3	(0.4)	3	0.64
Moderate or severe impairment	0				1	(0.4)	1	0.67
Pyrexia								
Normal	8	(0.9)	8	1.02	13	(1.4)	14	1.98
Mild impairment	22	(2.9)	23	3.87	20	(2.8)	21	3.58
Moderate or severe impairment	2	(1.0)	2	1.44	4	(1.7)	4	2.41
Oedema peripheral								
Normal	6	(0.7)	6	1.06	4	(0.4)	5	0.54
Mild impairment	6	(0.8)	6	1.07	4	(0.6)	4	0.65
Moderate or severe impairment	5	(2.5)	5	2.55	1	(0.5)	1	0.87
Chest pain								
Normal	6	(0.6)	6	0.80	3	(0.3)	3	0.32
Mild impairment	5	(0.7)	5	0.75	2	(0.3)	2	0.27
Moderate or severe impairment	3	(1.4)	3	2.04	0			
Chest discomfort								
Normal	4	(0.4)	4	0.59	0			
Mild impairment	4	(0.5)	4	0.70	2	(0.3)	2	0.39
Moderate or severe impairment	0				0			
Asthenia								
Normal	4	(0.4)	4	0.59	3	(0.3)	3	0.39
Mild impairment	6	(0.8)	6	1.10	5	(0.7)	5	0.90
Moderate or severe impairment	0				0			
Medical device site pruritus								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	4	(0.4)	4	0.52	0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Influenza like illness								
Normal	3	(0.3)	3	0.58	2	(0.2)	2	0.21
Mild impairment	1	(0.1)	2	0.27	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Medical device site bruise								
Normal	3	(0.3)	5	0.71	1	(0.1)	1	0.11
Mild impairment	2	(0.3)	2	0.27	0			
Moderate or severe impairment	0				0			
Malaise								
Normal	3	(0.3)	4	0.50	3	(0.3)	5	0.66
Mild impairment	9	(1.2)	10	1.53	8	(1.1)	10	1.74
Moderate or severe impairment	1	(0.4)	1	0.78	1	(0.4)	1	0.43
Pain								
Normal	3	(0.3)	3	0.49	7	(0.7)	7	1.03
Mild impairment	6	(0.8)	7	1.30	4	(0.6)	4	0.57
Moderate or severe impairment	1	(0.4)	1	0.78	3	(1.3)	4	2.55
Peripheral swelling								
Normal	3	(0.3)	4	0.58	3	(0.3)	3	0.40
Mild impairment	2	(0.3)	2	0.27	0			
Moderate or severe impairment	0				1	(0.5)	1	0.87
Medical device site erythema								
Normal	2	(0.2)	2	0.39	1	(0.1)	1	0.11
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Injection site pruritus								
Normal	2	(0.2)	17	3.23	1	(0.1)	1	0.18
Mild impairment	2	(0.3)	2	0.27	0			
Moderate or severe impairment	0				0			
Injection site erythema								
Normal	2	(0.2)	2	0.30	1	(0.1)	1	0.11
Mild impairment	1	(0.1)	3	0.67	2	(0.3)	2	0.29
Moderate or severe impairment	0				1	(0.4)	1	0.43
Thirst								
Normal	2	(0.2)	2	0.30	1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.22	0			
Moderate or severe impairment	0				0			
Injection site mass								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	2	(0.2)	2	0.21	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Inflammation								
Normal	1	(0.1)	1	0.19	1	(0.1)	1	0.10
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				1	(0.4)	1	0.43
Injection site haemorrhage								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	1	(0.1)	1	0.22	2	(0.3)	2	0.39
Moderate or severe impairment	0				0			
Injection site pain								
Normal	1	(0.1)	1	0.19	7	(0.7)	25	2.87
Mild impairment	2	(0.3)	2	0.45	5	(0.7)	5	1.02
Moderate or severe impairment	0				0			
Injection site swelling								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	1	(0.1)	1	0.21	1	(0.1)	1	0.25
Moderate or severe impairment	0				0			
Medical device site reaction								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	2	(0.3)	4	0.62	1	(0.1)	1	0.14
Moderate or severe impairment	1	(0.4)	1	0.78	0			
Multiple organ dysfunction syndrome								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Vaccination site inflammation								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Vaccination site pruritus								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Xerosis								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Discomfort								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	1	(0.1)	1	0.11	0			
Mild impairment	1	(0.1)	1	0.22	1	(0.1)	8	1.90
Moderate or severe impairment	0				0			
Drug intolerance								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	2	(0.3)	2	0.27	0			
Moderate or severe impairment	0				0			
Feeling hot								
Normal	1	(0.1)	1	0.11	1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gait disturbance								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	1	(0.5)	1	0.48	1	(0.4)	1	0.42
Hunger								
Normal	1	(0.1)	2	0.22	0			
Mild impairment	4	(0.5)	4	0.62	2	(0.3)	2	0.40
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Injection site dermatitis								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Injection site hypersensitivity								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Medical device site eczema								
Normal	1	(0.1)	1	0.11	1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Medical device site haemorrhage								
Normal	1	(0.1)	1	0.11	1	(0.1)	1	0.11
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	2	(1.0)	2	1.06	1	(0.4)	1	0.43
Medical device site hypersensitivity								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Medical device site pain								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	1	(0.1)	1	0.11	2	(0.2)	2	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Injection site bruising								
Normal	1	(0.1)	1	0.10	2	(0.2)	2	0.21
Mild impairment	1	(0.1)	1	0.22	3	(0.4)	3	0.53
Moderate or severe impairment	1	(0.4)	1	0.79	0			
Localised oedema								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Application site bruise								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.22	0			
Moderate or severe impairment	0				0			
Application site pruritus								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.22	0			
Moderate or severe impairment	0				0			
Axillary pain								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.87
Chills								
Normal	0				1	(0.1)	1	0.11
Mild impairment	4	(0.5)	4	0.61	0			
Moderate or severe impairment	0				0			
Condition aggravated								
Normal	0				0			
Mild impairment	0				1	(0.2)	1	0.26
Moderate or severe impairment	0				0			
Cyst								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				1	(0.4)	1	0.42
Death								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				1	(0.4)	1	0.43
Early satiety								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Facial pain								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Feeling abnormal								
Normal	0				0			
Mild impairment	3	(0.4)	5	0.89	0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Hernia								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Implant site pruritus								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Injection site haematoma								
Normal	0				3	(0.3)	8	1.41
Mild impairment	2	(0.3)	6	1.34	0			
Moderate or severe impairment	0				0			
Injection site hypertrophy								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Injection site induration								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Injection site oedema								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Injection site rash								
Normal	0				1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.22	0			
Moderate or severe impairment	0				0			
Injection site urticaria								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Medical device site dermatitis								
Normal	0				1	(0.1)	1	0.11
Mild impairment	4	(0.5)	7	1.13	5	(0.7)	11	1.57
Moderate or severe impairment	0				2	(0.8)	2	0.86
Medical device site haematoma								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Medical device site inflammation								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Medical device site rash								
Normal	0				0			
Mild impairment	0				1	(0.2)	1	0.26
Moderate or severe impairment	0				0			
Non-cardiac chest pain								
Normal	0				3	(0.3)	5	0.52
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Oedema								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				2	(0.3)	2	0.38
Moderate or severe impairment	1	(0.4)	1	0.78	0			
Oedema due to renal disease								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.24	0			
Moderate or severe impairment	0				0			
Procedural failure								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Swelling								
Normal	0				1	(0.1)	1	0.11
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Swelling face								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	1	(0.1)	1	0.25
Moderate or severe impairment	0				1	(0.4)	1	0.42
Systemic inflammatory response syndrome								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Vaccination site erythema								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Vaccination site pain								
Normal	0				3	(0.3)	3	0.33
Mild impairment	9	(1.2)	11	2.02	3	(0.4)	3	0.76
Moderate or severe impairment	1	(0.5)	1	0.91	2	(0.9)	2	1.55
Vaccination site reaction								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Vessel puncture site bruise								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Injury, poisoning and procedural complications								
All								
Normal	64	(6.9)	78	10.43	67	(7.1)	79	11.39
Mild impairment	83	(11.0)	104	18.12	56	(8.0)	63	12.12
Moderate or severe impairment	17	(8.4)	22	15.13	24	(10.3)	36	20.84
Fall								
Normal	10	(1.1)	10	1.22	4	(0.4)	5	0.52
Mild impairment	9	(1.2)	9	1.50	3	(0.4)	3	0.64
Moderate or severe impairment	0				3	(1.3)	3	1.94
Vaccination complication								
Normal	5	(0.5)	6	0.91	5	(0.5)	7	0.90
Mild impairment	9	(1.2)	12	2.01	9	(1.3)	11	1.88
Moderate or severe impairment	1	(0.5)	1	0.91	7	(2.9)	9	4.80
Contusion								
Normal	5	(0.5)	6	0.81	1	(0.1)	1	0.11

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	7	(0.9)	7	1.12	5	(0.7)	5	0.80
Moderate or severe impairment	2	(0.9)	2	1.26	1	(0.4)	1	0.43
Limb injury								
Normal	4	(0.4)	4	0.51	1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.22	3	(0.4)	3	0.61
Moderate or severe impairment	0				2	(0.8)	3	1.77
Ligament sprain								
Normal	3	(0.3)	3	0.57	6	(0.6)	6	0.92
Mild impairment	6	(0.8)	6	0.95	2	(0.3)	2	0.38
Moderate or severe impairment	0				0			
Skin laceration								
Normal	3	(0.3)	3	0.32	0			
Mild impairment	3	(0.4)	3	0.58	0			
Moderate or severe impairment	1	(0.5)	1	0.91	0			
Ankle fracture								
Normal	3	(0.3)	3	0.31	1	(0.1)	1	0.10
Mild impairment	1	(0.1)	1	0.13	1	(0.1)	1	0.14
Moderate or severe impairment	0				1	(0.4)	1	0.42
Incorrect dose administered								
Normal	2	(0.2)	2	0.38	3	(0.3)	4	0.63
Mild impairment	0				2	(0.3)	3	0.72
Moderate or severe impairment	1	(0.4)	1	0.78	0			
Thermal burn								
Normal	2	(0.2)	2	0.30	0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				2	(0.9)	2	1.30
Road traffic accident								
Normal	2	(0.2)	2	0.29	1	(0.1)	1	0.10
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	1	(0.5)	1	0.91	0			
Tendon rupture								
Normal	2	(0.2)	2	0.29	0			
Mild impairment	0				1	(0.2)	1	0.26
Moderate or severe impairment	0				0			
Joint injury								
Normal	2	(0.2)	2	0.30	4	(0.4)	4	0.49
Mild impairment	3	(0.4)	3	0.57	0			
Moderate or severe impairment	0				0			
Accidental overdose								
Normal	2	(0.2)	2	0.29	3	(0.3)	4	0.73

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	4	(0.5)	4	0.76	0			
Moderate or severe impairment	1	(0.5)	1	0.91	0			
Fibula fracture								
Normal	2	(0.2)	2	0.22	0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Hand fracture								
Normal	2	(0.2)	2	0.21	1	(0.1)	1	0.10
Mild impairment	4	(0.5)	4	0.79	0			
Moderate or severe impairment	0				0			
Skin abrasion								
Normal	2	(0.2)	4	0.41	0			
Mild impairment	5	(0.7)	5	0.94	3	(0.4)	3	0.64
Moderate or severe impairment	1	(0.5)	1	0.91	1	(0.5)	1	0.87
Upper limb fracture								
Normal	2	(0.2)	2	0.20	0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Facial bones fracture								
Normal	1	(0.1)	1	0.20	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Overdose								
Normal	1	(0.1)	1	0.20	1	(0.1)	1	0.18
Mild impairment	2	(0.3)	2	0.34	0			
Moderate or severe impairment	1	(0.4)	1	0.78	2	(0.9)	2	1.28
Procedural complication								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Rib fracture								
Normal	1	(0.1)	1	0.19	2	(0.2)	2	0.35
Mild impairment	2	(0.3)	2	0.34	1	(0.1)	1	0.14
Moderate or severe impairment	1	(0.5)	1	0.48	2	(0.9)	2	0.83
Extra dose administered								
Normal	1	(0.1)	1	0.19	1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Subdural haematoma								
Normal	1	(0.1)	1	0.19	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Wrong product administered								
Normal	1	(0.1)	2	0.38	0			
Mild impairment	0				2	(0.3)	2	0.49
Moderate or severe impairment	0				0			
Injury								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Muscle strain								
Normal	1	(0.1)	1	0.11	3	(0.3)	3	0.40
Mild impairment	0				1	(0.1)	1	0.25
Moderate or severe impairment	0				0			
Post procedural fistula								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Post procedural hypothyroidism								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Radius fracture								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Wound								
Normal	1	(0.1)	1	0.11	4	(0.4)	4	0.64
Mild impairment	2	(0.3)	2	0.38	1	(0.2)	1	0.26
Moderate or severe impairment	0				0			
Animal bite								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				2	(0.8)	2	0.85
Back injury								
Normal	1	(0.1)	1	0.10	1	(0.1)	1	0.10
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Injury of conjunctiva								
Normal	1	(0.1)	1	0.10	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Neck injury								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Procedural pain								
Normal	1	(0.1)	1	0.10	1	(0.1)	1	0.18
Mild impairment	2	(0.3)	2	0.45	0			
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Spinal compression fracture								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Tooth fracture								
Normal	1	(0.1)	1	0.10	1	(0.1)	1	0.11
Mild impairment	2	(0.3)	2	0.38	0			
Moderate or severe impairment	1	(0.4)	1	0.78	1	(0.5)	1	0.87
Accidental underdose								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.24	0			
Moderate or severe impairment	0				0			
Arthropod bite								
Normal	0				2	(0.2)	2	0.36
Mild impairment	3	(0.4)	3	0.69	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Arthropod sting								
Normal	0				0			
Mild impairment	3	(0.4)	3	0.51	0			
Moderate or severe impairment	0				1	(0.4)	1	0.67
Bone contusion								
Normal	0				2	(0.2)	2	0.28
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Burn oral cavity								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Burns first degree								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Cervical vertebral fracture								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Chillblains								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	1	(0.4)	1	0.78	0			
Concussion								
Normal	0				2	(0.2)	2	0.37
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Craniocerebral injury								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Crush injury								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.87
Deafness traumatic								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Endotracheal intubation complication								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Epicondylitis								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Exposure to SARS-CoV-2								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Eye injury								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Face injury								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Femoral neck fracture								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Foot fracture								
Normal	0				0			
Mild impairment	2	(0.3)	2	0.37	3	(0.4)	3	0.55
Moderate or severe impairment	1	(0.4)	1	0.78	0			
Gun shot wound								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.22	0			
Moderate or severe impairment	0				0			
Head injury								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Heat illness								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	2	(0.3)	2	0.40
Moderate or severe impairment	0				1	(0.4)	2	0.86
Hip fracture								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Humerus fracture								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Inflammation of wound								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Intentional overdose								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.67
Intentional product use issue								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Ligament rupture								
Normal	0				0			
Mild impairment	1	(0.1)	2	0.45	0			
Moderate or severe impairment	0				0			
Lower limb fracture								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Medication error								
Normal	0				1	(0.1)	1	0.18
Mild impairment	2	(0.3)	2	0.45	0			
Moderate or severe impairment	0				1	(0.5)	1	0.87
Meniscus injury								
Normal	0				2	(0.2)	2	0.21
Mild impairment	2	(0.3)	2	0.27	3	(0.4)	3	0.51
Moderate or severe impairment	0				0			
Multiple injuries								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Muscle contusion								
Normal	0				0			
Mild impairment	0				1	(0.2)	1	0.26
Moderate or severe impairment	0				0			
Muscle injury								
Normal	0				1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.13	1	(0.2)	1	0.26
Moderate or severe impairment	0				0			
Penile contusion								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Periprocedural myocardial infarction								
Normal	0				1	(0.1)	1	0.10

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Post procedural complication								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Post procedural haematuria								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Post procedural haemorrhage								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Post procedural inflammation								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Post procedural stroke								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Post procedural swelling								
Normal	0				1	(0.1)	2	0.22
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Post-traumatic neck syndrome								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Product administration error								
Normal	0				2	(0.2)	2	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Radiation skin injury								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Scar								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Scratch								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Seroma								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Soft tissue injury								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Spinal column injury								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Stab wound								
Normal	0				0			
Mild impairment	0				1	(0.2)	1	0.26
Moderate or severe impairment	0				0			
Subcutaneous haematoma								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Sunburn								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Tendon injury								
Normal	0				1	(0.1)	1	0.17
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Tibia fracture								
Normal	0				0			
Mild impairment	0				1	(0.2)	1	0.26
Moderate or severe impairment	0				0			
Traumatic haematoma								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Underdose								
Normal	0				2	(0.2)	2	0.35
Mild impairment	1	(0.1)	1	0.21	1	(0.2)	1	0.26
Moderate or severe impairment	0				2	(0.8)	2	1.10
Wrist fracture								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	1	(0.5)	1	0.91	0			
Wrong dose								
Normal	0				2	(0.2)	2	0.35
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Metabolism and nutrition disorders								
All								
Normal	62	(6.7)	80	11.02	60	(6.4)	72	9.64
Mild impairment	45	(6.1)	53	8.30	47	(6.7)	62	11.65
Moderate or severe impairment	17	(8.3)	20	12.61	18	(7.8)	24	13.37
Dyslipidaemia								
Normal	13	(1.4)	14	1.99	9	(0.9)	9	1.32
Mild impairment	6	(0.8)	6	1.09	8	(1.1)	8	1.76
Moderate or severe impairment	2	(1.0)	2	1.32	0			
Hypoglycaemia								
Normal	11	(1.2)	17	2.82	5	(0.5)	8	1.07
Mild impairment	1	(0.1)	1	0.14	11	(1.6)	20	3.89
Moderate or severe impairment	1	(0.4)	1	0.78	4	(1.7)	8	4.11
Vitamin D deficiency								
Normal	8	(0.8)	8	0.90	9	(1.0)	9	1.00
Mild impairment	7	(1.0)	7	0.95	2	(0.3)	2	0.29
Moderate or severe impairment	1	(0.5)	1	0.48	1	(0.5)	1	0.87
Hyperlipidaemia								
Normal	7	(0.8)	7	0.99	10	(1.1)	10	1.25
Mild impairment	5	(0.7)	5	0.76	2	(0.3)	2	0.40
Moderate or severe impairment	2	(0.9)	2	1.27	1	(0.4)	1	0.43
Hypertriglyceridaemia								
Normal	6	(0.6)	6	0.80	6	(0.6)	6	0.94
Mild impairment	4	(0.5)	4	0.65	2	(0.3)	2	0.29
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Vitamin B12 deficiency								
Normal	5	(0.5)	5	0.51	1	(0.1)	1	0.10
Mild impairment	5	(0.7)	5	0.66	0			
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Iron deficiency								
Normal	4	(0.4)	4	0.41	3	(0.3)	3	0.31
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Hyperuricaemia								
Normal	3	(0.3)	3	0.40	0			
Mild impairment	0				2	(0.3)	2	0.28
Moderate or severe impairment	0				1	(0.4)	1	0.42
Hypercholesterolaemia								
Normal	3	(0.3)	3	0.49	1	(0.1)	1	0.18
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				1	(0.4)	1	0.67
Decreased appetite								
Normal	2	(0.2)	2	0.22	2	(0.2)	2	0.21
Mild impairment	2	(0.3)	2	0.36	2	(0.3)	2	0.37
Moderate or severe impairment	0				1	(0.4)	1	0.42
Abnormal weight gain								
Normal	1	(0.1)	1	0.20	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hyperglycaemia								
Normal	1	(0.1)	1	0.19	9	(1.0)	9	1.26
Mild impairment	3	(0.4)	3	0.47	3	(0.4)	3	0.64
Moderate or severe impairment	2	(1.0)	3	2.49	2	(1.0)	2	1.75
Hyperkalaemia								
Normal	1	(0.1)	1	0.19	2	(0.2)	2	0.37
Mild impairment	4	(0.5)	4	0.65	4	(0.6)	4	0.79
Moderate or severe impairment	3	(1.6)	4	2.49	4	(1.8)	4	2.14
Hyponatraemia								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	1	(0.1)	1	0.24	1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Fluid retention								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.78	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ 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 appetite								
Normal	1	(0.1)	1	0.11	3	(0.3)	3	0.46
Mild impairment	2	(0.3)	2	0.27	2	(0.3)	3	0.64
Moderate or severe impairment	0				1	(0.5)	1	0.87
Dehydration								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	1	(0.1)	1	0.24	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Diabetes mellitus inadequate control								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Folate deficiency								
Normal	1	(0.1)	1	0.10	1	(0.1)	1	0.10
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Vitamin B complex deficiency								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Zinc deficiency								
Normal	1	(0.1)	1	0.10	1	(0.1)	1	0.10
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Appetite disorder								
Normal	0				0			
Mild impairment	0				1	(0.1)	2	0.29
Moderate or severe impairment	0				0			
Diabetes mellitus								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	1	(0.1)	1	0.14
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Electrolyte imbalance								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Food craving								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.25
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ 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								
Normal	0				0			
Mild impairment	3	(0.4)	4	0.54	2	(0.3)	3	0.42
Moderate or severe impairment	1	(0.5)	1	0.48	4	(1.7)	4	1.69
Hyperammonaemia								
Normal	0				0			
Mild impairment	0				1	(0.2)	1	0.26
Moderate or severe impairment	0				0			
Hypercalcaemia								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hypernatraemia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Hypoalbuminaemia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.24	0			
Moderate or severe impairment	0				0			
Hypokalaemia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.24	1	(0.1)	1	0.14
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Insulin resistance								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Lactic acidosis								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Lipomatosis								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Magnesium deficiency								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.48	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Malnutrition								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Metabolic acidosis								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Metabolic disorder								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Obesity								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Respiratory, thoracic and mediastinal disorders								
All								
Normal	56	(6.0)	76	10.43	47	(5.0)	56	7.87
Mild impairment	45	(6.0)	61	10.57	42	(6.0)	53	9.55
Moderate or severe impairment	10	(4.9)	14	9.91	12	(5.2)	15	7.97
Cough								
Normal	15	(1.6)	16	2.13	8	(0.8)	8	1.15
Mild impairment	7	(0.9)	7	1.21	12	(1.7)	13	2.13
Moderate or severe impairment	1	(0.4)	1	0.78	0			
Oropharyngeal pain								
Normal	10	(1.1)	10	1.14	7	(0.7)	7	1.03
Mild impairment	5	(0.7)	6	0.99	8	(1.1)	10	1.97
Moderate or severe impairment	4	(2.0)	5	3.23	1	(0.4)	1	0.43
Rhinorrhoea								
Normal	5	(0.5)	5	0.71	1	(0.1)	1	0.11
Mild impairment	5	(0.6)	8	1.44	4	(0.6)	4	0.65
Moderate or severe impairment	0				2	(0.8)	2	1.10
Dyspnoea								
Normal	5	(0.5)	5	0.77	6	(0.6)	7	0.98
Mild impairment	3	(0.4)	3	0.49	3	(0.4)	3	0.52
Moderate or severe impairment	1	(0.4)	1	0.78	4	(1.8)	4	2.59

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Asthma								
Normal	5	(0.5)	6	0.89	0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Sleep apnoea syndrome								
Normal	4	(0.4)	4	0.51	0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	2	(1.0)	2	1.44	0			
Nasal congestion								
Normal	4	(0.4)	4	0.42	2	(0.2)	2	0.21
Mild impairment	5	(0.7)	5	0.86	2	(0.3)	2	0.28
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Epistaxis								
Normal	3	(0.3)	3	0.58	0			
Mild impairment	2	(0.3)	6	1.27	2	(0.3)	4	0.76
Moderate or severe impairment	0				0			
Productive cough								
Normal	2	(0.2)	2	0.30	0			
Mild impairment	1	(0.1)	1	0.21	2	(0.3)	2	0.40
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Respiratory disorder								
Normal	2	(0.2)	2	0.38	1	(0.1)	1	0.11
Mild impairment	2	(0.3)	2	0.38	3	(0.4)	3	0.52
Moderate or severe impairment	0				1	(0.5)	1	0.87
Emphysema								
Normal	2	(0.2)	2	0.30	2	(0.2)	2	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pulmonary fibrosis								
Normal	2	(0.2)	3	0.40	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nasal obstruction								
Normal	1	(0.1)	1	0.20	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Chronic obstructive pulmonary disease								
Normal	1	(0.1)	1	0.19	1	(0.1)	1	0.11
Mild impairment	2	(0.3)	2	0.34	0			
Moderate or severe impairment	1	(0.5)	1	0.91	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Pleurisy								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pulmonary hypertension								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Sinus pain								
Normal	1	(0.1)	1	0.19	1	(0.1)	1	0.18
Mild impairment	1	(0.1)	2	0.27	0			
Moderate or severe impairment	0				0			
Acquired diaphragmatic eventration								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Acute respiratory failure								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	1	(0.5)	1	0.91	1	(0.4)	1	0.43
Bronchiectasis								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Laryngeal cyst								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nasal turbinate hypertrophy								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Sneezing								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Increased viscosity of upper respiratory secretion								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Rhinitis allergic								
Normal	1	(0.1)	1	0.10	5	(0.5)	9	1.26
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Upper respiratory tract inflammation								
Normal	1	(0.1)	1	0.10	1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Acute pulmonary oedema								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Allergic bronchitis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Allergic cough								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Aphonia								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Bronchitis chronic								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Bronchospasm								
Normal	0				1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.22	0			
Moderate or severe impairment	0				0			
Dry throat								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Dysphonia								
Normal	0				0			
Mild impairment	0				1	(0.1)	2	0.50
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Dyspnoea exertional								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	1	(0.1)	1	0.14
Moderate or severe impairment	0				1	(0.4)	1	0.42
Haemoptysis								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Interstitial lung disease								
Normal	0				0			
Mild impairment	2	(0.3)	2	0.27	0			
Moderate or severe impairment	0				0			
Lung disorder								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nasal dryness								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Nasal septum deviation								
Normal	0				0			
Mild impairment	2	(0.3)	2	0.45	1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Paranasal cyst								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Paranasal sinus discomfort								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pleural disorder								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.25
Moderate or severe impairment	0				0			
Pleural effusion								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				2	(0.8)	2	0.85

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Pleuritic pain								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Pulmonary embolism								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Pulmonary mass								
Normal	0				3	(0.3)	3	0.46
Mild impairment	1	(0.1)	1	0.14	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Respiratory failure								
Normal	0				2	(0.2)	2	0.21
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.91	0			
Respiratory tract inflammation								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Sinus congestion								
Normal	0				0			
Mild impairment	4	(0.5)	5	0.87	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Throat irritation								
Normal	0				1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Upper-airway cough syndrome								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Eye disorders								
All								
Normal	52	(5.7)	63	9.75	70	(7.3)	86	12.48
Mild impairment	78	(10.4)	106	18.80	57	(8.1)	76	15.28
Moderate or severe impairment	17	(8.3)	19	12.71	25	(10.8)	37	23.80
Diabetic retinopathy								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	21	(2.3)	25	4.15	32	(3.3)	34	5.19
Mild impairment	25	(3.3)	27	5.40	19	(2.7)	21	4.33
Moderate or severe impairment	6	(2.9)	6	4.35	7	(3.0)	7	4.11
Cataract								
Normal	6	(0.7)	7	0.99	8	(0.8)	8	1.19
Mild impairment	16	(2.2)	20	3.16	11	(1.5)	14	2.44
Moderate or severe impairment	2	(1.0)	2	1.01	6	(2.5)	6	2.77
Macular oedema								
Normal	3	(0.3)	3	0.49	2	(0.2)	2	0.21
Mild impairment	6	(0.8)	6	1.19	1	(0.1)	1	0.14
Moderate or severe impairment	0				1	(0.5)	1	0.87
Eye pain								
Normal	3	(0.3)	3	0.39	2	(0.2)	2	0.29
Mild impairment	1	(0.1)	1	0.13	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Diabetic retinal oedema								
Normal	2	(0.2)	2	0.38	4	(0.4)	5	0.75
Mild impairment	2	(0.3)	2	0.45	4	(0.6)	4	0.76
Moderate or severe impairment	0				1	(0.4)	1	0.67
Retinal haemorrhage								
Normal	2	(0.2)	2	0.38	0			
Mild impairment	2	(0.3)	2	0.37	0			
Moderate or severe impairment	0				0			
Blepharitis								
Normal	2	(0.2)	2	0.29	0			
Mild impairment	2	(0.3)	2	0.27	0			
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Vision blurred								
Normal	2	(0.2)	2	0.29	2	(0.2)	2	0.29
Mild impairment	2	(0.3)	2	0.36	1	(0.1)	1	0.14
Moderate or severe impairment	0				2	(0.8)	2	1.10
Retinopathy hypertensive								
Normal	2	(0.2)	3	0.39	3	(0.3)	3	0.47
Mild impairment	3	(0.4)	3	0.60	2	(0.3)	2	0.48
Moderate or severe impairment	1	(0.4)	1	0.79	0			
Vitreous detachment								
Normal	2	(0.2)	2	0.29	0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Cataract nuclear								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	1	(0.1)	1	0.20	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Epiretinal membrane								
Normal	1	(0.1)	1	0.20	0			
Mild impairment	0				1	(0.1)	1	0.25
Moderate or severe impairment	0				1	(0.4)	1	0.42
Retinal exudates								
Normal	1	(0.1)	1	0.20	1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.87
Non-proliferative retinopathy								
Normal	1	(0.1)	2	0.38	1	(0.1)	1	0.18
Mild impairment	0				1	(0.2)	1	0.26
Moderate or severe impairment	0				0			
Conjunctival erosion								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Conjunctival haemorrhage								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Retinal aneurysm								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.85
Dry eye								
Normal	1	(0.1)	1	0.10	1	(0.1)	1	0.18
Mild impairment	4	(0.5)	4	0.61	5	(0.7)	5	0.72
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Glaucoma								
Normal	1	(0.1)	1	0.10	2	(0.2)	2	0.28
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	1	(0.5)	1	0.48	1	(0.4)	1	0.42
Maculopathy								
Normal	1	(0.1)	1	0.10	1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Retinal degeneration								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	1	(0.1)	1	0.10	1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Acquired epiblepharon								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Age-related macular degeneration								
Normal	0				0			
Mild impairment	2	(0.3)	2	0.37	0			
Moderate or severe impairment	0				0			
Amaurosis fugax								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Angle closure glaucoma								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Arteriosclerotic retinopathy								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Asthenopia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Astigmatism								
Normal	0				3	(0.3)	3	0.39
Mild impairment	1	(0.1)	2	0.27	1	(0.2)	1	0.26
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Chorioretinal atrophy								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Conjunctival hyperaemia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Conjunctival suffusion								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Conjunctivitis allergic								
Normal	0				0			
Mild impairment	2	(0.3)	3	0.50	0			
Moderate or severe impairment	0				0			
Corneal bleeding								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.85
Corneal erosion								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Cystoid macular oedema								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Dacryoadenitis acquired								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Diplopia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	1	(0.1)	1	0.24
Moderate or severe impairment	1	(0.4)	1	0.78	0			
Dry age-related macular degeneration								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Eye discharge								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				1	(0.4)	1	0.43
Eye inflammation								
Normal	0				1	(0.1)	1	0.18
Mild impairment	2	(0.3)	2	0.36	0			
Moderate or severe impairment	0				1	(0.5)	1	0.87
Eye irritation								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Eye pruritus								
Normal	0				0			
Mild impairment	0				1	(0.1)	2	0.50
Moderate or severe impairment	0				0			
Eyelid oedema								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hypermetropia								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Lacrimation increased								
Normal	0				1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Macular degeneration								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				1	(0.4)	1	0.42
Macular hole								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.25
Moderate or severe impairment	0				0			
Meibomianitis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Myopia								
Normal	0				2	(0.2)	2	0.21
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Normal tension glaucoma								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Ocular hyperaemia								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	0				1	(0.1)	2	0.50
Moderate or severe impairment	2	(1.0)	3	2.49	0			
Ocular hypertension								
Normal	0				0			
Mild impairment	2	(0.3)	2	0.34	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Ocular ischaemic syndrome								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Open angle glaucoma								
Normal	0				0			
Mild impairment	0				1	(0.1)	2	0.48
Moderate or severe impairment	0				0			
Ophthalmic vein thrombosis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Optic disc haemorrhage								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Optic disc vascular disorder								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Photophobia								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Post thrombotic retinopathy								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Posterior capsule opacification								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Presbyopia								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	1	(0.1)	1	0.24	2	(0.3)	2	0.52
Moderate or severe impairment	0				0			
Retinal artery occlusion								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Retinal deposits								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.24	0			
Moderate or severe impairment	0				0			
Retinal detachment								
Normal	0				2	(0.2)	2	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Retinal drusen								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.24	1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Retinal scar								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.78	0			
Retinal tear								
Normal	0				1	(0.1)	1	0.10
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Retinal vascular disorder								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Retinal vein occlusion								
Normal	0				1	(0.1)	1	0.11
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Retinopathy								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Scintillating scotoma								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Uveitis								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Visual acuity reduced								
Normal	0				0			
Mild impairment	0				1	(0.2)	1	0.26
Moderate or severe impairment	0				0			
Visual impairment								
Normal	0				1	(0.1)	1	0.11
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				1	(0.5)	9	7.85
Vitreous degeneration								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.25
Moderate or severe impairment	0				0			
Vitreous floaters								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Vitreous haemorrhage								
Normal	0				0			
Mild impairment	2	(0.3)	2	0.45	2	(0.3)	2	0.38
Moderate or severe impairment	0				0			
Vitreous opacities								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Skin and subcutaneous tissue disorders								
All								
Normal	36	(3.9)	37	4.84	50	(5.3)	55	7.50
Mild impairment	53	(7.1)	59	10.08	38	(5.4)	48	7.93
Moderate or severe impairment	10	(4.9)	11	6.87	16	(6.7)	20	10.62
Eczema								
Normal	5	(0.5)	5	0.70	3	(0.3)	3	0.46
Mild impairment	5	(0.7)	5	0.78	1	(0.1)	1	0.24

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				2	(0.8)	2	1.10
Hyperhidrosis								
Normal	3	(0.3)	3	0.39	4	(0.4)	4	0.56
Mild impairment	4	(0.5)	4	0.72	1	(0.1)	1	0.14
Moderate or severe impairment	1	(0.4)	1	0.78	0			
Pruritus								
Normal	3	(0.3)	3	0.39	7	(0.7)	7	1.04
Mild impairment	5	(0.7)	5	0.85	1	(0.1)	1	0.14
Moderate or severe impairment	0				3	(1.3)	3	1.73
Rash								
Normal	3	(0.3)	3	0.39	4	(0.4)	4	0.51
Mild impairment	8	(1.1)	8	1.40	6	(0.8)	7	0.98
Moderate or severe impairment	0				1	(0.4)	1	0.67
Acne								
Normal	2	(0.2)	2	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Alopecia								
Normal	2	(0.2)	2	0.22	1	(0.1)	1	0.11
Mild impairment	3	(0.4)	3	0.58	2	(0.3)	2	0.39
Moderate or severe impairment	0				0			
Dermatitis contact								
Normal	2	(0.2)	2	0.22	3	(0.3)	3	0.39
Mild impairment	2	(0.3)	3	0.41	3	(0.4)	3	0.43
Moderate or severe impairment	1	(0.5)	1	0.53	2	(0.9)	2	1.30
Dermatitis								
Normal	2	(0.2)	2	0.21	3	(0.3)	4	0.56
Mild impairment	0				2	(0.3)	2	0.29
Moderate or severe impairment	1	(0.4)	1	0.79	1	(0.4)	1	0.67
Ingrowing nail								
Normal	2	(0.2)	2	0.21	1	(0.1)	1	0.10
Mild impairment	0				2	(0.3)	2	0.29
Moderate or severe impairment	0				0			
Blister								
Normal	1	(0.1)	1	0.20	0			
Mild impairment	0				2	(0.3)	2	0.38
Moderate or severe impairment	0				0			
Urticaria								
Normal	1	(0.1)	1	0.20	3	(0.3)	3	0.39
Mild impairment	6	(0.8)	6	1.05	5	(0.7)	5	0.70

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				1	(0.4)	1	0.43
Rash erythematous								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Skin ulcer								
Normal	1	(0.1)	1	0.19	3	(0.3)	3	0.54
Mild impairment	3	(0.4)	3	0.51	1	(0.1)	1	0.24
Moderate or severe impairment	0				1	(0.4)	1	0.42
Umbilical haematoma								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Dermatitis allergic								
Normal	1	(0.1)	1	0.11	1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Dry skin								
Normal	1	(0.1)	1	0.11	4	(0.4)	4	0.49
Mild impairment	2	(0.3)	2	0.27	0			
Moderate or severe impairment	0				0			
Granuloma annulare								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Myxoid cyst								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Skin exfoliation								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Skin lesion								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Urticaria contact								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Nail bed inflammation								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Actinic keratosis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Alopecia areata								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Angioedema								
Normal	0				0			
Mild impairment	0				2	(0.3)	2	0.28
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Asteatosis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Cold sweat								
Normal	0				0			
Mild impairment	3	(0.4)	3	0.51	2	(0.3)	2	0.38
Moderate or severe impairment	1	(0.4)	1	0.78	1	(0.4)	1	0.43
Cold urticaria								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Decubitus ulcer								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.22	0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Dermal cyst								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				2	(0.3)	2	0.40
Moderate or severe impairment	0				0			
Diabetic foot								
Normal	0				2	(0.2)	2	0.21
Mild impairment	1	(0.1)	1	0.13	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Drug eruption								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Ecchymosis								
Normal	0				2	(0.2)	2	0.22
Mild impairment	1	(0.1)	1	0.22	0			
Moderate or severe impairment	0				0			
Erythema								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				2	(0.3)	2	0.39
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Haemorrhage subcutaneous								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Hidradenitis								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hyperkeratosis								
Normal	0				0			
Mild impairment	2	(0.3)	2	0.36	1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Intertrigo								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.24	0			
Moderate or severe impairment	0				0			
Lentigo								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Leukoplakia								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Lipodystrophy acquired								
Normal	0				0			
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Lipohypertrophy								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Livedo reticularis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Macule								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Miliaria								
Normal	0				0			
Mild impairment	2	(0.2)	2	0.41	2	(0.3)	2	0.29
Moderate or severe impairment	0				2	(0.8)	2	0.86
Neurodermatitis								
Normal	0				0			
Mild impairment	0				1	(0.2)	1	0.26
Moderate or severe impairment	0				0			
Night sweats								
Normal	0				0			
Mild impairment	2	(0.3)	2	0.36	0			
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Pruritus allergic								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.25
Moderate or severe impairment	0				0			
Psoriasis								
Normal	0				1	(0.1)	1	0.10
Mild impairment	2	(0.3)	2	0.27	0			
Moderate or severe impairment	0				1	(0.5)	1	0.85
Purpura								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Rash maculo-papular								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Rash papular								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.91	0			
Seborrhoea								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Skin discolouration								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Skin fissures								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Skin irritation								
Normal	0				2	(0.2)	2	0.21
Mild impairment	2	(0.3)	3	0.41	0			
Moderate or severe impairment	0				0			
Skin odour abnormal								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.22	0			
Moderate or severe impairment	0				0			
Skin reaction								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Urticaria thermal								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Investigations								
All								
Normal	36	(3.9)	44	6.11	37	(3.9)	42	5.60
Mild impairment	33	(4.5)	38	6.34	22	(3.1)	23	4.41
Moderate or severe impairment	11	(5.4)	12	8.67	7	(3.1)	8	5.14

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Weight increased								
Normal	8	(0.9)	8	1.17	11	(1.2)	11	1.47
Mild impairment	9	(1.2)	9	1.49	7	(1.0)	7	1.30
Moderate or severe impairment	2	(1.0)	2	1.31	0			
SARS-CoV-2 test positive								
Normal	4	(0.4)	4	0.59	0			
Mild impairment	2	(0.3)	2	0.46	0			
Moderate or severe impairment	1	(0.5)	1	0.91	0			
Blood creatinine increased								
Normal	2	(0.2)	2	0.30	0			
Mild impairment	1	(0.1)	1	0.22	0			
Moderate or severe impairment	5	(2.4)	5	3.87	0			
Occult blood								
Normal	2	(0.2)	2	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Blood triglycerides increased								
Normal	2	(0.2)	2	0.30	2	(0.2)	2	0.21
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Liver function test increased								
Normal	2	(0.2)	2	0.29	1	(0.1)	1	0.10
Mild impairment	1	(0.1)	1	0.24	0			
Moderate or severe impairment	0				0			
Blood cholesterol increased								
Normal	2	(0.2)	2	0.22	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Blood immunoglobulin E increased								
Normal	2	(0.2)	2	0.20	3	(0.3)	3	0.31
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Alanine aminotransferase increased								
Normal	1	(0.1)	1	0.20	0			
Mild impairment	3	(0.4)	3	0.58	0			
Moderate or severe impairment	0				0			
Arthroscopy								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Blood glucose fluctuation								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Monocyte count decreased								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.85
Monofilament pressure perception test								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Blood alkaline phosphatase increased								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	2	(0.3)	2	0.45	0			
Moderate or severe impairment	0				0			
Catheterisation cardiac								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Liver function test abnormal								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				1	(0.2)	2	0.52
Moderate or severe impairment	0				0			
Glycosylated haemoglobin increased								
Normal	1	(0.1)	1	0.11	2	(0.2)	3	0.31
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Blood pressure increased								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	1	(0.1)	1	0.14	2	(0.3)	2	0.38
Moderate or severe impairment	1	(0.4)	1	0.79	2	(0.8)	2	0.85
Blood urine present								
Normal	1	(0.1)	3	0.31	1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Bone density decreased								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Electrocardiogram abnormal								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				2	(0.3)	2	0.37
Moderate or severe impairment	0				0			
Electrocardiogram ST segment abnormal								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Electrocardiogram T wave inversion								
Normal	1	(0.1)	1	0.10	1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Low density lipoprotein increased								
Normal	1	(0.1)	1	0.10	1	(0.1)	1	0.18
Mild impairment	0				1	(0.1)	1	0.25
Moderate or severe impairment	0				0			
QRS axis abnormal								
Normal	1	(0.1)	1	0.10	1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Transaminases increased								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Amylase increased								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.87
Antinuclear antibody positive								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Aspartate aminotransferase increased								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.22	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Blood creatine increased								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Blood creatine phosphokinase increased								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Blood glucose decreased								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Blood glucose increased								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Blood potassium increased								
Normal	0				1	(0.1)	1	0.17
Mild impairment	1	(0.1)	1	0.22	0			
Moderate or severe impairment	0				0			
Blood pressure decreased								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Body temperature increased								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Breath sounds abnormal								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Carbohydrate antigen 19-9 increased								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cardiac murmur								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cardiac stress test abnormal								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Ejection fraction decreased								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Electrocardiogram P wave biphasic								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Electrocardiogram repolarisation abnormality								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Electrocardiogram ST segment depression								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Eosinophil count increased								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.78	0			
Free fatty acids increased								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.85
Glomerular filtration rate decreased								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.87
Grip strength decreased								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Haematocrit increased								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Haemoglobin decreased								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Haemoglobin increased								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hepatic enzyme increased								
Normal	0				1	(0.1)	1	0.11
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
International normalised ratio abnormal								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
International normalised ratio decreased								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
International normalised ratio increased								
Normal	0				0			
Mild impairment	1	(0.1)	2	0.27	0			
Moderate or severe impairment	0				0			
Intraocular pressure increased								
Normal	0				0			
Mild impairment	0				1	(0.2)	1	0.26
Moderate or severe impairment	0				0			
Lipase increased								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Lipids increased								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Platelet count decreased								
Normal	0				2	(0.2)	2	0.35
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Prostatic specific antigen increased								
Normal	0				0			
Mild impairment	2	(0.3)	2	0.27	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Red blood cell count decreased								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Thyroid function test abnormal								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Transferrin saturation decreased								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Vitamin D decreased								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Weight decreased								
Normal	0				1	(0.1)	1	0.11
Mild impairment	4	(0.5)	4	0.54	0			
Moderate or severe impairment	0				0			
Vascular disorders								
All								
Normal	36	(3.9)	42	5.62	33	(3.5)	47	6.64
Mild impairment	32	(4.3)	35	6.01	32	(4.6)	34	6.19
Moderate or severe impairment	5	(2.5)	5	2.90	11	(4.8)	14	7.69
Hypertension								
Normal	16	(1.7)	16	2.29	14	(1.5)	18	2.46
Mild impairment	14	(1.9)	14	2.42	15	(2.2)	15	3.09
Moderate or severe impairment	2	(1.0)	2	1.06	6	(2.6)	7	3.41
Peripheral arterial occlusive disease								
Normal	3	(0.3)	4	0.51	1	(0.1)	1	0.11
Mild impairment	1	(0.1)	1	0.22	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Hypotension								
Normal	3	(0.3)	3	0.32	1	(0.1)	1	0.10
Mild impairment	3	(0.4)	3	0.58	0			
Moderate or severe impairment	0				2	(0.9)	2	1.30
Arteriosclerosis								
Normal	3	(0.3)	3	0.31	4	(0.4)	4	0.64

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				3	(0.4)	3	0.42
Moderate or severe impairment	0				0			
Peripheral artery stenosis								
Normal	2	(0.2)	5	0.78	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Blood pressure inadequately controlled								
Normal	2	(0.2)	2	0.20	1	(0.1)	1	0.11
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Varicose ulceration								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Haematoma								
Normal	1	(0.1)	1	0.19	1	(0.1)	1	0.11
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				2	(1.0)	2	1.72
Hypertensive crisis								
Normal	1	(0.1)	1	0.19	1	(0.1)	3	0.55
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Aortic arteriosclerosis								
Normal	1	(0.1)	1	0.11	3	(0.3)	3	0.48
Mild impairment	1	(0.1)	1	0.14	1	(0.1)	1	0.25
Moderate or severe impairment	0				0			
Brachiocephalic arteriosclerosis								
Normal	1	(0.1)	1	0.11	1	(0.1)	1	0.11
Mild impairment	0				2	(0.3)	2	0.29
Moderate or severe impairment	0				0			
Flushing								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hot flush								
Normal	1	(0.1)	1	0.10	1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Superficial vein thrombosis								
Normal	1	(0.1)	1	0.10	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	2	(0.3)	2	0.27	0			
Moderate or severe impairment	0				0			
Venous stenosis								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Aneurysm								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Aortic aneurysm								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Aortic dilatation								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Aortic stenosis								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Arterial insufficiency								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.22	0			
Moderate or severe impairment	0				0			
Blood pressure fluctuation								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Deep vein thrombosis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.78	0			
Diabetic vascular disorder								
Normal	0				1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.24	1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Hypertensive urgency								
Normal	0				2	(0.2)	3	0.39

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Iliac artery stenosis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Intermittent claudication								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Macroangiopathy								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Neovascularisation								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Orthostatic hypotension								
Normal	0				0			
Mild impairment	2	(0.3)	2	0.45	0			
Moderate or severe impairment	0				0			
Peripheral artery aneurysm								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.25
Moderate or severe impairment	0				0			
Peripheral artery occlusion								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Peripheral coldness								
Normal	0				0			
Mild impairment	3	(0.4)	3	0.41	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Peripheral ischaemia								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Peripheral vascular disorder								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Peripheral venous disease								
Normal	0				1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.24	1	(0.1)	1	0.14
Moderate or severe impairment	1	(0.5)	1	0.53	1	(0.4)	1	0.42
Phlebitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Thrombophlebitis								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Thrombosis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Varicose vein								
Normal	0				1	(0.1)	1	0.10
Mild impairment	1	(0.1)	1	0.14	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Cardiac disorders								
All								
Normal	36	(3.9)	51	6.37	34	(3.6)	50	6.22
Mild impairment	35	(4.7)	52	8.12	28	(4.0)	33	5.47
Moderate or severe impairment	15	(7.4)	21	11.65	17	(7.3)	26	14.89
Coronary artery disease								
Normal	5	(0.5)	5	0.52	5	(0.5)	5	0.60
Mild impairment	5	(0.7)	5	0.85	2	(0.3)	2	0.28
Moderate or severe impairment	2	(1.0)	2	1.01	3	(1.3)	3	1.72
Atrial fibrillation								
Normal	4	(0.4)	4	0.51	0			
Mild impairment	5	(0.7)	5	0.68	3	(0.4)	3	0.42
Moderate or severe impairment	3	(1.5)	4	2.07	3	(1.3)	3	1.73
Myocardial ischaemia								
Normal	3	(0.3)	3	0.49	2	(0.2)	2	0.21
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Angina unstable								
Normal	3	(0.3)	3	0.32	1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Myocardial infarction								
Normal	3	(0.3)	3	0.32	2	(0.2)	2	0.21
Mild impairment	3	(0.4)	3	0.69	1	(0.1)	1	0.14
Moderate or severe impairment	0				1	(0.4)	1	0.43
Acute coronary syndrome								
Normal	3	(0.3)	3	0.31	0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Angina pectoris								
Normal	3	(0.3)	3	0.31	3	(0.3)	3	0.39
Mild impairment	2	(0.3)	2	0.27	1	(0.1)	1	0.14
Moderate or severe impairment	1	(0.4)	1	0.78	0			
Supraventricular extrasystoles								
Normal	2	(0.2)	2	0.38	0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	1	(0.5)	1	0.53	1	(0.4)	1	0.42
Supraventricular tachycardia								
Normal	2	(0.2)	2	0.30	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cardiac failure chronic								
Normal	2	(0.2)	2	0.22	1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Ventricular extrasystoles								
Normal	2	(0.2)	2	0.22	1	(0.1)	2	0.21
Mild impairment	3	(0.4)	3	0.41	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Palpitations								
Normal	2	(0.2)	2	0.21	1	(0.1)	1	0.11
Mild impairment	3	(0.4)	3	0.49	2	(0.3)	2	0.38
Moderate or severe impairment	1	(0.5)	1	0.53	2	(0.8)	2	0.85
Acute myocardial infarction								
Normal	2	(0.2)	2	0.20	3	(0.3)	3	0.39
Mild impairment	5	(0.7)	5	0.94	3	(0.4)	3	0.52
Moderate or severe impairment	2	(1.0)	2	1.01	2	(0.8)	2	1.10

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ 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								
Normal	2	(0.2)	2	0.20	0			
Mild impairment	0				3	(0.4)	3	0.54
Moderate or severe impairment	0				0			
Cardiac failure								
Normal	2	(0.2)	2	0.20	1	(0.1)	1	0.10
Mild impairment	4	(0.5)	4	0.63	0			
Moderate or severe impairment	2	(1.0)	2	1.01	1	(0.5)	2	1.75
Tachycardia								
Normal	2	(0.2)	2	0.20	4	(0.4)	4	0.49
Mild impairment	0				2	(0.3)	2	0.39
Moderate or severe impairment	1	(0.5)	1	0.48	1	(0.5)	1	0.87
Cardiac flutter								
Normal	1	(0.1)	1	0.20	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Bundle branch block left								
Normal	1	(0.1)	1	0.19	1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Left ventricular dysfunction								
Normal	1	(0.1)	1	0.19	1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Mitral valve incompetence								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	2	(0.3)	2	0.27	2	(0.3)	2	0.27
Moderate or severe impairment	0				0			
Aortic valve sclerosis								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Left atrial enlargement								
Normal	1	(0.1)	1	0.19	2	(0.2)	2	0.28
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Coronary artery occlusion								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Arteriosclerosis coronary artery								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Left ventricular hypertrophy								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	2	(0.3)	2	0.27	1	(0.1)	1	0.24
Moderate or severe impairment	0				1	(0.4)	1	0.43
Aortic valve calcification								
Normal	0				2	(0.2)	2	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Aortic valve incompetence								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Atrial enlargement								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Atrial flutter								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Atrial thrombosis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Atrioventricular block complete								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Atrioventricular block first degree								
Normal	0				0			
Mild impairment	2	(0.3)	2	0.36	0			
Moderate or severe impairment	0				0			
Bradycardia								
Normal	0				0			
Mild impairment	0				1	(0.2)	1	0.26
Moderate or severe impairment	1	(0.5)	1	0.53	1	(0.4)	1	0.43

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Bundle branch block right								
Normal	0				2	(0.2)	2	0.29
Mild impairment	1	(0.1)	1	0.14	4	(0.6)	5	0.80
Moderate or severe impairment	0				0			
Cardiac arrest								
Normal	0				2	(0.2)	2	0.21
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cardiac dysfunction								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Cardiac failure acute								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Cardiac failure congestive								
Normal	0				0			
Mild impairment	3	(0.4)	3	0.48	0			
Moderate or severe impairment	1	(0.5)	1	0.53	2	(1.0)	3	2.62
Cardiac perfusion defect								
Normal	0				1	(0.1)	2	0.37
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cardiac ventricular thrombosis								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Cardio-respiratory arrest								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.79	0			
Chronic coronary syndrome								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Coronary artery stenosis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Diastolic dysfunction								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Left atrial dilatation								
Normal	0				1	(0.1)	1	0.11
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Mitral valve stenosis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.79	0			
Pericardial effusion								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Pericarditis								
Normal	0				1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Sinus arrhythmia								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Sinus bradycardia								
Normal	0				2	(0.2)	2	0.21
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Sinus tachycardia								
Normal	0				3	(0.3)	3	0.31
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Subendocardial ischaemia								
Normal	0				2	(0.2)	2	0.21
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Tricuspid valve incompetence								
Normal	0				1	(0.1)	1	0.10
Mild impairment	1	(0.1)	1	0.14	2	(0.3)	2	0.28
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Ventricular arrhythmia								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Ventricular tachycardia								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Renal and urinary disorders								
All								
Normal	22	(2.4)	26	3.49	17	(1.8)	22	2.73
Mild impairment	20	(2.6)	27	4.92	19	(2.7)	21	3.61
Moderate or severe impairment	9	(4.4)	9	5.92	15	(6.6)	21	11.11
Renal cyst								
Normal	5	(0.5)	5	0.70	2	(0.2)	2	0.21
Mild impairment	2	(0.3)	2	0.45	1	(0.1)	1	0.14
Moderate or severe impairment	0				1	(0.5)	1	0.87
Urine odour abnormal								
Normal	2	(0.2)	2	0.30	1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nephrolithiasis								
Normal	2	(0.2)	2	0.21	2	(0.2)	2	0.29
Mild impairment	2	(0.3)	2	0.27	1	(0.1)	2	0.50
Moderate or severe impairment	1	(0.5)	1	0.53	1	(0.4)	2	0.83
Dysuria								
Normal	2	(0.2)	3	0.31	1	(0.1)	1	0.11
Mild impairment	2	(0.3)	2	0.38	3	(0.4)	3	0.52
Moderate or severe impairment	0				0			
Urethral stenosis								
Normal	1	(0.1)	1	0.20	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Chromaturia								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pollakiuria								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	1	(0.1)	1	0.19	0			
Mild impairment	4	(0.5)	4	0.79	1	(0.1)	1	0.14
Moderate or severe impairment	0				1	(0.4)	1	0.43
Ureterolithiasis								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	2	(0.3)	2	0.27	2	(0.3)	2	0.29
Moderate or severe impairment	0				1	(0.4)	1	0.42
Acute kidney injury								
Normal	1	(0.1)	1	0.19	1	(0.1)	1	0.10
Mild impairment	2	(0.3)	2	0.36	0			
Moderate or severe impairment	0				4	(1.7)	4	1.68
Chronic kidney disease								
Normal	1	(0.1)	1	0.19	1	(0.1)	1	0.10
Mild impairment	2	(0.3)	2	0.36	0			
Moderate or severe impairment	1	(0.4)	1	0.78	4	(1.7)	4	2.15
Microalbuminuria								
Normal	1	(0.1)	1	0.11	1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pyelocaliectasis								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Renal colic								
Normal	1	(0.1)	1	0.11	2	(0.2)	2	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.85
Nocturia								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				2	(0.3)	2	0.29
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Renal pain								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Urinary incontinence								
Normal	1	(0.1)	1	0.10	3	(0.3)	3	0.31
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Urinary retention								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				1	(0.4)	1	0.43
Urinary tract disorder								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Bladder mass								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Bladder prolapse								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Calculus urinary								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Cystitis haemorrhagic								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Diabetic nephropathy								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	2	(0.3)	2	0.50
Moderate or severe impairment	2	(1.0)	2	1.44	0			
Haematuria								
Normal	0				1	(0.1)	1	0.10
Mild impairment	1	(0.1)	2	0.48	4	(0.6)	4	0.68
Moderate or severe impairment	0				0			
Hydrocalyx								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.87
Hydronephrosis								
Normal	0				1	(0.1)	1	0.18
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Hypertonic bladder								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Micturition urgency								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nephropathy								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.87
Nephrotic syndrome								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Polyuria								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Proteinuria								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Renal failure								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.79	0			
Renal impairment								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	2	(0.3)	2	0.28
Moderate or severe impairment	3	(1.5)	3	1.85	1	(0.4)	1	0.43
Renal mass								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Strangury								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Stress urinary incontinence								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Urinary tract inflammation								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Urinary tract obstruction								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Blood and lymphatic system disorders								
All								
Normal	19	(2.1)	21	3.23	16	(1.7)	16	1.90
Mild impairment	11	(1.5)	11	1.79	8	(1.1)	8	1.52
Moderate or severe impairment	3	(1.5)	3	1.84	6	(2.7)	6	3.84
Anaemia								
Normal	12	(1.3)	14	2.24	5	(0.5)	5	0.53
Mild impairment	5	(0.7)	5	0.87	5	(0.7)	5	0.90
Moderate or severe impairment	2	(1.0)	2	1.06	4	(1.9)	4	2.99
Leukopenia								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Blood loss anaemia								
Normal	1	(0.1)	1	0.19	1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Lymphadenopathy mediastinal								
Normal	1	(0.1)	1	0.19	1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Iron deficiency anaemia								
Normal	1	(0.1)	1	0.11	1	(0.1)	1	0.11
Mild impairment	1	(0.1)	1	0.24	1	(0.1)	1	0.24
Moderate or severe impairment	0				1	(0.4)	1	0.42
Lymphadenopathy								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	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, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Moderate or severe impairment	0				0			
Leukocytosis								
Normal	1	(0.1)	1	0.10	3	(0.3)	3	0.31
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Splenomegaly								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Eosinophilia								
Normal	0				1	(0.1)	1	0.11
Mild impairment	2	(0.3)	2	0.27	1	(0.1)	1	0.24
Moderate or severe impairment	1	(0.4)	1	0.78	0			
Hypochromic anaemia								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Normocytic anaemia								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pancytopenia								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Polycythaemia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Thrombocytopenia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Thrombocytosis								
Normal	0				1	(0.1)	1	0.17
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Psychiatric disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ 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								
Normal	17	(1.8)	19	2.67	23	(2.4)	24	3.22
Mild impairment	16	(2.1)	18	2.69	11	(1.6)	11	2.44
Moderate or severe impairment	3	(1.6)	3	1.97	3	(1.4)	4	2.58
Depression								
Normal	4	(0.4)	4	0.51	6	(0.6)	6	0.71
Mild impairment	4	(0.5)	4	0.65	2	(0.3)	2	0.52
Moderate or severe impairment	0				1	(0.5)	1	0.87
Insomnia								
Normal	3	(0.3)	3	0.49	3	(0.3)	4	0.57
Mild impairment	6	(0.8)	6	0.96	2	(0.3)	2	0.38
Moderate or severe impairment	1	(0.5)	1	0.53	1	(0.4)	1	0.42
Agitation								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Anxiety								
Normal	1	(0.1)	1	0.19	3	(0.3)	3	0.32
Mild impairment	4	(0.5)	4	0.54	2	(0.3)	2	0.27
Moderate or severe impairment	0				1	(0.4)	1	0.42
Drug abuse								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Irritability								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Mental status changes								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Depressed mood								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nightmare								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ 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								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Disorientation								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Post-traumatic stress disorder								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Sleep disorder								
Normal	1	(0.1)	1	0.10	3	(0.3)	3	0.53
Mild impairment	2	(0.3)	2	0.27	1	(0.2)	1	0.26
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Stress								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Adjustment disorder								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.91	0			
Adjustment disorder with depressed mood								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.25
Moderate or severe impairment	0				0			
Affect lability								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.87
Anxiety disorder								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Bruxism								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Drug dependence								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Emotional distress								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.25
Moderate or severe impairment	0				0			
Fear								
Normal	0				2	(0.2)	2	0.37
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Listless								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Major depression								
Normal	0				0			
Mild impairment	0				1	(0.2)	1	0.26
Moderate or severe impairment	0				0			
Mixed anxiety and depressive disorder								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Mood swings								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Persistent depressive disorder								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Phobia								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Reproductive system and breast disorders								
All								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	11	(1.2)	11	1.58	11	(1.2)	11	1.35
Mild impairment	15	(2.0)	15	2.43	9	(1.3)	11	1.74
Moderate or severe impairment	3	(1.5)	3	1.59	3	(1.3)	5	2.55
Intermenstrual bleeding								
Normal	2	(0.2)	2	0.38	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Erectile dysfunction								
Normal	2	(0.2)	2	0.21	0			
Mild impairment	2	(0.3)	2	0.34	0			
Moderate or severe impairment	1	(0.5)	1	0.53	1	(0.5)	1	0.85
Prostatitis								
Normal	1	(0.1)	1	0.20	1	(0.1)	1	0.17
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Breast pain								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Prostatic calcification								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Uterine prolapse								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Ejaculation failure								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Menstruation irregular								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pelvic discomfort								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Atrophic vulvovaginitis								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Benign prostatic hyperplasia								
Normal	0				1	(0.1)	1	0.10
Mild impairment	5	(0.7)	5	0.85	2	(0.3)	2	0.38
Moderate or severe impairment	0				0			
Breast mass								
Normal	0				1	(0.1)	1	0.10
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Cervical polyp								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Colpocele								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Dysmenorrhoea								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Galactorrhoea								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Genital prolapse								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Menopausal disorder								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Menopausal symptoms								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Menstruation delayed								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	1	(0.1)	1	0.22	0			
Moderate or severe impairment	0				0			
Ovarian cyst								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Penile rash								
Normal	0				0			
Mild impairment	0				1	(0.1)	2	0.29
Moderate or severe impairment	0				0			
Pruritus genital								
Normal	0				1	(0.1)	1	0.17
Mild impairment	1	(0.1)	1	0.14	1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Testicular cyst								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Uterine enlargement								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Uterine polyp								
Normal	0				0			
Mild impairment	2	(0.3)	2	0.27	0			
Moderate or severe impairment	0				0			
Vaginal discharge								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Vaginal haemorrhage								
Normal	0				0			
Mild impairment	0				2	(0.3)	2	0.27
Moderate or severe impairment	0				0			
Vulvovaginal dryness								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Vulvovaginal pruritus								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	1	(0.5)	1	0.53	1	(0.4)	1	0.42
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
Normal	11	(1.2)	12	1.60	8	(0.9)	10	1.43
Mild impairment	14	(1.9)	19	3.02	13	(1.9)	19	3.34
Moderate or severe impairment	6	(2.9)	8	5.31	6	(2.5)	11	4.87
Colon adenoma								
Normal	3	(0.3)	3	0.49	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Osteoma								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Small cell lung cancer								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Acrochordon								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Basal cell carcinoma								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				2	(0.3)	2	0.28
Moderate or severe impairment	0				1	(0.4)	1	0.43
Salivary gland neoplasm								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Seborrhoeic keratosis								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	1	(0.1)	2	0.27	0			
Moderate or severe impairment	0				0			
Metastases to liver								
Normal	1	(0.1)	1	0.10	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Pancreatic carcinoma								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Squamous cell carcinoma of skin								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Adenocarcinoma of colon								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Adenocarcinoma pancreas								
Normal	0				0			
Mild impairment	2	(0.3)	2	0.36	0			
Moderate or severe impairment	0				0			
Adrenal adenoma								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				1	(0.1)	1	0.25
Moderate or severe impairment	0				0			
Benign renal neoplasm								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Bladder cancer								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Bladder papilloma								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.79	0			
Bowen's disease								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Breast cancer								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.67
Breast cancer metastatic								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Chronic myeloid leukaemia								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Colon cancer								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Colon cancer stage II								
Normal	0				0			
Mild impairment	0				1	(0.2)	1	0.26
Moderate or severe impairment	0				0			
Colorectal cancer								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	1	(0.4)	1	0.79	0			
Dysplastic naevus								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Endometrial adenocarcinoma								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Eye naevus								
Normal	0				0			
Mild impairment	2	(0.3)	3	0.50	0			
Moderate or severe impairment	0				0			
Gastric cancer								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.91	0			
Gastrointestinal tract adenoma								
Normal	0				1	(0.1)	1	0.10

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Glioblastoma multiforme								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Haemangioma of liver								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Hepatocellular carcinoma								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Invasive breast carcinoma								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Invasive ductal breast carcinoma								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Invasive lobular breast carcinoma								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Lipoma								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Lung adenocarcinoma								
Normal	0				0			
Mild impairment	0				2	(0.3)	2	0.49
Moderate or severe impairment	0				0			
Lung cancer metastatic								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.79	0			
Lymphangioma								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				1	(0.2)	1	0.26
Moderate or severe impairment	0				0			
Malignant melanoma								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Malignant melanoma in situ								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Malignant peritoneal neoplasm								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Metastases to bone marrow								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Metastases to lymph nodes								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Myxoma								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Neoplasm skin								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Oral fibroma								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Ovarian cancer metastatic								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Pancreatic carcinoma metastatic								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				1	(0.2)	1	0.26
Moderate or severe impairment	0				0			
Pancreatic neoplasm								
Normal	0				0			
Mild impairment	2	(0.3)	2	0.38	0			
Moderate or severe impairment	0				0			
Prostate cancer								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.53	0			
Prostatic adenoma								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Renal cell carcinoma								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Renal hamartoma								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Renal neoplasm								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Skin papilloma								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.22	0			
Moderate or severe impairment	0				0			
Small intestine neuroendocrine tumour								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Uterine cancer								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Uterine leiomyoma								
Normal	0				2	(0.2)	2	0.29

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Hepatobiliary disorders								
All								
Normal	10	(1.1)	16	2.11	12	(1.3)	12	1.62
Mild impairment	7	(0.9)	7	1.13	5	(0.7)	8	1.53
Moderate or severe impairment	2	(1.0)	2	1.39	4	(1.8)	5	2.55
Hepatic steatosis								
Normal	5	(0.5)	5	0.62	6	(0.6)	6	0.76
Mild impairment	3	(0.4)	3	0.41	3	(0.4)	3	0.52
Moderate or severe impairment	0				0			
Hepatomegaly								
Normal	2	(0.2)	2	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cholecystitis								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hepatic function abnormal								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				2	(0.3)	2	0.38
Moderate or severe impairment	0				0			
Cholecystitis chronic								
Normal	1	(0.1)	1	0.19	1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gallbladder cholesterolosis								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hypertransaminasaemia								
Normal	1	(0.1)	2	0.22	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Non-alcoholic steatohepatitis								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Cholelithiasis								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	1	(0.5)	1	0.48	1	(0.4)	1	0.42
Hepatic mass								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Alcoholic liver disease								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.91	0			
Bile duct stone								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	2	0.83
Biliary colic								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.25
Moderate or severe impairment	0				0			
Biliary dyskinesia								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gallbladder polyp								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.21	1	(0.1)	1	0.24
Moderate or severe impairment	0				0			
Hepatic cirrhosis								
Normal	0				2	(0.2)	2	0.28
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hepatic cyst								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Hyperplastic cholecystopathy								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.24	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Liver disorder								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				1	(0.5)	1	0.87
Nonalcoholic fatty liver disease								
Normal	0				2	(0.2)	2	0.21
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Steatohepatitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.43
Ear and labyrinth disorders								
All								
Normal	9	(1.0)	9	1.22	8	(0.8)	8	1.28
Mild impairment	12	(1.6)	15	2.18	9	(1.3)	9	1.49
Moderate or severe impairment	5	(2.5)	5	3.56	5	(2.1)	6	3.25
Ear pain								
Normal	2	(0.2)	2	0.30	1	(0.1)	1	0.17
Mild impairment	2	(0.3)	2	0.36	0			
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Vertigo								
Normal	2	(0.2)	2	0.30	1	(0.1)	1	0.18
Mild impairment	6	(0.8)	7	1.03	5	(0.7)	5	0.83
Moderate or severe impairment	2	(1.1)	2	1.82	2	(0.9)	3	1.73
Tinnitus								
Normal	2	(0.2)	2	0.21	0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				1	(0.4)	1	0.67
Hypoacusis								
Normal	1	(0.1)	1	0.20	1	(0.1)	1	0.10
Mild impairment	1	(0.1)	1	0.13	1	(0.1)	1	0.14
Moderate or severe impairment	0				1	(0.4)	1	0.43
Ear inflammation								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Eustachian tube dysfunction								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	1	(0.1)	1	0.11	1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cerumen impaction								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.24
Moderate or severe impairment	1	(0.4)	1	0.78	0			
Deafness bilateral								
Normal	0				0			
Mild impairment	2	(0.3)	2	0.27	0			
Moderate or severe impairment	0				0			
Deafness unilateral								
Normal	0				1	(0.1)	1	0.17
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Ear discomfort								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
External ear pain								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Meniere's disease								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				0			
Middle ear inflammation								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Motion sickness								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Presbyacusis								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Vertigo positional								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				1	(0.1)	1	0.11
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	1	(0.5)	1	0.48	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ 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								
Normal	5	(0.5)	6	0.89	10	(1.0)	11	1.59
Mild impairment	5	(0.7)	5	0.75	3	(0.4)	3	0.52
Moderate or severe impairment	2	(0.9)	2	1.26	2	(0.8)	2	1.35
Seasonal allergy								
Normal	4	(0.4)	4	0.59	5	(0.5)	5	0.75
Mild impairment	4	(0.5)	4	0.54	3	(0.4)	3	0.52
Moderate or severe impairment	0				0			
Drug hypersensitivity								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Allergy to arthropod bite								
Normal	1	(0.1)	1	0.11	1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.67
Allergy to arthropod sting								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.67
Anaphylactic reaction								
Normal	0				1	(0.1)	1	0.17
Mild impairment	1	(0.1)	1	0.21	0			
Moderate or severe impairment	0				0			
Food allergy								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	1	(0.5)	1	0.48	0			
Hypersensitivity								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	1	(0.4)	1	0.78	0			
Immunisation reaction								
Normal	0				1	(0.1)	2	0.22
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ 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								
Normal	4	(0.4)	4	0.68	3	(0.3)	3	0.39
Mild impairment	2	(0.3)	2	0.36	2	(0.3)	2	0.27
Moderate or severe impairment	0				0			
Type V hyperlipidaemia								
Normal	3	(0.3)	3	0.49	1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Corneal dystrophy								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Atrial septal defect								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Congenital syphilitic osteochondritis								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cystic fibrosis lung								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.22	0			
Moderate or severe impairment	0				0			
Hydrocele								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.14	0			
Moderate or severe impairment	0				0			
Hypertrophic cardiomyopathy								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Myotonic dystrophy								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ 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								
Normal	4	(0.4)	4	0.58	10	(1.1)	10	1.34
Mild impairment	2	(0.3)	2	0.27	4	(0.6)	4	0.57
Moderate or severe impairment	0				4	(1.7)	4	2.36
Hypothyroidism								
Normal	2	(0.2)	2	0.29	0			
Mild impairment	0				2	(0.3)	2	0.28
Moderate or severe impairment	0				2	(0.8)	2	1.09
Hypogonadism								
Normal	1	(0.1)	1	0.19	1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Autoimmune thyroiditis								
Normal	1	(0.1)	1	0.10	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Adrenal mass								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.42
Adrenocortical insufficiency acute								
Normal	0				2	(0.2)	2	0.36
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Goitre								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Hyperplasia adrenal								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Hyperprolactinaemia								
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hyperthyroidism								
Normal	0				2	(0.2)	2	0.21
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Inappropriate antidiuretic hormone secretion								
Normal	0				1	(0.1)	1	0.17
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Secondary hypogonadism								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.5)	1	0.85
Thyroid mass								
Normal	0				2	(0.2)	2	0.28
Mild impairment	2	(0.3)	2	0.27	0			
Moderate or severe impairment	0				0			
Surgical and medical procedures								
All								
Normal	3	(0.3)	3	0.49	2	(0.2)	2	0.21
Mild impairment	1	(0.1)	1	0.13	2	(0.3)	2	0.28
Moderate or severe impairment	0				2	(0.9)	2	1.55
Shoulder operation								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Tooth extraction								
Normal	1	(0.1)	1	0.19	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Knee operation								
Normal	1	(0.1)	1	0.11	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cardiac pacemaker replacement								
Normal	0				0			
Mild impairment	1	(0.1)	1	0.13	0			
Moderate or severe impairment	0				1	(0.5)	1	0.87
Large intestinal polypectomy								

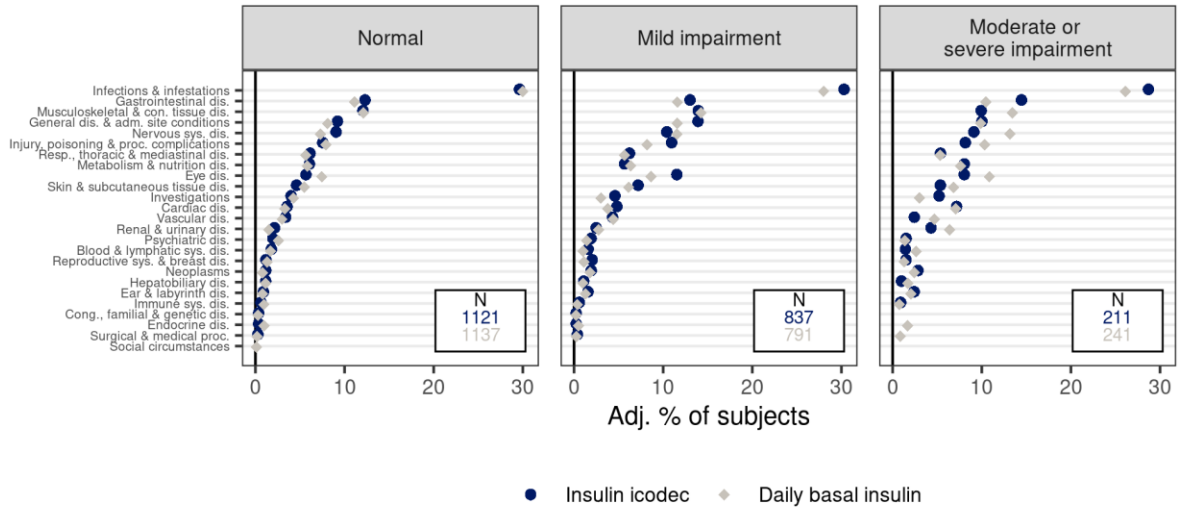
%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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 renal function, system organ class and preferred term - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Normal	0				1	(0.1)	1	0.11
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Removal of foreign body								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Skin neoplasm excision								
Normal	0				1	(0.1)	1	0.10
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Spinal operation								
Normal	0				0			
Mild impairment	0				1	(0.1)	1	0.14
Moderate or severe impairment	0				0			
Toe amputation								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(0.4)	1	0.67
Social circumstances								
All								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Menopause								
Normal	0				1	(0.1)	1	0.18
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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.

7.7.69 Adverse events by baseline renal function and system organ class - on-treatment/main-on-treatment - dot plot - safety analysis set - phase 3a pool

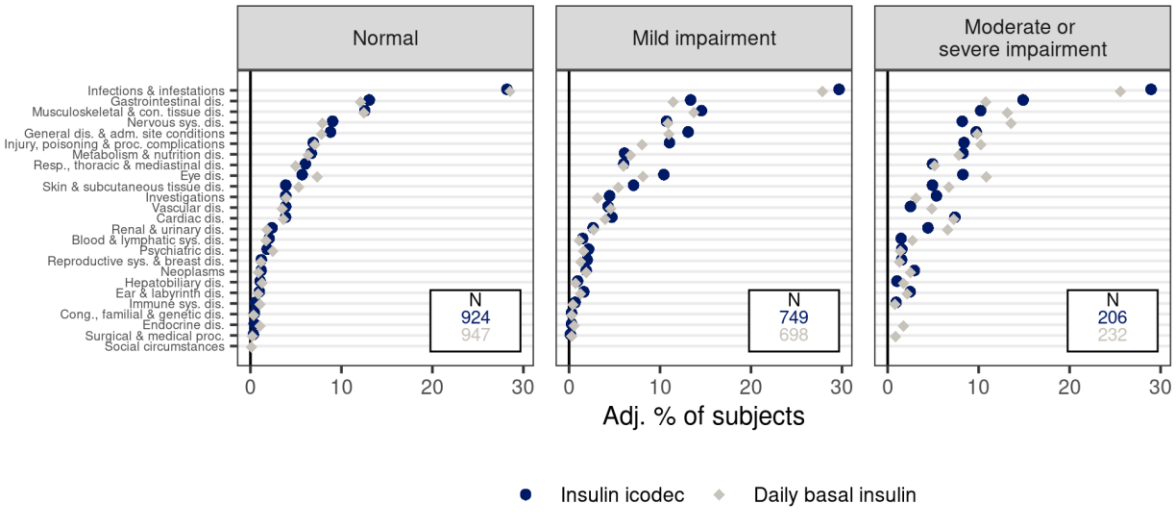


% of subjects: Percentage of subjects with one or more events, N: Number of subjects, dis.: disorders, adm.: administration, con.: connective, proc.: procedural/procedures, sys.: system, resp.: respiratory, cong.: congenital, eGFR: Estimated glomerular filtration rate (mL/min/1.73m$^{2)}$. Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. 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): GFRGR3;criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS GFRGR3;criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:59:52 - faedotgrp/faesocgrprenaldotontp3asas.png

7.7.70 Adverse events by baseline renal function and system organ class - on-treatment/main-on-treatment - dot plot - safety analysis set - T2D pool

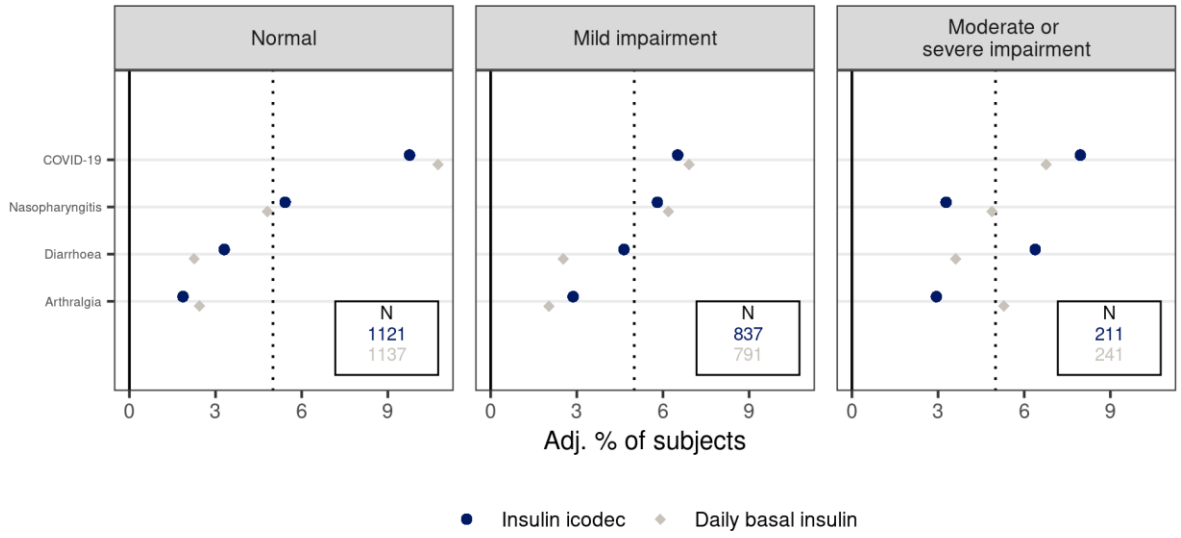


% of subjects: Percentage of subjects with one or more events, N: Number of subjects, dis.: disorders, adm.: administration, con.: connective, proc.: procedural/procedures, sys.: system, resp.: respiratory, cong.: congenital, eGFR: Estimated glomerular filtration rate (mL/min/1.73m$^{2)}$, Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. 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): GFRGR3;criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS GFRGR3;criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:59:56 - faedotgrp/faesocgrprenaldotontt2dsas.png

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

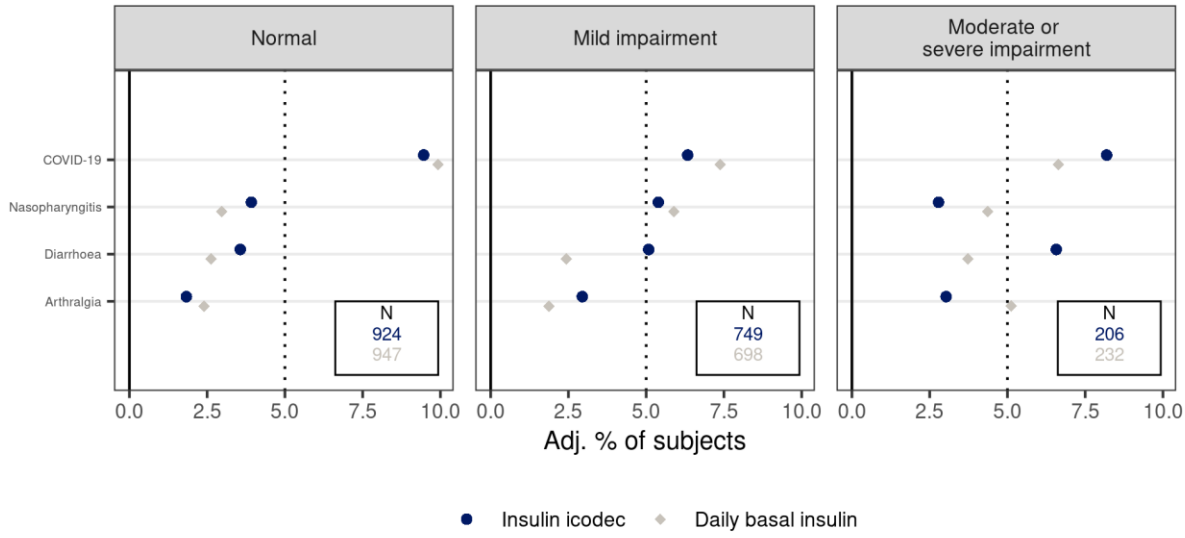


% of subjects: Percentage of subjects with one or more events, N: Number of subjects, eGFR: Estimated glomerular filtration rate (mL/min/1.73m$^{2)}$. Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. 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): GFRGR3;criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEDECOD GFRGR3;criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:00:01 - faedotgrp/faept5pctgrprenaldotontp3asas.png

7.7.72 Adverse events by baseline renal function 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, eGFR: Estimated glomerular filtration rate (mL/min/1.73m$^{2)}$, Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. Adj.: Adjusted percentages were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. 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): GFRGR3;criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEDECOD GFRGR3;criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:00:06 - faedotgrp/faept5pctgrprenaldotontt2dsas.png

7.7.73 Adverse events by pre-trial insulin treatment - on-treatment/main-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								
Insulin naïve	1327				1324			
Basal insulin	262				263			
Basal-bolus insulin regimen	581				583			
PYE (years)								
Insulin naïve	1216.31				1216.89			
Basal insulin	155.25				152.77			
Basal-bolus insulin regimen	309.67				310.92			
Events								
Insulin naïve	807	(60.8)	2557	219.57	772	(58.3)	2381	201.55
Basal insulin	161	(61.5)	466	300.17	134	(51.0)	328	214.70
Basal-bolus insulin regimen	360	(62.0)	962	314.07	357	(61.2)	1169	379.62
Serious								
Yes								
Insulin naïve	111	(8.4)	165	13.53	121	(9.1)	176	14.09
Basal insulin	22	(8.4)	30	19.32	16	(6.1)	20	13.09
Basal-bolus insulin regimen	33	(5.7)	50	15.73	32	(5.5)	42	13.01
No								
Insulin naïve	780	(58.8)	2392	206.05	748	(56.5)	2205	187.45
Basal insulin	158	(60.3)	436	280.84	128	(48.7)	308	201.61
Basal-bolus insulin regimen	349	(60.1)	912	298.34	347	(59.5)	1127	366.61
Missing								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	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 insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 and 6 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by pre-trial insulin treatment - on-treatment/main-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								
Insulin naïve	59	(4.4)	74	6.28	62	(4.7)	101	7.70
Basal insulin	11	(4.2)	17	10.95	11	(4.2)	13	8.51
Basal-bolus insulin regimen	22	(3.8)	30	9.49	16	(2.7)	19	5.93
Moderate								
Insulin naïve	338	(25.5)	620	51.03	312	(23.6)	564	45.86
Basal insulin	64	(24.4)	122	78.58	54	(20.5)	82	53.67
Basal-bolus insulin regimen	110	(18.9)	189	61.20	112	(19.2)	210	67.15
Mild								
Insulin naïve	674	(50.8)	1863	162.27	646	(48.8)	1716	147.98
Basal insulin	132	(50.4)	327	210.63	109	(41.4)	233	152.51
Basal-bolus insulin regimen	307	(52.8)	743	243.38	318	(54.5)	940	306.54
Missing								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Related to basal insulin								
Probable								
Insulin naïve	47	(3.5)	78	7.59	56	(4.2)	104	9.21
Basal insulin	9	(3.4)	9	5.80	6	(2.3)	13	8.51
Basal-bolus insulin regimen	26	(4.5)	33	10.91	14	(2.4)	16	5.17
Possible								
Insulin naïve	64	(4.8)	93	8.53	64	(4.8)	87	7.63
Basal insulin	16	(6.1)	26	16.75	7	(2.7)	7	4.58
Basal-bolus insulin regimen	45	(7.7)	60	19.29	34	(5.8)	84	27.11
Unlikely								
Insulin naïve	786	(59.2)	2384	203.31	745	(56.3)	2187	184.48
Basal insulin	155	(59.2)	421	271.18	130	(49.4)	305	199.64
Basal-bolus insulin regimen	335	(57.7)	869	283.86	351	(60.2)	1069	347.33
Missing								
Insulin naïve	2	(0.2)	2	0.15	3	(0.2)	3	0.22
Basal insulin	6	(2.3)	10	6.44	3	(1.1)	3	1.96
Basal-bolus insulin regimen	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 insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 and 6 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by pre-trial insulin treatment - on-treatment/main-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								
Insulin naïve	5	(0.4)	5	0.65	3	(0.2)	3	0.39
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	5	(0.9)	5	1.49	3	(0.5)	4	1.20
No								
Insulin naïve	806	(60.8)	2550	218.78	770	(58.1)	2375	200.94
Basal insulin	160	(61.1)	454	292.44	131	(49.8)	323	211.43
Basal-bolus insulin regimen	359	(61.8)	957	312.57	357	(61.2)	1164	378.12
NA								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Missing								
Insulin naïve	2	(0.2)	2	0.15	3	(0.2)	3	0.22
Basal insulin	6	(2.3)	10	6.44	3	(1.1)	3	1.96
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, 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 insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 and 6 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by pre-trial insulin treatment - on-treatment/main-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								
Insulin naïve	9	(0.7)	10	0.86	10	(0.8)	12	0.94
Basal insulin	2	(0.8)	3	1.93	2	(0.8)	2	1.31
Basal-bolus insulin regimen	3	(0.5)	5	1.55	1	(0.2)	1	0.30
Not recovered/not resolved								
Insulin naïve	370	(27.9)	717	59.50	366	(27.6)	683	56.82
Basal insulin	55	(21.0)	97	62.48	48	(18.3)	63	41.24
Basal-bolus insulin regimen	164	(28.2)	273	88.61	156	(26.8)	296	95.52
Recovered/resolved with sequelae								
Insulin naïve	10	(0.8)	10	0.86	10	(0.8)	12	0.95
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				5	(0.9)	5	1.64
Recovering/resolving								
Insulin naïve	55	(4.1)	74	6.67	55	(4.2)	64	5.70
Basal insulin	19	(7.3)	24	15.46	16	(6.1)	17	11.13
Basal-bolus insulin regimen	22	(3.8)	38	11.67	21	(3.6)	30	9.37
Recovered/resolved								
Insulin naïve	684	(51.6)	1745	151.61	636	(48.0)	1608	137.00
Basal insulin	135	(51.5)	342	220.29	100	(38.0)	245	160.37
Basal-bolus insulin regimen	303	(52.2)	646	212.25	303	(52.0)	837	272.79
Unknown								
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Missing								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	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 insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 and 6 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.7.74 Adverse events by pre-trial insulin treatment - on-treatment/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								
Insulin naïve	1327				1324			
Basal insulin	262				263			
Basal-bolus insulin regimen	291				291			
PYE (years)								
Insulin naïve	1216.31				1216.89			
Basal insulin	155.25				152.77			
Basal-bolus insulin regimen	167.36				166.80			
Events								
Insulin naïve	807	(60.8)	2557	219.57	772	(58.3)	2381	201.55
Basal insulin	161	(61.5)	466	300.17	134	(51.0)	328	214.70
Basal-bolus insulin regimen	171	(58.8)	455	271.87	167	(57.4)	550	329.74
Serious								
Yes								
Insulin naïve	111	(8.4)	165	13.53	121	(9.1)	176	14.09
Basal insulin	22	(8.4)	30	19.32	16	(6.1)	20	13.09
Basal-bolus insulin regimen	22	(7.6)	35	20.91	25	(8.6)	33	19.78
No								
Insulin naïve	780	(58.8)	2392	206.05	748	(56.5)	2205	187.45
Basal insulin	158	(60.3)	436	280.84	128	(48.7)	308	201.61
Basal-bolus insulin regimen	164	(56.4)	420	250.95	160	(55.0)	517	309.96
Missing								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	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 insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 contributes, hence the percentages and rates are unadjusted. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by pre-trial insulin treatment - on-treatment/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								
Insulin naïve	59	(4.4)	74	6.28	62	(4.7)	101	7.70
Basal insulin	11	(4.2)	17	10.95	11	(4.2)	13	8.51
Basal-bolus insulin regimen	13	(4.5)	20	11.95	12	(4.1)	14	8.39
Moderate								
Insulin naïve	338	(25.5)	620	51.03	312	(23.6)	564	45.86
Basal insulin	64	(24.4)	122	78.58	54	(20.5)	82	53.67
Basal-bolus insulin regimen	59	(20.3)	99	59.15	61	(21.0)	121	72.54
Mild								
Insulin naïve	674	(50.8)	1863	162.27	646	(48.8)	1716	147.98
Basal insulin	132	(50.4)	327	210.63	109	(41.4)	233	152.51
Basal-bolus insulin regimen	138	(47.4)	336	200.76	148	(50.9)	415	248.80
Missing								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Related to basal insulin								
Probable								
Insulin naïve	47	(3.5)	78	7.59	56	(4.2)	104	9.21
Basal insulin	9	(3.4)	9	5.80	6	(2.3)	13	8.51
Basal-bolus insulin regimen	9	(3.1)	13	7.77	7	(2.4)	8	4.80
Possible								
Insulin naïve	64	(4.8)	93	8.53	64	(4.8)	87	7.63
Basal insulin	16	(6.1)	26	16.75	7	(2.7)	7	4.58
Basal-bolus insulin regimen	23	(7.9)	34	20.32	17	(5.8)	43	25.78
Unlikely								
Insulin naïve	786	(59.2)	2384	203.31	745	(56.3)	2187	184.48
Basal insulin	155	(59.2)	421	271.18	130	(49.4)	305	199.64
Basal-bolus insulin regimen	157	(54.0)	408	243.78	162	(55.7)	499	299.16
Missing								
Insulin naïve	2	(0.2)	2	0.15	3	(0.2)	3	0.22
Basal insulin	6	(2.3)	10	6.44	3	(1.1)	3	1.96
Basal-bolus insulin regimen	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 insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 contributes, hence the percentages and rates are unadjusted. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by pre-trial insulin treatment - on-treatment/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								
Insulin naïve	5	(0.4)	5	0.65	3	(0.2)	3	0.39
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	5	(1.7)	5	2.99	3	(1.0)	4	2.40
No								
Insulin naïve	806	(60.8)	2550	218.78	770	(58.1)	2375	200.94
Basal insulin	160	(61.1)	454	292.44	131	(49.8)	323	211.43
Basal-bolus insulin regimen	170	(58.4)	450	268.88	167	(57.4)	545	326.74
NA								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Missing								
Insulin naïve	2	(0.2)	2	0.15	3	(0.2)	3	0.22
Basal insulin	6	(2.3)	10	6.44	3	(1.1)	3	1.96
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60

%: 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 insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 contributes, hence the percentages and rates are unadjusted. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by pre-trial insulin treatment - on-treatment/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								
Insulin naïve	9	(0.7)	10	0.86	10	(0.8)	12	0.94
Basal insulin	2	(0.8)	3	1.93	2	(0.8)	2	1.31
Basal-bolus insulin regimen	2	(0.7)	4	2.39	1	(0.3)	1	0.60
Not recovered/not resolved								
Insulin naïve	370	(27.9)	717	59.50	366	(27.6)	683	56.82
Basal insulin	55	(21.0)	97	62.48	48	(18.3)	63	41.24
Basal-bolus insulin regimen	78	(26.8)	139	83.05	73	(25.1)	152	91.13
Recovered/resolved with sequelae								
Insulin naïve	10	(0.8)	10	0.86	10	(0.8)	12	0.95
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				2	(0.7)	2	1.20
Recovering/resolving								
Insulin naïve	55	(4.1)	74	6.67	55	(4.2)	64	5.70
Basal insulin	19	(7.3)	24	15.46	16	(6.1)	17	11.13
Basal-bolus insulin regimen	16	(5.5)	32	19.12	16	(5.5)	22	13.19
Recovered/resolved								
Insulin naïve	684	(51.6)	1745	151.61	636	(48.0)	1608	137.00
Basal insulin	135	(51.5)	342	220.29	100	(38.0)	245	160.37
Basal-bolus insulin regimen	143	(49.1)	280	167.30	142	(48.8)	373	223.62
Unknown								
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Missing								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	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 insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 contributes, hence the percentages and rates are unadjusted. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

7.7.75 Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ main-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								
Insulin naïve	1327				1324			
Basal insulin	262				263			
Basal-bolus insulin regimen	581				583			
PYE (years)								
Insulin naïve	1216.31				1216.89			
Basal insulin	155.25				152.77			
Basal-bolus insulin regimen	309.67				310.92			
Events								
Insulin naïve	807	(60.8)	2557	219.57	772	(58.3)	2381	201.55
Basal insulin	161	(61.5)	466	300.17	134	(51.0)	328	214.70
Basal-bolus insulin regimen	360	(62.0)	962	314.07	357	(61.2)	1169	379.62
Infections and infestations								
All								
Insulin naïve	381	(28.7)	558	48.32	395	(29.8)	571	47.99
Basal insulin	76	(29.0)	98	63.13	49	(18.6)	66	43.20
Basal-bolus insulin regimen	191	(32.9)	264	86.60	180	(30.9)	268	87.32
COVID-19								
Insulin naïve	117	(8.8)	120	10.33	130	(9.8)	133	10.70
Basal insulin	9	(3.4)	9	5.80	7	(2.7)	7	4.58
Basal-bolus insulin regimen	55	(9.5)	56	18.31	55	(9.4)	59	19.29
Nasopharyngitis								
Insulin naïve	53	(4.0)	63	5.40	57	(4.3)	63	5.46
Basal insulin	22	(8.4)	28	18.04	10	(3.8)	14	9.16
Basal-bolus insulin regimen	42	(7.2)	50	17.15	48	(8.2)	58	19.41
Upper respiratory tract infection								
Insulin naïve	48	(3.6)	58	4.84	35	(2.6)	38	3.27
Basal insulin	8	(3.1)	11	7.09	4	(1.5)	4	2.62
Basal-bolus insulin regimen	12	(2.1)	12	3.90	13	(2.2)	14	4.57
Urinary tract infection								
Insulin naïve	30	(2.3)	32	3.04	36	(2.7)	38	3.05
Basal insulin	4	(1.5)	5	3.22	3	(1.1)	3	1.96
Basal-bolus insulin regimen	9	(1.5)	9	3.00	11	(1.9)	15	4.87
Influenza								
Insulin naïve	22	(1.7)	25	2.90	16	(1.2)	16	1.68
Basal insulin	1	(0.4)	1	0.64	4	(1.5)	5	3.27
Basal-bolus insulin regimen	6	(1.0)	6	1.85	13	(2.2)	15	4.73

%: 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 insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 and 6 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Bronchitis								
Insulin naïve	16	(1.2)	17	1.44	14	(1.1)	14	1.26
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	12	(2.1)	12	3.80	5	(0.9)	5	1.59
Gastroenteritis								
Insulin naïve	14	(1.1)	14	1.37	9	(0.7)	9	0.84
Basal insulin	5	(1.9)	5	3.22	2	(0.8)	2	1.31
Basal-bolus insulin regimen	13	(2.2)	14	4.55	7	(1.2)	8	2.49
Pharyngitis								
Insulin naïve	13	(1.0)	15	1.20	11	(0.8)	14	1.17
Basal insulin	0				0			
Basal-bolus insulin regimen	8	(1.4)	8	2.65	7	(1.2)	7	2.15
Cystitis								
Insulin naïve	9	(0.7)	10	0.92	11	(0.8)	12	0.96
Basal insulin	1	(0.4)	1	0.64	2	(0.8)	3	1.96
Basal-bolus insulin regimen	5	(0.9)	5	1.65	4	(0.7)	4	1.25
Pneumonia								
Insulin naïve	9	(0.7)	9	0.78	5	(0.4)	5	0.48
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	4	(0.7)	4	1.25	1	(0.2)	1	0.30
Sinusitis								
Insulin naïve	9	(0.7)	10	0.75	12	(0.9)	15	1.23
Basal insulin	2	(0.8)	2	1.29	3	(1.1)	3	1.96
Basal-bolus insulin regimen	8	(1.4)	9	2.95	4	(0.7)	4	1.29
Herpes zoster								
Insulin naïve	8	(0.6)	8	0.60	11	(0.8)	12	0.90
Basal insulin	0				3	(1.1)	3	1.96
Basal-bolus insulin regimen	3	(0.5)	3	0.95	3	(0.5)	3	0.99
COVID-19 pneumonia								
Insulin naïve	8	(0.6)	8	0.60	9	(0.7)	9	0.78
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	5	(0.9)	5	1.55	2	(0.3)	2	0.65
Rhinitis								
Insulin naïve	7	(0.5)	7	0.59	6	(0.5)	6	0.56
Basal insulin	0				1	(0.4)	3	1.96
Basal-bolus insulin regimen	2	(0.3)	2	0.70	4	(0.7)	5	1.73
Fungal infection								
Insulin naïve	6	(0.5)	6	0.56	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	2	1.29	0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Conjunctivitis								
Insulin naïve	6	(0.5)	6	0.45	6	(0.5)	6	0.56
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	5	(0.9)	5	1.70	1	(0.2)	1	0.30
Tooth infection								
Insulin naïve	6	(0.5)	7	0.57	4	(0.3)	4	0.41
Basal insulin	1	(0.4)	2	1.29	3	(1.1)	3	1.96
Basal-bolus insulin regimen	2	(0.3)	2	0.65	1	(0.2)	1	0.30
Lower respiratory tract infection								
Insulin naïve	5	(0.4)	5	0.38	2	(0.2)	4	0.31
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.35
Viral infection								
Insulin naïve	5	(0.4)	5	0.43	9	(0.7)	12	0.94
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.3)	2	0.65	4	(0.7)	4	1.39
Respiratory tract infection								
Insulin naïve	5	(0.4)	5	0.37	4	(0.3)	4	0.31
Basal insulin	0				0			
Basal-bolus insulin regimen	4	(0.7)	4	1.25	2	(0.3)	2	0.60
Acute sinusitis								
Insulin naïve	5	(0.4)	5	0.42	3	(0.2)	3	0.27
Basal insulin	0				0			
Basal-bolus insulin regimen	0				3	(0.5)	3	1.04
Tooth abscess								
Insulin naïve	4	(0.3)	4	0.36	5	(0.4)	5	0.37
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	4	(0.7)	4	1.30	2	(0.3)	3	0.90
Gastroenteritis viral								
Insulin naïve	4	(0.3)	4	0.31	3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.3)	2	0.65	3	(0.5)	3	0.99
Vaginal infection								
Insulin naïve	4	(0.3)	4	0.40	2	(0.2)	2	0.15
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	2	0.70	0			
Coronavirus infection								
Insulin naïve	4	(0.3)	4	0.30	3	(0.2)	4	0.31
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.3)	3	0.95

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

Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ main-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								
Insulin naïve	3	(0.2)	3	0.23	3	(0.2)	3	0.28
Basal insulin	0				0			
Basal-bolus insulin regimen	9	(1.5)	10	3.15	7	(1.2)	8	2.49
Erysipelas								
Insulin naïve	3	(0.2)	3	0.28	2	(0.2)	3	0.33
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Otitis media								
Insulin naïve	3	(0.2)	3	0.28	2	(0.2)	2	0.15
Basal insulin	3	(1.1)	3	1.93	1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.30	2	(0.3)	2	0.65
Ear infection								
Insulin naïve	3	(0.2)	3	0.23	4	(0.3)	4	0.35
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Laryngitis								
Insulin naïve	3	(0.2)	3	0.23	3	(0.2)	3	0.28
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.3)	2	0.65
Genital infection								
Insulin naïve	3	(0.2)	3	0.28	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cellulitis								
Insulin naïve	3	(0.2)	3	0.22	6	(0.5)	6	0.56
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	2	1.31
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Furuncle								
Insulin naïve	2	(0.2)	3	0.28	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Skin infection								
Insulin naïve	2	(0.2)	2	0.21	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.3)	2	0.69
Tinea infection								
Insulin naïve	2	(0.2)	2	0.21	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ main-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								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Gingivitis								
Insulin naïve	2	(0.2)	3	0.23	2	(0.2)	2	0.21
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.35	2	(0.3)	2	0.65
Hordeolum								
Insulin naïve	2	(0.2)	2	0.15	3	(0.2)	3	0.33
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.35
Localised infection								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.07
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.35
Periodontitis								
Insulin naïve	2	(0.2)	2	0.15	6	(0.5)	6	0.62
Basal insulin	0				0			
Basal-bolus insulin regimen	3	(0.5)	3	0.95	1	(0.2)	1	0.35
Vulvovaginal candidiasis								
Insulin naïve	2	(0.2)	3	0.23	4	(0.3)	4	0.31
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Otitis externa								
Insulin naïve	2	(0.2)	2	0.20	3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	0				3	(0.5)	3	1.04
Wound infection								
Insulin naïve	2	(0.2)	2	0.20	1	(0.1)	1	0.13
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Respiratory syncytial virus infection								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Tonsillitis								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Acarodermatitis								
Insulin naïve	2	(0.2)	2	0.15	4	(0.3)	4	0.29
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Escherichia bacteraemia								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Gastrointestinal infection								
Insulin naïve	1	(0.1)	1	0.13	3	(0.2)	4	0.29
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	2	(0.3)	3	1.04
Genital candidiasis								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Injection site abscess								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Oral candidiasis								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Oral herpes								
Insulin naïve	1	(0.1)	1	0.13	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	2	0.60	0			
Postoperative wound infection								
Insulin naïve	1	(0.1)	1	0.13	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Sepsis								
Insulin naïve	1	(0.1)	1	0.13	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Suspected COVID-19								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ main-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								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.35
Abscess								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Asymptomatic COVID-19								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Bacterial infection								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Balanitis candida								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Chlamydial infection								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Chronic tonsillitis								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Dermatophytosis of nail								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Escherichia urinary tract infection								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Folliculitis								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Genital infection fungal								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	2	0.70	0			
Helicobacter gastritis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Herpes simplex								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Herpes virus infection								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Infected bite								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Laryngopharyngitis								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Mastitis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Onychomycosis								
Insulin naïve	1	(0.1)	1	0.08	4	(0.3)	4	0.29
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Oropharyngeal candidiasis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Osteomyelitis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	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 insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 and 6 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Otitis media chronic								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pericoronitis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Purulence								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Tracheitis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Urethritis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Viral upper respiratory tract infection								
Insulin naïve	1	(0.1)	1	0.08	3	(0.2)	3	0.23
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vulvovaginal mycotic infection								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Appendicitis								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Chronic sinusitis								
Insulin naïve	1	(0.1)	1	0.07	3	(0.2)	3	0.23
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Clostridium difficile colitis								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Clostridium difficile infection								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ear infection fungal								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Fungal skin infection								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.30
Gangrene								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Helicobacter infection								
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	2	0.21
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Nail infection								
Insulin naïve	1	(0.1)	2	0.15	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Paronychia								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	2	0.60
Peritonsillar abscess								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Post-acute COVID-19 syndrome								
Insulin naïve	1	(0.1)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pyelonephritis								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ main-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								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Subcutaneous abscess								
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	3	0.23
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Tinea cruris								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Viral pharyngitis								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Abdominal abscess								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Abscess limb								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	2	0.69
Anal abscess								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Bacteraemia								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Bartholinitis								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Body tinea								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ main-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 abscess								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.30
Breast cellulitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Campylobacter gastroenteritis								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Cholecystitis infective								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Chronic hepatitis C								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cystitis escherichia								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Diabetic foot infection								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Diverticulitis								
Insulin naïve	0				5	(0.4)	5	0.38
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Empyema								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Endophthalmitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ main-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								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Epididymitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Eye infection								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.35	2	(0.3)	2	0.60
Eye infection bacterial								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Fungal balanitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Gastric infection								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Gastroenteritis norovirus								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Giardiasis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Herpes dermatitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Herpes zoster infection neurological								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ main-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 cyst								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Infected dermal cyst								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Infective iritis								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Kidney infection								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Labyrinthitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lyme disease								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Norovirus infection								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Oophoritis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Otitis media acute								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Paraspinal abscess								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Parotitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Peri-implantitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pharyngotonsillitis								
Insulin naïve	0				2	(0.2)	3	0.23
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Pneumonia viral								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Post procedural infection								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Pulmonary tuberculoma								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Pulpitis dental								
Insulin naïve	0				2	(0.2)	2	0.21
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Pustule								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Rotavirus infection								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Salpingitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Severe acute respiratory syndrome								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.35
Sinusitis bacterial								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Skin bacterial infection								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Soft tissue infection								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Sweat gland infection								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Tinea versicolour								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Urosepsis								
Insulin naïve	0				2	(0.2)	2	0.20
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Varicella								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Varicella zoster virus infection								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Viral rhinitis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Viral tracheitis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Vulvitis								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Vulvovaginitis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Gastrointestinal disorders								
All								
Insulin naïve	178	(13.4)	270	22.25	154	(11.6)	211	17.93
Basal insulin	38	(14.5)	60	38.65	32	(12.2)	42	27.49
Basal-bolus insulin regimen	61	(10.5)	88	28.29	59	(10.1)	90	28.91
Diarrhoea								
Insulin naïve	55	(4.1)	67	5.43	33	(2.5)	34	2.95
Basal insulin	14	(5.3)	17	10.95	9	(3.4)	9	5.89
Basal-bolus insulin regimen	20	(3.4)	24	7.49	13	(2.2)	14	4.43
Nausea								
Insulin naïve	25	(1.9)	26	2.06	17	(1.3)	19	1.52
Basal insulin	7	(2.7)	7	4.51	6	(2.3)	6	3.93
Basal-bolus insulin regimen	9	(1.5)	9	2.90	12	(2.1)	12	3.97
Vomiting								
Insulin naïve	14	(1.1)	20	1.92	11	(0.8)	14	1.12
Basal insulin	3	(1.1)	3	1.93	3	(1.1)	3	1.96
Basal-bolus insulin regimen	14	(2.4)	16	5.15	7	(1.2)	7	2.33
Abdominal pain								
Insulin naïve	12	(0.9)	12	1.01	13	(1.0)	13	1.13
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	3	(0.5)	3	0.95	5	(0.9)	6	1.80
Toothache								
Insulin naïve	11	(0.8)	11	0.83	4	(0.3)	4	0.41
Basal insulin	1	(0.4)	1	0.64	3	(1.1)	5	3.27
Basal-bolus insulin regimen	3	(0.5)	3	1.00	6	(1.0)	9	2.93
Gastrooesophageal reflux disease								
Insulin naïve	11	(0.8)	11	0.94	10	(0.8)	10	0.86
Basal insulin	1	(0.4)	1	0.64	2	(0.8)	2	1.31

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	2	(0.3)	2	0.65	3	(0.5)	3	0.95
Dental caries								
Insulin naïve	11	(0.8)	13	0.98	4	(0.3)	4	0.29
Basal insulin	0				2	(0.8)	2	1.31
Basal-bolus insulin regimen	1	(0.2)	1	0.35	4	(0.7)	4	1.20
Abdominal pain upper								
Insulin naïve	11	(0.8)	11	0.92	10	(0.8)	11	0.82
Basal insulin	1	(0.4)	3	1.93	3	(1.1)	3	1.96
Basal-bolus insulin regimen	4	(0.7)	4	1.35	3	(0.5)	3	0.95
Constipation								
Insulin naïve	10	(0.8)	10	0.80	13	(1.0)	13	1.30
Basal insulin	4	(1.5)	7	4.51	0			
Basal-bolus insulin regimen	3	(0.5)	3	0.95	3	(0.5)	3	0.90
Abdominal distension								
Insulin naïve	7	(0.5)	7	0.58	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	3	(0.5)	3	0.95
Haemorrhoids								
Insulin naïve	6	(0.5)	6	0.50	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	2	(0.8)	2	1.31
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Gastritis								
Insulin naïve	6	(0.5)	6	0.61	8	(0.6)	8	0.75
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Chronic gastritis								
Insulin naïve	4	(0.3)	4	0.30	3	(0.2)	3	0.23
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	3	(0.5)	3	0.95	3	(0.5)	3	0.99
Dyspepsia								
Insulin naïve	4	(0.3)	4	0.35	7	(0.5)	7	0.63
Basal insulin	3	(1.1)	3	1.93	1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.35
Food poisoning								
Insulin naïve	4	(0.3)	4	0.35	2	(0.2)	2	0.21
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	2	1.31
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Flatulence								
Insulin naïve	3	(0.2)	3	0.28	2	(0.2)	2	0.26
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			

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Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ main-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								
Insulin naïve	3	(0.2)	4	0.31	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Diverticulum intestinal								
Insulin naïve	3	(0.2)	3	0.22	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Large intestine polyp								
Insulin naïve	3	(0.2)	3	0.22	5	(0.4)	6	0.45
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Gastric polyps								
Insulin naïve	2	(0.2)	2	0.21	1	(0.1)	1	0.08
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				2	(0.3)	2	0.69
Abdominal discomfort								
Insulin naïve	2	(0.2)	2	0.15	4	(0.3)	4	0.36
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.3)	2	0.65	2	(0.3)	3	0.95
Abdominal pain lower								
Insulin naïve	2	(0.2)	2	0.15	2	(0.2)	2	0.15
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	0				0			
Dry mouth								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Rectal polyp								
Insulin naïve	2	(0.2)	2	0.15	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Aphthous ulcer								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Inguinal hernia								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Gastric dilatation								
Insulin naïve	1	(0.1)	1	0.13	0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Noninfective gingivitis								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Oral pain								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vomiting projectile								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Anal pruritus								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Colitis								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Colitis ischaemic								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Frequent bowel movements								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Haematochezia								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hyperaesthesia teeth								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Loose tooth								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ main-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 discomfort								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pancreatitis								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Periodontal disease								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Tooth disorder								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Tooth impacted								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Abdominal wall disorder								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Anal fissure								
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Colitis microscopic								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Diabetic gastropathy								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Eosinophilic oesophagitis								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Eructation								

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Gastric ulcer								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Gastrointestinal haemorrhage								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Haemorrhoidal haemorrhage								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hiatus hernia								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Hypoaesthesia oral								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.3)	4	1.20	0			
Impaired gastric emptying								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	2	0.70	0			
Intestinal dilatation								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lip swelling								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Umbilical hernia								
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Acid peptic disease								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				0			
Crohn's disease								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Diverticulum								
Insulin naïve	0				3	(0.2)	3	0.28
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Duodenitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Enteritis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Epigastric discomfort								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Faeces pale								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Faeces soft								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Gastric disorder								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Gastric dysplasia								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Gastric mucosal hypertrophy								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Gastritis erosive								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.3)	2	0.69
Gastrointestinal angiodysplasia								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Gastrointestinal disorder								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Gastrointestinal inflammation								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Gastrointestinal sounds abnormal								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Gingival bleeding								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Gingival disorder								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Gingival recession								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	2	0.69
Hyperchlorhydria								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ileus								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Intra-abdominal haematoma								
Insulin naïve	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. For insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 and 6 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Irritable bowel syndrome								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Lumbar hernia								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Melaena								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Mesenteric panniculitis								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Odynophagia								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Oesophageal pain								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Oesophagitis								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pancreatic duct dilatation								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Pancreatic failure								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.3)	2	0.65	0			
Pancreatic pseudocyst								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Pancreatitis acute								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pancreatitis chronic								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Peptic ulcer								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Periodontal inflammation								
Insulin naïve	0				1	(0.1)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pneumatosis intestinalis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Proctalgia								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Rectal prolapse								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Small intestinal obstruction								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Stomatitis								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Tongue rough								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Ulcerative gastritis								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Upper gastrointestinal haemorrhage								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Musculoskeletal and connective tissue disorders								
All								
Insulin naïve	176	(13.3)	268	22.29	181	(13.7)	245	20.70
Basal insulin	38	(14.5)	60	38.65	29	(11.0)	45	29.46
Basal-bolus insulin regimen	59	(10.2)	72	23.14	74	(12.7)	111	36.25
Back pain								
Insulin naïve	47	(3.5)	51	4.44	39	(2.9)	40	3.40
Basal insulin	7	(2.7)	7	4.51	11	(4.2)	13	8.51
Basal-bolus insulin regimen	11	(1.9)	11	3.44	22	(3.8)	36	11.97
Arthralgia								
Insulin naïve	34	(2.6)	40	3.41	32	(2.4)	35	2.96
Basal insulin	6	(2.3)	7	4.51	10	(3.8)	13	8.51
Basal-bolus insulin regimen	11	(1.9)	12	3.90	15	(2.6)	15	4.92
Pain in extremity								
Insulin naïve	27	(2.0)	29	2.34	24	(1.8)	28	2.66
Basal insulin	3	(1.1)	3	1.93	5	(1.9)	6	3.93
Basal-bolus insulin regimen	7	(1.2)	7	2.41	8	(1.4)	9	2.98
Osteoarthritis								
Insulin naïve	15	(1.1)	17	1.34	16	(1.2)	18	1.40
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	8	(1.4)	8	2.55	9	(1.5)	10	3.09
Muscle spasms								
Insulin naïve	12	(0.9)	12	0.96	6	(0.5)	6	0.45
Basal insulin	9	(3.4)	11	7.09	1	(0.4)	1	0.65
Basal-bolus insulin regimen	4	(0.7)	4	1.30	2	(0.3)	2	0.60
Neck pain								
Insulin naïve	9	(0.7)	9	0.73	7	(0.5)	7	0.59
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	5	(0.9)	5	1.55	1	(0.2)	1	0.30
Myalgia								
Insulin naïve	8	(0.6)	8	0.71	6	(0.5)	6	0.56
Basal insulin	4	(1.5)	4	2.58	2	(0.8)	2	1.31
Basal-bolus insulin regimen	4	(0.7)	4	1.30	8	(1.4)	9	3.08

%: 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. For insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 and 6 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Periarthritis								
Insulin naïve	6	(0.5)	6	0.46	5	(0.4)	5	0.38
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	4	(0.7)	4	1.34
Intervertebral disc protrusion								
Insulin naïve	6	(0.5)	10	0.75	6	(0.5)	7	0.64
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Tendonitis								
Insulin naïve	6	(0.5)	6	0.44	3	(0.2)	3	0.28
Basal insulin	2	(0.8)	4	2.58	0			
Basal-bolus insulin regimen	0				2	(0.3)	2	0.65
Arthritis								
Insulin naïve	5	(0.4)	5	0.42	2	(0.2)	2	0.15
Basal insulin	1	(0.4)	1	0.64	2	(0.8)	2	1.31
Basal-bolus insulin regimen	1	(0.2)	1	0.35	2	(0.3)	2	0.60
Spinal osteoarthritis								
Insulin naïve	4	(0.3)	4	0.30	5	(0.4)	6	0.44
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.3)	2	0.60	0			
Musculoskeletal stiffness								
Insulin naïve	3	(0.2)	3	0.28	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.35
Plantar fasciitis								
Insulin naïve	3	(0.2)	4	0.31	3	(0.2)	3	0.22
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Rotator cuff syndrome								
Insulin naïve	3	(0.2)	3	0.23	4	(0.3)	4	0.29
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Muscular weakness								
Insulin naïve	3	(0.2)	3	0.33	3	(0.2)	3	0.34
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Tendon disorder								
Insulin naïve	3	(0.2)	3	0.33	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Musculoskeletal chest pain								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	3	(0.2)	3	0.23	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Bursitis								
Insulin naïve	3	(0.2)	3	0.22	3	(0.2)	3	0.23
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Exostosis								
Insulin naïve	3	(0.2)	3	0.22	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Musculoskeletal pain								
Insulin naïve	2	(0.2)	2	0.21	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Fibromyalgia								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Groin pain								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Intervertebral disc disorder								
Insulin naïve	2	(0.2)	2	0.15	2	(0.2)	2	0.21
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Spinal stenosis								
Insulin naïve	2	(0.2)	2	0.15	2	(0.2)	2	0.15
Basal insulin	2	(0.8)	4	2.58	0			
Basal-bolus insulin regimen	0				0			
Synovial cyst								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Joint effusion								
Insulin naïve	2	(0.2)	3	0.33	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Chondropathy								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				0			
Polyarthritis								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Trigger finger								
Insulin naïve	2	(0.2)	2	0.15	4	(0.3)	6	0.45
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	6	(1.0)	6	1.90	1	(0.2)	1	0.35
Foot deformity								
Insulin naïve	2	(0.2)	4	0.29	2	(0.2)	2	0.20
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.30
Arthropathy								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Muscle contracture								
Insulin naïve	1	(0.1)	1	0.13	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pain in jaw								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Torticollis								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Back disorder								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Bone cyst								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Coccydynia								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Costochondritis								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Fistula								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lumbar spinal stenosis								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Myositis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Osteopenia								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Spinal pain								
Insulin naïve	1	(0.1)	1	0.08	4	(0.3)	4	0.36
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Tenosynovitis								
Insulin naïve	1	(0.1)	1	0.08	7	(0.5)	8	0.60
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.30
Acquired claw toe								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Diastasis recti abdominis								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Facet joint syndrome								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Meniscopathy								
Insulin naïve	1	(0.1)	1	0.07	0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Osteochondrosis								
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	2	(0.3)	2	0.60
Psoriatic arthropathy								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Sacroiliitis								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Axillary mass								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Bone pain								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Cervical spinal stenosis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Chondromalacia								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Dupuytren's contracture								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Flank pain								
Insulin naïve	0				4	(0.3)	5	0.43
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Haemarthrosis								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Intervertebral disc degeneration								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Intervertebral disc space narrowing								
Insulin naïve	0				1	(0.1)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Jaw disorder								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Joint swelling								
Insulin naïve	0				3	(0.2)	3	0.34
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Limb deformity								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Limb discomfort								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Limb mass								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Mastication disorder								
Insulin naïve	0				1	(0.1)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Muscle twitching								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Neuropathic arthropathy								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Nodal osteoarthritis								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Osteochondritis								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Osteoporosis								
Insulin naïve	0				0			
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	0				0			
Periostitis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Polymyalgia rheumatica								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	3	1.96
Basal-bolus insulin regimen	0				0			
Rheumatoid arthritis								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				2	(0.3)	2	0.69
Scoliosis								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Soft tissue swelling								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	3	1.93	0			
Basal-bolus insulin regimen	0				0			
Spinal retrolisthesis								
Insulin naïve	0				1	(0.1)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Tenosynovitis stenosans								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vertebral osteophyte								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				0			
General disorders and administration site conditions								
All								
Insulin naïve	148	(11.2)	239	22.58	129	(9.7)	204	17.01
Basal insulin	25	(9.5)	36	23.19	19	(7.2)	21	13.75
Basal-bolus insulin regimen	67	(11.5)	88	28.92	60	(10.3)	119	39.59
Pyrexia								
Insulin naïve	23	(1.7)	24	1.98	25	(1.9)	26	2.09
Basal insulin	6	(2.3)	6	3.86	6	(2.3)	6	3.93
Basal-bolus insulin regimen	12	(2.1)	13	4.41	12	(2.1)	13	4.18
Fatigue								
Insulin naïve	21	(1.6)	22	1.82	11	(0.8)	11	0.82
Basal insulin	2	(0.8)	3	1.93	3	(1.1)	3	1.96
Basal-bolus insulin regimen	9	(1.5)	11	3.60	2	(0.3)	2	0.65
Oedema peripheral								
Insulin naïve	13	(1.0)	13	1.19	7	(0.5)	8	0.60
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	4	(0.7)	4	1.30	3	(0.5)	3	0.95
Injection site reaction								
Insulin naïve	11	(0.8)	25	3.13	5	(0.4)	7	0.63
Basal insulin	2	(0.8)	2	1.29	1	(0.4)	1	0.65
Basal-bolus insulin regimen	2	(0.3)	2	0.60	0			
Chest pain								
Insulin naïve	10	(0.8)	10	0.80	5	(0.4)	5	0.37
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	3	(0.5)	3	0.90	2	(0.3)	2	0.69
Malaise								
Insulin naïve	9	(0.7)	11	0.82	9	(0.7)	11	0.84
Basal insulin	2	(0.8)	2	1.29	2	(0.8)	3	1.96
Basal-bolus insulin regimen	5	(0.9)	5	1.65	4	(0.7)	46	15.86
Asthenia								
Insulin naïve	7	(0.5)	7	0.64	5	(0.4)	5	0.38
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	2	(0.3)	2	0.60	4	(0.7)	4	1.29
Chest discomfort								
Insulin naïve	6	(0.5)	6	0.56	2	(0.2)	2	0.21
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	0				0			
Hunger								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	5	(0.4)	6	0.46	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	2	0.69
Pain								
Insulin naïve	5	(0.4)	5	0.43	12	(0.9)	13	1.19
Basal insulin	2	(0.8)	2	1.29	1	(0.4)	1	0.65
Basal-bolus insulin regimen	6	(1.0)	7	2.25	1	(0.2)	1	0.30
Peripheral swelling								
Insulin naïve	5	(0.4)	6	0.56	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.3)	2	0.60
Medical device site bruise								
Insulin naïve	4	(0.3)	5	0.38	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	2	1.29	0			
Basal-bolus insulin regimen	2	(0.3)	2	0.70	0			
Medical device site haemorrhage								
Insulin naïve	4	(0.3)	4	0.31	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Vaccination site pain								
Insulin naïve	4	(0.3)	5	0.38	3	(0.2)	3	0.23
Basal insulin	3	(1.1)	4	2.58	3	(1.1)	3	1.96
Basal-bolus insulin regimen	3	(0.5)	3	0.90	3	(0.5)	3	0.95
Injection site pruritus								
Insulin naïve	4	(0.3)	19	2.35	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Injection site pain								
Insulin naïve	3	(0.2)	3	0.39	11	(0.8)	29	2.46
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.3)	2	0.65
Injection site erythema								
Insulin naïve	3	(0.2)	5	0.59	4	(0.3)	4	0.31
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Medical device site pruritus								
Insulin naïve	3	(0.2)	3	0.23	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	3	(0.5)	3	1.04
Influenza like illness								
Insulin naïve	3	(0.2)	4	0.40	3	(0.2)	3	0.22
Basal insulin	1	(0.4)	1	0.64	0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	3	(0.5)	3	1.05	1	(0.2)	1	0.35
Injection site bruising								
Insulin naïve	3	(0.2)	3	0.33	5	(0.4)	5	0.43
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Chills								
Insulin naïve	3	(0.2)	3	0.23	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Drug intolerance								
Insulin naïve	3	(0.2)	3	0.23	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Gait disturbance								
Insulin naïve	3	(0.2)	3	0.23	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Injection site haematoma								
Insulin naïve	2	(0.2)	6	0.78	3	(0.2)	8	1.04
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Injection site haemorrhage								
Insulin naïve	2	(0.2)	2	0.26	2	(0.2)	2	0.21
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Discomfort								
Insulin naïve	2	(0.2)	2	0.21	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	8	2.40
Thirst								
Insulin naïve	2	(0.2)	2	0.21	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Injection site hypersensitivity								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Medical device site dermatitis								
Insulin naïve	2	(0.2)	5	0.38	8	(0.6)	14	1.07
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	4	(0.7)	4	1.35	3	(0.5)	4	1.39

%: 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 insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 and 6 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Injection site mass								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Application site bruise								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Application site pruritus								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Inflammation								
Insulin naïve	1	(0.1)	1	0.13	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.30
Injection site rash								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Injection site swelling								
Insulin naïve	1	(0.1)	1	0.13	1	(0.1)	1	0.13
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Feeling abnormal								
Insulin naïve	1	(0.1)	3	0.23	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.3)	2	0.60	0			
Feeling hot								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Implant site pruritus								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Injection site dermatitis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Medical device site eczema								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.15

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Medical device site hypersensitivity								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Medical device site pain								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	2	(0.3)	2	0.65
Medical device site reaction								
Insulin naïve	1	(0.1)	3	0.23	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	5	(0.9)	5	1.65	0			
Swelling								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vaccination site reaction								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Early satiety								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Localised oedema								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Swelling face								
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	2	0.20
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Vessel puncture site bruise								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Axillary pain								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Condition aggravated								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Cyst								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Death								
Insulin naïve	0				3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Facial pain								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Hernia								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hyperthermia								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Injection site hypertrophy								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Injection site induration								
Insulin naïve	0				2	(0.2)	2	0.20
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Injection site oedema								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Injection site urticaria								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	2	0.70	0			
Medical device site erythema								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	0				4	(0.7)	5	1.69
Medical device site haematoma								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Medical device site inflammation								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Medical device site irritation								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Medical device site rash								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	6	(1.0)	6	2.11	7	(1.2)	7	2.43
Multiple organ dysfunction syndrome								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Non-cardiac chest pain								
Insulin naïve	0				4	(0.3)	6	0.44
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Oedema								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.30
Oedema due to renal disease								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Procedural failure								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Systemic inflammatory response syndrome								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				0			
Vaccination site erythema								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vaccination site inflammation								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Vaccination site pruritus								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Xerosis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Nervous system disorders								
All								
Insulin naïve	134	(10.1)	178	15.43	129	(9.7)	167	14.28
Basal insulin	27	(10.3)	42	27.05	25	(9.5)	34	22.26
Basal-bolus insulin regimen	46	(7.9)	78	25.72	53	(9.1)	125	41.15
Headache								
Insulin naïve	35	(2.6)	43	3.88	36	(2.7)	45	3.82
Basal insulin	14	(5.3)	20	12.88	9	(3.4)	10	6.55
Basal-bolus insulin regimen	21	(3.6)	29	9.66	19	(3.3)	25	8.11
Dizziness								
Insulin naïve	29	(2.2)	34	2.93	26	(2.0)	28	2.49
Basal insulin	4	(1.5)	5	3.22	9	(3.4)	13	8.51
Basal-bolus insulin regimen	7	(1.2)	12	3.74	4	(0.7)	6	1.94
Tremor								
Insulin naïve	10	(0.8)	11	0.88	4	(0.3)	4	0.41
Basal insulin	0				2	(0.8)	2	1.31
Basal-bolus insulin regimen	2	(0.3)	2	0.65	4	(0.7)	55	18.80
Hypoaesthesia								
Insulin naïve	9	(0.7)	12	1.18	7	(0.5)	8	0.71
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				2	(0.3)	2	0.65
Sciatica								
Insulin naïve	9	(0.7)	9	0.84	9	(0.7)	10	0.81

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	2	(0.8)	2	1.29	2	(0.8)	2	1.31
Basal-bolus insulin regimen	2	(0.3)	2	0.60	1	(0.2)	1	0.30
Carpal tunnel syndrome								
Insulin naïve	8	(0.6)	8	0.65	3	(0.2)	3	0.23
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	2	(0.3)	2	0.60	5	(0.9)	5	1.55
Paraesthesia								
Insulin naïve	8	(0.6)	9	0.73	9	(0.7)	9	0.89
Basal insulin	0				0			
Basal-bolus insulin regimen	0				3	(0.5)	3	0.90
Syncope								
Insulin naïve	5	(0.4)	5	0.38	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Neuropathy peripheral								
Insulin naïve	5	(0.4)	6	0.61	8	(0.6)	8	0.70
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.35
Migraine								
Insulin naïve	4	(0.3)	4	0.35	2	(0.2)	2	0.21
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	2	(0.3)	3	1.05	3	(0.5)	3	0.99
Diabetic neuropathy								
Insulin naïve	3	(0.2)	3	0.28	9	(0.7)	9	0.84
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	3	(0.5)	3	0.95	2	(0.3)	2	0.60
Transient ischaemic attack								
Insulin naïve	3	(0.2)	3	0.28	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Burning sensation								
Insulin naïve	2	(0.2)	2	0.15	2	(0.2)	2	0.15
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Tension headache								
Insulin naïve	2	(0.2)	3	0.23	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Amnesia								
Insulin naïve	2	(0.2)	2	0.20	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Dysgeusia								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Carotid artery stenosis								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vascular headache								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ageusia								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Anosmia								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Balance disorder								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cerebral haemorrhage								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cerebrovascular disorder								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Cervical radiculopathy								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Dizziness postural								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.3)	2	0.65
Lumbar radiculopathy								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	1	(0.1)	1	0.08	4	(0.3)	5	0.37
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Memory impairment								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.30
Neuroglycopenia								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	3	0.23
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Post herpetic neuralgia								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Presyncope								
Insulin naïve	1	(0.1)	1	0.08	4	(0.3)	4	0.30
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Trigeminal neuralgia								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cerebral atrophy								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cluster headache								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cognitive disorder								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Disturbance in attention								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	9	3.16	0			
Intracranial pressure increased								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				0			
Neuralgia								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Autonomic nervous system imbalance								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Basilar migraine								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Brain injury								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Carotid arteriosclerosis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Carotid artery aneurysm								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Cerebral arteriosclerosis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Cerebral artery embolism								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cerebral infarction								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Cerebrovascular accident								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Cervicobrachial syndrome								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Dementia Alzheimer's type								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Encephalopathy								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Essential tremor								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Facial nerve disorder								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Facial paralysis								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Haemorrhage intracranial								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Hemiparesis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Hypoglycaemic coma								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Hypoglycaemic seizure								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.35
Hypoglycaemic unconsciousness								
Insulin naïve	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Hyporeflexia								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Hypotonia								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Ischaemic stroke								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lethargy								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Loss of consciousness								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.35
Mental impairment								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Meralgia paraesthetica								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Morton's neuralgia								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Myelopathy								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ophthalmic migraine								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Orthostatic tremor								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Parkinsonian gait								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Peripheral paralysis								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Piriformis syndrome								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Radiculopathy								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Restless legs syndrome								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Sinus headache								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.35
Sleep deficit								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Somnolence								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Speech disorder								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Thalamic 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. For insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 and 6 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Thrombotic stroke								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Vascular encephalopathy								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Vertebral artery occlusion								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
White matter lesion								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Injury, poisoning and procedural complications								
All								
Insulin naïve	118	(8.9)	140	11.73	98	(7.4)	117	10.23
Basal insulin	27	(10.3)	39	25.12	22	(8.4)	26	17.02
Basal-bolus insulin regimen	49	(8.4)	62	20.47	60	(10.3)	74	24.02
Fall								
Insulin naïve	13	(1.0)	13	0.96	7	(0.5)	8	0.64
Basal insulin	5	(1.9)	5	3.22	2	(0.8)	2	1.31
Basal-bolus insulin regimen	2	(0.3)	2	0.65	2	(0.3)	2	0.65
Vaccination complication								
Insulin naïve	11	(0.8)	11	0.89	14	(1.1)	20	1.58
Basal insulin	4	(1.5)	8	5.15	3	(1.1)	3	1.96
Basal-bolus insulin regimen	5	(0.9)	5	1.76	12	(2.1)	15	5.02
Contusion								
Insulin naïve	10	(0.8)	11	0.88	6	(0.5)	6	0.46
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	3	(0.5)	3	0.95	3	(0.5)	3	0.99
Ligament sprain								
Insulin naïve	7	(0.5)	7	0.69	5	(0.4)	5	0.48
Basal insulin	2	(0.8)	2	1.29	1	(0.4)	1	0.65
Basal-bolus insulin regimen	3	(0.5)	3	1.05	2	(0.3)	2	0.60

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

Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ main-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								
Insulin naïve	5	(0.4)	5	0.49	3	(0.2)	3	0.27
Basal insulin	0				1	(0.4)	2	1.31
Basal-bolus insulin regimen	1	(0.2)	1	0.35	2	(0.3)	2	0.60
Hand fracture								
Insulin naïve	5	(0.4)	5	0.48	1	(0.1)	1	0.07
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Skin abrasion								
Insulin naïve	5	(0.4)	7	0.58	1	(0.1)	1	0.07
Basal insulin	2	(0.8)	2	1.29	1	(0.4)	1	0.65
Basal-bolus insulin regimen	2	(0.3)	3	1.00	3	(0.5)	3	0.95
Procedural pain								
Insulin naïve	4	(0.3)	4	0.41	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Skin laceration								
Insulin naïve	4	(0.3)	4	0.30	0			
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.35
Ankle fracture								
Insulin naïve	4	(0.3)	4	0.29	3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Joint injury								
Insulin naïve	3	(0.2)	3	0.28	3	(0.2)	3	0.22
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.35
Rib fracture								
Insulin naïve	3	(0.2)	3	0.28	5	(0.4)	5	0.48
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Road traffic accident								
Insulin naïve	3	(0.2)	3	0.28	1	(0.1)	1	0.07
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	2	0.70	0			
Upper limb fracture								
Insulin naïve	3	(0.2)	3	0.22	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Medication error								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	2	(0.2)	2	0.26	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.3)	2	0.65
Thermal burn								
Insulin naïve	2	(0.2)	2	0.21	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Fibula fracture								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Injury								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Meniscus injury								
Insulin naïve	2	(0.2)	2	0.15	4	(0.3)	4	0.29
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Wound								
Insulin naïve	2	(0.2)	2	0.15	4	(0.3)	4	0.46
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.35
Tendon rupture								
Insulin naïve	2	(0.2)	2	0.20	0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Accidental overdose								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.13
Basal insulin	4	(1.5)	4	2.58	0			
Basal-bolus insulin regimen	8	(1.4)	9	3.11	3	(0.5)	4	1.25
Arthropod sting								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Hip fracture								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Radius fracture								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Basal insulin	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Tooth fracture								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.3)	2	0.60	2	(0.3)	2	0.65
Back injury								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Gun shot wound								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ligament rupture								
Insulin naïve	1	(0.1)	2	0.26	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Procedural complication								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Burn oral cavity								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Burns first degree								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Cervical vertebral fracture								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Eye injury								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Heat illness								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	3	0.23
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			

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Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ main-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 strain								
Insulin naïve	1	(0.1)	1	0.08	3	(0.2)	3	0.28
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.3)	2	0.65
Overdose								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.21
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.30
Post procedural fistula								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Post procedural haemorrhage								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Post procedural hypothyroidism								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Scar								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Traumatic haematoma								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Animal bite								
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Bone contusion								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Femoral neck fracture								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Foot fracture								
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	2	0.15

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	2	(0.3)	2	0.60	0			
Inflammation of wound								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Injury of conjunctiva								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Multiple injuries								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Muscle injury								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Neck injury								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Penile contusion								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Post procedural complication								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Post procedural haematuria								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Post procedural inflammation								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Radiation skin injury								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ main-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 compression fracture								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Accidental underdose								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Anaemia postoperative								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Animal scratch								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Arthropod bite								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	2	(0.3)	2	0.60	2	(0.3)	2	0.65
Chillblains								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Clavicle fracture								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Concussion								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.3)	2	0.60
Corneal abrasion								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Craniocerebral injury								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Crush injury								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Deafness traumatic								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Endotracheal intubation complication								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Epicondylitis								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Exposure to SARS-CoV-2								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Extra dose administered								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Face injury								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.35
Facial bones fracture								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Head injury								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Heat stroke								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Humerus fracture								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				0			
Incorrect dose administered								
Insulin naïve	0				4	(0.3)	5	0.59
Basal insulin	0				0			
Basal-bolus insulin regimen	6	(1.0)	6	1.95	1	(0.2)	2	0.60
Intentional overdose								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Intentional product use issue								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lower limb fracture								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Muscle contusion								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Nerve injury								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Periprocedural myocardial infarction								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Post procedural stroke								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Post procedural swelling								
Insulin naïve	0				1	(0.1)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Post-traumatic neck syndrome								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Prescribed overdose								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	5	(0.9)	5	1.76	0			
Product administration error								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.30
Product dispensing error								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Scratch								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Seroma								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Soft tissue injury								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Spinal column injury								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Stab wound								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Subcutaneous haematoma								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Subdural haematoma								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Sunburn								
Insulin naïve	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. For insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 and 6 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Tendon injury								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Tibia fracture								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Underdose								
Insulin naïve	0				2	(0.2)	2	0.21
Basal insulin	1	(0.4)	1	0.64	3	(1.1)	3	1.96
Basal-bolus insulin regimen	0				0			
Wound dehiscence								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Wrist fracture								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Wrong dose								
Insulin naïve	0				2	(0.2)	2	0.26
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Wrong product administered								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	2	0.60	5	(0.9)	5	1.69
Metabolism and nutrition disorders								
All								
Insulin naïve	102	(7.7)	128	10.96	94	(7.1)	120	10.31
Basal insulin	7	(2.7)	7	4.51	11	(4.2)	16	10.47
Basal-bolus insulin regimen	23	(4.0)	28	8.89	29	(5.0)	33	10.41
Dyslipidaemia								
Insulin naïve	18	(1.4)	18	1.69	14	(1.1)	14	1.49
Basal insulin	0				0			
Basal-bolus insulin regimen	3	(0.5)	4	1.20	3	(0.5)	3	0.90
Vitamin D deficiency								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	15	(1.1)	15	1.11	11	(0.8)	11	0.87
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.3)	2	0.65	3	(0.5)	3	0.99
Hyperlipidaemia								
Insulin naïve	13	(1.0)	13	1.19	10	(0.8)	10	0.79
Basal insulin	1	(0.4)	1	0.64	3	(1.1)	3	1.96
Basal-bolus insulin regimen	0				0			
Vitamin B12 deficiency								
Insulin naïve	11	(0.8)	11	0.80	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hypoglycaemia								
Insulin naïve	9	(0.7)	15	1.62	15	(1.1)	26	2.19
Basal insulin	1	(0.4)	1	0.64	3	(1.1)	8	5.24
Basal-bolus insulin regimen	8	(1.4)	10	3.36	5	(0.9)	6	1.99
Hypertriglyceridaemia								
Insulin naïve	8	(0.6)	8	0.66	6	(0.5)	6	0.56
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.3)	2	0.60	2	(0.3)	2	0.60
Hyperkalaemia								
Insulin naïve	6	(0.5)	7	0.58	5	(0.4)	5	0.37
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.30	4	(0.7)	4	1.20
Iron deficiency								
Insulin naïve	5	(0.4)	5	0.37	3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Decreased appetite								
Insulin naïve	4	(0.3)	4	0.36	4	(0.3)	4	0.29
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Hyperglycaemia								
Insulin naïve	4	(0.3)	5	0.53	7	(0.5)	7	0.59
Basal insulin	2	(0.8)	2	1.29	2	(0.8)	2	1.31
Basal-bolus insulin regimen	0				5	(0.9)	5	1.50
Gout								
Insulin naïve	4	(0.3)	5	0.37	6	(0.5)	7	0.52
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Increased appetite								
Insulin naïve	3	(0.2)	3	0.23	5	(0.4)	6	0.67
Basal insulin	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Hypercholesterolaemia								
Insulin naïve	2	(0.2)	2	0.21	1	(0.1)	1	0.08
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.30	2	(0.3)	2	0.65
Zinc deficiency								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Diabetes mellitus								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Folate deficiency								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hyperuricaemia								
Insulin naïve	2	(0.2)	2	0.15	3	(0.2)	3	0.22
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Fluid retention								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Hypokalaemia								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Obesity								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Dehydration								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	2	0.69
Diabetes mellitus inadequate control								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hypernatraemia								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Magnesium deficiency								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Malnutrition								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vitamin B complex deficiency								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Abnormal weight gain								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Appetite disorder								
Insulin naïve	0				1	(0.1)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Electrolyte imbalance								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Food craving								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hyperammonaemia								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Hypercalcaemia								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hypoalbuminaemia								
Insulin naïve	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Hyponatraemia								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	3	(0.5)	3	0.95	1	(0.2)	1	0.30
Insulin resistance								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Lactic acidosis								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lipomatosis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Metabolic acidosis								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Metabolic disorder								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Eye disorders								
All								
Insulin naïve	94	(7.1)	124	11.03	89	(6.7)	112	9.68
Basal insulin	27	(10.3)	31	19.97	25	(9.5)	30	19.64
Basal-bolus insulin regimen	55	(9.5)	70	22.86	66	(11.3)	94	29.92
Diabetic retinopathy								
Insulin naïve	30	(2.3)	33	3.32	27	(2.0)	30	2.59
Basal insulin	10	(3.8)	11	7.09	16	(6.1)	17	11.13
Basal-bolus insulin regimen	24	(4.1)	26	8.40	29	(5.0)	29	9.35
Cataract								
Insulin naïve	20	(1.5)	25	2.09	17	(1.3)	18	1.38
Basal insulin	2	(0.8)	2	1.29	4	(1.5)	4	2.62
Basal-bolus insulin regimen	6	(1.0)	6	2.00	6	(1.0)	8	2.49
Blepharitis								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	5	(0.4)	5	0.43	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Dry eye								
Insulin naïve	5	(0.4)	5	0.37	6	(0.5)	6	0.51
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.35
Vision blurred								
Insulin naïve	4	(0.3)	4	0.41	3	(0.2)	3	0.23
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	2	(0.3)	2	0.70	1	(0.2)	1	0.30
Retinopathy hypertensive								
Insulin naïve	4	(0.3)	5	0.48	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	4	(0.7)	4	1.30	4	(0.7)	4	1.20
Macular oedema								
Insulin naïve	4	(0.3)	4	0.35	3	(0.2)	3	0.22
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	6	(1.0)	7	2.30	2	(0.3)	2	0.65
Eye pain								
Insulin naïve	4	(0.3)	4	0.35	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Glaucoma								
Insulin naïve	3	(0.2)	3	0.22	2	(0.2)	2	0.15
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.35	3	(0.5)	3	1.04
Conjunctivitis allergic								
Insulin naïve	2	(0.2)	3	0.28	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Eye inflammation								
Insulin naïve	2	(0.2)	2	0.21	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.3)	2	0.60
Astigmatism								
Insulin naïve	2	(0.2)	3	0.22	2	(0.2)	2	0.15
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				2	(0.3)	2	0.65
Vitreous detachment								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	1	(0.2)	1	0.30	2	(0.3)	2	0.69
Non-proliferative retinopathy								
Insulin naïve	1	(0.1)	2	0.26	1	(0.1)	1	0.13
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	2	(0.3)	2	0.70	2	(0.3)	2	0.69
Ocular hyperaemia								
Insulin naïve	1	(0.1)	2	0.26	1	(0.1)	2	0.26
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Acquired epiblepharon								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Asthenopia								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Conjunctival erosion								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Conjunctival haemorrhage								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Diplopia								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.30
Optic disc vascular disorder								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Post thrombotic retinopathy								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Posterior capsule opacification								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Retinal aneurysm								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Retinal tear								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Age-related macular degeneration								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Amaurosis fugax								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Angle closure glaucoma								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Arteriosclerotic retinopathy								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Conjunctival hyperaemia								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Conjunctival suffusion								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Maculopathy								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ocular hypertension								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				1	(0.2)	2	0.69
Retinal degeneration								
Insulin naïve	1	(0.1)	1	0.07	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. For insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 and 6 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Retinal haemorrhage								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	2	(0.3)	2	0.60	0			
Visual impairment								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	9	2.70
Vitreous opacities								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cataract nuclear								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Chorioretinal atrophy								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Corneal bleeding								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Corneal erosion								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.30
Cystoid macular oedema								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Dacryoadenitis acquired								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Diabetic retinal oedema								
Insulin naïve	0				4	(0.3)	4	0.29
Basal insulin	2	(0.8)	2	1.29	2	(0.8)	2	1.31
Basal-bolus insulin regimen	4	(0.7)	4	1.30	4	(0.7)	5	1.55

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Dry age-related macular degeneration								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Epiretinal membrane								
Insulin naïve	0				2	(0.2)	2	0.20
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.35
Eye discharge								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Eye irritation								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Eye pruritus								
Insulin naïve	0				1	(0.1)	2	0.26
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Eyelid oedema								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hypermetropia								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lacrimation increased								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Macular degeneration								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Macular hole								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Meibomianitis								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Myopia								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Normal tension glaucoma								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ocular ischaemic syndrome								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Open angle glaucoma								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	2	0.60
Ophthalmic vein thrombosis								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Optic disc haemorrhage								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Photophobia								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Photopsia								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Presbyopia								
Insulin naïve	0				0			
Basal insulin	0				2	(0.8)	2	1.31
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.35
Pterygium								
Insulin naïve	0				0			
Basal insulin	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Retinal artery occlusion								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Retinal deposits								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Retinal detachment								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Retinal drusen								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.30
Retinal exudates								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				2	(0.3)	2	0.60
Retinal scar								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Retinal vascular disorder								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.30
Retinal vein occlusion								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Retinopathy								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Scintillating scotoma								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Uveitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Visual acuity reduced								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Vitreous degeneration								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vitreous floaters								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.3)	2	0.69
Vitreous haemorrhage								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.30
Respiratory, thoracic and mediastinal disorders								
All								
Insulin naïve	79	(6.0)	102	8.49	78	(5.9)	96	8.42
Basal insulin	15	(5.7)	29	18.68	4	(1.5)	5	3.27
Basal-bolus insulin regimen	38	(6.5)	46	15.11	40	(6.9)	52	16.96
Cough								
Insulin naïve	18	(1.4)	18	1.52	16	(1.2)	17	1.44
Basal insulin	2	(0.8)	3	1.93	0			
Basal-bolus insulin regimen	6	(1.0)	8	2.65	12	(2.1)	13	4.32
Oropharyngeal pain								
Insulin naïve	17	(1.3)	19	1.59	12	(0.9)	13	1.20
Basal insulin	1	(0.4)	1	0.64	2	(0.8)	3	1.96
Basal-bolus insulin regimen	6	(1.0)	6	2.06	5	(0.9)	5	1.64
Dyspnoea								
Insulin naïve	8	(0.6)	8	0.81	8	(0.6)	8	0.60
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	5	(0.9)	6	1.80
Nasal congestion								
Insulin naïve	8	(0.6)	8	0.60	4	(0.3)	4	0.30
Basal insulin	1	(0.4)	1	0.64	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 insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 and 6 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.35
Sleep apnoea syndrome								
Insulin naïve	6	(0.5)	6	0.50	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Rhinorrhoea								
Insulin naïve	5	(0.4)	6	0.45	5	(0.4)	5	0.37
Basal insulin	5	(1.9)	7	4.51	1	(0.4)	1	0.65
Basal-bolus insulin regimen	2	(0.3)	2	0.70	7	(1.2)	7	2.38
Asthma								
Insulin naïve	3	(0.2)	4	0.36	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.3)	2	0.60	1	(0.2)	1	0.30
Sinus congestion								
Insulin naïve	3	(0.2)	4	0.36	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	3	(0.5)	3	1.00	1	(0.2)	1	0.35
Chronic obstructive pulmonary disease								
Insulin naïve	2	(0.2)	2	0.21	1	(0.1)	1	0.08
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	0				0			
Interstitial lung disease								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Acute respiratory failure								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Productive cough								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Basal insulin	2	(0.8)	2	1.29	1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				2	(0.3)	2	0.69
Bronchospasm								
Insulin naïve	1	(0.1)	1	0.13	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Acquired diaphragmatic eventration								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Bronchiectasis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Dyspnoea exertional								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Emphysema								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.21
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Laryngeal cyst								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Nasal dryness								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Nasal turbinate hypertrophy								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pulmonary embolism								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pulmonary fibrosis								
Insulin naïve	1	(0.1)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Pulmonary mass								
Insulin naïve	1	(0.1)	1	0.08	4	(0.3)	4	0.41
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Respiratory disorder								
Insulin naïve	1	(0.1)	1	0.08	3	(0.2)	3	0.23
Basal insulin	0				0			
Basal-bolus insulin regimen	7	(1.2)	7	2.30	4	(0.7)	4	1.29
Sinus pain								
Insulin naïve	1	(0.1)	2	0.15	1	(0.1)	1	0.13

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Sneezing								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Throat irritation								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Upper-airway cough syndrome								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.35
Increased viscosity of upper respiratory secretion								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Rhinitis allergic								
Insulin naïve	1	(0.1)	1	0.07	4	(0.3)	8	0.77
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	2	(0.3)	2	0.65
Upper respiratory tract inflammation								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Acute pulmonary oedema								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Allergic bronchitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Allergic cough								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Aphonia								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				0			
Bronchial hyperreactivity								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Bronchitis chronic								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Dry throat								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Dysphonia								
Insulin naïve	0				1	(0.1)	2	0.26
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Epistaxis								
Insulin naïve	0				1	(0.1)	2	0.15
Basal insulin	3	(1.1)	7	4.51	0			
Basal-bolus insulin regimen	3	(0.5)	3	0.95	1	(0.2)	2	0.60
Haemoptysis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hiccups								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Lung disorder								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Nasal obstruction								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Nasal septum deviation								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.30

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Paranasal cyst								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.3)	2	0.60
Paranasal sinus discomfort								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pleural disorder								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pleural effusion								
Insulin naïve	0				3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pleurisy								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.35
Pleuritic pain								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pulmonary congestion								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Pulmonary hypertension								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Respiratory failure								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Respiratory tract inflammation								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

Skin and subcutaneous tissue disorders

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

Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ main-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								
Insulin naïve	74	(5.6)	80	6.66	83	(6.3)	101	8.57
Basal insulin	13	(5.0)	14	9.02	6	(2.3)	6	3.93
Basal-bolus insulin regimen	36	(6.2)	37	12.32	39	(6.7)	48	15.90
Eczema								
Insulin naïve	8	(0.6)	8	0.66	3	(0.2)	3	0.28
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.30	3	(0.5)	3	0.95
Rash								
Insulin naïve	7	(0.5)	7	0.57	9	(0.7)	10	0.75
Basal insulin	3	(1.1)	3	1.93	1	(0.4)	1	0.65
Basal-bolus insulin regimen	4	(0.7)	4	1.35	1	(0.2)	1	0.30
Pruritus								
Insulin naïve	6	(0.5)	6	0.50	8	(0.6)	8	0.71
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	4	(0.7)	4	1.25
Dermatitis contact								
Insulin naïve	5	(0.4)	6	0.46	7	(0.5)	7	0.59
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.3)	2	0.70	7	(1.2)	7	2.38
Hyperhidrosis								
Insulin naïve	5	(0.4)	5	0.43	3	(0.2)	3	0.22
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	2	(0.3)	2	0.60	1	(0.2)	1	0.30
Alopecia								
Insulin naïve	3	(0.2)	3	0.23	3	(0.2)	3	0.28
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	4	(0.7)	4	1.35	0			
Dry skin								
Insulin naïve	3	(0.2)	3	0.23	4	(0.3)	4	0.35
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.35
Dermatitis								
Insulin naïve	3	(0.2)	3	0.28	5	(0.4)	6	0.56
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	4	(0.7)	4	1.41	1	(0.2)	1	0.35
Night sweats								
Insulin naïve	3	(0.2)	3	0.28	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Urticaria								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	3	(0.2)	3	0.22	9	(0.7)	9	0.73
Basal insulin	3	(1.1)	3	1.93	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	3	(0.5)	3	1.04
Hyperkeratosis								
Insulin naïve	2	(0.2)	2	0.21	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.3)	2	0.65
Cold sweat								
Insulin naïve	2	(0.2)	2	0.15	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.3)	2	0.60	6	(1.0)	10	3.42
Psoriasis								
Insulin naïve	2	(0.2)	2	0.15	2	(0.2)	2	0.20
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Skin irritation								
Insulin naïve	2	(0.2)	3	0.23	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.3)	2	0.70	1	(0.2)	1	0.35
Acne								
Insulin naïve	2	(0.2)	2	0.20	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Dermatitis allergic								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ingrowing nail								
Insulin naïve	2	(0.2)	2	0.15	3	(0.2)	3	0.23
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Skin ulcer								
Insulin naïve	2	(0.2)	2	0.15	3	(0.2)	3	0.33
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.3)	2	0.60	2	(0.3)	2	0.60
Decubitus ulcer								
Insulin naïve	1	(0.1)	1	0.13	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ecchymosis								
Insulin naïve	1	(0.1)	1	0.13	2	(0.2)	2	0.15
Basal insulin	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				0			
Rash erythematous								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Skin odour abnormal								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Angioedema								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Granuloma annulare								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lipodystrophy acquired								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Myxoid cyst								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Skin exfoliation								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Skin fissures								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Skin lesion								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.35
Urticaria contact								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Diabetic foot								
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Erythema								
Insulin naïve	1	(0.1)	1	0.07	3	(0.2)	3	0.28
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Livedo reticularis								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Nail bed inflammation								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Actinic keratosis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Alopecia areata								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Asteatosis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blister								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.30
Chronic spontaneous urticaria								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Cold urticaria								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Dermal cyst								
Insulin naïve	0				2	(0.2)	2	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 insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 and 6 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.35
Dermatitis atopic								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.3)	2	0.69
Drug eruption								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Haemorrhage subcutaneous								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hidradenitis								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Ingrown hair								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Intertrigo								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Lentigo								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Leukoplakia								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lichen sclerosus								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Lipohypertrophy								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Macule								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Miliaria								
Insulin naïve	0				4	(0.3)	4	0.31
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	0				0			
Neurodermatitis								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Pruritus allergic								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Purpura								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Rash maculo-papular								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Rash papular								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Seborrhoea								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Skin discolouration								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Skin reaction								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Telangiectasia								

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Umbilical haematoma								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Urticaria thermal								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Xeroderma								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Cardiac disorders								
All								
Insulin naïve	74	(5.6)	109	8.84	63	(4.8)	85	6.66
Basal insulin	5	(1.9)	7	4.51	2	(0.8)	2	1.31
Basal-bolus insulin regimen	16	(2.8)	17	5.55	19	(3.3)	28	8.68
Atrial fibrillation								
Insulin naïve	11	(0.8)	12	0.91	5	(0.4)	5	0.38
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.30
Coronary artery disease								
Insulin naïve	10	(0.8)	10	0.75	8	(0.6)	8	0.59
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	2	(0.3)	2	0.60
Cardiac failure								
Insulin naïve	8	(0.6)	8	0.65	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.3)	3	0.95
Acute myocardial infarction								
Insulin naïve	7	(0.5)	7	0.57	6	(0.5)	6	0.51
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.30
Palpitations								
Insulin naïve	6	(0.5)	6	0.50	4	(0.3)	4	0.30
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	3	(0.5)	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 insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 and 6 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Ventricular extrasystoles								
Insulin naïve	5	(0.4)	5	0.38	2	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	3	(0.5)	3	1.05	0			
Angina pectoris								
Insulin naïve	5	(0.4)	5	0.37	3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.3)	2	0.65	1	(0.2)	1	0.30
Acute coronary syndrome								
Insulin naïve	4	(0.3)	4	0.30	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Supraventricular extrasystoles								
Insulin naïve	3	(0.2)	3	0.34	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Angina unstable								
Insulin naïve	3	(0.2)	3	0.23	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Myocardial infarction								
Insulin naïve	3	(0.2)	3	0.23	4	(0.3)	4	0.30
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	2	(0.3)	2	0.60	0			
Mitral valve incompetence								
Insulin naïve	3	(0.2)	3	0.28	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cardiac failure congestive								
Insulin naïve	3	(0.2)	3	0.23	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				2	(0.3)	3	0.90
Left ventricular hypertrophy								
Insulin naïve	3	(0.2)	3	0.23	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Tachycardia								
Insulin naïve	3	(0.2)	3	0.22	6	(0.5)	6	0.55
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Left ventricular dysfunction								
Insulin naïve	2	(0.2)	2	0.21	2	(0.2)	2	0.21

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Myocardial ischaemia								
Insulin naïve	2	(0.2)	2	0.21	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.35
Cardiac failure chronic								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Coronary artery occlusion								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Atrioventricular block first degree								
Insulin naïve	2	(0.2)	2	0.20	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Bundle branch block left								
Insulin naïve	2	(0.2)	2	0.20	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Arrhythmia								
Insulin naïve	2	(0.2)	2	0.15	3	(0.2)	3	0.28
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cardio-respiratory arrest								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Mitral valve stenosis								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Aortic valve incompetence								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Atrial flutter								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Atrial thrombosis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Bradycardia								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Bundle branch block right								
Insulin naïve	1	(0.1)	1	0.08	4	(0.3)	5	0.37
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	3	(0.5)	3	0.95
Cardiac ventricular thrombosis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Chronic coronary syndrome								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Diastolic dysfunction								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Left atrial dilatation								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pericardial effusion								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pericarditis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Sinus tachycardia								
Insulin naïve	1	(0.1)	1	0.08	3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Tricuspid valve incompetence								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	1	(0.1)	1	0.08	3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Arteriosclerosis coronary artery								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Supraventricular tachycardia								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Aortic valve calcification								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Aortic valve sclerosis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Atrial enlargement								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Atrioventricular block complete								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cardiac arrest								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cardiac dysfunction								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cardiac failure acute								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cardiac flutter								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				0			
Cardiac perfusion defect								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	2	0.60
Cardiomegaly								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Cardiovascular disorder								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Coronary artery stenosis								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Left atrial enlargement								
Insulin naïve	0				2	(0.2)	2	0.20
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Sinus arrhythmia								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Sinus bradycardia								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Subendocardial ischaemia								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ventricular arrhythmia								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ventricular tachycardia								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Investigations								
All								
Insulin naïve	63	(4.7)	74	6.55	50	(3.8)	55	4.82
Basal insulin	5	(1.9)	5	3.22	3	(1.1)	4	2.62
Basal-bolus insulin regimen	26	(4.5)	30	9.75	26	(4.5)	29	9.40
Weight increased								
Insulin naïve	13	(1.0)	13	1.08	14	(1.1)	14	1.23
Basal insulin	0				0			
Basal-bolus insulin regimen	7	(1.2)	7	2.14	4	(0.7)	4	1.20
SARS-CoV-2 test positive								
Insulin naïve	5	(0.4)	5	0.54	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	4	(0.7)	4	1.39
Weight decreased								
Insulin naïve	4	(0.3)	4	0.30	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Blood creatinine increased								
Insulin naïve	4	(0.3)	4	0.40	0			
Basal insulin	3	(1.1)	3	1.93	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Alanine aminotransferase increased								
Insulin naïve	3	(0.2)	3	0.34	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Blood pressure increased								
Insulin naïve	3	(0.2)	3	0.28	3	(0.2)	3	0.23
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.3)	2	0.70	1	(0.2)	1	0.30
Blood immunoglobulin E increased								
Insulin naïve	3	(0.2)	3	0.22	3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blood alkaline phosphatase increased								
Insulin naïve	2	(0.2)	2	0.26	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Blood cholesterol increased								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.35

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Occult blood								
Insulin naïve	2	(0.2)	2	0.20	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blood triglycerides increased								
Insulin naïve	2	(0.2)	2	0.15	3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.3)	2	0.65	0			
Prostatic specific antigen increased								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Arthroscopy								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Aspartate aminotransferase increased								
Insulin naïve	1	(0.1)	1	0.13	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Blood glucose fluctuation								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blood potassium increased								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Monocyte count decreased								
Insulin naïve	1	(0.1)	1	0.13	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Monofilament pressure perception test								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blood creatine increased								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blood creatine phosphokinase increased								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Body temperature increased								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Glycosylated haemoglobin increased								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
International normalised ratio abnormal								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
International normalised ratio decreased								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
International normalised ratio increased								
Insulin naïve	1	(0.1)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Red blood cell count decreased								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Transferrin saturation decreased								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blood urine present								
Insulin naïve	1	(0.1)	3	0.22	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Bone density decreased								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Electrocardiogram abnormal								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.07
Basal insulin	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.30
Electrocardiogram ST segment abnormal								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Electrocardiogram T wave inversion								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Hepatic enzyme increased								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.35
Liver function test increased								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.3)	2	0.60	0			
Low density lipoprotein increased								
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	2	0.26
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
QRS axis abnormal								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Thyroid function test abnormal								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Transaminases increased								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Amylase increased								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Angiogram								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Antinuclear antibody positive								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blood glucose decreased								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blood glucose increased								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Blood pressure decreased								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blood testosterone decreased								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Blood uric acid increased								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Breath sounds abnormal								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Carbohydrate antigen 19-9 increased								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cardiac murmur								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Cardiac stress test abnormal								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Catheterisation cardiac								
Insulin naïve	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Ejection fraction decreased								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Electrocardiogram P wave biphasic								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Electrocardiogram repolarisation abnormality								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Electrocardiogram ST segment depression								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Eosinophil count increased								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	2	0.69
Free fatty acids increased								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Glomerular filtration rate decreased								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Grip strength decreased								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Haematocrit increased								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Haemoglobin decreased								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	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 insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 and 6 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Haemoglobin increased								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Heart rate increased								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Hepatitis B virus test positive								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Intraocular pressure increased								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Lipase increased								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lipids abnormal								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Lipids increased								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Liver function test abnormal								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	2	1.31
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Mycobacterium tuberculosis complex test positive								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Occult blood positive								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Platelet count decreased								
Insulin naïve	0				2	(0.2)	2	0.26
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Vitamin D decreased								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
White blood cell count decreased								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Vascular disorders								
All								
Insulin naïve	60	(4.5)	65	5.55	55	(4.2)	71	6.18
Basal insulin	5	(1.9)	5	3.22	5	(1.9)	5	3.27
Basal-bolus insulin regimen	14	(2.4)	18	5.69	20	(3.4)	23	7.08
Hypertension								
Insulin naïve	26	(2.0)	26	2.34	24	(1.8)	29	2.55
Basal insulin	4	(1.5)	4	2.58	5	(1.9)	5	3.27
Basal-bolus insulin regimen	7	(1.2)	7	2.35	9	(1.5)	9	2.84
Hypotension								
Insulin naïve	6	(0.5)	6	0.56	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Peripheral coldness								
Insulin naïve	3	(0.2)	3	0.23	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Peripheral arterial occlusive disease								
Insulin naïve	3	(0.2)	4	0.36	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Arteriosclerosis								
Insulin naïve	3	(0.2)	3	0.22	6	(0.5)	6	0.56
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.30
Superficial vein thrombosis								
Insulin naïve	3	(0.2)	3	0.22	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Aortic arteriosclerosis								
Insulin naïve	2	(0.2)	2	0.15	2	(0.2)	2	0.21
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.3)	2	0.60
Blood pressure inadequately controlled								
Insulin naïve	2	(0.2)	2	0.15	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Arterial insufficiency								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Varicose ulceration								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Aortic stenosis								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Brachiocephalic arteriosclerosis								
Insulin naïve	1	(0.1)	1	0.08	3	(0.2)	3	0.23
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Flushing								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Haematoma								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.21
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.30
Hypertensive urgency								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Peripheral artery occlusion								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Peripheral artery stenosis								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	1	(0.1)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	3	0.90	0			
Peripheral vascular disorder								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Peripheral venous disease								
Insulin naïve	1	(0.1)	1	0.08	3	(0.2)	3	0.28
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Thrombosis								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Varicose vein								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Hot flush								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Venous stenosis								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Aneurysm								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Aortic aneurysm								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Aortic dilatation								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blood pressure fluctuation								
Insulin naïve	0				0			
Basal insulin	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Deep vein thrombosis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Diabetic vascular disorder								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.30
Hypertensive crisis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	3	0.90
Iliac artery stenosis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Intermittent claudication								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Macroangiopathy								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Neovascularisation								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Orthostatic hypotension								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Peripheral artery aneurysm								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Peripheral ischaemia								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Phlebitis								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Thrombophlebitis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Renal and urinary disorders								
All								
Insulin naïve	39	(2.9)	45	3.97	45	(3.4)	58	4.92
Basal insulin	8	(3.1)	10	6.44	0			
Basal-bolus insulin regimen	7	(1.2)	10	3.15	9	(1.5)	12	3.88
Renal cyst								
Insulin naïve	5	(0.4)	5	0.48	3	(0.2)	3	0.22
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	2	(0.3)	2	0.65
Nephrolithiasis								
Insulin naïve	5	(0.4)	5	0.37	4	(0.3)	6	0.61
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pollakiuria								
Insulin naïve	4	(0.3)	4	0.47	2	(0.2)	2	0.15
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Renal impairment								
Insulin naïve	3	(0.2)	3	0.28	3	(0.2)	3	0.23
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Ureterolithiasis								
Insulin naïve	3	(0.2)	3	0.28	3	(0.2)	3	0.23
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Dysuria								
Insulin naïve	3	(0.2)	4	0.29	3	(0.2)	3	0.23
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.30
Chronic kidney disease								
Insulin naïve	2	(0.2)	2	0.21	4	(0.3)	4	0.30
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.3)	2	0.60	2	(0.3)	2	0.65

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Diabetic nephropathy								
Insulin naïve	2	(0.2)	2	0.15	2	(0.2)	2	0.26
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				2	(0.3)	2	0.69
Acute kidney injury								
Insulin naïve	2	(0.2)	2	0.20	5	(0.4)	5	0.37
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Nocturia								
Insulin naïve	2	(0.2)	2	0.15	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Chromaturia								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Renal failure								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Calculus urinary								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Microalbuminuria								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Pyelocaliectasis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Renal colic								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.20
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Urine odour abnormal								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.13
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Hypertonic bladder								

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Proteinuria								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Renal pain								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.3)	2	0.70	0			
Urinary incontinence								
Insulin naïve	1	(0.1)	1	0.07	3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Urinary retention								
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Urinary tract disorder								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Bladder mass								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Bladder prolapse								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Cystitis haemorrhagic								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Haematuria								
Insulin naïve	0				5	(0.4)	5	0.43
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	2	0.60	0			
Hydrocalyx								
Insulin naïve	0				0			
Basal insulin	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				2	(0.3)	2	0.65
Hydronephrosis								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Hypertensive nephropathy								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Micturition urgency								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Nephropathy								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Nephrotic syndrome								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Polyuria								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Renal mass								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Strangury								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Stress urinary incontinence								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Urethral stenosis								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Urinary tract inflammation								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Urinary tract obstruction								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Psychiatric disorders								
All								
Insulin naïve	30	(2.3)	33	2.74	23	(1.7)	25	2.14
Basal insulin	4	(1.5)	5	3.22	5	(1.9)	5	3.27
Basal-bolus insulin regimen	7	(1.2)	7	2.35	15	(2.6)	16	5.13
Insomnia								
Insulin naïve	7	(0.5)	7	0.59	5	(0.4)	6	0.56
Basal insulin	3	(1.1)	3	1.93	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.30
Depression								
Insulin naïve	6	(0.5)	6	0.45	5	(0.4)	5	0.37
Basal insulin	1	(0.4)	1	0.64	2	(0.8)	2	1.31
Basal-bolus insulin regimen	1	(0.2)	1	0.30	5	(0.9)	5	1.64
Anxiety								
Insulin naïve	5	(0.4)	5	0.43	6	(0.5)	6	0.44
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	4	(0.7)	4	1.39
Sleep disorder								
Insulin naïve	4	(0.3)	4	0.30	1	(0.1)	1	0.13
Basal insulin	0				2	(0.8)	2	1.31
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.30
Irritability								
Insulin naïve	2	(0.2)	2	0.20	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Agitation								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Drug abuse								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Depressed mood								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Nightmare								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Adjustment disorder with mixed anxiety and depressed mood								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Disorientation								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Listless								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Post-traumatic stress disorder								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Stress								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Adjustment disorder								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Adjustment disorder with depressed mood								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Affect lability								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Anxiety disorder								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Attention deficit hyperactivity disorder								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Bruxism								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Drug dependence								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Emotional distress								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Fear								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.3)	2	0.60
Major depression								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Mental status changes								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Mixed anxiety and depressive disorder								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Mood swings								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Persistent depressive disorder								
Insulin naïve	0				1	(0.1)	1	0.08

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Phobia								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Blood and lymphatic system disorders								
All								
Insulin naïve	25	(1.9)	25	2.20	24	(1.8)	24	2.01
Basal insulin	1	(0.4)	3	1.93	1	(0.4)	1	0.65
Basal-bolus insulin regimen	10	(1.7)	10	3.15	8	(1.4)	8	2.54
Anaemia								
Insulin naïve	15	(1.1)	15	1.40	11	(0.8)	11	0.94
Basal insulin	1	(0.4)	3	1.93	0			
Basal-bolus insulin regimen	4	(0.7)	4	1.25	3	(0.5)	3	0.90
Eosinophilia								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.30
Lymphadenopathy								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.35
Leukopenia								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Iron deficiency anaemia								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	2	(0.3)	2	0.65
Polycythaemia								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Thrombocytopenia								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
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 insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 and 6 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	1	(0.1)	1	0.07	3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Splenomegaly								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blood loss anaemia								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Hypochromic anaemia								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lymphadenitis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Lymphadenopathy mediastinal								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Normocytic anaemia								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pancytopenia								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Thrombocytosis								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
Insulin naïve	24	(1.8)	32	2.72	20	(1.5)	31	2.46
Basal insulin	3	(1.1)	3	1.93	4	(1.5)	4	2.62
Basal-bolus insulin regimen	8	(1.4)	8	2.60	5	(0.9)	8	2.54

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Seborrhoeic keratosis								
Insulin naïve	2	(0.2)	3	0.23	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Adenocarcinoma pancreas								
Insulin naïve	2	(0.2)	2	0.20	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Colon adenoma								
Insulin naïve	2	(0.2)	2	0.20	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Colorectal cancer								
Insulin naïve	2	(0.2)	2	0.20	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Metastases to liver								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Bladder papilloma								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lung cancer metastatic								
Insulin naïve	1	(0.1)	1	0.13	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Skin papilloma								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Acrochordon								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Basal cell carcinoma								
Insulin naïve	1	(0.1)	1	0.08	3	(0.2)	3	0.23
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Glioblastoma multiforme								

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Haemangioma of liver								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Neoplasm skin								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Oral fibroma								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pancreatic neoplasm								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Prostate cancer								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Salivary gland neoplasm								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Bladder cancer								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Eye naevus								
Insulin naïve	1	(0.1)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.3)	2	0.65	0			
Invasive ductal breast carcinoma								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Invasive lobular breast carcinoma								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				0			
Lipoma								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pancreatic carcinoma								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Renal neoplasm								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Squamous cell carcinoma of skin								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Adenocarcinoma of colon								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Adrenal adenoma								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Benign neoplasm of thyroid gland								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Benign renal neoplasm								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Bowen's disease								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Breast cancer								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			

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

Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ main-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 metastatic								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Chronic myeloid leukaemia								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Colon cancer								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Colon cancer stage II								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Dysplastic naevus								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Endometrial adenocarcinoma								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Gastric cancer								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Gastrointestinal tract adenoma								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hepatocellular carcinoma								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Invasive breast carcinoma								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lung adenocarcinoma								
Insulin naïve	0				1	(0.1)	1	0.13

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Lymphangioma								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Malignant melanoma								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Malignant melanoma in situ								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Malignant peritoneal neoplasm								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Melanocytic naevus								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Metastases to bone marrow								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Metastases to lymph nodes								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Myxoma								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Osteoma								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Ovarian cancer metastatic								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Pancreatic carcinoma metastatic								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Prostatic adenoma								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Renal cell carcinoma								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Renal hamartoma								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Small cell lung cancer								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Small intestine neuroendocrine tumour								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Uterine cancer								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Uterine leiomyoma								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				3	(0.5)	3	0.99
Reproductive system and breast disorders								
All								
Insulin naïve	24	(1.8)	24	2.07	19	(1.4)	23	1.82
Basal insulin	4	(1.5)	4	2.58	2	(0.8)	2	1.31
Basal-bolus insulin regimen	5	(0.9)	5	1.70	6	(1.0)	8	2.68
Erectile dysfunction								
Insulin naïve	4	(0.3)	4	0.30	1	(0.1)	1	0.13
Basal insulin	1	(0.4)	1	0.64	0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				0			
Benign prostatic hyperplasia								
Insulin naïve	3	(0.2)	3	0.22	2	(0.2)	2	0.15
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	2	(0.3)	2	0.65	1	(0.2)	1	0.30
Intermenstrual bleeding								
Insulin naïve	2	(0.2)	2	0.26	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Uterine polyp								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Breast pain								
Insulin naïve	1	(0.1)	1	0.13	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Menstruation delayed								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Prostatic calcification								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Breast mass								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Menopausal symptoms								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ovarian cyst								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pruritus genital								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			

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Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ main-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								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vulvovaginal pruritus								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Atrophic vulvovaginitis								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ejaculation failure								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Menstruation irregular								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pelvic discomfort								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cervical polyp								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Colpocele								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Dysmenorrhoea								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.35
Ectropion of cervix								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Fibrocystic breast disease								
Insulin naïve	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Galactorrhoea								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Genital prolapse								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Menopausal disorder								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Ovarian disorder								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Penile pain								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Penile rash								
Insulin naïve	0				1	(0.1)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Premenstrual syndrome								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.35
Prostatitis								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Prostatomegaly								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Testicular cyst								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ main-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 enlargement								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vaginal discharge								
Insulin naïve	0				2	(0.2)	2	0.20
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vaginal haemorrhage								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vulvovaginal dryness								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ear and labyrinth disorders								
All								
Insulin naïve	21	(1.6)	24	1.95	13	(1.0)	14	1.11
Basal insulin	4	(1.5)	4	2.58	4	(1.5)	4	2.62
Basal-bolus insulin regimen	3	(0.5)	3	1.00	7	(1.2)	7	2.19
Vertigo								
Insulin naïve	8	(0.6)	9	0.78	5	(0.4)	6	0.46
Basal insulin	2	(0.8)	2	1.29	1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				3	(0.5)	3	0.95
Ear pain								
Insulin naïve	4	(0.3)	4	0.35	0			
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.35	1	(0.2)	1	0.35
Tinnitus								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Deafness bilateral								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vertigo positional								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Basal insulin	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				0			
Ear inflammation								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Eustachian tube dysfunction								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
External ear pain								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hypoacusis								
Insulin naïve	1	(0.1)	1	0.07	3	(0.2)	3	0.22
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Meniere's disease								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cerumen impaction								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.30
Deafness neurosensory								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Deafness unilateral								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Ear discomfort								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Middle ear inflammation								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Motion sickness								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Presbyacusis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hepatobiliary disorders								
All								
Insulin naïve	15	(1.1)	20	1.67	16	(1.2)	18	1.51
Basal insulin	2	(0.8)	2	1.29	1	(0.4)	1	0.65
Basal-bolus insulin regimen	7	(1.2)	9	3.00	8	(1.4)	10	3.19
Hepatic steatosis								
Insulin naïve	8	(0.6)	8	0.66	8	(0.6)	8	0.70
Basal insulin	0				0			
Basal-bolus insulin regimen	3	(0.5)	3	1.05	2	(0.3)	2	0.65
Cholelithiasis								
Insulin naïve	3	(0.2)	3	0.22	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cholecystitis								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hepatic function abnormal								
Insulin naïve	1	(0.1)	1	0.13	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Gallbladder cholesterolosis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hypertransaminasaemia								
Insulin naïve	1	(0.1)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Liver disorder								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Non-alcoholic steatohepatitis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hepatic mass								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hepatomegaly								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Alcoholic liver disease								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Bile duct stone								
Insulin naïve	0				1	(0.1)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Biliary colic								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Biliary dyskinesia								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Cholecystitis chronic								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.30
Gallbladder disorder								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.35
Gallbladder polyp								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	3	(0.5)	3	0.99
Hepatic calcification								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Hepatic cirrhosis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Hepatic cyst								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hyperplastic cholecystopathy								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Nonalcoholic fatty liver disease								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Steatohepatitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ main-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								
Insulin naïve	7	(0.5)	8	0.60	8	(0.6)	9	0.79
Basal insulin	2	(0.8)	2	1.29	5	(1.9)	5	3.27
Basal-bolus insulin regimen	5	(0.9)	5	1.60	3	(0.5)	3	0.95
Seasonal allergy								
Insulin naïve	6	(0.5)	6	0.45	4	(0.3)	4	0.31
Basal insulin	1	(0.4)	1	0.64	2	(0.8)	2	1.31
Basal-bolus insulin regimen	1	(0.2)	1	0.30	3	(0.5)	3	0.95
Allergy to arthropod bite								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.13
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Food allergy								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Allergy to arthropod sting								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Anaphylactic reaction								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Drug hypersensitivity								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Hypersensitivity								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	3	(0.5)	3	1.00	0			
Immunisation reaction								
Insulin naïve	0				1	(0.1)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ main-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								
Insulin naïve	5	(0.4)	5	0.54	5	(0.4)	5	0.42
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Type V hyperlipidaemia								
Insulin naïve	3	(0.2)	3	0.34	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cystic fibrosis lung								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hydrocele								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Atrial septal defect								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Congenital syphilitic osteochondritis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Corneal dystrophy								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Hypertrophic cardiomyopathy								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Myotonic dystrophy								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Endocrine 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 insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 and 6 contribute. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ main-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								
Insulin naïve	4	(0.3)	4	0.30	14	(1.1)	14	1.15
Basal insulin	0				3	(1.1)	3	1.96
Basal-bolus insulin regimen	2	(0.3)	2	0.60	2	(0.3)	2	0.65
Thyroid mass								
Insulin naïve	2	(0.2)	2	0.15	2	(0.2)	2	0.20
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Autoimmune thyroiditis								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hypothyroidism								
Insulin naïve	1	(0.1)	1	0.07	3	(0.2)	3	0.22
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.2)	1	0.30	1	(0.2)	1	0.35
Adrenal mass								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Adrenocortical insufficiency acute								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Goitre								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hyperplasia adrenal								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hyperprolactinaemia								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hyperthyroidism								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ main-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								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Inappropriate antidiuretic hormone secretion								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Secondary hypogonadism								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Surgical and medical procedures								
All								
Insulin naïve	2	(0.2)	2	0.15	4	(0.3)	4	0.30
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	4	(0.7)	4	1.30	1	(0.2)	1	0.30
Knee operation								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cardiac pacemaker replacement								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.2)	1	0.30
Cardiac ablation								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Large intestinal polypectomy								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Removal of foreign body								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Shoulder operation								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Skin neoplasm excision								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.35	0			
Spinal operation								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Toe amputation								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Tooth extraction								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.2)	1	0.30	0			
Social circumstances								
All								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Menopause								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

7.7.76 Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ 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								
Insulin naïve	1327				1324			
Basal insulin	262				263			
Basal-bolus insulin regimen	291				291			
PYE (years)								
Insulin naïve	1216.31				1216.89			
Basal insulin	155.25				152.77			
Basal-bolus insulin regimen	167.36				166.80			
Events								
Insulin naïve	807	(60.8)	2557	219.57	772	(58.3)	2381	201.55
Basal insulin	161	(61.5)	466	300.17	134	(51.0)	328	214.70
Basal-bolus insulin regimen	171	(58.8)	455	271.87	167	(57.4)	550	329.74
Infections and infestations								
All								
Insulin naïve	381	(28.7)	558	48.32	395	(29.8)	571	47.99
Basal insulin	76	(29.0)	98	63.13	49	(18.6)	66	43.20
Basal-bolus insulin regimen	87	(29.9)	117	69.91	79	(27.1)	120	71.94
COVID-19								
Insulin naïve	117	(8.8)	120	10.33	130	(9.8)	133	10.70
Basal insulin	9	(3.4)	9	5.80	7	(2.7)	7	4.58
Basal-bolus insulin regimen	26	(8.9)	26	15.54	23	(7.9)	25	14.99
Nasopharyngitis								
Insulin naïve	53	(4.0)	63	5.40	57	(4.3)	63	5.46
Basal insulin	22	(8.4)	28	18.04	10	(3.8)	14	9.16
Basal-bolus insulin regimen	8	(2.7)	8	4.78	12	(4.1)	15	8.99
Upper respiratory tract infection								
Insulin naïve	48	(3.6)	58	4.84	35	(2.6)	38	3.27
Basal insulin	8	(3.1)	11	7.09	4	(1.5)	4	2.62
Basal-bolus insulin regimen	6	(2.1)	6	3.59	6	(2.1)	6	3.60
Urinary tract infection								
Insulin naïve	30	(2.3)	32	3.04	36	(2.7)	38	3.05
Basal insulin	4	(1.5)	5	3.22	3	(1.1)	3	1.96
Basal-bolus insulin regimen	3	(1.0)	3	1.79	5	(1.7)	7	4.20
Influenza								
Insulin naïve	22	(1.7)	25	2.90	16	(1.2)	16	1.68
Basal insulin	1	(0.4)	1	0.64	4	(1.5)	5	3.27
Basal-bolus insulin regimen	5	(1.7)	5	2.99	8	(2.7)	10	6.00

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Bronchitis								
Insulin naïve	16	(1.2)	17	1.44	14	(1.1)	14	1.26
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	8	(2.7)	8	4.78	3	(1.0)	3	1.80
Gastroenteritis								
Insulin naïve	14	(1.1)	14	1.37	9	(0.7)	9	0.84
Basal insulin	5	(1.9)	5	3.22	2	(0.8)	2	1.31
Basal-bolus insulin regimen	7	(2.4)	7	4.18	5	(1.7)	6	3.60
Pharyngitis								
Insulin naïve	13	(1.0)	15	1.20	11	(0.8)	14	1.17
Basal insulin	0				0			
Basal-bolus insulin regimen	3	(1.0)	3	1.79	6	(2.1)	6	3.60
Cystitis								
Insulin naïve	9	(0.7)	10	0.92	11	(0.8)	12	0.96
Basal insulin	1	(0.4)	1	0.64	2	(0.8)	3	1.96
Basal-bolus insulin regimen	2	(0.7)	2	1.20	3	(1.0)	3	1.80
Pneumonia								
Insulin naïve	9	(0.7)	9	0.78	5	(0.4)	5	0.48
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	3	(1.0)	3	1.79	1	(0.3)	1	0.60
Sinusitis								
Insulin naïve	9	(0.7)	10	0.75	12	(0.9)	15	1.23
Basal insulin	2	(0.8)	2	1.29	3	(1.1)	3	1.96
Basal-bolus insulin regimen	3	(1.0)	4	2.39	2	(0.7)	2	1.20
Herpes zoster								
Insulin naïve	8	(0.6)	8	0.60	11	(0.8)	12	0.90
Basal insulin	0				3	(1.1)	3	1.96
Basal-bolus insulin regimen	2	(0.7)	2	1.20	1	(0.3)	1	0.60
COVID-19 pneumonia								
Insulin naïve	8	(0.6)	8	0.60	9	(0.7)	9	0.78
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	4	(1.4)	4	2.39	1	(0.3)	1	0.60
Rhinitis								
Insulin naïve	7	(0.5)	7	0.59	6	(0.5)	6	0.56
Basal insulin	0				1	(0.4)	3	1.96
Basal-bolus insulin regimen	0				0			
Fungal infection								
Insulin naïve	6	(0.5)	6	0.56	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	2	1.29	0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Conjunctivitis								
Insulin naïve	6	(0.5)	6	0.45	6	(0.5)	6	0.56
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	1	0.60
Tooth infection								
Insulin naïve	6	(0.5)	7	0.57	4	(0.3)	4	0.41
Basal insulin	1	(0.4)	2	1.29	3	(1.1)	3	1.96
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	1	0.60
Lower respiratory tract infection								
Insulin naïve	5	(0.4)	5	0.38	2	(0.2)	4	0.31
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Viral infection								
Insulin naïve	5	(0.4)	5	0.43	9	(0.7)	12	0.94
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Respiratory tract infection								
Insulin naïve	5	(0.4)	5	0.37	4	(0.3)	4	0.31
Basal insulin	0				0			
Basal-bolus insulin regimen	3	(1.0)	3	1.79	2	(0.7)	2	1.20
Acute sinusitis								
Insulin naïve	5	(0.4)	5	0.42	3	(0.2)	3	0.27
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Tooth abscess								
Insulin naïve	4	(0.3)	4	0.36	5	(0.4)	5	0.37
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	2	(0.7)	2	1.20	2	(0.7)	3	1.80
Gastroenteritis viral								
Insulin naïve	4	(0.3)	4	0.31	3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	1	0.60
Vaginal infection								
Insulin naïve	4	(0.3)	4	0.40	2	(0.2)	2	0.15
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Coronavirus infection								
Insulin naïve	4	(0.3)	4	0.30	3	(0.2)	4	0.31
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	2	1.20

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Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ 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 viral								
Insulin naïve	3	(0.2)	3	0.23	3	(0.2)	3	0.28
Basal insulin	0				0			
Basal-bolus insulin regimen	6	(2.1)	7	4.18	5	(1.7)	6	3.60
Erysipelas								
Insulin naïve	3	(0.2)	3	0.28	2	(0.2)	3	0.33
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Otitis media								
Insulin naïve	3	(0.2)	3	0.28	2	(0.2)	2	0.15
Basal insulin	3	(1.1)	3	1.93	1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	1	0.60
Ear infection								
Insulin naïve	3	(0.2)	3	0.23	4	(0.3)	4	0.35
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Laryngitis								
Insulin naïve	3	(0.2)	3	0.23	3	(0.2)	3	0.28
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Genital infection								
Insulin naïve	3	(0.2)	3	0.28	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cellulitis								
Insulin naïve	3	(0.2)	3	0.22	6	(0.5)	6	0.56
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	2	1.31
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Furuncle								
Insulin naïve	2	(0.2)	3	0.28	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Skin infection								
Insulin naïve	2	(0.2)	2	0.21	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Tinea infection								
Insulin naïve	2	(0.2)	2	0.21	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Candida infection								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Gingivitis								
Insulin naïve	2	(0.2)	3	0.23	2	(0.2)	2	0.21
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Hordeolum								
Insulin naïve	2	(0.2)	2	0.15	3	(0.2)	3	0.33
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Localised infection								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.07
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Periodontitis								
Insulin naïve	2	(0.2)	2	0.15	6	(0.5)	6	0.62
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.7)	2	1.20	0			
Vulvovaginal candidiasis								
Insulin naïve	2	(0.2)	3	0.23	4	(0.3)	4	0.31
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Otitis externa								
Insulin naïve	2	(0.2)	2	0.20	3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Wound infection								
Insulin naïve	2	(0.2)	2	0.20	1	(0.1)	1	0.13
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Respiratory syncytial virus infection								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Tonsillitis								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Acarodermatitis								
Insulin naïve	2	(0.2)	2	0.15	4	(0.3)	4	0.29
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Escherichia bacteraemia								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Gastrointestinal infection								
Insulin naïve	1	(0.1)	1	0.13	3	(0.2)	4	0.29
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Genital candidiasis								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Injection site abscess								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Oral candidiasis								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Oral herpes								
Insulin naïve	1	(0.1)	1	0.13	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	2	1.20	0			
Postoperative wound infection								
Insulin naïve	1	(0.1)	1	0.13	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Sepsis								
Insulin naïve	1	(0.1)	1	0.13	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Suspected COVID-19								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ 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 pedis								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Abscess								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Asymptomatic COVID-19								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Bacterial infection								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Balanitis candida								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Chlamydial infection								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Chronic tonsillitis								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Dermatophytosis of nail								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Escherichia urinary tract infection								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Folliculitis								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			

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

Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ 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 infection fungal								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Helicobacter gastritis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Herpes simplex								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Herpes virus infection								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Infected bite								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Laryngopharyngitis								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Mastitis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Onychomycosis								
Insulin naïve	1	(0.1)	1	0.08	4	(0.3)	4	0.29
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Oropharyngeal candidiasis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Osteomyelitis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			

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Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ 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 media chronic								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pericoronitis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Purulence								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Tracheitis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Urethritis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Viral upper respiratory tract infection								
Insulin naïve	1	(0.1)	1	0.08	3	(0.2)	3	0.23
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vulvovaginal mycotic infection								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Appendicitis								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Chronic sinusitis								
Insulin naïve	1	(0.1)	1	0.07	3	(0.2)	3	0.23
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Clostridium difficile colitis								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ 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 infection								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ear infection fungal								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Fungal skin infection								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Gangrene								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Helicobacter infection								
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	2	0.21
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Nail infection								
Insulin naïve	1	(0.1)	2	0.15	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Paronychia								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	2	1.20
Peritonsillar abscess								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Post-acute COVID-19 syndrome								
Insulin naïve	1	(0.1)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pyelonephritis								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ 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 candida								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Subcutaneous abscess								
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	3	0.23
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Tinea cruris								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Viral pharyngitis								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Abdominal abscess								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Abscess limb								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Anal abscess								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Bacteraemia								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Bartholinitis								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Body tinea								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ 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								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Breast cellulitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Campylobacter gastroenteritis								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Cholecystitis infective								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Chronic hepatitis C								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Diabetic foot infection								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Diverticulitis								
Insulin naïve	0				5	(0.4)	5	0.38
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Empyema								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Endophthalmitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Enteritis infectious								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Epididymitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Eye infection								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				2	(0.7)	2	1.20
Eye infection bacterial								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Fungal balanitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Gastroenteritis norovirus								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Giardiasis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Herpes dermatitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Herpes zoster infection neurological								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Infected dermal cyst								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Infective iritis								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ 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								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Labyrinthitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lyme disease								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Oophoritis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Otitis media acute								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Paraspinal abscess								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Parotitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Peri-implantitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pharyngotonsillitis								
Insulin naïve	0				2	(0.2)	3	0.23
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Pneumonia viral								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			

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Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ 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 infection								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Pulmonary tuberculoma								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Pulpitis dental								
Insulin naïve	0				2	(0.2)	2	0.21
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Pustule								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Rotavirus infection								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Salpingitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Sinusitis bacterial								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Skin bacterial infection								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Soft tissue infection								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Sweat gland infection								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ 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								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Urosepsis								
Insulin naïve	0				2	(0.2)	2	0.20
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Varicella								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Varicella zoster virus infection								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Viral rhinitis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Viral tracheitis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Vulvitis								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Gastrointestinal disorders								
All								
Insulin naïve	178	(13.4)	270	22.25	154	(11.6)	211	17.93
Basal insulin	38	(14.5)	60	38.65	32	(12.2)	42	27.49
Basal-bolus insulin regimen	35	(12.0)	50	29.88	35	(12.0)	49	29.38
Diarrhoea								
Insulin naïve	55	(4.1)	67	5.43	33	(2.5)	34	2.95
Basal insulin	14	(5.3)	17	10.95	9	(3.4)	9	5.89
Basal-bolus insulin regimen	15	(5.2)	18	10.76	9	(3.1)	9	5.40
Nausea								
Insulin naïve	25	(1.9)	26	2.06	17	(1.3)	19	1.52
Basal insulin	7	(2.7)	7	4.51	6	(2.3)	6	3.93

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	5	(1.7)	5	2.99	4	(1.4)	4	2.40
Vomiting								
Insulin naïve	14	(1.1)	20	1.92	11	(0.8)	14	1.12
Basal insulin	3	(1.1)	3	1.93	3	(1.1)	3	1.96
Basal-bolus insulin regimen	7	(2.4)	9	5.38	2	(0.7)	2	1.20
Abdominal pain								
Insulin naïve	12	(0.9)	12	1.01	13	(1.0)	13	1.13
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	2	(0.7)	2	1.20	5	(1.7)	6	3.60
Toothache								
Insulin naïve	11	(0.8)	11	0.83	4	(0.3)	4	0.41
Basal insulin	1	(0.4)	1	0.64	3	(1.1)	5	3.27
Basal-bolus insulin regimen	1	(0.3)	1	0.60	3	(1.0)	4	2.40
Gastrooesophageal reflux disease								
Insulin naïve	11	(0.8)	11	0.94	10	(0.8)	10	0.86
Basal insulin	1	(0.4)	1	0.64	2	(0.8)	2	1.31
Basal-bolus insulin regimen	1	(0.3)	1	0.60	2	(0.7)	2	1.20
Dental caries								
Insulin naïve	11	(0.8)	13	0.98	4	(0.3)	4	0.29
Basal insulin	0				2	(0.8)	2	1.31
Basal-bolus insulin regimen	0				4	(1.4)	4	2.40
Abdominal pain upper								
Insulin naïve	11	(0.8)	11	0.92	10	(0.8)	11	0.82
Basal insulin	1	(0.4)	3	1.93	3	(1.1)	3	1.96
Basal-bolus insulin regimen	1	(0.3)	1	0.60	2	(0.7)	2	1.20
Constipation								
Insulin naïve	10	(0.8)	10	0.80	13	(1.0)	13	1.30
Basal insulin	4	(1.5)	7	4.51	0			
Basal-bolus insulin regimen	2	(0.7)	2	1.20	3	(1.0)	3	1.80
Abdominal distension								
Insulin naïve	7	(0.5)	7	0.58	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.7)	2	1.20
Haemorrhoids								
Insulin naïve	6	(0.5)	6	0.50	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	2	(0.8)	2	1.31
Basal-bolus insulin regimen	0				0			
Gastritis								
Insulin naïve	6	(0.5)	6	0.61	8	(0.6)	8	0.75
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			

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Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ 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 gastritis								
Insulin naïve	4	(0.3)	4	0.30	3	(0.2)	3	0.23
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	2	(0.7)	2	1.20	1	(0.3)	1	0.60
Dyspepsia								
Insulin naïve	4	(0.3)	4	0.35	7	(0.5)	7	0.63
Basal insulin	3	(1.1)	3	1.93	1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Food poisoning								
Insulin naïve	4	(0.3)	4	0.35	2	(0.2)	2	0.21
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	2	1.31
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Flatulence								
Insulin naïve	3	(0.2)	3	0.28	2	(0.2)	2	0.26
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Enterocolitis								
Insulin naïve	3	(0.2)	4	0.31	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Diverticulum intestinal								
Insulin naïve	3	(0.2)	3	0.22	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Large intestine polyp								
Insulin naïve	3	(0.2)	3	0.22	5	(0.4)	6	0.45
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Gastric polyps								
Insulin naïve	2	(0.2)	2	0.21	1	(0.1)	1	0.08
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Abdominal discomfort								
Insulin naïve	2	(0.2)	2	0.15	4	(0.3)	4	0.36
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	2	1.20
Abdominal pain lower								
Insulin naïve	2	(0.2)	2	0.15	2	(0.2)	2	0.15
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	0				0			
Dry mouth								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Rectal polyp								
Insulin naïve	2	(0.2)	2	0.15	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Aphthous ulcer								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Inguinal hernia								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Gastric dilatation								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Noninfective gingivitis								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Oral pain								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vomiting projectile								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Anal pruritus								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Colitis								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Colitis ischaemic								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Frequent bowel movements								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Haematochezia								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hyperaesthesia teeth								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Loose tooth								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Oral discomfort								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pancreatitis								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Periodontal disease								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Tooth disorder								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Tooth impacted								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Abdominal wall disorder								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Anal fissure								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Colitis microscopic								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Diabetic gastropathy								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Eosinophilic oesophagitis								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Eructation								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Gastric ulcer								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Gastrointestinal haemorrhage								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Haemorrhoidal haemorrhage								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hiatus hernia								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Hypoaesthesia oral								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.7)	4	2.39	0			
Impaired gastric emptying								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				0			
Intestinal dilatation								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lip swelling								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Umbilical hernia								
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Acid peptic disease								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Crohn's disease								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Diverticulum								
Insulin naïve	0				3	(0.2)	3	0.28
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Duodenitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Enteritis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Epigastric discomfort								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Faeces pale								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60

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

Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ 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								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Gastric dysplasia								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Gastric mucosal hypertrophy								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Gastrointestinal angiodysplasia								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Gastrointestinal disorder								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Gastrointestinal inflammation								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Gastrointestinal sounds abnormal								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Gingival bleeding								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Gingival disorder								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Hyperchlorhydria								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ileus								
Insulin naïve	0				2	(0.2)	2	0.15

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Intra-abdominal haematoma								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Irritable bowel syndrome								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Melaena								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Mesenteric panniculitis								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Odynophagia								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Oesophageal pain								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Oesophagitis								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pancreatic duct dilatation								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Pancreatic failure								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Pancreatic pseudocyst								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Pancreatitis acute								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pancreatitis chronic								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Peptic ulcer								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Periodontal inflammation								
Insulin naïve	0				1	(0.1)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Proctalgia								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Rectal prolapse								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Small intestinal obstruction								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Stomatitis								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Tongue rough								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Ulcerative gastritis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Upper gastrointestinal haemorrhage								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Musculoskeletal and connective tissue disorders								
All								
Insulin naïve	176	(13.3)	268	22.29	181	(13.7)	245	20.70
Basal insulin	38	(14.5)	60	38.65	29	(11.0)	45	29.46
Basal-bolus insulin regimen	32	(11.0)	41	24.50	35	(12.0)	48	28.78
Back pain								
Insulin naïve	47	(3.5)	51	4.44	39	(2.9)	40	3.40
Basal insulin	7	(2.7)	7	4.51	11	(4.2)	13	8.51
Basal-bolus insulin regimen	8	(2.7)	8	4.78	11	(3.8)	11	6.59
Arthralgia								
Insulin naïve	34	(2.6)	40	3.41	32	(2.4)	35	2.96
Basal insulin	6	(2.3)	7	4.51	10	(3.8)	13	8.51
Basal-bolus insulin regimen	5	(1.7)	6	3.59	6	(2.1)	6	3.60
Pain in extremity								
Insulin naïve	27	(2.0)	29	2.34	24	(1.8)	28	2.66
Basal insulin	3	(1.1)	3	1.93	5	(1.9)	6	3.93
Basal-bolus insulin regimen	1	(0.3)	1	0.60	2	(0.7)	3	1.80
Osteoarthritis								
Insulin naïve	15	(1.1)	17	1.34	16	(1.2)	18	1.40
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	5	(1.7)	5	2.99	7	(2.4)	8	4.80
Muscle spasms								
Insulin naïve	12	(0.9)	12	0.96	6	(0.5)	6	0.45
Basal insulin	9	(3.4)	11	7.09	1	(0.4)	1	0.65
Basal-bolus insulin regimen	2	(0.7)	2	1.20	2	(0.7)	2	1.20
Neck pain								
Insulin naïve	9	(0.7)	9	0.73	7	(0.5)	7	0.59
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	4	(1.4)	4	2.39	1	(0.3)	1	0.60
Myalgia								
Insulin naïve	8	(0.6)	8	0.71	6	(0.5)	6	0.56
Basal insulin	4	(1.5)	4	2.58	2	(0.8)	2	1.31
Basal-bolus insulin regimen	2	(0.7)	2	1.20	1	(0.3)	1	0.60
Periarthritis								
Insulin naïve	6	(0.5)	6	0.46	5	(0.4)	5	0.38
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	1	0.60

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Intervertebral disc protrusion								
Insulin naïve	6	(0.5)	10	0.75	6	(0.5)	7	0.64
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Tendonitis								
Insulin naïve	6	(0.5)	6	0.44	3	(0.2)	3	0.28
Basal insulin	2	(0.8)	4	2.58	0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Arthritis								
Insulin naïve	5	(0.4)	5	0.42	2	(0.2)	2	0.15
Basal insulin	1	(0.4)	1	0.64	2	(0.8)	2	1.31
Basal-bolus insulin regimen	0				2	(0.7)	2	1.20
Spinal osteoarthritis								
Insulin naïve	4	(0.3)	4	0.30	5	(0.4)	6	0.44
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.7)	2	1.20	0			
Musculoskeletal stiffness								
Insulin naïve	3	(0.2)	3	0.28	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Plantar fasciitis								
Insulin naïve	3	(0.2)	4	0.31	3	(0.2)	3	0.22
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Rotator cuff syndrome								
Insulin naïve	3	(0.2)	3	0.23	4	(0.3)	4	0.29
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Muscular weakness								
Insulin naïve	3	(0.2)	3	0.33	3	(0.2)	3	0.34
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Tendon disorder								
Insulin naïve	3	(0.2)	3	0.33	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Musculoskeletal chest pain								
Insulin naïve	3	(0.2)	3	0.23	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Bursitis								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	3	(0.2)	3	0.22	3	(0.2)	3	0.23
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Exostosis								
Insulin naïve	3	(0.2)	3	0.22	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Musculoskeletal pain								
Insulin naïve	2	(0.2)	2	0.21	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Fibromyalgia								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Groin pain								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Intervertebral disc disorder								
Insulin naïve	2	(0.2)	2	0.15	2	(0.2)	2	0.21
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Spinal stenosis								
Insulin naïve	2	(0.2)	2	0.15	2	(0.2)	2	0.15
Basal insulin	2	(0.8)	4	2.58	0			
Basal-bolus insulin regimen	0				0			
Synovial cyst								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Joint effusion								
Insulin naïve	2	(0.2)	3	0.33	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Chondropathy								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Polyarthritis								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				0			
Trigger finger								
Insulin naïve	2	(0.2)	2	0.15	4	(0.3)	6	0.45
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	4	(1.4)	4	2.39	0			
Foot deformity								
Insulin naïve	2	(0.2)	4	0.29	2	(0.2)	2	0.20
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	1	0.60
Arthropathy								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Muscle contracture								
Insulin naïve	1	(0.1)	1	0.13	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pain in jaw								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Torticollis								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Back disorder								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Bone cyst								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Coccydynia								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Costochondritis								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Fistula								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lumbar spinal stenosis								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Myositis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Osteopenia								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Spinal pain								
Insulin naïve	1	(0.1)	1	0.08	4	(0.3)	4	0.36
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Tenosynovitis								
Insulin naïve	1	(0.1)	1	0.08	7	(0.5)	8	0.60
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Acquired claw toe								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Diastasis recti abdominis								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Facet joint syndrome								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Meniscopathy								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Osteochondrosis								
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	2	0.15

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	2	(0.7)	2	1.20
Psoriatic arthropathy								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Sacroiliitis								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Axillary mass								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Bone pain								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Cervical spinal stenosis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Dupuytren's contracture								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Flank pain								
Insulin naïve	0				4	(0.3)	5	0.43
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Haemarthrosis								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Intervertebral disc degeneration								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Intervertebral disc space narrowing								
Insulin naïve	0				1	(0.1)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Jaw disorder								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Joint swelling								
Insulin naïve	0				3	(0.2)	3	0.34
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Limb deformity								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Mastication disorder								
Insulin naïve	0				1	(0.1)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Muscle twitching								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Neuropathic arthropathy								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Nodal osteoarthritis								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Osteochondritis								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Osteoporosis								
Insulin naïve	0				0			
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	0				0			
Periostitis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Polymyalgia rheumatica								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	3	1.96
Basal-bolus insulin regimen	0				0			
Rheumatoid arthritis								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Scoliosis								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Soft tissue swelling								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	3	1.93	0			
Basal-bolus insulin regimen	0				0			
Spinal retrolisthesis								
Insulin naïve	0				1	(0.1)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Tenosynovitis stenosans								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vertebral osteophyte								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
General disorders and administration site conditions								
All								
Insulin naïve	148	(11.2)	239	22.58	129	(9.7)	204	17.01
Basal insulin	25	(9.5)	36	23.19	19	(7.2)	21	13.75
Basal-bolus insulin regimen	26	(8.9)	38	22.71	26	(8.9)	36	21.58
Pyrexia								
Insulin naïve	23	(1.7)	24	1.98	25	(1.9)	26	2.09
Basal insulin	6	(2.3)	6	3.86	6	(2.3)	6	3.93
Basal-bolus insulin regimen	3	(1.0)	3	1.79	6	(2.1)	7	4.20
Fatigue								
Insulin naïve	21	(1.6)	22	1.82	11	(0.8)	11	0.82
Basal insulin	2	(0.8)	3	1.93	3	(1.1)	3	1.96
Basal-bolus insulin regimen	4	(1.4)	5	2.99	1	(0.3)	1	0.60

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Oedema peripheral								
Insulin naïve	13	(1.0)	13	1.19	7	(0.5)	8	0.60
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	2	(0.7)	2	1.20	2	(0.7)	2	1.20
Injection site reaction								
Insulin naïve	11	(0.8)	25	3.13	5	(0.4)	7	0.63
Basal insulin	2	(0.8)	2	1.29	1	(0.4)	1	0.65
Basal-bolus insulin regimen	2	(0.7)	2	1.20	0			
Chest pain								
Insulin naïve	10	(0.8)	10	0.80	5	(0.4)	5	0.37
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	3	(1.0)	3	1.79	0			
Malaise								
Insulin naïve	9	(0.7)	11	0.82	9	(0.7)	11	0.84
Basal insulin	2	(0.8)	2	1.29	2	(0.8)	3	1.96
Basal-bolus insulin regimen	2	(0.7)	2	1.20	1	(0.3)	2	1.20
Asthenia								
Insulin naïve	7	(0.5)	7	0.64	5	(0.4)	5	0.38
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	2	(0.7)	2	1.20	2	(0.7)	2	1.20
Chest discomfort								
Insulin naïve	6	(0.5)	6	0.56	2	(0.2)	2	0.21
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	0				0			
Hunger								
Insulin naïve	5	(0.4)	6	0.46	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Pain								
Insulin naïve	5	(0.4)	5	0.43	12	(0.9)	13	1.19
Basal insulin	2	(0.8)	2	1.29	1	(0.4)	1	0.65
Basal-bolus insulin regimen	3	(1.0)	4	2.39	1	(0.3)	1	0.60
Peripheral swelling								
Insulin naïve	5	(0.4)	6	0.56	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.7)	2	1.20
Medical device site bruise								
Insulin naïve	4	(0.3)	5	0.38	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	2	1.29	0			
Basal-bolus insulin regimen	0				0			
Medical device site haemorrhage								

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	4	(0.3)	4	0.31	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vaccination site pain								
Insulin naïve	4	(0.3)	5	0.38	3	(0.2)	3	0.23
Basal insulin	3	(1.1)	4	2.58	3	(1.1)	3	1.96
Basal-bolus insulin regimen	3	(1.0)	3	1.79	2	(0.7)	2	1.20
Injection site pruritus								
Insulin naïve	4	(0.3)	19	2.35	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Injection site pain								
Insulin naïve	3	(0.2)	3	0.39	11	(0.8)	29	2.46
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Injection site erythema								
Insulin naïve	3	(0.2)	5	0.59	4	(0.3)	4	0.31
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Medical device site pruritus								
Insulin naïve	3	(0.2)	3	0.23	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Influenza like illness								
Insulin naïve	3	(0.2)	4	0.40	3	(0.2)	3	0.22
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Injection site bruising								
Insulin naïve	3	(0.2)	3	0.33	5	(0.4)	5	0.43
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Chills								
Insulin naïve	3	(0.2)	3	0.23	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Drug intolerance								
Insulin naïve	3	(0.2)	3	0.23	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Gait disturbance								
Insulin naïve	3	(0.2)	3	0.23	1	(0.1)	1	0.07
Basal insulin	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				0			
Injection site haematoma								
Insulin naïve	2	(0.2)	6	0.78	3	(0.2)	8	1.04
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Injection site haemorrhage								
Insulin naïve	2	(0.2)	2	0.26	2	(0.2)	2	0.21
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Discomfort								
Insulin naïve	2	(0.2)	2	0.21	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	8	4.80
Thirst								
Insulin naïve	2	(0.2)	2	0.21	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Injection site hypersensitivity								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Medical device site dermatitis								
Insulin naïve	2	(0.2)	5	0.38	8	(0.6)	14	1.07
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Injection site mass								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Application site bruise								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Application site pruritus								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Inflammation								
Insulin naïve	1	(0.1)	1	0.13	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60

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Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ 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								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Injection site swelling								
Insulin naïve	1	(0.1)	1	0.13	1	(0.1)	1	0.13
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Feeling abnormal								
Insulin naïve	1	(0.1)	3	0.23	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.7)	2	1.20	0			
Feeling hot								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Implant site pruritus								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Injection site dermatitis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Medical device site eczema								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Medical device site hypersensitivity								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Medical device site pain								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Medical device site reaction								
Insulin naïve	1	(0.1)	3	0.23	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	2	(0.7)	2	1.20	0			
Swelling								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vaccination site reaction								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Early satiety								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Localised oedema								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Swelling face								
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	2	0.20
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vessel puncture site bruise								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Axillary pain								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Condition aggravated								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Cyst								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Death								
Insulin naïve	0				3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Facial pain								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hernia								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Injection site hypertrophy								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Injection site induration								
Insulin naïve	0				2	(0.2)	2	0.20
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Injection site oedema								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Injection site urticaria								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Medical device site erythema								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Medical device site haematoma								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Medical device site inflammation								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Medical device site rash								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Multiple organ dysfunction syndrome								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Non-cardiac chest pain								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	0				4	(0.3)	6	0.44
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Oedema								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	1	0.60
Oedema due to renal disease								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Procedural failure								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Systemic inflammatory response syndrome								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vaccination site erythema								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vaccination site inflammation								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Vaccination site pruritus								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Xerosis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Nervous system disorders								
All								
Insulin naïve	134	(10.1)	178	15.43	129	(9.7)	167	14.28
Basal insulin	27	(10.3)	42	27.05	25	(9.5)	34	22.26
Basal-bolus insulin regimen	19	(6.5)	32	19.12	29	(10.0)	47	28.18

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Headache								
Insulin naïve	35	(2.6)	43	3.88	36	(2.7)	45	3.82
Basal insulin	14	(5.3)	20	12.88	9	(3.4)	10	6.55
Basal-bolus insulin regimen	8	(2.7)	10	5.98	9	(3.1)	12	7.19
Dizziness								
Insulin naïve	29	(2.2)	34	2.93	26	(2.0)	28	2.49
Basal insulin	4	(1.5)	5	3.22	9	(3.4)	13	8.51
Basal-bolus insulin regimen	5	(1.7)	9	5.38	2	(0.7)	3	1.80
Tremor								
Insulin naïve	10	(0.8)	11	0.88	4	(0.3)	4	0.41
Basal insulin	0				2	(0.8)	2	1.31
Basal-bolus insulin regimen	1	(0.3)	1	0.60	2	(0.7)	6	3.60
Hypoaesthesia								
Insulin naïve	9	(0.7)	12	1.18	7	(0.5)	8	0.71
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Sciatica								
Insulin naïve	9	(0.7)	9	0.84	9	(0.7)	10	0.81
Basal insulin	2	(0.8)	2	1.29	2	(0.8)	2	1.31
Basal-bolus insulin regimen	2	(0.7)	2	1.20	1	(0.3)	1	0.60
Carpal tunnel syndrome								
Insulin naïve	8	(0.6)	8	0.65	3	(0.2)	3	0.23
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	2	(0.7)	2	1.20	4	(1.4)	4	2.40
Paraesthesia								
Insulin naïve	8	(0.6)	9	0.73	9	(0.7)	9	0.89
Basal insulin	0				0			
Basal-bolus insulin regimen	0				3	(1.0)	3	1.80
Syncope								
Insulin naïve	5	(0.4)	5	0.38	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Neuropathy peripheral								
Insulin naïve	5	(0.4)	6	0.61	8	(0.6)	8	0.70
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Migraine								
Insulin naïve	4	(0.3)	4	0.35	2	(0.2)	2	0.21
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Diabetic neuropathy								
Insulin naïve	3	(0.2)	3	0.28	9	(0.7)	9	0.84

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	2	(0.7)	2	1.20	2	(0.7)	2	1.20
Transient ischaemic attack								
Insulin naïve	3	(0.2)	3	0.28	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Burning sensation								
Insulin naïve	2	(0.2)	2	0.15	2	(0.2)	2	0.15
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Tension headache								
Insulin naïve	2	(0.2)	3	0.23	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Amnesia								
Insulin naïve	2	(0.2)	2	0.20	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Dysgeusia								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Carotid artery stenosis								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vascular headache								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ageusia								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Anosmia								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Balance disorder								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Cerebral haemorrhage								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cerebrovascular disorder								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Cervical radiculopathy								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Dizziness postural								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Lumbar radiculopathy								
Insulin naïve	1	(0.1)	1	0.08	4	(0.3)	5	0.37
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Memory impairment								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	1	0.60
Neuroglycopenia								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	3	0.23
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Post herpetic neuralgia								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Presyncope								
Insulin naïve	1	(0.1)	1	0.08	4	(0.3)	4	0.30
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Trigeminal neuralgia								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cerebral atrophy								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cluster headache								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cognitive disorder								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Disturbance in attention								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Intracranial pressure increased								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Neuralgia								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Autonomic nervous system imbalance								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Basilar migraine								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Brain injury								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Carotid arteriosclerosis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Carotid artery aneurysm								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	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 insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 contributes, hence the percentages and rates are unadjusted. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				0			
Cerebral arteriosclerosis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Cerebral artery embolism								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cerebral infarction								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Cerebrovascular accident								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Cervicobrachial syndrome								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Dementia Alzheimer's type								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Essential tremor								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Facial nerve disorder								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Facial paralysis								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Hemiparesis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hypoglycaemic coma								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Hyporeflexia								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Ischaemic stroke								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lethargy								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Loss of consciousness								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Mental impairment								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Meralgia paraesthetica								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Morton's neuralgia								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Myelopathy								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ophthalmic migraine								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Orthostatic tremor								
Insulin naïve	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. For insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 contributes, hence the percentages and rates are unadjusted. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Parkinsonian gait								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Peripheral paralysis								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Piriformis syndrome								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Radiculopathy								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Restless legs syndrome								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Sleep deficit								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Somnolence								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Thalamic infarction								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Thrombotic stroke								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Vascular encephalopathy								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Vertebral artery occlusion								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
White matter lesion								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Injury, poisoning and procedural complications								
All								
Insulin naïve	118	(8.9)	140	11.73	98	(7.4)	117	10.23
Basal insulin	27	(10.3)	39	25.12	22	(8.4)	26	17.02
Basal-bolus insulin regimen	19	(6.5)	25	14.94	27	(9.3)	35	20.98
Fall								
Insulin naïve	13	(1.0)	13	0.96	7	(0.5)	8	0.64
Basal insulin	5	(1.9)	5	3.22	2	(0.8)	2	1.31
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	1	0.60
Vaccination complication								
Insulin naïve	11	(0.8)	11	0.89	14	(1.1)	20	1.58
Basal insulin	4	(1.5)	8	5.15	3	(1.1)	3	1.96
Basal-bolus insulin regimen	0				4	(1.4)	4	2.40
Contusion								
Insulin naïve	10	(0.8)	11	0.88	6	(0.5)	6	0.46
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	2	(0.7)	2	1.20	1	(0.3)	1	0.60
Ligament sprain								
Insulin naïve	7	(0.5)	7	0.69	5	(0.4)	5	0.48
Basal insulin	2	(0.8)	2	1.29	1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				2	(0.7)	2	1.20
Limb injury								
Insulin naïve	5	(0.4)	5	0.49	3	(0.2)	3	0.27
Basal insulin	0				1	(0.4)	2	1.31
Basal-bolus insulin regimen	0				2	(0.7)	2	1.20
Hand fracture								
Insulin naïve	5	(0.4)	5	0.48	1	(0.1)	1	0.07
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Skin abrasion								
Insulin naïve	5	(0.4)	7	0.58	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. For insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 contributes, hence the percentages and rates are unadjusted. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	2	(0.8)	2	1.29	1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.3)	1	0.60	2	(0.7)	2	1.20
Procedural pain								
Insulin naïve	4	(0.3)	4	0.41	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Skin laceration								
Insulin naïve	4	(0.3)	4	0.30	0			
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Ankle fracture								
Insulin naïve	4	(0.3)	4	0.29	3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Joint injury								
Insulin naïve	3	(0.2)	3	0.28	3	(0.2)	3	0.22
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Rib fracture								
Insulin naïve	3	(0.2)	3	0.28	5	(0.4)	5	0.48
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Road traffic accident								
Insulin naïve	3	(0.2)	3	0.28	1	(0.1)	1	0.07
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Upper limb fracture								
Insulin naïve	3	(0.2)	3	0.22	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Medication error								
Insulin naïve	2	(0.2)	2	0.26	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Thermal burn								
Insulin naïve	2	(0.2)	2	0.21	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Fibula fracture								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Injury								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Meniscus injury								
Insulin naïve	2	(0.2)	2	0.15	4	(0.3)	4	0.29
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Wound								
Insulin naïve	2	(0.2)	2	0.15	4	(0.3)	4	0.46
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Tendon rupture								
Insulin naïve	2	(0.2)	2	0.20	0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Accidental overdose								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.13
Basal insulin	4	(1.5)	4	2.58	0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	2	(0.7)	3	1.80
Arthropod sting								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Hip fracture								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Radius fracture								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Tooth fracture								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.7)	2	1.20	1	(0.3)	1	0.60
Back injury								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Gun shot wound								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ligament rupture								
Insulin naïve	1	(0.1)	2	0.26	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Procedural complication								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Burn oral cavity								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Burns first degree								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cervical vertebral fracture								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Eye injury								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Heat illness								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	3	0.23
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Muscle strain								
Insulin naïve	1	(0.1)	1	0.08	3	(0.2)	3	0.28
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Overdose								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.21
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	1	0.60
Post procedural fistula								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				0			
Post procedural haemorrhage								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Post procedural hypothyroidism								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Scar								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Traumatic haematoma								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Animal bite								
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Bone contusion								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Femoral neck fracture								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Foot fracture								
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	2	0.15
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	2	(0.7)	2	1.20	0			
Inflammation of wound								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Injury of conjunctiva								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Multiple injuries								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Muscle injury								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Neck injury								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Penile contusion								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Post procedural complication								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Post procedural haematuria								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Post procedural inflammation								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Radiation skin injury								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Spinal compression fracture								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Accidental underdose								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Arthropod bite								
Insulin naïve	0				1	(0.1)	1	0.07

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	2	(0.7)	2	1.20	1	(0.3)	1	0.60
Chillblains								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Concussion								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.7)	2	1.20
Craniocerebral injury								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Crush injury								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Deafness traumatic								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Endotracheal intubation complication								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Epicondylitis								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Exposure to SARS-CoV-2								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Extra dose administered								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Face injury								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Facial bones fracture								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Head injury								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Humerus fracture								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Incorrect dose administered								
Insulin naïve	0				4	(0.3)	5	0.59
Basal insulin	0				0			
Basal-bolus insulin regimen	3	(1.0)	3	1.79	1	(0.3)	2	1.20
Intentional overdose								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Intentional product use issue								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lower limb fracture								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Muscle contusion								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Periprocedural myocardial infarction								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Post procedural stroke								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Post procedural swelling								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	0				1	(0.1)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Post-traumatic neck syndrome								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Product administration error								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Scratch								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Seroma								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Soft tissue injury								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Spinal column injury								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Stab wound								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Subcutaneous haematoma								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Subdural haematoma								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Sunburn								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				0			
Tendon injury								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Tibia fracture								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Underdose								
Insulin naïve	0				2	(0.2)	2	0.21
Basal insulin	1	(0.4)	1	0.64	3	(1.1)	3	1.96
Basal-bolus insulin regimen	0				0			
Wrist fracture								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Wrong dose								
Insulin naïve	0				2	(0.2)	2	0.26
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Wrong product administered								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	2	1.20	1	(0.3)	1	0.60
Metabolism and nutrition disorders								
All								
Insulin naïve	102	(7.7)	128	10.96	94	(7.1)	120	10.31
Basal insulin	7	(2.7)	7	4.51	11	(4.2)	16	10.47
Basal-bolus insulin regimen	15	(5.2)	18	10.76	20	(6.9)	22	13.19
Dyslipidaemia								
Insulin naïve	18	(1.4)	18	1.69	14	(1.1)	14	1.49
Basal insulin	0				0			
Basal-bolus insulin regimen	3	(1.0)	4	2.39	3	(1.0)	3	1.80
Vitamin D deficiency								
Insulin naïve	15	(1.1)	15	1.11	11	(0.8)	11	0.87
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	1	0.60
Hyperlipidaemia								
Insulin naïve	13	(1.0)	13	1.19	10	(0.8)	10	0.79

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	1	(0.4)	1	0.64	3	(1.1)	3	1.96
Basal-bolus insulin regimen	0				0			
Vitamin B12 deficiency								
Insulin naïve	11	(0.8)	11	0.80	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hypoglycaemia								
Insulin naïve	9	(0.7)	15	1.62	15	(1.1)	26	2.19
Basal insulin	1	(0.4)	1	0.64	3	(1.1)	8	5.24
Basal-bolus insulin regimen	3	(1.0)	3	1.79	2	(0.7)	2	1.20
Hypertriglyceridaemia								
Insulin naïve	8	(0.6)	8	0.66	6	(0.5)	6	0.56
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.7)	2	1.20	2	(0.7)	2	1.20
Hyperkalaemia								
Insulin naïve	6	(0.5)	7	0.58	5	(0.4)	5	0.37
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.3)	1	0.60	4	(1.4)	4	2.40
Iron deficiency								
Insulin naïve	5	(0.4)	5	0.37	3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Decreased appetite								
Insulin naïve	4	(0.3)	4	0.36	4	(0.3)	4	0.29
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Hyperglycaemia								
Insulin naïve	4	(0.3)	5	0.53	7	(0.5)	7	0.59
Basal insulin	2	(0.8)	2	1.29	2	(0.8)	2	1.31
Basal-bolus insulin regimen	0				5	(1.7)	5	3.00
Gout								
Insulin naïve	4	(0.3)	5	0.37	6	(0.5)	7	0.52
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Increased appetite								
Insulin naïve	3	(0.2)	3	0.23	5	(0.4)	6	0.67
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Hypercholesterolaemia								
Insulin naïve	2	(0.2)	2	0.21	1	(0.1)	1	0.08
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	1	0.60

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Zinc deficiency								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Diabetes mellitus								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Folate deficiency								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hyperuricaemia								
Insulin naïve	2	(0.2)	2	0.15	3	(0.2)	3	0.22
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Fluid retention								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Hypokalaemia								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Obesity								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Dehydration								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Diabetes mellitus inadequate control								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hypernatraemia								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Magnesium deficiency								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Malnutrition								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vitamin B complex deficiency								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Abnormal weight gain								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Appetite disorder								
Insulin naïve	0				1	(0.1)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Electrolyte imbalance								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Food craving								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hyperammonaemia								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Hypercalcaemia								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hypoalbuminaemia								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Hyponatraemia								
Insulin naïve	0				0			
Basal insulin	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	2	(0.7)	2	1.20	1	(0.3)	1	0.60
Insulin resistance								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lactic acidosis								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lipomatosis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Metabolic acidosis								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Metabolic disorder								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Eye disorders								
All								
Insulin naïve	94	(7.1)	124	11.03	89	(6.7)	112	9.68
Basal insulin	27	(10.3)	31	19.97	25	(9.5)	30	19.64
Basal-bolus insulin regimen	26	(8.9)	33	19.72	38	(13.1)	57	34.17
Diabetic retinopathy								
Insulin naïve	30	(2.3)	33	3.32	27	(2.0)	30	2.59
Basal insulin	10	(3.8)	11	7.09	16	(6.1)	17	11.13
Basal-bolus insulin regimen	12	(4.1)	14	8.37	15	(5.2)	15	8.99
Cataract								
Insulin naïve	20	(1.5)	25	2.09	17	(1.3)	18	1.38
Basal insulin	2	(0.8)	2	1.29	4	(1.5)	4	2.62
Basal-bolus insulin regimen	2	(0.7)	2	1.20	4	(1.4)	6	3.60
Blepharitis								
Insulin naïve	5	(0.4)	5	0.43	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Dry eye								
Insulin naïve	5	(0.4)	5	0.37	6	(0.5)	6	0.51

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Vision blurred								
Insulin naïve	4	(0.3)	4	0.41	3	(0.2)	3	0.23
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Retinopathy hypertensive								
Insulin naïve	4	(0.3)	5	0.48	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.7)	2	1.20	4	(1.4)	4	2.40
Macular oedema								
Insulin naïve	4	(0.3)	4	0.35	3	(0.2)	3	0.22
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	3	(1.0)	3	1.79	1	(0.3)	1	0.60
Eye pain								
Insulin naïve	4	(0.3)	4	0.35	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Glaucoma								
Insulin naïve	3	(0.2)	3	0.22	2	(0.2)	2	0.15
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Conjunctivitis allergic								
Insulin naïve	2	(0.2)	3	0.28	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Eye inflammation								
Insulin naïve	2	(0.2)	2	0.21	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.7)	2	1.20
Astigmatism								
Insulin naïve	2	(0.2)	3	0.22	2	(0.2)	2	0.15
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Vitreous detachment								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Non-proliferative retinopathy								
Insulin naïve	1	(0.1)	2	0.26	1	(0.1)	1	0.13
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Ocular hyperaemia								
Insulin naïve	1	(0.1)	2	0.26	1	(0.1)	2	0.26
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Acquired epiblepharon								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Asthenopia								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Conjunctival erosion								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Conjunctival haemorrhage								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Diplopia								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	1	0.60
Optic disc vascular disorder								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Post thrombotic retinopathy								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Posterior capsule opacification								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Retinal aneurysm								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Retinal tear								

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Age-related macular degeneration								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Amaurosis fugax								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Angle closure glaucoma								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Arteriosclerotic retinopathy								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Conjunctival hyperaemia								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Conjunctival suffusion								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Maculopathy								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ocular hypertension								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Retinal degeneration								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Retinal haemorrhage								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	1	(0.4)	1	0.64	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 insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 contributes, hence the percentages and rates are unadjusted. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	2	(0.7)	2	1.20	0			
Visual impairment								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	9	5.40
Vitreous opacities								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cataract nuclear								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Chorioretinal atrophy								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Corneal bleeding								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Corneal erosion								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Cystoid macular oedema								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Dacryoadenitis acquired								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Diabetic retinal oedema								
Insulin naïve	0				4	(0.3)	4	0.29
Basal insulin	2	(0.8)	2	1.29	2	(0.8)	2	1.31
Basal-bolus insulin regimen	2	(0.7)	2	1.20	3	(1.0)	4	2.40
Dry age-related macular degeneration								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Epiretinal membrane								
Insulin naïve	0				2	(0.2)	2	0.20
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Eye discharge								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Eye irritation								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Eye pruritus								
Insulin naïve	0				1	(0.1)	2	0.26
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Eyelid oedema								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hypermetropia								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lacrimation increased								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Macular degeneration								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Macular hole								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Meibomianitis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Myopia								
Insulin naïve	0				2	(0.2)	2	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 insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 contributes, hence the percentages and rates are unadjusted. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Normal tension glaucoma								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ocular ischaemic syndrome								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Open angle glaucoma								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	2	1.20
Ophthalmic vein thrombosis								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Optic disc haemorrhage								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Photophobia								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Presbyopia								
Insulin naïve	0				0			
Basal insulin	0				2	(0.8)	2	1.31
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Retinal artery occlusion								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Retinal deposits								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Retinal detachment								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Retinal drusen								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	1	0.60
Retinal exudates								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				2	(0.7)	2	1.20
Retinal scar								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Retinal vascular disorder								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Retinal vein occlusion								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Retinopathy								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Scintillating scotoma								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Uveitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Visual acuity reduced								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Vitreous degeneration								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vitreous floaters								

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Vitreous haemorrhage								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	1	0.60
Respiratory, thoracic and mediastinal disorders								
All								
Insulin naïve	79	(6.0)	102	8.49	78	(5.9)	96	8.42
Basal insulin	15	(5.7)	29	18.68	4	(1.5)	5	3.27
Basal-bolus insulin regimen	17	(5.8)	20	11.95	19	(6.5)	23	13.79
Cough								
Insulin naïve	18	(1.4)	18	1.52	16	(1.2)	17	1.44
Basal insulin	2	(0.8)	3	1.93	0			
Basal-bolus insulin regimen	3	(1.0)	3	1.79	4	(1.4)	4	2.40
Oropharyngeal pain								
Insulin naïve	17	(1.3)	19	1.59	12	(0.9)	13	1.20
Basal insulin	1	(0.4)	1	0.64	2	(0.8)	3	1.96
Basal-bolus insulin regimen	1	(0.3)	1	0.60	2	(0.7)	2	1.20
Dyspnoea								
Insulin naïve	8	(0.6)	8	0.81	8	(0.6)	8	0.60
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	5	(1.7)	6	3.60
Nasal congestion								
Insulin naïve	8	(0.6)	8	0.60	4	(0.3)	4	0.30
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Sleep apnoea syndrome								
Insulin naïve	6	(0.5)	6	0.50	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Rhinorrhoea								
Insulin naïve	5	(0.4)	6	0.45	5	(0.4)	5	0.37
Basal insulin	5	(1.9)	7	4.51	1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Asthma								
Insulin naïve	3	(0.2)	4	0.36	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.7)	2	1.20	1	(0.3)	1	0.60

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Sinus congestion								
Insulin naïve	3	(0.2)	4	0.36	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Chronic obstructive pulmonary disease								
Insulin naïve	2	(0.2)	2	0.21	1	(0.1)	1	0.08
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	0				0			
Interstitial lung disease								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Acute respiratory failure								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Productive cough								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Basal insulin	2	(0.8)	2	1.29	1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Bronchospasm								
Insulin naïve	1	(0.1)	1	0.13	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Acquired diaphragmatic eventration								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Bronchiectasis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Dyspnoea exertional								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Emphysema								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.21
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Laryngeal cyst								

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Nasal dryness								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Nasal turbinate hypertrophy								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pulmonary embolism								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pulmonary fibrosis								
Insulin naïve	1	(0.1)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Pulmonary mass								
Insulin naïve	1	(0.1)	1	0.08	4	(0.3)	4	0.41
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Respiratory disorder								
Insulin naïve	1	(0.1)	1	0.08	3	(0.2)	3	0.23
Basal insulin	0				0			
Basal-bolus insulin regimen	3	(1.0)	3	1.79	2	(0.7)	2	1.20
Sinus pain								
Insulin naïve	1	(0.1)	2	0.15	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Sneezing								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Throat irritation								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Upper-airway cough syndrome								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				0			
Increased viscosity of upper respiratory secretion								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Rhinitis allergic								
Insulin naïve	1	(0.1)	1	0.07	4	(0.3)	8	0.77
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Upper respiratory tract inflammation								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Acute pulmonary oedema								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Allergic bronchitis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Allergic cough								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Aphonia								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Bronchitis chronic								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Dry throat								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Dysphonia								
Insulin naïve	0				1	(0.1)	2	0.26
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Epistaxis								
Insulin naïve	0				1	(0.1)	2	0.15
Basal insulin	3	(1.1)	7	4.51	0			
Basal-bolus insulin regimen	2	(0.7)	2	1.20	1	(0.3)	2	1.20
Haemoptysis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lung disorder								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Nasal obstruction								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Nasal septum deviation								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	1	0.60
Paranasal cyst								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.7)	2	1.20
Paranasal sinus discomfort								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pleural disorder								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pleural effusion								
Insulin naïve	0				3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pleurisy								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Pleuritic pain								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pulmonary hypertension								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Respiratory failure								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Respiratory tract inflammation								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Skin and subcutaneous tissue disorders								
All								
Insulin naïve	74	(5.6)	80	6.66	83	(6.3)	101	8.57
Basal insulin	13	(5.0)	14	9.02	6	(2.3)	6	3.93
Basal-bolus insulin regimen	12	(4.1)	13	7.77	15	(5.2)	16	9.59
Eczema								
Insulin naïve	8	(0.6)	8	0.66	3	(0.2)	3	0.28
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.3)	1	0.60	2	(0.7)	2	1.20
Rash								
Insulin naïve	7	(0.5)	7	0.57	9	(0.7)	10	0.75
Basal insulin	3	(1.1)	3	1.93	1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	1	0.60
Pruritus								
Insulin naïve	6	(0.5)	6	0.50	8	(0.6)	8	0.71
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	3	(1.0)	3	1.80
Dermatitis contact								
Insulin naïve	5	(0.4)	6	0.46	7	(0.5)	7	0.59
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Hyperhidrosis								
Insulin naïve	5	(0.4)	5	0.43	3	(0.2)	3	0.22
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	2	(0.7)	2	1.20	1	(0.3)	1	0.60

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Alopecia								
Insulin naïve	3	(0.2)	3	0.23	3	(0.2)	3	0.28
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Dry skin								
Insulin naïve	3	(0.2)	3	0.23	4	(0.3)	4	0.35
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Dermatitis								
Insulin naïve	3	(0.2)	3	0.28	5	(0.4)	6	0.56
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Night sweats								
Insulin naïve	3	(0.2)	3	0.28	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Urticaria								
Insulin naïve	3	(0.2)	3	0.22	9	(0.7)	9	0.73
Basal insulin	3	(1.1)	3	1.93	0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Hyperkeratosis								
Insulin naïve	2	(0.2)	2	0.21	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Cold sweat								
Insulin naïve	2	(0.2)	2	0.15	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.7)	2	1.20	1	(0.3)	1	0.60
Psoriasis								
Insulin naïve	2	(0.2)	2	0.15	2	(0.2)	2	0.20
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Skin irritation								
Insulin naïve	2	(0.2)	3	0.23	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Acne								
Insulin naïve	2	(0.2)	2	0.20	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Dermatitis allergic								
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.13

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ingrowing nail								
Insulin naïve	2	(0.2)	2	0.15	3	(0.2)	3	0.23
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Skin ulcer								
Insulin naïve	2	(0.2)	2	0.15	3	(0.2)	3	0.33
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.7)	2	1.20	2	(0.7)	2	1.20
Decubitus ulcer								
Insulin naïve	1	(0.1)	1	0.13	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ecchymosis								
Insulin naïve	1	(0.1)	1	0.13	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Rash erythematous								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Skin odour abnormal								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Angioedema								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Granuloma annulare								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lipodystrophy acquired								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Myxoid cyst								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ 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 exfoliation								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Skin fissures								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Skin lesion								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Urticaria contact								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Diabetic foot								
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Erythema								
Insulin naïve	1	(0.1)	1	0.07	3	(0.2)	3	0.28
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Livedo reticularis								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Nail bed inflammation								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Actinic keratosis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Alopecia areata								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Asteatosis								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blister								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Cold urticaria								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Dermal cyst								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Drug eruption								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Haemorrhage subcutaneous								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hidradenitis								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Intertrigo								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Lentigo								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Leukoplakia								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lipohypertrophy								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Macule								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Miliaria								
Insulin naïve	0				4	(0.3)	4	0.31
Basal insulin	2	(0.8)	2	1.29	0			
Basal-bolus insulin regimen	0				0			
Neurodermatitis								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Pruritus allergic								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Purpura								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Rash maculo-papular								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Rash papular								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Seborrhoea								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Skin discolouration								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Skin reaction								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Umbilical haematoma								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Urticaria thermal								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cardiac disorders								
All								
Insulin naïve	74	(5.6)	109	8.84	63	(4.8)	85	6.66
Basal insulin	5	(1.9)	7	4.51	2	(0.8)	2	1.31
Basal-bolus insulin regimen	7	(2.4)	8	4.78	14	(4.8)	22	13.19
Atrial fibrillation								
Insulin naïve	11	(0.8)	12	0.91	5	(0.4)	5	0.38
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Coronary artery disease								
Insulin naïve	10	(0.8)	10	0.75	8	(0.6)	8	0.59
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	2	(0.7)	2	1.20
Cardiac failure								
Insulin naïve	8	(0.6)	8	0.65	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	2	1.20
Acute myocardial infarction								
Insulin naïve	7	(0.5)	7	0.57	6	(0.5)	6	0.51
Basal insulin	1	(0.4)	1	0.64	1	(0.4)	1	0.65
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	1	0.60
Palpitations								
Insulin naïve	6	(0.5)	6	0.50	4	(0.3)	4	0.30
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Ventricular extrasystoles								
Insulin naïve	5	(0.4)	5	0.38	2	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Angina pectoris								
Insulin naïve	5	(0.4)	5	0.37	3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	1	0.60

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

Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ 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 coronary syndrome								
Insulin naïve	4	(0.3)	4	0.30	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Supraventricular extrasystoles								
Insulin naïve	3	(0.2)	3	0.34	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Angina unstable								
Insulin naïve	3	(0.2)	3	0.23	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Myocardial infarction								
Insulin naïve	3	(0.2)	3	0.23	4	(0.3)	4	0.30
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	2	(0.7)	2	1.20	0			
Mitral valve incompetence								
Insulin naïve	3	(0.2)	3	0.28	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cardiac failure congestive								
Insulin naïve	3	(0.2)	3	0.23	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				2	(0.7)	3	1.80
Left ventricular hypertrophy								
Insulin naïve	3	(0.2)	3	0.23	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Tachycardia								
Insulin naïve	3	(0.2)	3	0.22	6	(0.5)	6	0.55
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Left ventricular dysfunction								
Insulin naïve	2	(0.2)	2	0.21	2	(0.2)	2	0.21
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Myocardial ischaemia								
Insulin naïve	2	(0.2)	2	0.21	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Cardiac failure chronic								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	2	(0.2)	2	0.15	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Coronary artery occlusion								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Atrioventricular block first degree								
Insulin naïve	2	(0.2)	2	0.20	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Bundle branch block left								
Insulin naïve	2	(0.2)	2	0.20	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Arrhythmia								
Insulin naïve	2	(0.2)	2	0.15	3	(0.2)	3	0.28
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cardio-respiratory arrest								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Mitral valve stenosis								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Aortic valve incompetence								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Atrial flutter								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Atrial thrombosis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Bradycardia								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				1	(0.4)	1	0.65

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				0			
Bundle branch block right								
Insulin naïve	1	(0.1)	1	0.08	4	(0.3)	5	0.37
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.7)	2	1.20
Cardiac ventricular thrombosis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Chronic coronary syndrome								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Diastolic dysfunction								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Left atrial dilatation								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pericardial effusion								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pericarditis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Sinus tachycardia								
Insulin naïve	1	(0.1)	1	0.08	3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Tricuspid valve incompetence								
Insulin naïve	1	(0.1)	1	0.08	3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Arteriosclerosis coronary artery								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ 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 tachycardia								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Aortic valve calcification								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Aortic valve sclerosis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Atrial enlargement								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Atrioventricular block complete								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cardiac arrest								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cardiac dysfunction								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cardiac failure acute								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cardiac flutter								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Cardiac perfusion defect								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	2	1.20
Coronary artery stenosis								
Insulin naïve	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. For insulin naive, only ONWARDS 1, 3 and 5 contribute. For basal insulin, only ONWARDS 2 contributes, hence the percentages and rates are unadjusted. For basal-bolus, only ONWARDS 4 contributes, hence the percentages and rates are unadjusted. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Left atrial enlargement								
Insulin naïve	0				2	(0.2)	2	0.20
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Sinus arrhythmia								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Sinus bradycardia								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Subendocardial ischaemia								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ventricular arrhythmia								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Ventricular tachycardia								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Investigations								
All								
Insulin naïve	63	(4.7)	74	6.55	50	(3.8)	55	4.82
Basal insulin	5	(1.9)	5	3.22	3	(1.1)	4	2.62
Basal-bolus insulin regimen	12	(4.1)	15	8.96	13	(4.5)	14	8.39
Weight increased								
Insulin naïve	13	(1.0)	13	1.08	14	(1.1)	14	1.23
Basal insulin	0				0			
Basal-bolus insulin regimen	6	(2.1)	6	3.59	4	(1.4)	4	2.40
SARS-CoV-2 test positive								
Insulin naïve	5	(0.4)	5	0.54	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Weight decreased								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	4	(0.3)	4	0.30	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blood creatinine increased								
Insulin naïve	4	(0.3)	4	0.40	0			
Basal insulin	3	(1.1)	3	1.93	0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Alanine aminotransferase increased								
Insulin naïve	3	(0.2)	3	0.34	0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Blood pressure increased								
Insulin naïve	3	(0.2)	3	0.28	3	(0.2)	3	0.23
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Blood immunoglobulin E increased								
Insulin naïve	3	(0.2)	3	0.22	3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blood alkaline phosphatase increased								
Insulin naïve	2	(0.2)	2	0.26	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Blood cholesterol increased								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Occult blood								
Insulin naïve	2	(0.2)	2	0.20	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blood triglycerides increased								
Insulin naïve	2	(0.2)	2	0.15	3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Prostatic specific antigen increased								
Insulin naïve	2	(0.2)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Arthroscopy								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				0			
Aspartate aminotransferase increased								
Insulin naïve	1	(0.1)	1	0.13	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blood glucose fluctuation								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blood potassium increased								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Monocyte count decreased								
Insulin naïve	1	(0.1)	1	0.13	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Monofilament pressure perception test								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blood creatine increased								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blood creatine phosphokinase increased								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Body temperature increased								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Glycosylated haemoglobin increased								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
International normalised ratio abnormal								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
International normalised ratio decreased								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
International normalised ratio increased								
Insulin naïve	1	(0.1)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Red blood cell count decreased								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Transferrin saturation decreased								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blood urine present								
Insulin naïve	1	(0.1)	3	0.22	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Bone density decreased								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Electrocardiogram abnormal								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Electrocardiogram ST segment abnormal								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Electrocardiogram T wave inversion								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Hepatic enzyme increased								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Liver function test increased								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.07

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.7)	2	1.20	0			
Low density lipoprotein increased								
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	2	0.26
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
QRS axis abnormal								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Thyroid function test abnormal								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Transaminases increased								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Amylase increased								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Antinuclear antibody positive								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blood glucose decreased								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blood glucose increased								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blood pressure decreased								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Breath sounds abnormal								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Carbohydrate antigen 19-9 increased								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cardiac murmur								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Cardiac stress test abnormal								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Catheterisation cardiac								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Ejection fraction decreased								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Electrocardiogram P wave biphasic								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Electrocardiogram repolarisation abnormality								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Electrocardiogram ST segment depression								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Eosinophil count increased								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Free fatty acids increased								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Glomerular filtration rate decreased								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Grip strength decreased								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Haematocrit increased								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Haemoglobin decreased								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Haemoglobin increased								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Intraocular pressure increased								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	1	0.65
Basal-bolus insulin regimen	0				0			
Lipase increased								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Lipids increased								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Liver function test abnormal								
Insulin naïve	0				0			
Basal insulin	0				1	(0.4)	2	1.31
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Platelet count decreased								
Insulin naïve	0				2	(0.2)	2	0.26
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Vitamin D decreased								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal-bolus insulin regimen	0				0			
Vascular disorders								
All								
Insulin naïve	60	(4.5)	65	5.55	55	(4.2)	71	6.18
Basal insulin	5	(1.9)	5	3.22	5	(1.9)	5	3.27
Basal-bolus insulin regimen	8	(2.7)	12	7.17	16	(5.5)	19	11.39
Hypertension								
Insulin naïve	26	(2.0)	26	2.34	24	(1.8)	29	2.55
Basal insulin	4	(1.5)	4	2.58	5	(1.9)	5	3.27
Basal-bolus insulin regimen	2	(0.7)	2	1.20	6	(2.1)	6	3.60
Hypotension								
Insulin naïve	6	(0.5)	6	0.56	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Peripheral coldness								
Insulin naïve	3	(0.2)	3	0.23	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Peripheral arterial occlusive disease								
Insulin naïve	3	(0.2)	4	0.36	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Arteriosclerosis								
Insulin naïve	3	(0.2)	3	0.22	6	(0.5)	6	0.56
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Superficial vein thrombosis								
Insulin naïve	3	(0.2)	3	0.22	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Aortic arteriosclerosis								
Insulin naïve	2	(0.2)	2	0.15	2	(0.2)	2	0.21
Basal insulin	0				0			
Basal-bolus insulin regimen	0				2	(0.7)	2	1.20
Blood pressure inadequately controlled								
Insulin naïve	2	(0.2)	2	0.15	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Arterial insufficiency								
Insulin naïve	1	(0.1)	1	0.13	0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Varicose ulceration								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Aortic stenosis								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Brachiocephalic arteriosclerosis								
Insulin naïve	1	(0.1)	1	0.08	3	(0.2)	3	0.23
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Flushing								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Haematoma								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.21
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	1	0.60
Hypertensive urgency								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Peripheral artery occlusion								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Peripheral artery stenosis								
Insulin naïve	1	(0.1)	2	0.15	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	3	1.79	0			
Peripheral vascular disorder								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Peripheral venous disease								
Insulin naïve	1	(0.1)	1	0.08	3	(0.2)	3	0.28
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Thrombosis								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Varicose vein								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Hot flush								
Insulin naïve	1	(0.1)	1	0.07	1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Venous stenosis								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Aneurysm								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Aortic aneurysm								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Aortic dilatation								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Blood pressure fluctuation								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Deep vein thrombosis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Diabetic vascular disorder								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	1	0.60
Hypertensive crisis								

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	3	1.80
Iliac artery stenosis								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Intermittent claudication								
Insulin naïve	0				2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Macroangiopathy								
Insulin naïve	0				1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Neovascularisation								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Orthostatic hypotension								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Peripheral artery aneurysm								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Peripheral ischaemia								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Phlebitis								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Thrombophlebitis								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60

Renal and urinary disorders

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

Adverse events by pre-trial insulin treatment, system organ class and preferred term - on-treatment/ 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								
Insulin naïve	39	(2.9)	45	3.97	45	(3.4)	58	4.92
Basal insulin	8	(3.1)	10	6.44	0			
Basal-bolus insulin regimen	4	(1.4)	7	4.18	6	(2.1)	6	3.60
Renal cyst								
Insulin naïve	5	(0.4)	5	0.48	3	(0.2)	3	0.22
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	1	0.60
Nephrolithiasis								
Insulin naïve	5	(0.4)	5	0.37	4	(0.3)	6	0.61
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pollakiuria								
Insulin naïve	4	(0.3)	4	0.47	2	(0.2)	2	0.15
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Renal impairment								
Insulin naïve	3	(0.2)	3	0.28	3	(0.2)	3	0.23
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Ureterolithiasis								
Insulin naïve	3	(0.2)	3	0.28	3	(0.2)	3	0.23
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Dysuria								
Insulin naïve	3	(0.2)	4	0.29	3	(0.2)	3	0.23
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	1	(0.3)	1	0.60
Chronic kidney disease								
Insulin naïve	2	(0.2)	2	0.21	4	(0.3)	4	0.30
Basal insulin	0				0			
Basal-bolus insulin regimen	2	(0.7)	2	1.20	1	(0.3)	1	0.60
Diabetic nephropathy								
Insulin naïve	2	(0.2)	2	0.15	2	(0.2)	2	0.26
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Acute kidney injury								
Insulin naïve	2	(0.2)	2	0.20	5	(0.4)	5	0.37
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	1	0.60	0			
Nocturia								
Insulin naïve	2	(0.2)	2	0.15	2	(0.2)	2	0.15

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Chromaturia								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Renal failure								
Insulin naïve	1	(0.1)	1	0.13	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Calculus urinary								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.08
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Microalbuminuria								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Pyelocaliectasis								
Insulin naïve	1	(0.1)	1	0.08	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Renal colic								
Insulin naïve	1	(0.1)	1	0.08	2	(0.2)	2	0.20
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Urine odour abnormal								
Insulin naïve	1	(0.1)	1	0.08	1	(0.1)	1	0.13
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Hypertonic bladder								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Proteinuria								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Renal pain								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Urinary incontinence								
Insulin naïve	1	(0.1)	1	0.07	3	(0.2)	3	0.22
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Urinary retention								
Insulin naïve	1	(0.1)	1	0.07	2	(0.2)	2	0.15
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Urinary tract disorder								
Insulin naïve	1	(0.1)	1	0.07	0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Bladder mass								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Bladder prolapse								
Insulin naïve	0				0			
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Cystitis haemorrhagic								
Insulin naïve	0				1	(0.1)	1	0.07
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Haematuria								
Insulin naïve	0				5	(0.4)	5	0.43
Basal insulin	0				0			
Basal-bolus insulin regimen	1	(0.3)	2	1.20	0			
Hydrocalyx								
Insulin naïve	0				0			
Basal insulin	0				0			
Basal-bolus insulin regimen	0				1	(0.3)	1	0.60
Hydronephrosis								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	1	(0.4)	1	0.64	0			
Basal-bolus insulin regimen	0				0			
Micturition urgency								
Insulin naïve	0				1	(0.1)	1	0.13
Basal insulin	0				0			
Basal-bolus insulin regimen	0				0			
Nephropathy								

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