インスリン イコデク（遺伝子組換え）

2.7.4.7. 付録
17. 主要な心血管イベント（MACE）報告書の統計解析計画書

ノボ ノルディスク ファーマ株式会社

Statistical Analysis Plan

Project ID: NN1436

Plan for Analysing Cardiovascular Events across the NNC0148-0287 (insulin 287) Phase 3 Trials

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List of abbreviations

AE	adverse event
CI	confidence interval
CTR	clinical trial report
CV	cardiovascular
DBL	database lock
EAC	event adjudication committee
eCRF	electronic case report form
FAS	full analysis set
FDA	U.S. Food and Drug Administration
FU	follow-up
HbA1c	glycosylated haemoglobin
ICH	international council for harmonisation
IND	investigational new drug
ISS	integrated summary of safety
ITT	intention-to-treat
IWRS	interactive web response system
MACE	major cardiovascular events
MedDRA	Medical Dictionary for Regulatory Activities
MH	Maentel-Haenzel
NDA	new drug application
PT	preferred term
PYE	person years of exposure
PYO	person years of observation
SAP	statistical analysis plan
SAS	safety analysis set

1 Introduction

1.1 Background

As agreed upon by the Agency in the FDA Advice/Information Request letter dated September 25, 2018 (reference ID: 4325102), Novo Nordisk does not plan to conduct a pre-approval CVOT trial to assess the cardiovascular risk of insulin 287. Instead, a prospectively planned meta-analysis of Major Adverse Cardiovascular Events (MACE) will be carried out to investigate the cardiovascular profile of NNC0148-0287 (hereafter referred to as insulin 287).

This Statistical Analysis Plan (SAP) will be submitted for review to the Agency as an appendix to the Type B (EOP) Meeting Request and Scientific Advice Briefing Document. It has been finalised before the first database lock in the exploratory phase 2 development program for insulin 287 (NN1436-4383) and have been prepared with the principles outlined in the draft guidance for industry on meta-analyses of randomized controlled clinical trials to evaluate safety[1] in mind.

1.2 Scope of the statistical analysis plan

The meta-analysis described in this document intends to supplement the cardiovascular (CV) safety data package of insulin 287 with a prospectively planned CV meta-analysis from confirmatory phase 3 trials estimating the relative cardiovascular risk of insulin 287 versus basal insulin comparators. A December 2008 Food and Drug Administration (FDA) guidance[2] makes recommendations on the evaluation of cardiovascular risk in new anti-diabetic drugs intended to treat subjects with type 2 diabetes. However, with the well-established CV safety profile of the basal insulin analogues such as insulin glargine and insulin degludec, the molecular mode of action of insulin 287, as well as the absence of non-clinical signals of increased CV risk, it is not considered necessary to establish that the 95% confidence interval (CI) for the hazard ratio of time to first adjudicated MACE is strictly below 1.8 as recommended in this guidance. With an anticipated low number of adjudicated MACE events (25-40), CV safety for insulin 287 will be investigated by estimating the hazard ratio and the corresponding 95% CI with no formal statistical hypothesis testing being performed.

This analysis plan describes the trials in scope, including key trial design features in terms of definition and collection of MACE, observation periods and comparator drugs. It includes a description of descriptive summaries, primary statistical analysis, and sensitivity analyses to be made as well as special data handling considerations.

The results will be presented as part of the Integrated Summary of Safety (ISS) in the future Biologics License Application (BLA).

2 Objective

This meta-analysis of Event Adjudication Committee (EAC)-confirmed MACE combines evidence from the insulin 287 confirmatory phase 3 trials to investigate the cardiovascular safety of insulin 287.

The meta-analysis will be based on subject level data from these trials. For further details on the trials included, see section 4.1

Primary Objective
To investigate the cardiovascular safety of insulin 287. This is done by comparing the insulin 287 to the combined comparator basal insulin products used in the confirmatory phase 3 trials (insulin degludec, insulin glargine, and insulin detemir) in terms of the hazard ratio for time to first EAC-confirmed MACE.

Secondary Objective
To explore the cardiovascular safety of insulin 287 according to components of MACE: CV death, myocardial infarction (MI) and stroke (3-component MACE is henceforth referred to as MACE) and to subgroups (age, sex, race, ethnicity, type of diabetes, and cardiovascular history) across the trials.

3 Definition and collection of MACE

To ensure that data collected on cardiovascular events are appropriately adjudicated in an independent and consistent fashion, Novo Nordisk A/S has made a contract with an external independent Event Adjudication Committee (EAC) that will adjudicate cardiovascular events on an ongoing basis and in a blinded fashion across the confirmatory phase 3 trials. The cardiovascular events in scope for adjudication will originate from investigator reported events, preferred term (PT) search, and EAC identified events. Further details will be provided in the clinical trial protocols. The cardiovascular events will be adjudicated in accordance with FDA requirements[3].

The events defined as MACE and thus in scope for this meta-analysis are those with the adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke).

The same outcome definition and adjudication process will be used across all trials in scope for this meta-analysis.

4 Data included

4.1 Trials in scope

This meta-analysis of MACE will be made based on subject level data from all confirmatory phase 3 trials investigating insulin 287 where database lock has been achieved prior to the data lock point used for the submission for regulatory approval and where the comparator is a basal insulin analogue.

The confirmatory phase 3 trials have been chosen as basis for this meta-analysis as these will constitute the trials used in the pooled safety evaluation in the BLA. Hence, exploratory phase 2 trials are not included in this meta-analysis. MACE events reported in these trials will be described in the individual trial reports

The following table list and present key characteristics of the planned NN1436 confirmatory phase 3 trials in scope for this analysis. It is possible that additional phase 3 trials besides those planned and mentioned below will be included in the analysis provided they fulfil the requirements in terms of data lock point and comparator. The MACE analysis will be repeated at the planned 120-day safety update.

Table 1 Planned Confirmatory Phase 3 Trials to be included

Trial	Trial description	Subject population	Duration† (weeks)	Randomised I287:comparator	Planned No. subjects
NN1436-4477	I287 OW vs. IGlar OD add-on to OADs/GLP-1 open-label, TTT	T2, insulin-naïve	52*	1:1	I287: 355 IGlar: 355
NN1436-4478	I287 OW vs. IDeg OD add-on to OADs/GLP-1 open-label, TTT	T2, basal insulin-users	26	1:1	I287: 260 IDeg: 260
NN1436-4479	I287 OW vs. IDeg OD add-on to OADs/GLP-1 double-blind, TTT	T2, insulin-naïve	26	1:1	I287: 290 IDeg : 290
NN1436-4480	I287 OW vs. IGlar OD add-on to bolus insulin open-label, TTT	T2, basal-bolus insulin-users	26	1:1	I287: 290 IGlar : 290
		T2, insulin-naive	52	1:1	I287: 550 Comparator: 550

Trial	Trial description	Subject population	Duration† (weeks)	Randomised I287:comparator	Planned No. subjects
NN1436-4481	I287 OW vs. Basal insulin analogue OD add-on to OADs/GLP-1 open-label, TTT	T1	26*	1:1	I287: 280 IDeg: 280
NN1436-4625	I287 OW vs. IDeg OD add-on to bolus insulin open-label, TTT				

OW: Once weekly, OD: Once Daily, T2: type 2 diabetes, T1: type 1 diabetes, TTT: Treat-to-target, I287: insulin 287, IDeg: insulin degludec, IGlar: insulin glargine U100, OAD: oral antidiabetic drugs.
†All trials include an additional 5 weeks follow-up period
*Reporting of trials NN1436-4477 and NN1436-4625 will be split into a main part (4477: 52 weeks; 4625: 26 weeks) and an extension part (additional 26 weeks). Data lock point for the extension part is not expected to occur prior to the submission for regulatory approval. Data from the extension part will be included in the 120 days safety update.

4.2 Trials not in scope

The following planned or ongoing trials will also have insulin 287 exposure but *will not* be included in this meta-analysis. The rationale is provided in the table

Table 2 Planned or ongoing trials not in scope

Trial	Comparator	Duration† (Weeks)	Planned number exposed to I287/comparator	Trial description	Reason not in scope
NN1436-4383	IGlar	26	125/125	An investigational trial comparing the efficacy and safety of once weekly insulin 287 vs insulin glargine	Exploratory phase 2 trial not to be part of ISS
NN1436-4465	IGlar	16	150/50	A trial investigating 3 different titration algorithms of once weekly insulin 287.	Exploratory phase 2 trial not to be part of ISS
NN1436-4466	IGlar	16	100/50	A trial investigating 2 different loading doses of once weekly insulin 287	Exploratory phase 2 trial not to be part of ISS
NN1436-4583	-	12	300/0	A trial investigation 3 different types of automated titration of once weekly insulin 287	No basal insulin comparator

IGlar: insulin glargine
†All trials include an additional 5 weeks follow-up period

4.3 Definition of analysis sets

The following analysis sets have been defined in all protocols of the confirmatory phase 3a trials in scope for this meta-analysis in accordance with the International Council for Harmonisation (ICH)-E9 guidance[4].

Full Analysis Set (FAS): includes all randomised subjects. In exceptional cases, subjects may be eliminated from the full analysis set. In such cases the elimination will be justified and documented. The statistical evaluation of the FAS will follow the intention-to-treat (ITT) principle and subjects will contribute to the evaluation "as randomised".

Safety Analysis Set (SAS): includes all subjects receiving at least one dose of the investigational product or comparator. Subjects in the safety set will contribute to the evaluation "as treated".

The FAS and the SAS will be the same as in the individual CTRs.

All evaluations of MACE will be based on the SAS in line with the safety evaluations in the individual CTRs.

4.4 Treatment arms

Two treatment arms will be defined:

- insulin 287 treatment arm that comprises the investigational product. If more than one type of insulin 287 treatment regimen has been investigated in a given trial, then subjects from these treatment arms will be pooled.

- basal insulin comparator treatment arm that comprises all the confirmatory phase 3 basal insulin analogue comparators. I.e., insulin degludec, insulin detemir, and insulin glargine U100 and U300

The above definition of treatment arms means that all subjects in the selected trials as specified in Table 1 will be included in the analyses. The CV risk for insulin 287 will be compared to the CV risk for the comparator group consisting of approved and marketed basal insulin analogue products. This is considered a relevant comparator since the CV safety of approved marketed basal insulin analogues have been established.

4.5 Period definitions

All planned trials in scope for this meta-analysis will have a follow-up visit 5 weeks after last dose of once daily insulin and 6 weeks after last dose of once weekly insulin. The following periods will be considered for the evaluation of MACE in this meta-analysis. It is the event adjudication committee (EAC) determined onset date that determines if the event belongs to a certain period.

4.5.1 In-trial period

The in-trial period starts at randomisation (as registered in the interactive web response system (IWRS)) and ends at the date of:

- The last direct subject-site contact

- Withdrawal for subjects who withdraw their informed consent
- The last subject-investigator contact as defined by the investigator for subjects who are lost to follow-up (i.e. possibly an unscheduled phone visit)
- Death for subjects who die before any of the above

For subjects not randomised but exposed to trial product the in-trial period starts at the date of first dose of trial product. The end date is as defined as above.

The in-trial period will be the primary period used for the evaluation of MACE in accordance with the intention-to-treat (ITT) principle. The in-trial period will be the same as used for certain AE tabulations in the individual Clinical Trial Reports (CTRs) as well as in the BLA.

4.5.2 On-treatment period

The on-treatment period starts at the date of first dose of trial product as recorded on the electronic Case Record Form (eCRF), and ends at the first date of any of the following:

- The last follow-up visit
- The last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin
- The end-date for the in-trial observation period

The on-treatment period will be the same as used for evaluating safety in the individual CTRs and the BLA. This observation period will be used for the sensitivity analysis of MACE described in 7.1.3

4.6 Cut-off date for analysis of MACE

The statistical analyses and descriptive summaries including baseline and demographic summaries will be based on the individually locked databases for the trials described in section 4.2.

Consequently, the meta-analysis combines evidence on cardiovascular events collected and reported in the individual CTRs.

Adjudicated MACE reported after data base lock will be listed separately.

5 Subjects

5.1 Subject disposition

Subject disposition in terms of the number of randomised subjects, the number subjects discontinuing treatment prematurely, the number of withdrawals and the reason of discontinuation/withdrawal and the number of subjects in the FAS and the safety analysis set will be summarised by trial, treatment arm and in total across trials and treatment arms.

More detailed information on subject disposition will appear in the individual CTRs.

5.2 Baseline characteristics and demographics

Demographics in terms of age group, body mass index, country, sex, race, and ethnicity will be summarised by trial, treatment arm and in total across trials and treatment arms.

Baseline characteristics in terms of age (in years), HbA1c (in % and mmol/mol), fasting plasma glucose (in mmol/L and mg/dL), duration of diabetes (in years) and history of cardiovascular disease (yes/no) will be summarised by trial, treatment arm and in total across trials and treatment amrs.

More detailed information on baseline characteristics and demographics will appear in the individual CTRs.

6 Observation and exposure time

6.1 Patient years of observation

Patient years of observation (PYO) correspond to the in-trial period. This means that PYO will cover the same period as the events presented in the primary analysis. It will be derived as the time from randomisation (as registered in IWRS) until the first date of the following + 1 day divided by 365.25:

- The last direct subject-site contact
- Withdrawal for subjects who withdraw their informed consent
- The last subject-investigator contact as defined by the investigator for subjects who are lost to follow-up (i.e. possibly and unscheduled phone visit)
- Death for subjects who die before any of the above

For subjects not randomised but exposed to trial product PYO starts at the date of first dose of trial product and ends as defined above.

The PYO will be used when deriving the event rate of MACE and will be used in the primary analysis and all, but one sensitivity analysis of MACE.

6.2 Extent of Exposure

Patient years of exposure (PYE) is defined as the time where the subjects is considered exposed to the drug i.e. considered 'on-treatment'. Specifically, it is calculated as the time from the date of first dose of trial product as recorded on the eCRF until the first date of any of the following + 1 day and divided by 365.25

- The last follow-up visit
- The last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin
- The end date of the PYO period

PYE will be used for the first sensitivity analysis described in 7.1.3

The extent of exposure and observation time will be summarised by trial, treatment arm and in total.

7 Statistical methodology

All statistical analyses, including the primary analysis, are considered explorative in nature and no formal statistical hypothesis testing will be performed.

Descriptive summaries of MACE will be prepared including the number of subjects with at least one event, the percentage of subjects with at least one event, the number of events and the event rate per 100 PYO based on the SAS. The summaries will be made by trial and pooled across trials as well as for each MACE sub category (CV death, MI and stroke) separately. The summaries pooled across trials will be repeated for the following subgroups: age (≤65 and >65 years), sex, race, ethnicity, and cardiovascular history (yes and no).

The percentage and rate pooled across trials will be adjusted by means of the Mantel-Haenszel (MH) method to account for trial effects. No formal comparisons between treatment groups will be included in the summaries. A comparison between treatment groups will solely be made based on the cox regression model as described in section 7.1.2 . Furthermore, due to the anticipated low number of MACE, it is not planned to make any statistical analyses of neither the components of MACE, nor by trial or any other subgroup.

As no formal comparison between treatment groups will be made in the MH adjusted evaluation, trials with zero MACE events in one or both of the treatment arms can still be included and will still contribute when deriving the adjusted pooled percentages and rates.

A listing of all cardiovascular events sent for adjudication will be made sorting by trial, and treatment arm displaying source, adjudication phase, EAC outcome, onset day and with an indication on which trial periods the event belongs to.

7.1 Primary endpoint

7.1.1 Definition

The time-to-event endpoint used to evaluate cardiovascular profile is the time in days from start of the in-trial period until date of first adjudicated MACE.

All MACE with onset date within the in-trial period will contribute to the derivation of the primary endpoint.

Censoring

If a subject has no adjudicated MACE with onset date within the in-trial period at the time of database lock then the primary endpoint will be censored. Time of censoring will be at the end date of the in-trial period as defined in section 4.5.1.

7.1.2 Primary analysis

The primary endpoint will be analysed based on the SAS in a Cox proportional hazards model stratified by trial and with treatment (2 levels: I287 and basal insulin Comparators) as explanatory variable.

The primary model relies on the assumption that the baseline hazard rate may be different between trials to account for potential trial heterogeneity. Furthermore, this model is rather robust towards situations with sparse data.

From the primary statistical analysis the estimated hazard ratio and the corresponding 95% CI will be presented.

Plots of the cumulative incidence function of time to first MACE by treatment arm as well as by treatment arm and trial strata will be made.

7.1.3 Sensitivity analyses

A number of sensitivity analyses will be carried out to evaluate the robustness of the findings from the primary analysis.

Including adjudicated MACE only from the on-treatment period

The primary analysis will be repeated including only adjudicated MACE with onset date in the on-treatment period. In this analysis, subjects will be censored at the end date of the on-treatment period.

Impact of trials with zero events

Trials with no primary endpoint events will not contribute to the primary analysis. Two sensitivity analyses will be prepared to assess the robustness of the primary analysis result if there appear to be trials with no primary endpoint events. In the first sensitivity analysis, the primary analysis will be repeated with trial as a fixed effect instead of as a stratification factor. In the second sensitivity analysis, a trial with no primary endpoint events will be pooled in a naïve fashion with a similar trial that has at least one event. Similarities are determined in terms of size, trial duration, and patient population, i.e., insulin naïve vs. previous insulin users. The following trials can be pooled under such circumstances:

- NN1436-4478 and NN1436-4480; both trials are of approximately same size, of 26 weeks duration and in insulin users
- NN1436-4477 and NN1436-4481; both trials are large trials of 52 weeks duration in insulin naïve
- NN1436-4479 and NN1436-4477; both trials are of approximately same size, conducted in insulin naïve.
- NN1436-4480 and NN1436-4625; both trials are of approximately same size, of 26 weeks duration and in a progressed diabetes population (bolus insulin users)

The first choice for pooling of trials NN1436-4477 or NN1436-4480 with another trial if no events are observed in the specific trial will be to combine with trial NN1436-4481 and NN1436-4625 respectively.

Impact of trial duration

Three sensitivity analyses will be carried out to evaluate the impact of different trial duration. Trial duration for the trials in scope for this meta-analysis are either 52 weeks (2 trials) or 26 weeks (4 trials) all including an additional 5 weeks of follow-up period. This could result in a biased hazard-ratio estimate in the primary analysis. Therefore, the primary analysis will be repeated where the primary endpoint in the 52 weeks trials (NN1436-4477 and NN1436-4481) will be censored at the first date of the following

- The date of the 26 weeks visit plus 5 weeks
- The last direct subject-site contact
- Withdrawal for subjects who withdraw their informed consent
- The last subject-investigator contact as defined by the investigator for subjects who are lost to follow-up (i.e. possibly an unscheduled phone visit)
- Death for subjects who die before any of the above

In addition, separate meta analyses for the 52 weeks and 26 weeks trials respectively will be performed.

7.2 Data Decisions

Adjudicated MACE in the database with no information on exact onset date, if any, will be included in summaries and analyses with the onset date imputed as the first date of the relevant month if only month and year is given and the date for half the study duration if either month or year is missing.

8 References

1. FDA draft Guidance for Industry. Meta-analysis of Randomized Controlled Clinical Trials to Evaluate the Safety of Human Drugs or Biological Products.
2. FDA Guidance for Industry. Diabetes Mellitus — Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes
3. Hicks KA, Hung HMJ, Mahaffey KW, Mehran R, Nissen SE, Stockbridge NL, et al. Standardized Definitions for Cardiovascular and Stroke End Point Events in Clinical Trials (Draft). 20 Aug 2014.
4. International Conference on Harmonisation. ICH Harmonised Tripartite Guideline. Statistical principles for clinical trials E9. International Conference on Harmonisation E9 Expert Working Group. 5 Feb 1998.

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7.18 Cardiovascular meta-analysis

7.18.1 Subject disposition - summary by trial

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
ONWARDS 1						
Randomised	492	(100.0)	492	(100.0)	984	(100.0)
Exposed	492	(100.0)	492	(100.0)	984	(100.0)
Full analysis set (FAS)	492	(100.0)	492	(100.0)	984	(100.0)
Safety analysis set (SAS)	492	(100.0)	492	(100.0)	984	(100.0)
Permanent discontinuation of trial product	17	(3.5)	12	(2.4)	29	(2.9)
Adverse event	8	(1.6)	4	(0.8)	12	(1.2)
Hypoglycaemic episode	0		1	(0.2)	1	(0.1)
Protocol deviation	0		0		0	
Lack of efficacy	1	(0.2)	0		1	(0.1)
Lost to follow-up	1	(0.2)	0		1	(0.1)
Pregnancy	0		0		0	
Site closure	1	(0.2)	0		1	(0.1)
Epi/pandemic	0		0		0	
Withdrawal of consent	2	(0.4)	5	(1.0)	7	(0.7)
Safety concern related to trial product or unacceptable intolerability	0		0		0	
Other	4	(0.8)	2	(0.4)	6	(0.6)
Withdrawn from trial	10	(2.0)	7	(1.4)	17	(1.7)
Withdrawal of consent by subject	3	(0.6)	5	(1.0)	8	(0.8)
Lost to follow-up	2	(0.4)	0		2	(0.2)
Investigator decision	2	(0.4)	0		2	(0.2)
Death	2	(0.4)	2	(0.4)	4	(0.4)
Site closure	1	(0.2)	0		1	(0.1)
Epi/pandemic	0		0		0	
Completed scheduled end-of-treatment visit	482	(98.0)	482	(98.0)	964	(98.0)
Completed scheduled end-of-treatment visit without permanent discontinuation of trial product	475	(96.5)	479	(97.4)	954	(97.0)
Completed scheduled end-of-treatment visit after permanent discontinuation of trial product	7	(1.4)	3	(0.6)	10	(1.0)

%: Percentage of subjects, N: Number of subjects. Lack of efficacy criterion applies to all trials except ONWARDS 5, while both switch to another basal insulin analogue and intensification to a basal bolus regime or continuous use of bolus insulin only apply to ONWARDS 5. Scheduled end-of-treatment visit refers to week 26 visit for ONWARDS 2-4 and 6 (main part), and to week 52 visit for ONWARDS 1 (main part) and 5. Daily basal insulin: IDeg (ONWARDS 2, ONWARDS 3, ONWARDS 6), IGlar U100 (ONWARDS 1, ONWARDS 4), and once-daily analogues (IDeg, IGlar U100, IGlar U300) (ONWARDS 5).

Subject disposition - summary by trial

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
ONWARDS 3						
Randomised	294	(100.0)	294	(100.0)	588	(100.0)
Exposed	293	(99.7)	294	(100.0)	587	(99.8)
Full analysis set (FAS)	294	(100.0)	294	(100.0)	588	(100.0)
Safety analysis set (SAS)	293	(99.7)	294	(100.0)	587	(99.8)
Permanent discontinuation of trial product	13	(4.4)	11	(3.7)	24	(4.1)
Adverse event	4	(1.4)	2	(0.7)	6	(1.0)
Hypoglycaemic episode	0		0		0	
Protocol deviation	1	(0.3)	1	(0.3)	2	(0.3)
Lack of efficacy	0		0		0	
Lost to follow-up	0		1	(0.3)	1	(0.2)
Pregnancy	0		0		0	
Site closure	0		0		0	
Epi/pandemic	0		0		0	
Withdrawal of consent	4	(1.4)	3	(1.0)	7	(1.2)
Safety concern related to trial product or unacceptable intolerability	0		0		0	
Other	4	(1.4)	4	(1.4)	8	(1.4)
Withdrawn from trial	6	(2.0)	8	(2.7)	14	(2.4)
Withdrawal of consent by subject	4	(1.4)	4	(1.4)	8	(1.4)
Lost to follow-up	0		1	(0.3)	1	(0.2)
Investigator decision	0		2	(0.7)	2	(0.3)
Death	2	(0.7)	1	(0.3)	3	(0.5)
Site closure	0		0		0	
Epi/pandemic	0		0		0	
Completed scheduled end-of-treatment visit	288	(98.0)	286	(97.3)	574	(97.6)
Completed scheduled end-of-treatment visit without permanent discontinuation of trial product	281	(95.6)	283	(96.3)	564	(95.9)
Completed scheduled end-of-treatment visit after permanent discontinuation of trial product	7	(2.4)	3	(1.0)	10	(1.7)

%: Percentage of subjects, N: Number of subjects. Lack of efficacy criterion applies to all trials except ONWARDS 5, while both switch to another basal insulin analogue and intensification to a basal bolus regime or continuous use of bolus insulin only apply to ONWARDS 5. Scheduled end-of-treatment visit refers to week 26 visit for ONWARDS 2-4 and 6 (main part), and to week 52 visit for ONWARDS 1 (main part) and 5. Daily basal insulin: IDeg (ONWARDS 2, ONWARDS 3, ONWARDS 6), IGlar U100 (ONWARDS 1, ONWARDS 4), and once-daily analogues (IDeg, IGlar U100, IGlar U300) (ONWARDS 5).

Subject disposition - summary by trial

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
ONWARDS 5						
Randomised	542	(100.0)	543	(100.0)	1085	(100.0)
Exposed	542	(100.0)	538	(99.1)	1080	(99.5)
Full analysis set (FAS)	542	(100.0)	543	(100.0)	1085	(100.0)
Safety analysis set (SAS)	542	(100.0)	538	(99.1)	1080	(99.5)
Permanent discontinuation of trial product	59	(10.9)	50	(9.2)	109	(10.0)
Adverse event	8	(1.5)	11	(2.0)	19	(1.8)
Hypoglycaemic episode	3	(0.6)	0		3	(0.3)
Protocol deviation	1	(0.2)	1	(0.2)	2	(0.2)
Switch to another basal insulin analogue	0		0		0	
Intensification to a basal bolus regime or continuous use of bolus insulin	2	(0.4)	0		2	(0.2)
Lost to follow-up	10	(1.8)	14	(2.6)	24	(2.2)
Pregnancy	1	(0.2)	0		1	(0.1)
Site closure	0		0		0	
Epi/pandemic	0		0		0	
Withdrawal of consent	18	(3.3)	17	(3.1)	35	(3.2)
Safety concern related to trial product or unacceptable intolerability	0		0		0	
Other	16	(3.0)	7	(1.3)	23	(2.1)
Withdrawn from trial	45	(8.3)	50	(9.2)	95	(8.8)
Withdrawal of consent by subject	24	(4.4)	20	(3.7)	44	(4.1)
Lost to follow-up	14	(2.6)	19	(3.5)	33	(3.0)
Investigator decision	3	(0.6)	5	(0.9)	8	(0.7)
Death	3	(0.6)	6	(1.1)	9	(0.8)
Site closure	1	(0.2)	0		1	(0.1)
Epi/pandemic	0		0		0	
Completed scheduled end-of-treatment visit	496	(91.5)	496	(91.3)	992	(91.4)
Completed scheduled end-of-treatment visit without permanent discontinuation of trial product	483	(89.1)	493	(90.8)	976	(90.0)
Completed scheduled end-of-treatment visit after permanent discontinuation of trial product	13	(2.4)	3	(0.6)	16	(1.5)

%: Percentage of subjects, N: Number of subjects. Lack of efficacy criterion applies to all trials except ONWARDS 5, while both switch to another basal insulin analogue and intensification to a basal bolus regime or continuous use of bolus insulin only apply to ONWARDS 5. Scheduled end-of-treatment visit refers to week 26 visit for ONWARDS 2-4 and 6 (main part), and to week 52 visit for ONWARDS 1 (main part) and 5. Daily basal insulin: IDeg (ONWARDS 2, ONWARDS 3, ONWARDS 6), IGlar U100 (ONWARDS 1, ONWARDS 4), and once-daily analogues (IDeg, IGlar U100, IGlar U300) (ONWARDS 5).

Subject disposition - summary by trial

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
ONWARDS 2						
Randomised	263	(100.0)	263	(100.0)	526	(100.0)
Exposed	262	(99.6)	263	(100.0)	525	(99.8)
Full analysis set (FAS)	263	(100.0)	263	(100.0)	526	(100.0)
Safety analysis set (SAS)	262	(99.6)	263	(100.0)	525	(99.8)
Permanent discontinuation of trial product	7	(2.7)	10	(3.8)	17	(3.2)
Adverse event	5	(1.9)	3	(1.1)	8	(1.5)
Hypoglycaemic episode	0		0		0	
Protocol deviation	1	(0.4)	1	(0.4)	2	(0.4)
Lack of efficacy	0		0		0	
Lost to follow-up	0		0		0	
Pregnancy	0		0		0	
Site closure	0		0		0	
Epi/pandemic	0		0		0	
Withdrawal of consent	0		2	(0.8)	2	(0.4)
Safety concern related to trial product or unacceptable intolerability	0		0		0	
Other	1	(0.4)	4	(1.5)	5	(1.0)
Withdrawn from trial	3	(1.1)	5	(1.9)	8	(1.5)
Withdrawal of consent by subject	0		3	(1.1)	3	(0.6)
Lost to follow-up	0		0		0	
Investigator decision	1	(0.4)	0		1	(0.2)
Death	2	(0.8)	2	(0.8)	4	(0.8)
Site closure	0		0		0	
Epi/pandemic	0		0		0	
Completed scheduled end-of-treatment visit	260	(98.9)	259	(98.5)	519	(98.7)
Completed scheduled end-of-treatment visit without permanent discontinuation of trial product	256	(97.3)	253	(96.2)	509	(96.8)
Completed scheduled end-of-treatment visit after permanent discontinuation of trial product	4	(1.5)	6	(2.3)	10	(1.9)

%: Percentage of subjects, N: Number of subjects. Lack of efficacy criterion applies to all trials except ONWARDS 5, while both switch to another basal insulin analogue and intensification to a basal bolus regime or continuous use of bolus insulin only apply to ONWARDS 5. Scheduled end-of-treatment visit refers to week 26 visit for ONWARDS 2-4 and 6 (main part), and to week 52 visit for ONWARDS 1 (main part) and 5. Daily basal insulin: IDeg (ONWARDS 2, ONWARDS 3, ONWARDS 6), IGlar U100 (ONWARDS 1, ONWARDS 4), and once-daily analogues (IDeg, IGlar U100, IGlar U300) (ONWARDS 5).

Subject disposition - summary by trial

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
ONWARDS 4						
Randomised	291	(100.0)	291	(100.0)	582	(100.0)
Exposed	291	(100.0)	291	(100.0)	582	(100.0)
Full analysis set (FAS)	291	(100.0)	291	(100.0)	582	(100.0)
Safety analysis set (SAS)	291	(100.0)	291	(100.0)	582	(100.0)
Permanent discontinuation of trial product	17	(5.8)	22	(7.6)	39	(6.7)
Adverse event	4	(1.4)	3	(1.0)	7	(1.2)
Hypoglycaemic episode	0		0		0	
Protocol deviation	0		0		0	
Lack of efficacy	0		0		0	
Lost to follow-up	3	(1.0)	6	(2.1)	9	(1.5)
Pregnancy	0		0		0	
Site closure	0		0		0	
Epi/pandemic	0		0		0	
Withdrawal of consent	6	(2.1)	8	(2.7)	14	(2.4)
Safety concern related to trial product or unacceptable intolerability	0		0		0	
Other	4	(1.4)	5	(1.7)	9	(1.5)
Withdrawn from trial	16	(5.5)	18	(6.2)	34	(5.8)
Withdrawal of consent by subject	9	(3.1)	10	(3.4)	19	(3.3)
Lost to follow-up	3	(1.0)	6	(2.1)	9	(1.5)
Investigator decision	2	(0.7)	1	(0.3)	3	(0.5)
Death	2	(0.7)	1	(0.3)	3	(0.5)
Site closure	0		0		0	
Epi/pandemic	0		0		0	
Completed scheduled end-of-treatment visit	278	(95.5)	275	(94.5)	553	(95.0)
Completed scheduled end-of-treatment visit without permanent discontinuation of trial product	274	(94.2)	269	(92.4)	543	(93.3)
Completed scheduled end-of-treatment visit after permanent discontinuation of trial product	4	(1.4)	6	(2.1)	10	(1.7)

%: Percentage of subjects, N: Number of subjects. Lack of efficacy criterion applies to all trials except ONWARDS 5, while both switch to another basal insulin analogue and intensification to a basal bolus regime or continuous use of bolus insulin only apply to ONWARDS 5. Scheduled end-of-treatment visit refers to week 26 visit for ONWARDS 2-4 and 6 (main part), and to week 52 visit for ONWARDS 1 (main part) and 5. Daily basal insulin: IDeg (ONWARDS 2, ONWARDS 3, ONWARDS 6), IGlar U100 (ONWARDS 1, ONWARDS 4), and once-daily analogues (IDeg, IGlar U100, IGlar U300) (ONWARDS 5).

Subject disposition - summary by trial

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
ONWARDS 6						
Randomised	290	(100.0)	292	(100.0)	582	(100.0)
Exposed	290	(100.0)	292	(100.0)	582	(100.0)
Full analysis set (FAS)	290	(100.0)	292	(100.0)	582	(100.0)
Safety analysis set (SAS)	290	(100.0)	292	(100.0)	582	(100.0)
Permanent discontinuation of trial product	18	(6.2)	9	(3.1)	27	(4.6)
Adverse event	1	(0.3)	1	(0.3)	2	(0.3)
Hypoglycaemic episode	1	(0.3)	0		1	(0.2)
Protocol deviation	1	(0.3)	0		1	(0.2)
Lack of efficacy	0		0		0	
Lost to follow-up	0		1	(0.3)	1	(0.2)
Pregnancy	2	(0.7)	0		2	(0.3)
Site closure	0		0		0	
Epi/pandemic	0		0		0	
Withdrawal of consent	4	(1.4)	3	(1.0)	7	(1.2)
Safety concern related to trial product or unacceptable intolerability	0		0		0	
Other	9	(3.1)	4	(1.4)	13	(2.2)
Withdrawn from trial	11	(3.8)	8	(2.7)	19	(3.3)
Withdrawal of consent by subject	9	(3.1)	7	(2.4)	16	(2.7)
Lost to follow-up	1	(0.3)	1	(0.3)	2	(0.3)
Investigator decision	0		0		0	
Death	1	(0.3)	0		1	(0.2)
Site closure	0		0		0	
Epi/pandemic	0		0		0	
Completed scheduled end-of-treatment visit	277	(95.5)	285	(97.6)	562	(96.6)
Completed scheduled end-of-treatment visit without permanent discontinuation of trial product	272	(93.8)	283	(96.9)	555	(95.4)
Completed scheduled end-of-treatment visit after permanent discontinuation of trial product	5	(1.7)	2	(0.7)	7	(1.2)

%: Percentage of subjects, N: Number of subjects. Lack of efficacy criterion applies to all trials except ONWARDS 5, while both switch to another basal insulin analogue and intensification to a basal bolus regime or continuous use of bolus insulin only apply to ONWARDS 5. Scheduled end-of-treatment visit refers to week 26 visit for ONWARDS 2-4 and 6 (main part), and to week 52 visit for ONWARDS 1 (main part) and 5. Daily basal insulin: IDeg (ONWARDS 2, ONWARDS 3, ONWARDS 6), IGlar U100 (ONWARDS 1, ONWARDS 4), and once-daily analogues (IDeg, IGlar U100, IGlar U300) (ONWARDS 5).

adsl.xpt; variable(s): STDNM EOTSTT VAADT EOSSTT DCTGR1 DCSGR1 METVISDT EOTVISDT TRTSDT RANDFL FASFL SAFFL; criteria: NA

7.18.2 Subject disposition - summary - Phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Randomised	2172	(100.0)	2175	(100.0)	4347	(100.0)
Exposed	2170	(99.9)	2170	(99.8)	4340	(99.8)
Full analysis set (FAS)	2172	(100.0)	2175	(100.0)	4347	(100.0)
Safety analysis set (SAS)	2170	(99.9)	2170	(99.8)	4340	(99.8)
Permanent discontinuation of trial product	131	(6.0)	114	(5.2)	245	(5.6)
Adverse event	30	(1.4)	24	(1.1)	54	(1.2)
Hypoglycaemic episode	4	(0.2)	1	(0.0)	5	(0.1)
Protocol deviation	4	(0.2)	3	(0.1)	7	(0.2)
Lack of efficacy	1	(0.0)	0		1	(0.0)
Switch to another basal insulin analogue	0		0		0	
Intensification to a basal bolus regime or continuous use of bolus insulin	2	(0.1)	0		2	(0.0)
Lost to follow-up	14	(0.6)	22	(1.0)	36	(0.8)
Pregnancy	3	(0.1)	0		3	(0.1)
Site closure	1	(0.0)	0		1	(0.0)
Epi/pandemic	0		0		0	
Withdrawal of consent	34	(1.6)	38	(1.7)	72	(1.7)
Safety concern related to trial product or unacceptable intolerability	0		0		0	
Other	38	(1.7)	26	(1.2)	64	(1.5)
Withdrawn from trial	91	(4.2)	96	(4.4)	187	(4.3)
Withdrawal of consent by subject	49	(2.3)	49	(2.3)	98	(2.3)
Lost to follow-up	20	(0.9)	27	(1.2)	47	(1.1)
Investigator decision	8	(0.4)	8	(0.4)	16	(0.4)
Death	12	(0.6)	12	(0.6)	24	(0.6)
Site closure	2	(0.1)	0		2	(0.0)
Epi/pandemic	0		0		0	
Completed scheduled end-of-treatment visit	2081	(95.8)	2083	(95.8)	4164	(95.8)
Completed scheduled end-of-treatment visit without permanent discontinuation of trial product	2041	(94.0)	2060	(94.7)	4101	(94.3)
Completed scheduled end-of-treatment visit after permanent discontinuation of trial product	40	(1.8)	23	(1.1)	63	(1.4)

%: Percentage of subjects, N: Number of subjects. Lack of efficacy criterion applies to all trials except ONWARDS 5, while both switch to another basal insulin analogue and intensification to a basal bolus regime or continuous use of bolus insulin only apply to ONWARDS 5. Scheduled end-of-treatment visit refers to week 26 visit for ONWARDS 2-4 and 6 (main part), and to week 52 visit for ONWARDS 1 (main part) and 5. Daily basal insulin: IDeg (ONWARDS 2, ONWARDS 3, ONWARDS 6), IGlar U100 (ONWARDS 1, ONWARDS 4), and once-daily analogues (IDeg, IGlar U100, IGlar U300) (ONWARDS 5). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.18.3 Exposure by pool and trial - summary - safety analysis set

	Insulin icodec		Daily basal insulin		Total	
	N	(PYE)	N	(PYE)	N	(PYE)
Phase 3a pool	2170	(1681.23)	2170	(1680.58)	4340	(3361.81)
ONWARDS 1	492	(485.88)	492	(485.03)	984	(970.91)
ONWARDS 3	293	(170.90)	294	(171.13)	587	(342.03)
ONWARDS 5	542	(559.54)	538	(560.72)	1080	(1120.26)
ONWARDS 2	262	(155.25)	263	(152.77)	525	(308.02)
ONWARDS 4	291	(167.36)	291	(166.80)	582	(334.16)
ONWARDS 6	290	(142.31)	292	(144.12)	582	(286.43)

N: Number of subjects, PYE: Patient years of exposure (1 PYE = 365.25 days). Daily basal insulin: IDeg (ONWARDS 2, ONWARDS 3, ONWARDS 6), IGlar U100 (ONWARDS 1, ONWARDS 4), and once-daily analogues (IDeg, IGlar U100, IGlar U300) (ONWARDS 5). Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adsl.xpt; variable(s): TR01AG1 OTMTDURY STDNM POOLGR2 ; criteria: SAFFL == "Y"
nn1436/nn1436-meta-analysis/submission_20221107_er
21NOV2022:14:34:42 - tecexptrialsumsas/tecexptrialsumsas.txt

7.18.4 Observation time by pool and trial - summary - safety analysis set

	Insulin icodec		Daily basal insulin		Total	
	N	(PYO)	N	(PYO)	N	(PYO)
Phase 3a pool	2170	(1707.11)	2170	(1702.14)	4340	(3409.25)
ONWARDS 1	492	(488.06)	492	(486.95)	984	(975.01)
ONWARDS 3	293	(173.32)	294	(173.51)	587	(346.83)
ONWARDS 5	542	(575.88)	538	(571.11)	1080	(1146.99)
ONWARDS 2	262	(156.59)	263	(155.90)	525	(312.49)
ONWARDS 4	291	(170.01)	291	(169.98)	582	(339.99)
ONWARDS 6	290	(143.24)	292	(144.68)	582	(287.93)

N: Number of subjects, PYO: Patient years of observation (1 PYO = 365.25 days). Daily basal insulin: IDeg (ONWARDS 2, ONWARDS 3, ONWARDS 6), IGlar U100 (ONWARDS 1, ONWARDS 4), and once-daily analogues (IDeg, IGlar U100, IGlar U300) (ONWARDS 5). Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adsl.xpt; variable(s): TR01AG1 INTRDURY STDNM POOLGR2; criteria: SAFFL == "Y"
nn1436/nn1436-meta-analysis/submission_20221107_er
21NOV2022:14:34:43 - tecobstrialsumsas/tecobstrialsumsas.txt

7.18.5 EAC confirmed MACE - summary by trial - in-trial - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
ONWARDS 1								
Number of subjects	492				492			
PYO (years)	488.1				487.0			
EAC confirmed MACE	7	(1.4)	8	1.64	11	(2.2)	12	2.46
CV death	1	(0.2)	1	0.20	2	(0.4)	2	0.41
Acute myocardial infarction	6	(1.2)	6	1.23	5	(1.0)	6	1.23
STEMI	4	(0.8)	4	0.82	2	(0.4)	2	0.41
NSTEMI	1	(0.2)	1	0.20	3	(0.6)	4	0.82
Undetermined	1	(0.2)	1	0.20	0			
Stroke	1	(0.2)	1	0.20	4	(0.8)	4	0.82
Ischaemic stroke	0				4	(0.8)	4	0.82
Hemorrhagic stroke	1	(0.2)	1	0.20	0			
Undetermined stroke	0				0			
EAC confirmed first MACE	7	(1.4)	7	1.43	11	(2.2)	11	2.26
ONWARDS 3								
Number of subjects	293				294			
PYO (years)	173.3				173.5			
EAC confirmed MACE	1	(0.3)	1	0.58	1	(0.3)	2	1.15
CV death	0				1	(0.3)	1	0.58
Acute myocardial infarction	0				1	(0.3)	1	0.58
STEMI	0				1	(0.3)	1	0.58
NSTEMI	0				0			
Undetermined	0				0			
Stroke	1	(0.3)	1	0.58	0			
Ischaemic stroke	1	(0.3)	1	0.58	0			
Hemorrhagic stroke	0				0			
Undetermined stroke	0				0			
EAC confirmed first MACE	1	(0.3)	1	0.58	1	(0.3)	1	0.58
ONWARDS 5								
Number of subjects	542				538			
PYO (years)	575.9				571.1			
EAC confirmed MACE	5	(0.9)	6	1.04	9	(1.7)	10	1.75
CV death	0				2	(0.4)	2	0.35
Acute myocardial infarction	5	(0.9)	6	1.04	4	(0.7)	4	0.70
STEMI	2	(0.4)	2	0.35	2	(0.4)	2	0.35
NSTEMI	3	(0.6)	4	0.69	2	(0.4)	2	0.35
Undetermined	0				0			
Stroke	0				4	(0.7)	4	0.70
Ischaemic stroke	0				4	(0.7)	4	0.70
Hemorrhagic stroke	0				0			
Undetermined stroke	0				0			
EAC confirmed first MACE	5	(0.9)	5	0.87	9	(1.7)	9	1.58

%: Percentage of subjects with one or more events, CV: Cardiovascular, E: Number of adverse events, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke), N: Number of subjects with one or more events, NSTEMI: Non-ST-segment elevation myocardial infarction, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). STEMI: ST-segment elevation myocardial infarction. In-trial status is defined based on the onset date as decided by the EAC. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg (ONWARDS 2, ONWARDS 3, ONWARDS 6), IGlar U100 (ONWARDS 1, ONWARDS 4), and once-daily analogues (IDeg, IGlar U100, IGlar U300) (ONWARDS 5).

EAC confirmed MACE - summary by trial - in-trial - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
ONWARDS 2								
Number of subjects	262				263			
PYO (years)	156.6				155.9			
EAC confirmed MACE	4	(1.5)	4	2.55	3	(1.1)	4	2.57
CV death	0				1	(0.4)	1	0.64
Acute myocardial infarction	2	(0.8)	2	1.28	1	(0.4)	1	0.64
STEMI	0				1	(0.4)	1	0.64
NSTEMI	2	(0.8)	2	1.28	0			
Undetermined	0				0			
Stroke	2	(0.8)	2	1.28	2	(0.8)	2	1.28
Ischaemic stroke	2	(0.8)	2	1.28	2	(0.8)	2	1.28
Hemorrhagic stroke	0				0			
Undetermined stroke	0				0			
EAC confirmed first MACE	4	(1.5)	4	2.55	3	(1.1)	3	1.92
ONWARDS 4								
Number of subjects	291				291			
PYO (years)	170.0				170.0			
EAC confirmed MACE	5	(1.7)	5	2.94	2	(0.7)	2	1.18
CV death	1	(0.3)	1	0.59	0			
Acute myocardial infarction	4	(1.4)	4	2.35	1	(0.3)	1	0.59
STEMI	1	(0.3)	1	0.59	1	(0.3)	1	0.59
NSTEMI	3	(1.0)	3	1.76	0			
Undetermined	0				0			
Stroke	0				1	(0.3)	1	0.59
Ischaemic stroke	0				1	(0.3)	1	0.59
Hemorrhagic stroke	0				0			
Undetermined stroke	0				0			
EAC confirmed first MACE	5	(1.7)	5	2.94	2	(0.7)	2	1.18
ONWARDS 6								
Number of subjects	290				292			
PYO (years)	143.2				144.7			
EAC confirmed MACE	0				0			
CV death	0				0			
Acute myocardial infarction	0				0			
STEMI	0				0			
NSTEMI	0				0			
Undetermined	0				0			
Stroke	0				0			
Ischaemic stroke	0				0			
Hemorrhagic stroke	0				0			
Undetermined stroke	0				0			

%: Percentage of subjects with one or more events, CV: Cardiovascular, E: Number of adverse events, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke), N: Number of subjects with one or more events, NSTEMI: Non-ST-segment elevation myocardial infarction, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). STEMI: ST-segment elevation myocardial infarction. In-trial status is defined based on the onset date as decided by the EAC. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg (ONWARDS 2, ONWARDS 3, ONWARDS 6), IGlar U100 (ONWARDS 1, ONWARDS 4), and once-daily analogues (IDeg, IGlar U100, IGlar U300) (ONWARDS 5).

7.18.6 EAC confirmed MACE - summary - in-trial - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects	2170				2170			
PYO (years)	1707.1				1702.1			
EAC confirmed MACE	22	(1.0)	24	1.41	26	(1.2)	30	1.62
CV death	2	(0.1)	2	0.13	6	(0.3)	6	0.34
Acute myocardial infarction	17	(0.8)	18	1.01	12	(0.6)	13	0.69
STEMI	7	(0.3)	7	0.35	7	(0.3)	7	0.41
NSTEMI	9	(0.4)	10	0.61	5	(0.2)	6	0.27
Undetermined	1	(0.0)	1	0.05	0			
Stroke	4	(0.2)	4	0.28	11	(0.5)	11	0.59
Ischaemic stroke	3	(0.1)	3	0.23	11	(0.5)	11	0.59
Hemorrhagic stroke	1	(0.0)	1	0.05	0			
Undetermined stroke	0				0			
EAC confirmed first MACE	22	(1.0)	22	1.32	26	(1.2)	26	1.37

%: Percentage of subjects with one or more events, CV: Cardiovascular, E: Number of adverse events, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke), N: Number of subjects with one or more events, NSTEMI: Non-ST-segment elevation myocardial infarction, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). STEMI: ST-segment elevation myocardial infarction. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial status is defined based on the onset date as decided by the EAC. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.18.7 EAC confirmed cardiovascular death - summary by trial - in-trial - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
ONWARDS 1								
Number of subjects	492				492			
PYO (years)	488.1				487.0			
EAC confirmed cardiovascular death	1	(0.2)	1	0.20	2	(0.4)	2	0.41
Acute myocardial infarction	1	(0.2)	1	0.20	0			
Sudden cardiac death	0				1	(0.2)	1	0.21
Heart failure	0				0			
Stroke	0				0			
Cardiovascular procedures	0				1	(0.2)	1	0.21
Cardiovascular hemorrhage	0				0			
Other cardiovascular causes	0				0			
ONWARDS 3								
Number of subjects	293				294			
PYO (years)	173.3				173.5			
EAC confirmed cardiovascular death	0				1	(0.3)	1	0.58
Acute myocardial infarction	0				1	(0.3)	1	0.58
Sudden cardiac death	0				0			
Heart failure	0				0			
Stroke	0				0			
Cardiovascular procedures	0				0			
Cardiovascular hemorrhage	0				0			
Other cardiovascular causes	0				0			
ONWARDS 5								
Number of subjects	542				538			
PYO (years)	575.9				571.1			
EAC confirmed cardiovascular death	0				2	(0.4)	2	0.35
Acute myocardial infarction	0				1	(0.2)	1	0.18
Sudden cardiac death	0				1	(0.2)	1	0.18
Heart failure	0				0			
Stroke	0				0			
Cardiovascular procedures	0				0			
Cardiovascular hemorrhage	0				0			
Other cardiovascular causes	0				0			
ONWARDS 2								
Number of subjects	262				263			
PYO (years)	156.6				155.9			
EAC confirmed cardiovascular death	0				1	(0.4)	1	0.64
Acute myocardial infarction	0				0			
Sudden cardiac death	0				0			
Heart failure	0				0			
Stroke	0				1	(0.4)	1	0.64
Cardiovascular procedures	0				0			
Cardiovascular hemorrhage	0				0			
Other cardiovascular causes	0				0			

%: Percentage of subjects with one or more events, CV: Cardiovascular, E: Number of adverse events, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke), N: Number of subjects with one or more events, NSTEMI: Non-ST-segment elevation myocardial infarction, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). STEMI: ST-segment elevation myocardial infarction. In-trial status is defined based on the onset date as decided by the EAC. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg (ONWARDS 2, ONWARDS 3, ONWARDS 6), IGlar U100 (ONWARDS 1, ONWARDS 4), and once-daily analogues (IDeg, IGlar U100, IGlar U300) (ONWARDS 5).

EAC confirmed cardiovascular death - summary by trial - in-trial - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
ONWARDS 4								
Number of subjects	291				291			
PYO (years)	170.0				170.0			
EAC confirmed cardiovascular death	1	(0.3)	1	0.59	0			
Acute myocardial infarction	0				0			
Sudden cardiac death	0				0			
Heart failure	0				0			
Stroke	0				0			
Cardiovascular procedures	0				0			
Cardiovascular hemorrhage	0				0			
Other cardiovascular causes	1	(0.3)	1	0.59	0			
ONWARDS 6								
Number of subjects	290				292			
PYO (years)	143.2				144.7			
EAC confirmed cardiovascular death	0				0			
Acute myocardial infarction	0				0			
Sudden cardiac death	0				0			
Heart failure	0				0			
Stroke	0				0			
Cardiovascular procedures	0				0			
Cardiovascular hemorrhage	0				0			
Other cardiovascular causes	0				0			

%: Percentage of subjects with one or more events, CV: Cardiovascular, E: Number of adverse events, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke), N: Number of subjects with one or more events, NSTEMI: Non-ST-segment elevation myocardial infarction, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). STEMI: ST-segment elevation myocardial infarction. In-trial status is defined based on the onset date as decided by the EAC. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg (ONWARDS 2, ONWARDS 3, ONWARDS 6), IGlar U100 (ONWARDS 1, ONWARDS 4), and once-daily analogues (IDeg, IGlar U100, IGlar U300) (ONWARDS 5).

7.18.8 EAC confirmed cardiovascular death - summary - in-trial - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects	2170				2170			
PYO (years)	1707.1				1702.1			
EAC confirmed cardiovascular death	2	(0.1)	2	0.13	6	(0.3)	6	0.34
Acute myocardial infarction	1	(0.0)	1	0.05	2	(0.1)	2	0.12
Sudden cardiac death	0				2	(0.1)	2	0.09
Heart failure	0				0			
Stroke	0				1	(0.0)	1	0.08
Cardiovascular procedures	0				1	(0.0)	1	0.05
Cardiovascular hemorrhage	0				0			
Other cardiovascular causes	1	(0.0)	1	0.08	0			

%: Percentage of subjects with one or more events, CV: Cardiovascular, E: Number of adverse events, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke), N: Number of subjects with one or more events, NSTEMI: Non-ST-segment elevation myocardial infarction, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). STEMI: ST-segment elevation myocardial infarction. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial status is defined based on the onset date as decided by the EAC. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adsl.xpt; variable(s): INTRDURY; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool"
adadj.xpt; variable(s): ADJOUT CAUSEDEA; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool" & (ANL01FL) == "Y" & ADJOUT == "Cardiovascular death"
nn1436/nn1436-meta-analysis/submission_20221107_er
21NOV2022:14:34:43 - tadjdthcmh/tsumcvdthp3ait.txt

7.18.9 EAC confirmed MACE by age group - summary - in-trial - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects								
<=65 years	1562				1559			
>65 years	608				611			
PYO (years)								
<=65 years	1216.87				1214.33			
>65 years	490.24				487.81			
EAC confirmed MACE								
All								
<=65 years	11	(0.7)	13	0.95	14	(0.9)	16	1.13
>65 years	11	(1.8)	11	2.62	12	(2.0)	14	2.89
CV death								
<=65 years	1	(0.1)	1	0.06	3	(0.2)	3	0.23
>65 years	1	(0.2)	1	0.28	3	(0.5)	3	0.62
Acute myocardial infarction								
<=65 years	10	(0.6)	11	0.78	9	(0.6)	9	0.65
>65 years	7	(1.2)	7	1.61	3	(0.5)	4	0.77
Stroke								
<=65 years	1	(0.1)	1	0.11	4	(0.3)	4	0.24
>65 years	3	(0.5)	3	0.73	7	(1.1)	7	1.50

%: Percentage of subjects with one or more events, CV: Cardiovascular, E: Number of adverse events, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke), N: Number of subjects with one or more events, NSTEMI: Non-ST-segment elevation myocardial infarction, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). STEMI: ST-segment elevation myocardial infarction. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial status is defined based on the onset date as decided by the EAC. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adsl.xpt; variable(s): INTRDURY AGEGR3; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool"
adadj.xpt; variable(s): ADJOUT AGEGR3; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool" & (ANL01FL) == "Y" & MACEFL == "Y"
nn1436/nn1436-meta-analysis/submission_20221107_er
21NOV2022:14:34:48 - tadjdthgrp/tsummaceagep3ait.txt

7.18.10 EAC confirmed MACE by sex - summary - in-trial - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects								
Male	1268				1219			
Female	902				951			
PYO (years)								
Male	997.16				953.96			
Female	709.95				748.18			
EAC confirmed MACE								
All								
Male	17	(1.3)	19	1.84	18	(1.5)	22	2.20
Female	5	(0.6)	5	0.77	8	(0.8)	8	0.90
CV death								
Male	2	(0.2)	2	0.21	5	(0.4)	5	0.52
Female	0				1	(0.1)	1	0.10
Acute myocardial infarction								
Male	14	(1.1)	15	1.42	8	(0.7)	9	0.91
Female	3	(0.3)	3	0.39	4	(0.4)	4	0.41
Stroke								
Male	2	(0.2)	2	0.20	8	(0.7)	8	0.78
Female	2	(0.2)	2	0.38	3	(0.3)	3	0.39

%: Percentage of subjects with one or more events, CV: Cardiovascular, E: Number of adverse events, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke), N: Number of subjects with one or more events, NSTEMI: Non-ST-segment elevation myocardial infarction, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). STEMI: ST-segment elevation myocardial infarction. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial status is defined based on the onset date as decided by the EAC. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adsl.xpt; variable(s): INTRDURY SEX; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool"
adadj.xpt; variable(s): ADJOUT SEX; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool" & (ANL01FL) == "Y" & MACEFL == "Y"

7.18.11 EAC confirmed MACE by race - summary - in-trial - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects								
White	1563				1522			
Black or African American	76				73			
Asian	469				524			
Other	47				34			
Missing	15				17			
PYO (years)								
White	1262.41				1236.06			
Black or African American	57.64				60.25			
Asian	336.28				368.69			
Other	41.25				27.03			
Missing	9.53				10.10			
EAC confirmed MACE								
All								
White	16	(1.0)	17	1.33	21	(1.4)	24	1.89
Black or African American	1	(1.5)	1	2.48	1	(1.3)	2	2.67
Asian	3	(0.6)	3	1.07	4	(0.8)	4	0.92
Other	2		3		0			
Missing	0				0			
CV death								
White	1	(0.1)	1	0.11	3	(0.2)	3	0.30
Black or African American	0				1	(1.3)	1	1.34
Asian	0				2	(0.4)	2	0.42
Other	1		1		0			
Missing	0				0			
Acute myocardial infarction								
White	12	(0.8)	13	0.95	10	(0.7)	11	0.80
Black or African American	0				1	(1.3)	1	1.34
Asian	3	(0.6)	3	1.07	1	(0.2)	1	0.30
Other	2		2		0			
Missing	0				0			
Stroke								
White	3	(0.2)	3	0.27	10	(0.7)	10	0.79
Black or African American	1	(1.5)	1	2.48	0			
Asian	0				1	(0.2)	1	0.19
Other	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, CV: Cardiovascular, E: Number of adverse events, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke), N: Number of subjects with one or more events, NSTEMI: Non-ST-segment elevation myocardial infarction, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). STEMI: ST-segment elevation myocardial infarction. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial status is defined based on the onset date as decided by the EAC. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.18.12 EAC confirmed MACE by ethnicity - summary - in-trial - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects								
Hispanic or Latino	257				264			
Not Hispanic or Latino	1898				1889			
Missing	15				17			
PYO (years)								
Hispanic or Latino	195.33				197.63			
Not Hispanic or Latino	1502.41				1494.40			
Missing	9.37				10.10			
EAC confirmed MACE								
All								
Hispanic or Latino	3	(1.2)	3	2.01	1	(0.4)	2	0.77
Not Hispanic or Latino	19	(1.0)	21	1.35	25	(1.3)	28	1.75
Missing	0				0			
CV death								
Hispanic or Latino	0				0			
Not Hispanic or Latino	2	(0.1)	2	0.14	6	(0.3)	6	0.39
Missing	0				0			
Acute myocardial infarction								
Hispanic or Latino	2	(0.8)	2	1.32	1	(0.4)	2	0.77
Not Hispanic or Latino	15	(0.8)	16	0.98	11	(0.6)	11	0.68
Missing	0				0			
Stroke								
Hispanic or Latino	1	(0.4)	1	0.69	0			
Not Hispanic or Latino	3	(0.2)	3	0.23	11	(0.6)	11	0.68
Missing	0				0			

%: Percentage of subjects with one or more events, CV: Cardiovascular, E: Number of adverse events, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke), N: Number of subjects with one or more events, NSTEMI: Non-ST-segment elevation myocardial infarction, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). STEMI: ST-segment elevation myocardial infarction. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial status is defined based on the onset date as decided by the EAC. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.18.13 EAC confirmed MACE by cardiovascular history - summary - in-trial - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects								
Yes	501				472			
No	1669				1698			
PYO (years)								
Yes	410.77				369.02			
No	1296.34				1333.11			
EAC confirmed MACE								
All								
Yes	10	(2.0)	11	2.77	10	(2.2)	11	2.96
No	12	(0.7)	13	1.01	16	(0.9)	19	1.23
CV death								
Yes	1	(0.2)	1	0.42	2	(0.5)	2	0.61
No	1	(0.1)	1	0.06	4	(0.2)	4	0.27
Acute myocardial infarction								
Yes	7	(1.4)	8	1.83	3	(0.6)	3	0.76
No	10	(0.6)	10	0.75	9	(0.5)	10	0.65
Stroke								
Yes	2	(0.4)	2	0.52	6	(1.3)	6	1.59
No	2	(0.1)	2	0.20	5	(0.3)	5	0.32

%: Percentage of subjects with one or more events, CV: Cardiovascular, E: Number of adverse events, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke), N: Number of subjects with one or more events, NSTEMI: Non-ST-segment elevation myocardial infarction, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). STEMI: ST-segment elevation myocardial infarction. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial status is defined based on the onset date as decided by the EAC. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.18.14 All cardiovascular events sent to event adjudication committee - safety analysis set - phase 3a pool

Study ID/Subject ID/ Treatment/Age/Sex/BMI	AE no./ Source	Adjudicated event type	Onset date/ trial day (Investigator)	Onset date/ trial day (EAC)	Adjudication phase	EAC outcome
NN1436-4477/106008/ Ico/4[redacted]/Male/3[redacted]	NA/ Investigator reported	Death		03SEP2021/ 219	Event adjudication committee	Non-cardiovascular death
NN1436-4477/110004/ Ico/5[redacted]/Female/3[redacted]	5/ Ae preferred term search	Acute coronary syndrome	27SEP2021/ 176		Event adjudication committee	Diagnostic criteria unmet
NN1436-4477/111001/ Ico/7[redacted]/Male/3[redacted]	4/ Ae preferred term search	Heart failure	20JUL2021/ 162	27JUL2021/ 169	Event adjudication committee	Heart failure
NN1436-4477/116002/ IGlar/6[redacted]/Female/3[redacted]	5/ Investigator reported	Cerebrovascular event	16NOV2021/ 344	16NOV2021/ 344	Primary adjudicator	Stroke
NN1436-4477/120005/ IGlar/7[redacted]/Female/3[redacted]	1/ Investigator reported	Acute coronary syndrome	16DEC2021/ 290		Primary adjudicator	Diagnostic criteria unmet
NN1436-4477/124005/ IGlar/6[redacted]/Male/3[redacted]	2/ Investigator reported	Acute coronary syndrome	09MAY2021/ 31	09MAY2021/ 31	Primary adjudicator	Acute myocardial infarction
	5/ Ae preferred term search	Heart failure	09MAY2021/ 31	09MAY2021/ 31	Primary adjudicator	Heart failure
	11/ Investigator reported	Acute coronary syndrome	09MAY2021/ 31	09MAY2021/ 31	Primary adjudicator	Acute myocardial infarction
	4/ Investigator reported	Heart failure	13MAY2021/ 35		Primary adjudicator	Diagnostic criteria unmet
NN1436-4477/125002/ Ico/6[redacted]/Male/3[redacted]	2/ Ae preferred term search	Acute coronary syndrome	31DEC2021/ 291	03JAN2022/ 294	Primary adjudicator	Unstable angina pectoris
	3/ Investigator reported	Acute coronary syndrome	31DEC2021/ 291		Event adjudication committee	Diagnostic criteria unmet
NN1436-4477/144007/ Ico/6[redacted]/Female/3[redacted]	7/ Investigator reported	Acute coronary syndrome	02SEP2021/ 128		Primary adjudicator	Diagnostic criteria unmet
NN1436-4477/159001/ Ico/7[redacted]/Male/2[redacted]	6/ Ae preferred term search	Heart failure	09DEC2021/ 324		Primary adjudicator	Diagnostic criteria unmet

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke). Death events are always adjudicated in Consensus. Trial day is derived as onset date minus date of first dose of trial product + 1. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adadj.xpt; variable(s): STUDYID SUBJID TRTA AGE SEX BMIBL ZALNKID SOURCE ZAOBJ AESTDT AESTDY ADJDT ADJDY ZAEVALID ADJOUT; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool"

All cardiovascular events sent to event adjudication committee - safety analysis set - phase 3a pool

Study ID/Subject ID/ Treatment/Age/Sex/BMI	AE no./ Source	Adjudicated event type	Onset date/ trial day (Investigator)	Onset date/ trial day (EAC)	Adjudication phase	EAC outcome
NN1436-4477/204006/ IGlar/6[redacted]/Male/2[redacted]	1/ Ae preferred term search	Cerebrovascular event	22JUL2021/ 130		Primary adjudicator	Diagnostic criteria unmet
	2/ Investigator reported	Cerebrovascular event	20JUL2021/ 128	20JUL2021/ 128	Primary adjudicator	Stroke
NN1436-4477/206010/ Ico/6[redacted]/Female/3[redacted]	1/ Investigator reported	Cerebrovascular event	19JAN2022/ 296		Primary adjudicator	Diagnostic criteria unmet
	2/ Ae preferred term search	Cerebrovascular event	26JAN2022/ 303		Primary adjudicator	Diagnostic criteria unmet
	3/ Ae preferred term search	Cerebrovascular event	20JAN2022/ 297		Primary adjudicator	Diagnostic criteria unmet
	6/ Ae preferred term search	Heart failure	19JAN2022/ 296		Primary adjudicator	Diagnostic criteria unmet
NN1436-4477/208009/ IGlar/6[redacted]/Male/3[redacted]	2/ Investigator reported	Cerebrovascular event	12OCT2021/ 203		Primary adjudicator	Diagnostic criteria unmet
NN1436-4477/210005/ IGlar/5[redacted]/Female/2[redacted]	1/ Investigator reported	Heart failure	21MAY2021/ 60		Event adjudication committee	Diagnostic criteria unmet
	3/ Investigator reported	Acute coronary syndrome	20SEP2021/ 182	20SEP2021/ 182	Event adjudication committee	Acute myocardial infarction
NN1436-4477/211005/ IGlar/6[redacted]/Female/2[redacted]	1/ Investigator reported	Cerebrovascular event	25NOV2021/ 240		Primary adjudicator	Diagnostic criteria unmet
NN1436-4477/213003/ IGlar/6[redacted]/Male/3[redacted]	4/ Ae preferred term search	Cerebrovascular event	01OCT2021/ 199		Event adjudication committee	Diagnostic criteria unmet
	5/ Ae preferred term search	Cerebrovascular event	01OCT2021/ 199		Primary adjudicator	Diagnostic criteria unmet

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke). Death events are always adjudicated in Consensus. Trial day is derived as onset date minus date of first dose of trial product + 1. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adadj.xpt; variable(s): STUDYID SUBJID TRTA AGE SEX BMIBL ZALNKID SOURCE ZAOBJ AESTDT AESTDY ADJDT ADJDY ZAEVALID ADJOUT; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool"

All cardiovascular events sent to event adjudication committee - safety analysis set - phase 3a pool

Study ID/Subject ID/ Treatment/Age/Sex/BMI	AE no./ Source	Adjudicated event type	Onset date/ trial day (Investigator)	Onset date/ trial day (EAC)	Adjudication phase	EAC outcome
NN1436-4477/213010/ Ico/5[redacted]/Male/2[redacted]	3/ Investigator reported	Acute coronary syndrome	24FEB2022/ 324		Primary adjudicator	Diagnostic criteria unmet
	6/ Ae preferred term search	Heart failure	09MAR2022/ 337		Primary adjudicator	Diagnostic criteria unmet
	4/ Ae preferred term search	Acute coronary syndrome	28FEB2022/ 328		Event adjudication committee	Diagnostic criteria unmet
	5/ Ae preferred term search	Acute coronary syndrome	01MAR2022/ 329		Event adjudication committee	Diagnostic criteria unmet
NN1436-4477/214001/ Ico/5[redacted]/Male/3[redacted]	5/ Ae preferred term search	Cerebrovascular event	12OCT2021/ 216		Event adjudication committee	Diagnostic criteria unmet
NN1436-4477/214004/ IGlar/6[redacted]/Female/2[redacted]	1/ Ae preferred term search	Cerebrovascular event	07MAY2021/ 51		Primary adjudicator	Diagnostic criteria unmet
	3/ Ae preferred term search	Cerebrovascular event	12JUL2021/ 117		Primary adjudicator	Diagnostic criteria unmet
NN1436-4477/301004/ IGlar/6[redacted]/Male/3[redacted]	2/ Ae preferred term search	Cerebrovascular event	24NOV2021/ 276	24NOV2021/ 276	Primary adjudicator	Stroke
NN1436-4477/301010/ Ico/6[redacted]/Male/3[redacted]	5/ Investigator reported	Cerebrovascular event	13JUL2021/ 85	13JUL2021/ 85	Primary adjudicator	Stroke
NN1436-4477/406001/ IGlar/7[redacted]/Male/2[redacted]	NA/ Investigator reported	Death		23NOV2021/ 349	Event adjudication committee	Cardiovascular death
NN1436-4477/408002/ IGlar/5[redacted]/Male/2[redacted]	1/ Ae preferred term search	Cerebrovascular event	07AUG2021/ 103	15AUG2021/ 111	Event adjudication committee	Stroke
	5/ Ae preferred term search	Acute coronary syndrome	26APR2022/ 365		Primary adjudicator	Diagnostic criteria unmet
NN1436-4477/453001/ IGlar/5[redacted]/Male/2[redacted]	1/ Ae preferred term search	Cerebrovascular event	26FEB2021/ 78		Primary adjudicator	Diagnostic criteria unmet

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke). Death events are always adjudicated in Consensus. Trial day is derived as onset date minus date of first dose of trial product + 1. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adadj.xpt; variable(s): STUDYID SUBJID TRTA AGE SEX BMIBL ZALNKID SOURCE ZAOBJ AESTDT AESTDY ADJDT ADJDY ZAEVALID ADJOUT; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool"

All cardiovascular events sent to event adjudication committee - safety analysis set - phase 3a pool

Study ID/Subject ID/ Treatment/Age/Sex/BMI	AE no./ Source	Adjudicated event type	Onset date/ trial day (Investigator)	Onset date/ trial day (EAC)	Adjudication phase	EAC outcome
NN1436-4477/453005/ Ico/6[redacted]/Female/3[redacted]	9/ Investigator reported	Heart failure	07JUL2021/ 169	06JUL2021/ 168	Primary adjudicator	Heart failure
	801/ Adjudicator	Acute coronary syndrome			Event adjudication committee	Diagnostic criteria unmet
NN1436-4477/453006/ Ico/6[redacted]/Male/3[redacted]	4/ Investigator reported	Heart failure	12JAN2022/ 350		Primary adjudicator	Diagnostic criteria unmet
NN1436-4477/453012/ Ico/5[redacted]/Male/3[redacted]	4/ Investigator reported	Heart failure	06OCT2021/ 195		Primary adjudicator	Diagnostic criteria unmet
NN1436-4477/455002/ Ico/7[redacted]/Male/2[redacted]	NA/ Investigator reported	Death			Event adjudication committee	Non-cardiovascular death
NN1436-4477/456002/ Ico/7[redacted]/Male/2[redacted]	4/ Investigator reported	Cerebrovascular event	17MAR2021/ 80		Primary adjudicator	Diagnostic criteria unmet
	NA/ Investigator reported	Death		04JUN2021/ 159	Event adjudication committee	Non-cardiovascular death
NN1436-4477/456006/ IGlar/7[redacted]/Female/3[redacted]	NA/ Investigator reported	Death		11JUN2021/ 134	Event adjudication committee	Cardiovascular death
NN1436-4477/458003/ Ico/7[redacted]/Male/2[redacted]	1/ Investigator reported	Acute coronary syndrome	23FEB2022/ 345	23FEB2022/ 345	Primary adjudicator	Acute myocardial infarction
NN1436-4477/501012/ IGlar/6[redacted]/Female/3[redacted]	5/ Investigator reported	Heart failure	20MAR2022/ 355		Event adjudication committee	Another type of event
	5/ Eac decided event type	Acute coronary syndrome	20MAR2022/ 355	20MAR2022/ 355	Primary adjudicator	Acute myocardial infarction
NN1436-4477/502003/ Ico/5[redacted]/Male/2[redacted]	1/ Investigator reported	Acute coronary syndrome	13MAR2022/ 321	13MAR2022/ 321	Primary adjudicator	Acute myocardial infarction
NN1436-4477/604010/ Ico/5[redacted]/Male/2[redacted]	1/ Investigator reported	Acute coronary syndrome	11OCT2021/ 182	12OCT2021/ 183	Event adjudication committee	Acute myocardial infarction

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke). Death events are always adjudicated in Consensus. Trial day is derived as onset date minus date of first dose of trial product + 1. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adadj.xpt; variable(s): STUDYID SUBJID TRTA AGE SEX BMIBL ZALNKID SOURCE ZAOBJ AESTDT AESTDY ADJDT ADJDY ZAEVALID ADJOUT; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool"

All cardiovascular events sent to event adjudication committee - safety analysis set - phase 3a pool

Study ID/Subject ID/ Treatment/Age/Sex/BMI	AE no./ Source	Adjudicated event type	Onset date/ trial day (Investigator)	Onset date/ trial day (EAC)	Adjudication phase	EAC outcome
NN1436-4477/604011/ Ico/6[redacted]/Male/2[redacted]	1/ Investigator reported	Acute coronary syndrome	22SEP2021/ 169	23SEP2021/ 170	Event adjudication committee	Acute myocardial infarction
	NA/ Investigator reported	Death		27SEP2021/ 174	Event adjudication committee	Cardiovascular death
NN1436-4477/701003/ Ico/6[redacted]/Male/3[redacted]	1/ Investigator reported	Acute coronary syndrome	25MAR2021/ 9	25MAR2021/ 9	Primary adjudicator	Acute myocardial infarction
NN1436-4477/701007/ IGlar/6[redacted]/Male/2[redacted]	1/ Investigator reported	Acute coronary syndrome	31AUG2021/ 141	31AUG2021/ 141	Event adjudication committee	Acute myocardial infarction
NN1436-4477/801008/ IGlar/6[redacted]/Female/2[redacted]	2/ Investigator reported	Acute coronary syndrome	17JUN2021/ 80	17JUN2021/ 80	Event adjudication committee	Acute myocardial infarction
NN1436-4477/851001/ Ico/6[redacted]/Male/3[redacted]	1/ Investigator reported	Heart failure	06AUG2021/ 241		Primary adjudicator	Another type of event
	3/ Investigator reported	Heart failure	13SEP2021/ 279		Event adjudication committee	Diagnostic criteria unmet
	1/ Eac decided event type	Acute coronary syndrome	06AUG2021/ 241	09AUG2021/ 244	Event adjudication committee	Acute myocardial infarction
NN1436-4477/951007/ IGlar/4[redacted]/Male/2[redacted]	6/ Investigator reported	Acute coronary syndrome	17FEB2022/ 349		Event adjudication committee	Diagnostic criteria unmet
NN1436-4478/206001/ Ico/5[redacted]/Male/3[redacted]	5/ Investigator reported	Acute coronary syndrome	26AUG2021/ 122	26AUG2021/ 122	Primary adjudicator	Acute myocardial infarction
NN1436-4478/206002/ Ico/7[redacted]/Female/2[redacted]	1/ Ae preferred term search	Cerebrovascular event	27MAY2021/ 24	27MAY2021/ 24	Event adjudication committee	Stroke
NN1436-4478/218002/ Ico/5[redacted]/Male/3[redacted]	1/ Investigator reported	Cerebrovascular event	27AUG2021/ 115	27AUG2021/ 115	Event adjudication committee	Stroke
	2/ Ae preferred term search	Cerebrovascular event	28AUG2021/ 116		Primary adjudicator	Diagnostic criteria unmet

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke). Death events are always adjudicated in Consensus. Trial day is derived as onset date minus date of first dose of trial product + 1. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adadj.xpt; variable(s): STUDYID SUBJID TRTA AGE SEX BMIBL ZALNKID SOURCE ZAOBJ AESTDT AESTDY ADJDT ADJDY ZAEVALID ADJOUT; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool"

All cardiovascular events sent to event adjudication committee - safety analysis set - phase 3a pool

Study ID/Subject ID/ Treatment/Age/Sex/BMI	AE no./ Source	Adjudicated event type	Onset date/ trial day (Investigator)	Onset date/ trial day (EAC)	Adjudication phase	EAC outcome
NN1436-4478/504008/ Ico/7[redacted]/Male/2[redacted]	NA/ Investigator reported	Death		17OCT2021/ 158	Event adjudication committee	Non-cardiovascular death
NN1436-4478/505005/ Ico/6[redacted]/Male/3[redacted]	NA/ Investigator reported	Death		27SEP2021/ 110	Event adjudication committee	Non-cardiovascular death
NN1436-4478/601005/ IDeg/7[redacted]/Male/3[redacted]	1/ Investigator reported	Cerebrovascular event	30JUL2021/ 101	30JUL2021/ 101	Primary adjudicator	Stroke
	NA/ Investigator reported	Death		10AUG2021/ 112	Event adjudication committee	Cardiovascular death
NN1436-4478/601012/ IDeg/7[redacted]/Male/3[redacted]	1/ Investigator reported	Cerebrovascular event	09DEC2021/ 184	09DEC2021/ 184	Event adjudication committee	Stroke
NN1436-4478/803010/ Ico/6[redacted]/Male/2[redacted]	1/ Investigator reported	Acute coronary syndrome	08JUN2021/ 68	08JUN2021/ 68	Event adjudication committee	Acute myocardial infarction
	2/ Ae preferred term search	Heart failure	08JUN2021/ 68		Primary adjudicator	Diagnostic criteria unmet
NN1436-4478/804006/ IDeg/6[redacted]/Female/2[redacted]	NA/ Investigator reported	Death		16SEP2021/ 168	Event adjudication committee	Non-cardiovascular death
NN1436-4478/904001/ IDeg/6[redacted]/Male/2[redacted]	1/ Investigator reported	Acute coronary syndrome	05JUL2021/ 105	05JUL2021/ 105	Event adjudication committee	Acute myocardial infarction
NN1436-4479/314008/ Ico/7[redacted]/Male/3[redacted]	NA/ Investigator reported	Death		30SEP2021/ 15	Event adjudication committee	Undetermined cause of death
NN1436-4479/315013/ Ico/6[redacted]/Male/3[redacted]	5/ Ae preferred term search	Acute coronary syndrome	10FEB2022/ 162		Event adjudication committee	Diagnostic criteria unmet
NN1436-4479/402030/ Ico/6[redacted]/Female/3[redacted]	6/ Investigator reported	Cerebrovascular event	01MAY2022/ 173	01MAY2022/ 173	Event adjudication committee	Stroke

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke). Death events are always adjudicated in Consensus. Trial day is derived as onset date minus date of first dose of trial product + 1. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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All cardiovascular events sent to event adjudication committee - safety analysis set - phase 3a pool

Study ID/Subject ID/ Treatment/Age/Sex/BMI	AE no./ Source	Adjudicated event type	Onset date/ trial day (Investigator)	Onset date/ trial day (EAC)	Adjudication phase	EAC outcome
NN1436-4479/601005/ Ico/6[redacted]/Male/3[redacted]	3/ Investigator reported	Heart failure	14JAN2022/ 94		Primary adjudicator	Diagnostic criteria unmet
NN1436-4479/713002/ Ico/4[redacted]/Male/3[redacted]	2/ Ae preferred term search	Acute coronary syndrome			Primary adjudicator	Diagnostic criteria unmet
NN1436-4479/716004/ IDeg/6[redacted]/Male/2[redacted]	4/ Investigator reported	Acute coronary syndrome	01DEC2021/ 64	01DEC2021/ 64	Primary adjudicator	Acute myocardial infarction
	NA/ Investigator reported	Death		01DEC2021/ 64	Event adjudication committee	Cardiovascular death
NN1436-4479/901010/ Ico/6[redacted]/Male/3[redacted]	NA/ Investigator reported	Death		01APR2022/ 180	Event adjudication committee	Non-cardiovascular death
NN1436-4480/203024/ Ico/6[redacted]/Male/3[redacted]	1/ Investigator reported	Acute coronary syndrome	14OCT2021/ 3	18OCT2021/ 7	Event adjudication committee	Acute myocardial infarction
NN1436-4480/303002/ Ico/6[redacted]/Male/3[redacted]	4/ Ae preferred term search	Cerebrovascular event	27OCT2021/ 77		Primary adjudicator	Diagnostic criteria unmet
	5/ Ae preferred term search	Cerebrovascular event	27OCT2021/ 77		Primary adjudicator	Diagnostic criteria unmet
	6/ Ae preferred term search	Cerebrovascular event	27OCT2021/ 77		Primary adjudicator	Diagnostic criteria unmet
NN1436-4480/304004/ IGlar/5[redacted]/Male/2[redacted]	NA/ Investigator reported	Death		15JAN2022/ 138	Event adjudication committee	Non-cardiovascular death
NN1436-4480/311010/ IGlar/5[redacted]/Female/3[redacted]	3/ Ae preferred term search	Heart failure	23DEC2021/ 116		Event adjudication committee	Diagnostic criteria unmet
	5/ Investigator reported	Heart failure	25JAN2022/ 149		Primary adjudicator	Diagnostic criteria unmet
NN1436-4480/311015/ Ico/7[redacted]/Male/3[redacted]	NA/ Investigator reported	Death		21MAR2022/ 174	Event adjudication committee	Cardiovascular death

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke). Death events are always adjudicated in Consensus. Trial day is derived as onset date minus date of first dose of trial product + 1. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adadj.xpt; variable(s): STUDYID SUBJID TRTA AGE SEX BMIBL ZALNKID SOURCE ZAOBJ AESTDT AESTDY ADJDT ADJDY ZAEVALID ADJOUT; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool"

All cardiovascular events sent to event adjudication committee - safety analysis set - phase 3a pool

Study ID/Subject ID/ Treatment/Age/Sex/BMI	AE no./ Source	Adjudicated event type	Onset date/ trial day (Investigator)	Onset date/ trial day (EAC)	Adjudication phase	EAC outcome
NN1436-4480/406001/ IGlar/6[redacted]/Female/3[redacted]	13/ Ae preferred term search	Cerebrovascular event	01OCT2021/ 92		Primary adjudicator	Diagnostic criteria unmet
	28/ Investigator reported	Acute coronary syndrome	26JAN2022/ 209		Primary adjudicator	Diagnostic criteria unmet
NN1436-4480/416011/ Ico/7[redacted]/Male/3[redacted]	2/ Ae preferred term search	Cerebrovascular event	07MAR2022/ 119		Primary adjudicator	Diagnostic criteria unmet
NN1436-4480/423002/ IGlar/6[redacted]/Male/3[redacted]	2/ Investigator reported	Acute coronary syndrome	18FEB2022/ 183	18FEB2022/ 183	Event adjudication committee	Acute myocardial infarction
NN1436-4480/423004/ IGlar/6[redacted]/Female/2[redacted]	1/ Investigator reported	Cerebrovascular event	16OCT2021/ 5	16OCT2021/ 5	Primary adjudicator	Stroke
	801/ Adjudicator	Acute coronary syndrome			Event adjudication committee	Diagnostic criteria unmet
NN1436-4480/428004/ Ico/6[redacted]/Male/2[redacted]	3/ Investigator reported	Acute coronary syndrome	19JAN2022/ 190	19JAN2022/ 190	Primary adjudicator	Acute myocardial infarction
NN1436-4480/430006/ IGlar/6[redacted]/Male/3[redacted]	1/ Investigator reported	Heart failure	13JAN2022/ 92	13JAN2022/ 92	Primary adjudicator	Heart failure
NN1436-4480/507012/ Ico/5[redacted]/Male/3[redacted]	1/ Investigator reported	Acute coronary syndrome	19NOV2021/ 65	20NOV2021/ 66	Event adjudication committee	Acute myocardial infarction
NN1436-4480/517009/ Ico/6[redacted]/Female/3[redacted]	1/ Ae preferred term search	Acute coronary syndrome	17FEB2022/ 135	18FEB2022/ 136	Event adjudication committee	Acute myocardial infarction
NN1436-4480/702001/ IGlar/5[redacted]/Male/3[redacted]	4/ Investigator reported	Cerebrovascular event	24NOV2021/ 133		Primary adjudicator	Diagnostic criteria unmet
NN1436-4480/804006/ IGlar/6[redacted]/Male/3[redacted]	3/ Investigator reported	Heart failure	27DEC2021/ 90	27DEC2021/ 90	Primary adjudicator	Heart failure
	7/ Investigator reported	Heart failure	04FEB2022/ 129	07FEB2022/ 132	Event adjudication committee	Heart failure

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke). Death events are always adjudicated in Consensus. Trial day is derived as onset date minus date of first dose of trial product + 1. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adadj.xpt; variable(s): STUDYID SUBJID TRTA AGE SEX BMIBL ZALNKID SOURCE ZAOBJ AESTDT AESTDY ADJDT ADJDY ZAEVALID ADJOUT; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool"

All cardiovascular events sent to event adjudication committee - safety analysis set - phase 3a pool

Study ID/Subject ID/ Treatment/Age/Sex/BMI	AE no./ Source	Adjudicated event type	Onset date/ trial day (Investigator)	Onset date/ trial day (EAC)	Adjudication phase	EAC outcome
NN1436-4480/905004/ Ico/6[redacted]/Male/3[redacted]	NA/ Investigator reported	Death		04FEB2022/ 136	Event adjudication committee	Non-cardiovascular death
NN1436-4481/104008/ OD analogues/5[redacted]/ Female/2[redacted]	NA/ Investigator reported	Death		06AUG2022/ 410	Event adjudication committee	Non-cardiovascular death
NN1436-4481/107001/ OD analogues/6[redacted]/ Male/2[redacted]	2/ Investigator reported	Cerebrovascular event	03DEC2021/ 190	03DEC2021/ 190	Primary adjudicator	Stroke
	4/ Ae preferred term search	Heart failure	07DEC2021/ 194		Primary adjudicator	Diagnostic criteria unmet
NN1436-4481/108005/ OD analogues/5[redacted]/ Male/4[redacted]	4/ Ae preferred term search	Cerebrovascular event	20JUN2022/ 377	21JUN2022/ 378	Event adjudication committee	Stroke
NN1436-4481/109003/ OD analogues/6[redacted]/ Male/2[redacted]	2/ Investigator reported	Acute coronary syndrome	02JUL2021/ 38	02JUL2021/ 38	Primary adjudicator	Acute myocardial infarction
NN1436-4481/109009/ Ico/5[redacted]/Male/2[redacted]	1/ Investigator reported	Acute coronary syndrome	26JUL2021/ 20	26JUL2021/ 20	Primary adjudicator	Acute myocardial infarction
	2/ Investigator reported	Acute coronary syndrome	26JUL2021/ 20	26JUL2021/ 20	Event adjudication committee	Acute myocardial infarction
NN1436-4481/111006/ OD analogues/7[redacted]/ Female/3[redacted]	NA/ Investigator reported	Death		21MAR2022/ 266	Event adjudication committee	Undetermined cause of death
NN1436-4481/114006/ Ico/6[redacted]/Male/3[redacted]	3/ Investigator reported	Acute coronary syndrome	19JUN2022/ 384	19JUN2022/ 384	Event adjudication committee	Acute myocardial infarction

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke). Death events are always adjudicated in Consensus. Trial day is derived as onset date minus date of first dose of trial product + 1. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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All cardiovascular events sent to event adjudication committee - safety analysis set - phase 3a pool

Study ID/Subject ID/ Treatment/Age/Sex/BMI	AE no./ Source	Adjudicated event type	Onset date/ trial day (Investigator)	Onset date/ trial day (EAC)	Adjudication phase	EAC outcome
NN1436-4481/200006/ Ico/5[redacted]/Male/3[redacted]	3/ Investigator reported	Heart failure	30JUL2021/ 51	30JUL2021/ 51	Primary adjudicator	Heart failure
NN1436-4481/203005/ Ico/5[redacted]/Female/3[redacted]	3/ Investigator reported	Heart failure	17MAR2022/ 281		Primary adjudicator	Diagnostic criteria unmet
	5/ Investigator reported	Cerebrovascular event	25MAY2022/ 350		Event adjudication committee	Stroke
	801/ Adjudicator	Cerebrovascular event			Event adjudication committee	Stroke
NN1436-4481/204004/ Ico/5[redacted]/Male/2[redacted]	1/ Investigator reported	Acute coronary syndrome	11OCT2021/ 120		Primary adjudicator	Diagnostic criteria unmet
	801/ Adjudicator	Acute coronary syndrome			Event adjudication committee	Diagnostic criteria unmet
NN1436-4481/204007/ Ico/5[redacted]/Male/3[redacted]	1/ Investigator reported	Acute coronary syndrome	16SEP2021/ 94		Primary adjudicator	Diagnostic criteria unmet
NN1436-4481/205028/ Ico/6[redacted]/Female/1[redacted]	4/ Investigator reported	Heart failure	01DEC2021/ 178	09DEC2021/ 186	Event adjudication committee	Heart failure
	13/ Investigator reported	Heart failure		03MAY2022/ 331	Primary adjudicator	Heart failure
	15/ Investigator reported	Heart failure			Event adjudication committee	Diagnostic criteria unmet
	NA/ Investigator reported	Death		16JUL2022/ 405	Event adjudication committee	Undetermined cause of death
NN1436-4481/214001/ OD analogues/5[redacted]/ Female/4[redacted]	2/ Investigator reported	Acute coronary syndrome	13NOV2021/ 180		Event adjudication committee	Diagnostic criteria unmet
NN1436-4481/402002/ OD analogues/6[redacted]/ Male/2[redacted]	2/ Investigator reported	Acute coronary syndrome	27MAY2021/ 72		Primary adjudicator	Diagnostic criteria unmet

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke). Death events are always adjudicated in Consensus. Trial day is derived as onset date minus date of first dose of trial product + 1. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adadj.xpt; variable(s): STUDYID SUBJID TRTA AGE SEX BMIBL ZALNKID SOURCE ZAOBJ AESTDT AESTDY ADJDT ADJDY ZAEVALID ADJOUT; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool"

All cardiovascular events sent to event adjudication committee - safety analysis set - phase 3a pool

Study ID/Subject ID/ Treatment/Age/Sex/BMI	AE no./ Source	Adjudicated event type	Onset date/ trial day (Investigator)	Onset date/ trial day (EAC)	Adjudication phase	EAC outcome
NN1436-4481/408005/ Ico/5[redacted]/Male/4[redacted]	1/ Investigator reported	Acute coronary syndrome	10FEB2022/ 246		Primary adjudicator	Diagnostic criteria unmet
NN1436-4481/501007/ Ico/6[redacted]/Male/2[redacted]	1/ Investigator reported	Heart failure	22FEB2022/ 247		Primary adjudicator	Diagnostic criteria unmet
	NA/ Investigator reported	Death		24FEB2022/ 249	Event adjudication committee	Undetermined cause of death
NN1436-4481/520005/ Ico/5[redacted]/Male/3[redacted]	2/ Ae preferred term search	Cerebrovascular event	21APR2022/ 297		Primary adjudicator	Diagnostic criteria unmet
NN1436-4481/521010/ OD analogues/6[redacted]/ Male/3[redacted]	1/ Investigator reported	Acute coronary syndrome	20MAY2021/ 1	27MAY2021/ 8	Event adjudication committee	Unstable angina pectoris
	2/ Investigator reported	Acute coronary syndrome	01JUN2021/ 13		Primary adjudicator	Diagnostic criteria unmet
NN1436-4481/534001/ OD analogues/5[redacted]/ Female/3[redacted]	1/ Investigator reported	Cerebrovascular event	23FEB2022/ 331	23FEB2022/ 331	Primary adjudicator	Stroke
NN1436-4481/550005/ OD analogues/6[redacted]/ Male/2[redacted]	NA/ Investigator reported	Death		27JAN2022/ 226	Event adjudication committee	Cardiovascular death
NN1436-4481/551003/ Ico/7[redacted]/Male/4[redacted]	NA/ Investigator reported	Death		08APR2022/ 317	Event adjudication committee	Non-cardiovascular death
NN1436-4481/553005/ Ico/7[redacted]/Male/4[redacted]	1/ Ae preferred term search	Heart failure	14AUG2021/ 132	17AUG2021/ 135	Primary adjudicator	Heart failure

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke). Death events are always adjudicated in Consensus. Trial day is derived as onset date minus date of first dose of trial product + 1. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adadj.xpt; variable(s): STUDYID SUBJID TRTA AGE SEX BMIBL ZALNKID SOURCE ZAOBJ AESTDT AESTDY ADJDT ADJDY ZAEVALID ADJOUT; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool"

All cardiovascular events sent to event adjudication committee - safety analysis set - phase 3a pool

Study ID/Subject ID/ Treatment/Age/Sex/BMI	AE no./ Source	Adjudicated event type	Onset date/ trial day (Investigator)	Onset date/ trial day (EAC)	Adjudication phase	EAC outcome
NN1436-4481/564006/ OD analogues/6[redacted]/ Male/2[redacted]	1/ Investigator reported	Acute coronary syndrome	03SEP2021/ 66	03SEP2021/ 66	Event adjudication committee	Acute myocardial infarction
	NA/ Investigator reported	Death		19SEP2021/ 82	Event adjudication committee	Cardiovascular death
NN1436-4481/577002/ OD analogues/6[redacted]/ Male/4[redacted]	2/ Investigator reported	Acute coronary syndrome	17MAR2022/ 317		Primary adjudicator	Diagnostic criteria unmet
NN1436-4481/578002/ OD analogues/8[redacted]/ Male/5[redacted]	NA/ Investigator reported	Death		26JAN2022/ 219	Event adjudication committee	Non-cardiovascular death
NN1436-4481/601002/ OD analogues/6[redacted]/ Male/3[redacted]	NA/ Investigator reported	Death		11MAR2022/ 346	Event adjudication committee	Non-cardiovascular death
NN1436-4481/602025/ OD analogues/5[redacted]/ Male/2[redacted]	4/ Ae preferred term search	Cerebrovascular event	22SEP2021/ 80		Primary adjudicator	Diagnostic criteria unmet
	5/ Investigator reported	Cerebrovascular event	21JUL2021/ 17		Primary adjudicator	Diagnostic criteria unmet
NN1436-4481/608002/ Ico/6[redacted]/Male/3[redacted]	2/ Ae preferred term search	Cerebrovascular event	17MAR2022/ 364		Primary adjudicator	Diagnostic criteria unmet
NN1436-4481/609002/ Ico/5[redacted]/Male/3[redacted]	1/ Ae preferred term search	Cerebrovascular event	19NOV2021/ 183		Primary adjudicator	Diagnostic criteria unmet

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke). Death events are always adjudicated in Consensus. Trial day is derived as onset date minus date of first dose of trial product + 1. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adadj.xpt; variable(s): STUDYID SUBJID TRTA AGE SEX BMIBL ZALNKID SOURCE ZAOBJ AESTDT AESTDY ADJDT ADJDY ZAEVALID ADJOUT; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool"

All cardiovascular events sent to event adjudication committee - safety analysis set - phase 3a pool

Study ID/Subject ID/ Treatment/Age/Sex/BMI	AE no./ Source	Adjudicated event type	Onset date/ trial day (Investigator)	Onset date/ trial day (EAC)	Adjudication phase	EAC outcome
NN1436-4481/704001/ OD analogues/6[redacted]/ Male/3[redacted]	7/ Investigator reported	Acute coronary syndrome	18MAR2022/ 355		Event adjudication committee	Diagnostic criteria unmet
NN1436-4481/707011/ OD analogues/6[redacted]/ Male/3[redacted]	2/ Investigator reported	Cerebrovascular event	03OCT2021/ 125	03OCT2021/ 125	Primary adjudicator	Stroke
NN1436-4481/711006/ Ico/6[redacted]/Female/2[redacted]	1/ Ae preferred term search	Cerebrovascular event	23NOV2021/ 176		Primary adjudicator	Diagnostic criteria unmet
NN1436-4481/712008/ Ico/6[redacted]/Male/3[redacted]	2/ Ae preferred term search	Heart failure	08JUN2021/ 48		Primary adjudicator	Diagnostic criteria unmet
NN1436-4481/805002/ OD analogues/6[redacted]/ Female/3[redacted]	NA/ Investigator reported	Death		30MAR2022/ 325	Event adjudication committee	Undetermined cause of death
NN1436-4481/807005/ OD analogues/6[redacted]/ Female/2[redacted]	1/ Investigator reported	Acute coronary syndrome	13DEC2021/ 174	13DEC2021/ 174	Primary adjudicator	Acute myocardial infarction
	4/ Investigator reported	Heart failure	13DEC2021/ 174		Primary adjudicator	Diagnostic criteria unmet
NN1436-4481/812012/ Ico/6[redacted]/Female/2[redacted]	4/ Investigator reported	Acute coronary syndrome	21JUL2021/ 43	20JUL2021/ 42	Event adjudication committee	Acute myocardial infarction
NN1436-4481/812013/ Ico/5[redacted]/Male/2[redacted]	2/ Investigator reported	Acute coronary syndrome	14DEC2021/ 190	15DEC2021/ 191	Event adjudication committee	Acute myocardial infarction
NN1436-4481/812019/ OD analogues/6[redacted]/ Female/2[redacted]	1/ Ae preferred term search	Acute coronary syndrome			Primary adjudicator	Diagnostic criteria unmet

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke). Death events are always adjudicated in Consensus. Trial day is derived as onset date minus date of first dose of trial product + 1. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adadj.xpt; variable(s): STUDYID SUBJID TRTA AGE SEX BMIBL ZALNKID SOURCE ZAOBJ AESTDT AESTDY ADJDT ADJDY ZAEVALID ADJOUT; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool"

All cardiovascular events sent to event adjudication committee - safety analysis set - phase 3a pool

Study ID/Subject ID/ Treatment/Age/Sex/BMI	AE no./ Source	Adjudicated event type	Onset date/ trial day (Investigator)	Onset date/ trial day (EAC)	Adjudication phase	EAC outcome
NN1436-4481/815001/ Ico/6[redacted]/Female/3[redacted]	6/ Ae preferred term search	Acute coronary syndrome	17JUL2021/ 128	17JUL2021/ 128	Primary adjudicator	Acute myocardial infarction
NN1436-4481/835003/ OD analogues/6[redacted]/ Male/3[redacted]	1/ Investigator reported	Heart failure	15AUG2021/ 60		Primary adjudicator	Diagnostic criteria unmet
	1/ Eac decided event type	Acute coronary syndrome	15AUG2021/ 60	15AUG2021/ 60	Event adjudication committee	Acute myocardial infarction
	801/ Adjudicator	Heart failure			Event adjudication committee	Diagnostic criteria unmet
NN1436-4625/618007/ Ico/7[redacted]/Male/2[redacted]	NA/ Investigator reported	Death		24FEB2022/ 168	Event adjudication committee	Non-cardiovascular death
	1/ Ae preferred term search	Cerebrovascular event	18FEB2022/ 162		Event adjudication committee	Diagnostic criteria unmet
NN1436-4625/753008/ IDeg/5[redacted]/Female/3[redacted]	1/ Investigator reported	Acute coronary syndrome	17MAR2022/ 142		Primary adjudicator	Diagnostic criteria unmet
	2/ Investigator reported	Acute coronary syndrome	24MAR2022/ 149		Event adjudication committee	Diagnostic criteria unmet
NN1436-4625/806003/ IDeg/6[redacted]/Female/2[redacted]	4/ Ae preferred term search	Heart failure	10JAN2022/ 152		Primary adjudicator	Diagnostic criteria unmet

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke). Death events are always adjudicated in Consensus. Trial day is derived as onset date minus date of first dose of trial product + 1. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adadj.xpt; variable(s): STUDYID SUBJID TRTA AGE SEX BMIBL ZALNKID SOURCE ZAOBJ AESTDT AESTDY ADJDT ADJDY ZAEVALID ADJOUT; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool"

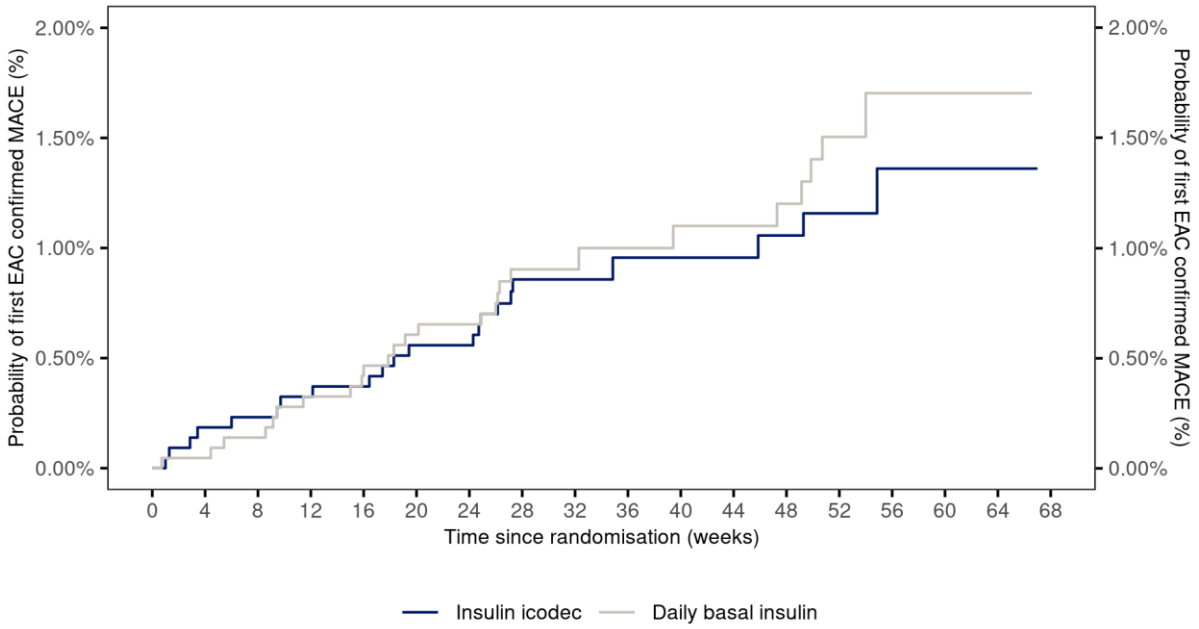
7.18.15 Time to first EAC confirmed MACE - Cox proportional hazard analysis - in-trial - safety analysis set - phase 3a pool

	Hazard Ratio	95% CI
Insulin icodec / Daily basal insulin	0.84	[0.48 ; 1.49]

CI: Confidence interval, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke). The time to first MACE is analysed using a Cox proportional hazard model stratified by trial and with treatment (2 levels: insulin icodec and basal insulin Comparators) as a fixed effect. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

nn1436/nn1436-meta-analysis/submission_20221107_er
21NOV2022:14:34:37 - acvsas/acvprimanalsas.txt

7.18.16 Time to first EAC confirmed MACE - cumulative incidence plot - in-trial - safety analysis set - phase 3a pool

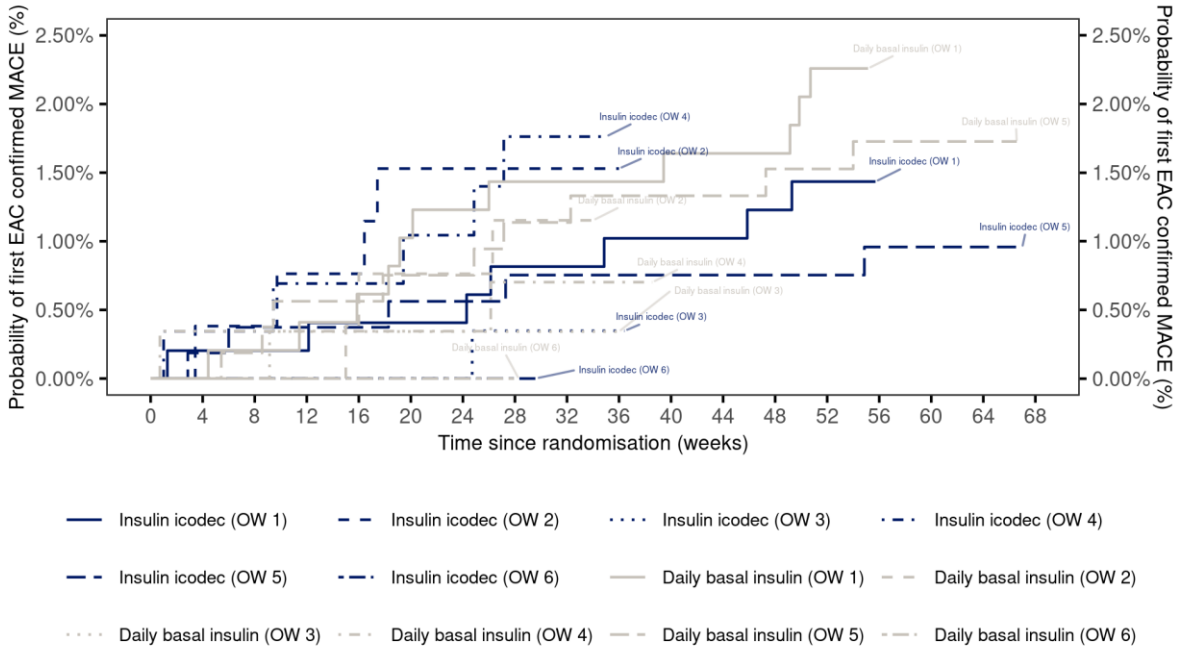


Cumulative incidence estimate for first EAC confirmed MACE during in-trial period. EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke). Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adtte.xpt; variable(s): SAFFL ANL01FL TRAG1 AVAL CNSR; criteria: SAFFL == "Y" & ANL01FL == "Y"

nn1436/nn1436-meta-analysis/submission_20221107_er
21NOV2022:14:34:38 - fmcfmace/fmcfmacep3aitsas.png

7.18.17 Time to first EAC confirmed MACE - cumulative incidence plot stratified by trial - in-trial - safety analysis set - phase 3a pool



Cumulative incidence estimate for first EAC confirmed MACE during in-trial period stratified by trials and treatment group. EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke).

adtte.xpt; variable(s): SAFFL ANL01FL TRAG1 AVAL CNSR STDNM; criteria: SAFFL == "Y" & ANL01FL == "Y"

nn1436/nn1436-meta-analysis/submission_20221107_er
21NOV2022:14:34:40 - fmcfmace/fmcfmaceitsas.png

7.18.18 Time to first EAC confirmed MACE - Cox proportional hazard analysis - sensitivity analysis 1 - on- treatment/main-on-treatment - safety analysis set - phase 3a pool

	Hazard Ratio	95% CI
Insulin icodec / Daily basal insulin	0.85	[0.48 ; 1.49]

CI: Confidence interval, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke). The time to first MACE is analysed using a Cox proportional hazard model stratified by trial and with treatment (2 levels: insulin icodec and basal insulin Comparators) as a fixed effect. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

nn1436/nn1436-meta-analysis/submission_20221107_er
21NOV2022:14:34:39 - acvsas/acvsensotsas.txt

7.18.19 Time to first EAC confirmed MACE - Cox proportional hazard analysis - sensitivity analysis 2 - trial included as fixed effect - in-trial - safety analysis set - phase 3a pool

	Hazard Ratio	95% CI
Insulin icodec / Daily basal insulin	0.84	[0.48 ; 1.49]

CI: Confidence interval, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke). The time to first MACE is analysed using a Cox proportional hazard model with trial and treatment (2 levels: insulin icodec and basal insulin Comparators) as a fixed effect. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

nn1436/nn1436-meta-analysis/submission_20221107_er
21NOV2022:14:34:40 - acvsas/acvsenzeroevent1sas.txt

7.18.20 Time to first EAC confirmed MACE - Cox proportional hazard analysis - sensitivity analysis 3 - trial with zero events pooled with other trials - in-trial - safety analysis set - phase 3a pool

	Hazard Ratio	95% CI
Insulin icodec / Daily basal insulin	0.85	[0.48 ; 1.49]

CI: Confidence interval, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke). The time to first MACE is analysed using a Cox proportional hazard model stratified by trial and with treatment (2 levels: insulin icodec and basal insulin Comparators) as a fixed effect. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. Trial NN1436-4625 had zero events and were pooled with NN1436-4480.

nn1436/nn1436-meta-analysis/submission_20221107_er
21NOV2022:14:34:41 - acvsas/acvsenzeroevent2sas.txt

7.18.21 Time to first EAC confirmed MACE - Cox proportional hazard analysis - sensitivity analysis 4 - censoring the longer trials - in-trial - safety analysis set - phase 3a pool

	Hazard Ratio	95% CI
Insulin icodec / Daily basal insulin	0.94	[0.50 ; 1.80]

CI: Confidence interval, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke). The time to first MACE is analysed using a Cox proportional hazard model stratified by trial and with treatment (2 levels: insulin icodec and basal insulin Comparators) as a fixed effect. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. 52 weeks trials (nn1436-4477 and nn1436-4481) will be censored at the first date of the following: the date of the 26 weeks visit plus 5 weeks or the last direct subject-site contact or withdrawal for subjects who withdraw their informed consent or the last subject-investigator contact as defined by the investigator for subjects who are lost to follow-up (i.e., possibly an unscheduled phone visit) or death for subjects who die before any of the above.

nn1436/nn1436-meta-analysis/submission_20221107_er
21NOV2022:14:34:43 - acvsas/acvsentrdur1sas.txt

7.18.22 Time to first EAC confirmed MACE - Cox proportional hazard analysis - sensitivity analysis 5 - Phase 3a trials with 52 weeks of treatment - in-trial - safety analysis set - phase 3a pool

	Hazard Ratio	95% CI
Insulin icodec / Daily basal insulin	0.60	[0.29 ; 1.22]

CI: Confidence interval, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke). The time to first MACE is analysed using a Cox proportional hazard model stratified by trial and with treatment (2 levels: insulin icodec and basal insulin Comparators) as a fixed effect. Phase 3a pool with 52 weeks of treatment: ONWARDS 1, 5, only main part of ONWARDS 1.

nn1436/nn1436-meta-analysis/submission_20221107_er
21NOV2022:14:34:44 - acvsas/acvsentrdur2sas.txt

7.18.23 Time to first EAC confirmed MACE - Cox proportional hazard analysis - sensitivity analysis 6 - Phase 3a trials with 26 weeks of treatment - in-trial - safety analysis set - phase 3a pool

	Hazard Ratio	95% CI
Insulin icodec / Daily basal insulin	1.67	[0.61 ; 4.60]

CI: Confidence interval, EAC: Event adjudication committee, MACE: Major adverse cardiovascular events with adjudicated outcome of either CV death, myocardial infarction (acute myocardial infarction) and stroke (ischaemic, haemorrhagic or undetermined stroke). The time to first MACE is analysed using a Cox proportional hazard model stratified by trial and with treatment (2 levels: insulin icodec and basal insulin Comparators) as a fixed effect. Phase 3a pool with 26 weeks of treatment: ONWARDS 2, 3, 4 and only main part of ONWARDS 6.

nn1436/nn1436-meta-analysis/submission_20221107_er
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インスリン イコデク（遺伝子組換え）

2.7.4.7. 付録
19. 過敏症報告書の要約

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Common Technical Document Summaries

NN1436 insulin icodec

2.7.4: Appendix 7.19

Summary of hypersensitivity reports

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Introduction

In all trials within the insulin icodec development program, additional blood analyses were performed in subjects treated with insulin icodec who experienced a hypersensitivity event that was judged as systemic by the investigator, in order to support the systemic nature of the event and to assess the relation with the trial product.

To this aim, the following parameters were analysed:

1. Anti-icodec IgE antibodies
2. Anti-human insulin IgE antibodies
3. Total IgE antibodies
4. Tryptase (optimally 0.5–2 hours post start of reaction)
5. Anti-icodec binding antibodies (analysed at special laboratory Celerion, Switzerland)

Analyses 1-4 were performed at Novo Nordisk and analysis 5 was performed by Celerion.

From each subject, 2 samples taken after the systemic hypersensitivity event were supposed to be obtained. According to protocol, the first sampling following the hypersensitivity event should be taken as soon as possible and repeated 2–4 weeks following onset of the systemic hypersensitivity reaction.

For materials and methods refer to individual hypersensitivity reports attached to the individual CTRs: Trial 4477 (M 5.3.5.1), Hypersensitivity report, Trial 4478 (M 5.3.5.1), Appendix 16.2.9, Trial 4480 (M 5.3.5.1), Appendix 16.2.9, Trial 4481 (M 5.3.5.1), Appendix 16.2.9, Trial 4625 (M 5.3.5.1), Hypersensitivity report, Trial 4569 (M 5.3.4.2), Appendix 16.2.9.

Table 1 summarises the results from blood analyses for the subjects with a suspected systemic hypersensitivity case.

Table 1 Analyses of suspected systemic hypersensitivity cases – insulin icodec – all trials

Trial	**Subject ID**	**Collection of blood samples (days from onset)**	**ADA (Pos/Neg; titre; CR)**	Anti-II IgE (kUA/L)	Total IgE (kIU/L)	Tryptase[b] (µg/L)	Anti-EI IgE (kUA/L)	**Supportive of a probable/possible association with insulin icodec**
ONWARDS 1	154001[a]	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	701004[c]	+7	Pos, 40, CR Pos	<0.1	20.79	7.36	<0.1	no
		+27	Pos, 80, CR Pos	<0.1	23.16	7.55	<0.1	
	851012[a]	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ONWARDS 2	205004[a]	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	207003[a]	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	702003a	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	903007[c,d]	+20	Neg	<0.1	>100	9.7	<0.1	inconclusive
ONWARDS 4	106005[c]	+3	Neg	<0.1	52.54	9.52	<0.1	yes
		+17	Pos, 16,000, CR Pos	0.38	93.97	10.34	4.31	
ONWARDS 5	535003[c]	+7	Neg	<0.1	58.53	7.37	<0.1	no
		+15	Neg	<0.1	56.15	5.93	<0.1	
	206003[c,d]	+6	Pos, 3200; CR Pos	0.14	>100	16.46	4.11	yes
	802002[c,e]	+83	Pos, 20; CR Neg	<0.1	23.64	9.62	<0.1	inconclusive
		+97	Pos, 20; CR Pos	<0.1	25.07	10.65	<0.1	
ONWARDS 6	612004[c,e]	+5	Pos; 3200; CR Pos	<0.1	>100	17.09	<0.1	no
		+32	Pos; 800; CR Pos	<0.1	>100	17.33	<0.1	
Trial 4569	101025	baseline	Neg	<0.1	>100	5.39	<0.1	no
		+6	Neg	<0.1	>100	6.52	<0.1	
		+25	Pos; 80,000; CR Pos	<0.1	>100	6.68	0.68	
	101036	baseline	Pos; 80; CR Pos	<0.1	13.85	9.53	<0.1	yes

Trial	**Subject ID**	**Collection of blood samples (days from onset)**	**ADA (Pos/Neg; titre; CR)**	Anti-II IgE (kUA/L)	Total IgE (kIU/L)	Tryptase[b] (µg/L)	Anti-EI IgE (kUA/L)	**Supportive of a probable/possible association with insulin icodec**
		+2	Pos; 320; CR Pos	3.83	27.62	10.49	7.08	
		+23	Pos; 80; CR Pos	8.78	57.08	11.28	14.11	
	101033	baseline	Pos; 20; CR Neg	<0.1	97.74	9.82	<0.1	yes
		+2	Pos; 4000; CR Pos	0.51	>100	11.91	1.15	
		+23	Pos; 6400; CR Pos	0.23	>100	11.17	0.64	

Notes: [a] blood samples were not collected for additional analyses because the investigator judged the event clearly unrelated to insulin icodec. [b] in all cases tryptase was taken much later than the optimal 2 hours, so tryptase results are inconclusive. [c] baseline values not available. [d] last time point values not available. [e] sampling was not optimal compared to recommendation.
Abbreviations: CR = cross-reacting with endogenous insulin; II = insulin icodec; EI =endogenous insulin.

インスリン イコデク（遺伝子組換え）

2.7.4.7. 付録
20. ONWARDS 6 試験における重大な低血糖（レベル 3）を発現した被験者の一覧

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詳細は Module 5.3.5.4、Listing of subjects experiencing severe (level 3) hypoglycaemic episodes in ONWARDS 6 に示した。

インスリン イコデク（遺伝子組換え）

2.7.4.7. 付録
21. ONWARDS 1 試験及び ONWARDS 6 試験（延長パートを含む）：重篤な有害事象及び治験薬の投与中止に至った有害事象（試験別）

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7.14 Serious adverse events and adverse events leading to discontinuation by trial (extension part)

7.21.1 Serious adverse events by system organ class and preferred term - ONWARDS 1 (extension part) - in- trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects	492				492			
PYO (years)	772.31				773.34			
Events	64	(13.0)	95	12.30	75	(15.2)	127	16.42
Cardiac disorders	20	(4.1)	32	4.14	17	(3.5)	23	2.97
Atrial fibrillation	5	(1.0)	5	0.65	2	(0.4)	2	0.26
Acute myocardial infarction	4	(0.8)	4	0.52	5	(1.0)	5	0.65
Angina unstable	4	(0.8)	4	0.52	1	(0.2)	1	0.13
Coronary artery disease	4	(0.8)	4	0.52	2	(0.4)	2	0.26
Myocardial infarction	3	(0.6)	3	0.39	3	(0.6)	3	0.39
Cardiac failure	2	(0.4)	2	0.26	0			
Coronary artery occlusion	2	(0.4)	2	0.26	0			
Acute coronary syndrome	1	(0.2)	1	0.13	0			
Angina pectoris	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Atrial flutter	1	(0.2)	2	0.26	1	(0.2)	1	0.13
Atrial thrombosis	1	(0.2)	1	0.13	0			
Cardiac failure congestive	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Chronic coronary syndrome	1	(0.2)	1	0.13	0			
Sinus tachycardia	1	(0.2)	1	0.13	0			
Atrioventricular block complete	0				2	(0.4)	2	0.26
Arteriosclerosis coronary artery	0				1	(0.2)	1	0.13
Atrioventricular block second degree	0				1	(0.2)	1	0.13
Cardio-respiratory arrest	0				1	(0.2)	1	0.13
Left ventricular dysfunction	0				1	(0.2)	1	0.13
Supraventricular tachycardia	0				1	(0.2)	1	0.13
Infections and infestations	12	(2.4)	17	2.20	23	(4.7)	26	3.36
COVID-19	4	(0.8)	4	0.52	3	(0.6)	3	0.39
COVID-19 pneumonia	4	(0.8)	4	0.52	2	(0.4)	2	0.26
Pneumonia	2	(0.4)	2	0.26	3	(0.6)	3	0.39
Bronchitis	1	(0.2)	1	0.13	0			
Cellulitis	1	(0.2)	1	0.13	2	(0.4)	2	0.26
Erysipelas	1	(0.2)	1	0.13	0			
Intestinal sepsis	1	(0.2)	1	0.13	0			
Osteomyelitis	1	(0.2)	1	0.13	0			
Osteomyelitis chronic	1	(0.2)	1	0.13	0			
Respiratory syncytial virus infection	1	(0.2)	1	0.13	0			
Anal abscess	0				2	(0.4)	2	0.26
Urinary tract infection	0				2	(0.4)	3	0.39
Chronic hepatitis C	0				1	(0.2)	1	0.13
Clostridium difficile infection	0				1	(0.2)	1	0.13
Diverticulitis	0				1	(0.2)	1	0.13
Empyema	0				1	(0.2)	1	0.13
Endophthalmitis	0				1	(0.2)	1	0.13
Escherichia urinary tract infection	0				1	(0.2)	1	0.13
Laryngitis	0				1	(0.2)	1	0.13
Otitis media acute	0				1	(0.2)	1	0.13
Parainfluenzae virus infection	0				1	(0.2)	1	0.13
Post procedural infection	0				1	(0.2)	1	0.13
Sepsis	0				1	(0.2)	1	0.13

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 24.1. Daily basal insulin: IGlar U100.

Serious adverse events by system organ class and preferred term - ONWARDS 1 (extension part) - in-trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7	(1.4)	8	1.04	6	(1.2)	8	1.03
Prostate cancer	2	(0.4)	2	0.26	1	(0.2)	1	0.13
Basal cell carcinoma	1	(0.2)	1	0.13	0			
Glioblastoma multiforme	1	(0.2)	1	0.13	0			
Metastases to liver	1	(0.2)	1	0.13	0			
Pancreatic carcinoma metastatic	1	(0.2)	1	0.13	0			
Pancreatic neoplasm	1	(0.2)	1	0.13	0			
Small cell lung cancer	1	(0.2)	1	0.13	0			
Colon cancer	0				1	(0.2)	1	0.13
Hepatocellular carcinoma	0				1	(0.2)	1	0.13
Lung adenocarcinoma	0				1	(0.2)	1	0.13
Malignant melanoma in situ	0				1	(0.2)	1	0.13
Metastatic renal cell carcinoma	0				1	(0.2)	1	0.13
Ovarian cancer metastatic	0				1	(0.2)	1	0.13
Plasma cell myeloma	0				1	(0.2)	1	0.13
Injury, poisoning and procedural complications	5	(1.0)	5	0.65	9	(1.8)	11	1.42
Fibula fracture	1	(0.2)	1	0.13	0			
Hip fracture	1	(0.2)	1	0.13	0			
Meniscus injury	1	(0.2)	1	0.13	0			
Periprocedural myocardial infarction	1	(0.2)	1	0.13	0			
Post procedural haemorrhage	1	(0.2)	1	0.13	0			
Lower limb fracture	0				2	(0.4)	2	0.26
Deafness traumatic	0				1	(0.2)	1	0.13
Endotracheal intubation complication	0				1	(0.2)	1	0.13
Fall	0				1	(0.2)	1	0.13
Post procedural stroke	0				1	(0.2)	1	0.13
Radius fracture	0				1	(0.2)	1	0.13
Rib fracture	0				1	(0.2)	1	0.13
Subdural haematoma	0				1	(0.2)	1	0.13
Tendon rupture	0				1	(0.2)	1	0.13
Upper limb fracture	0				1	(0.2)	1	0.13
Nervous system disorders	5	(1.0)	5	0.65	5	(1.0)	5	0.65
Carotid artery stenosis	1	(0.2)	1	0.13	0			
Cerebral haemorrhage	1	(0.2)	1	0.13	0			
Cervical radiculopathy	1	(0.2)	1	0.13	0			
Ischaemic stroke	1	(0.2)	1	0.13	0			
Transient ischaemic attack	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Cerebrovascular accident	0				1	(0.2)	1	0.13
Hypoglycaemic unconsciousness	0				1	(0.2)	1	0.13
Metabolic encephalopathy	0				1	(0.2)	1	0.13
Thrombotic stroke	0				1	(0.2)	1	0.13
Gastrointestinal disorders	4	(0.8)	4	0.52	6	(1.2)	9	1.16
Colitis ischaemic	1	(0.2)	1	0.13	0			
Gastritis	1	(0.2)	1	0.13	0			
Intestinal obstruction	1	(0.2)	1	0.13	0			
Pancreatitis acute	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Anal fissure	0				1	(0.2)	1	0.13
Duodenal ulcer	0				1	(0.2)	1	0.13
Gastrointestinal haemorrhage	0				1	(0.2)	1	0.13
Inguinal hernia	0				1	(0.2)	2	0.26
Large intestine polyp	0				1	(0.2)	1	0.13
Umbilical hernia	0				1	(0.2)	1	0.13
Vomiting	0				1	(0.2)	1	0.13

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 24.1. Daily basal insulin: IGlar U100.

Serious adverse events by system organ class and preferred term - ONWARDS 1 (extension part) - in-trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Musculoskeletal and connective tissue disorders	4	(0.8)	4	0.52	5	(1.0)	5	0.65
Back pain	1	(0.2)	1	0.13	0			
Intervertebral disc protrusion	1	(0.2)	1	0.13	0			
Osteoarthritis	1	(0.2)	1	0.13	3	(0.6)	3	0.39
Plantar fasciitis	1	(0.2)	1	0.13	0			
Spinal pain	0				2	(0.4)	2	0.26
Vascular disorders	4	(0.8)	5	0.65	6	(1.2)	6	0.78
Hypertensive urgency	1	(0.2)	1	0.13	0			
Peripheral arterial occlusive disease	1	(0.2)	1	0.13	2	(0.4)	2	0.26
Peripheral artery occlusion	1	(0.2)	1	0.13	0			
Peripheral artery stenosis	1	(0.2)	2	0.26	0			
Arteriosclerosis	0				1	(0.2)	1	0.13
Brachiocephalic arteriosclerosis	0				1	(0.2)	1	0.13
Haematoma	0				1	(0.2)	1	0.13
Iliac artery stenosis	0				1	(0.2)	1	0.13
Reproductive system and breast disorders	3	(0.6)	3	0.39	1	(0.2)	1	0.13
Benign prostatic hyperplasia	2	(0.4)	2	0.26	0			
Uterine prolapse	1	(0.2)	1	0.13	0			
Vaginal prolapse	0				1	(0.2)	1	0.13
Eye disorders	2	(0.4)	2	0.26	2	(0.4)	3	0.39
Cataract	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Optic ischaemic neuropathy	1	(0.2)	1	0.13	0			
Diabetic retinal oedema	0				1	(0.2)	1	0.13
Open angle glaucoma	0				1	(0.2)	1	0.13
Renal and urinary disorders	2	(0.4)	2	0.26	4	(0.8)	4	0.52
Ketonuria	1	(0.2)	1	0.13	0			
Ureterolithiasis	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Acute kidney injury	0				1	(0.2)	1	0.13
Renal impairment	0				1	(0.2)	1	0.13
Urinary tract obstruction	0				1	(0.2)	1	0.13
Respiratory, thoracic and mediastinal disorders	2	(0.4)	2	0.26	3	(0.6)	6	0.78
Acute respiratory failure	1	(0.2)	1	0.13	2	(0.4)	2	0.26
Interstitial lung disease	1	(0.2)	1	0.13	0			
Acute pulmonary oedema	0				1	(0.2)	1	0.13
Chronic obstructive pulmonary disease	0				1	(0.2)	1	0.13
Pleural effusion	0				1	(0.2)	1	0.13
Pneumothorax	0				1	(0.2)	1	0.13
Blood and lymphatic system disorders	1	(0.2)	1	0.13	2	(0.4)	2	0.26
Anaemia	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Blood loss anaemia	0				1	(0.2)	1	0.13
Congenital, familial and genetic disorders	1	(0.2)	1	0.13	0			
Hydrocele	1	(0.2)	1	0.13	0			
Investigations	1	(0.2)	1	0.13	3	(0.6)	3	0.39
Hepatic enzyme increased	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Cardiac stress test abnormal	0				1	(0.2)	1	0.13
Troponin increased	0				1	(0.2)	1	0.13

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 24.1. Daily basal insulin: IGlar U100.

Serious adverse events by system organ class and preferred term - ONWARDS 1 (extension part) - in-trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Metabolism and nutrition disorders	1	(0.2)	1	0.13	3	(0.6)	4	0.52
Hyperkalaemia	1	(0.2)	1	0.13	0			
Adult failure to thrive	0				1	(0.2)	1	0.13
Electrolyte depletion	0				1	(0.2)	1	0.13
Hypoglycaemia	0				1	(0.2)	1	0.13
Lactic acidosis	0				1	(0.2)	1	0.13
Psychiatric disorders	1	(0.2)	1	0.13	0			
Psychotic disorder	1	(0.2)	1	0.13	0			
Skin and subcutaneous tissue disorders	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Myxoid cyst	1	(0.2)	1	0.13	0			
Urticaria	0				1	(0.2)	1	0.13
General disorders and administration site conditions	0				4	(0.8)	4	0.52
Death	0				1	(0.2)	1	0.13
Non-cardiac chest pain	0				1	(0.2)	1	0.13
Oedema peripheral	0				1	(0.2)	1	0.13
Pyrexia	0				1	(0.2)	1	0.13
Hepatobiliary disorders	0				2	(0.4)	2	0.26
Hepatic cirrhosis	0				1	(0.2)	1	0.13
Hepatitis	0				1	(0.2)	1	0.13
Ear and labyrinth disorders	0				1	(0.2)	1	0.13
Presbyacusis	0				1	(0.2)	1	0.13
Immune system disorders	0				1	(0.2)	2	0.26
Immunisation reaction	0				1	(0.2)	2	0.26
Surgical and medical procedures	0				1	(0.2)	1	0.13
Removal of foreign body	0				1	(0.2)	1	0.13

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 24.1. Daily basal insulin: IGlar U100.

7.21.2 Serious adverse events by system organ class and preferred term - ONWARDS 6 (extension part) - in- trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects	290				292			
PYO (years)	307.05				312.83			
Events	24	(8.3)	40	13.03	21	(7.2)	28	8.95
Metabolism and nutrition disorders	10	(3.4)	15	4.89	3	(1.0)	3	0.96
Hypoglycaemia	8	(2.8)	13	4.23	1	(0.3)	1	0.32
Diabetic ketoacidosis	1	(0.3)	1	0.33	0			
Hypokalaemia	1	(0.3)	1	0.33	0			
Hyperglycaemia	0				1	(0.3)	1	0.32
Obesity	0				1	(0.3)	1	0.32
Infections and infestations	3	(1.0)	5	1.63	5	(1.7)	5	1.60
COVID-19	1	(0.3)	1	0.33	1	(0.3)	1	0.32
COVID-19 pneumonia	1	(0.3)	1	0.33	0			
Pyelonephritis acute	1	(0.3)	1	0.33	0			
Respiratory tract infection viral	1	(0.3)	1	0.33	0			
Sepsis	1	(0.3)	1	0.33	0			
Influenza	0				2	(0.7)	2	0.64
Cystitis escherichia	0				1	(0.3)	1	0.32
Pneumonia	0				1	(0.3)	1	0.32
Injury, poisoning and procedural complications	3	(1.0)	4	1.30	0			
Ankle fracture	1	(0.3)	1	0.33	0			
Ligament rupture	1	(0.3)	1	0.33	0			
Product administration error	1	(0.3)	1	0.33	0			
Tendon rupture	1	(0.3)	1	0.33	0			
Nervous system disorders	3	(1.0)	4	1.30	4	(1.4)	4	1.28
Cerebral haemorrhage	1	(0.3)	1	0.33	0			
Haemorrhage intracranial	1	(0.3)	1	0.33	0			
Hypoglycaemic seizure	1	(0.3)	1	0.33	1	(0.3)	1	0.32
Post stroke seizure	1	(0.3)	1	0.33	0			
Hypoglycaemic unconsciousness	0				1	(0.3)	1	0.32
Ischaemic stroke	0				1	(0.3)	1	0.32
Optic neuritis	0				1	(0.3)	1	0.32
Pregnancy, puerperium and perinatal conditions	2	(0.7)	2	0.65	0			
Abortion spontaneous	1	(0.3)	1	0.33	0			
Abortion threatened	1	(0.3)	1	0.33	0			
Cardiac disorders	1	(0.3)	2	0.65	2	(0.7)	3	0.96
Acute myocardial infarction	1	(0.3)	1	0.33	0			
Cardiac failure congestive	1	(0.3)	1	0.33	0			
Angina unstable	0				2	(0.7)	2	0.64
Myocardial ischaemia	0				1	(0.3)	1	0.32
Gastrointestinal disorders	1	(0.3)	1	0.33	4	(1.4)	4	1.28
Vomiting	1	(0.3)	1	0.33	1	(0.3)	1	0.32
Haemorrhoids	0				1	(0.3)	1	0.32
Lumbar hernia	0				1	(0.3)	1	0.32
Proctitis ulcerative	0				1	(0.3)	1	0.32
Musculoskeletal and connective tissue disorders	1	(0.3)	1	0.33	0			
Rotator cuff syndrome	1	(0.3)	1	0.33	0			

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 24.1. Daily basal insulin: IDeg.

Serious adverse events by system organ class and preferred term - ONWARDS 6 (extension part) - in-trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Psychiatric disorders	1	(0.3)	1	0.33	1	(0.3)	1	0.32
Major depression	1	(0.3)	1	0.33	0			
Alcohol abuse	0				1	(0.3)	1	0.32
Renal and urinary disorders	1	(0.3)	1	0.33	0			
Acute kidney injury	1	(0.3)	1	0.33	0			
Reproductive system and breast disorders	1	(0.3)	1	0.33	0			
Benign prostatic hyperplasia	1	(0.3)	1	0.33	0			
Respiratory, thoracic and mediastinal disorders	1	(0.3)	1	0.33	0			
Acute respiratory failure	1	(0.3)	1	0.33	0			
Surgical and medical procedures	1	(0.3)	1	0.33	0			
Cardiac ablation	1	(0.3)	1	0.33	0			
Vascular disorders	1	(0.3)	1	0.33	2	(0.7)	3	0.96
Hypotension	1	(0.3)	1	0.33	0			
Brachiocephalic artery stenosis	0				1	(0.3)	1	0.32
Hypertension	0				1	(0.3)	1	0.32
Hypertensive crisis	0				1	(0.3)	1	0.32
General disorders and administration site conditions	0				2	(0.7)	2	0.64
Asthenia	0				1	(0.3)	1	0.32
Medical device site dermatitis	0				1	(0.3)	1	0.32
Investigations	0				2	(0.7)	2	0.64
Blood glucose fluctuation	0				1	(0.3)	1	0.32
Blood glucose increased	0				1	(0.3)	1	0.32
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0				1	(0.3)	1	0.32
Uterine leiomyoma	0				1	(0.3)	1	0.32

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 24.1. Daily basal insulin: IDeg.

7.21.3 Adverse events leading to permanent discontinuation of insulin icodec or daily basal insulin by system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects	492				492			
PYE (years)	765.50				766.76			
Events	9	(1.8)	11	1.44	6	(1.2)	11	1.43
Investigations	3	(0.6)	3	0.39	0			
Weight increased	2	(0.4)	2	0.26	0			
Glycosylated haemoglobin increased	1	(0.2)	1	0.13	0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	(0.4)	3	0.39	1	(0.2)	1	0.13
Glioblastoma multiforme	1	(0.2)	1	0.13	0			
Metastases to liver	1	(0.2)	1	0.13	0			
Pancreatic neoplasm	1	(0.2)	1	0.13	0			
Ovarian cancer metastatic	0				1	(0.2)	1	0.13
Gastrointestinal disorders	1	(0.2)	2	0.26	0			
Abdominal distension	1	(0.2)	1	0.13	0			
Constipation	1	(0.2)	1	0.13	0			
Injury, poisoning and procedural complications	1	(0.2)	1	0.13	1	(0.2)	3	0.39
Hip fracture	1	(0.2)	1	0.13	0			
Lower limb fracture	0				1	(0.2)	1	0.13
Rib fracture	0				1	(0.2)	1	0.13
Upper limb fracture	0				1	(0.2)	1	0.13
Metabolism and nutrition disorders	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Obesity	1	(0.2)	1	0.13	0			
Adult failure to thrive	0				1	(0.2)	1	0.13
Psychiatric disorders	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Psychotic disorder	1	(0.2)	1	0.13	0			
Mood swings	0				1	(0.2)	1	0.13
Cardiac disorders	0				1	(0.2)	1	0.13
Angina pectoris	0				1	(0.2)	1	0.13
General disorders and administration site conditions	0				1	(0.2)	1	0.13
Death	0				1	(0.2)	1	0.13
Nervous system disorders	0				1	(0.2)	1	0.13
Metabolic encephalopathy	0				1	(0.2)	1	0.13
Respiratory, thoracic and mediastinal disorders	0				1	(0.2)	1	0.13
Pneumothorax	0				1	(0.2)	1	0.13
Vascular disorders	0				1	(0.2)	1	0.13
Haematoma	0				1	(0.2)	1	0.13

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

adsl.xpt; variable(s): ONTRDURY; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (AACN1 == "DRUG WITHDRAWN" | (AACN1 == "DRUG INTERRUPTED" & AOUT == "FATAL")) & (ANL02FL) == "Y" & (ANELFL) == "Y"
nn1436/nn1436-japan/submission_ext_20230612_er
21JUN2023:08:59:02 - taesocpt.R/taewdsocptsumontow1sas.txt

7.21.4 Adverse events leading to permanent discontinuation of insulin icodec or daily basal insulin by system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects	290				292			
PYE (years)	300.16				309.58			
Events	1	(0.3)	2	0.67	1	(0.3)	1	0.32
Nervous system disorders	1	(0.3)	2	0.67	0			
Cerebral haemorrhage	1	(0.3)	2	0.67	0			
Metabolism and nutrition disorders	0				1	(0.3)	1	0.32
Insulin resistance	0				1	(0.3)	1	0.32

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

adsl.xpt; variable(s): ONTRDURY; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (AACN1 == "DRUG WITHDRAWN" | (AACN1 == "DRUG INTERRUPTED" & AOUT == "FATAL")) & (ANL02FL) == "Y" & (ANELFL) == "Y"
nn1436/nn1436-japan/submission_ext_20230612_er
21JUN2023:08:59:05 - taesocpt.R/taewdsocptsumontow6sas.txt

インスリン イコデク（遺伝子組換え）

2.7.4.7. 付録
22. ONWARDS 1 試験及び ONWARDS 6 試験（延長パートを含む）：低血糖

ノボ ノルディスク ファーマ株式会社

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7.22 Hypoglycaemic episodes (extension part)

7.22.1 Hypoglycaemic episodes by trial, classification and month since randomisation - ONWARDS 1 and 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
ONWARDS 1								
Number of subjects	492				492			
PYE (years)	765.50				766.76			
Hypoglycaemia alert value (level 1)	278	(56.5)	2308	301.50	239	(48.6)	1067	139.16
0 < to <= 1 month	28	(5.7)	51	126.20	14	(2.8)	17	42.20
1 < to <= 2 months	38	(7.7)	73	174.82	21	(4.3)	29	70.04
2 < to <= 3 months	56	(11.4)	93	230.14	33	(6.8)	51	127.50
3 < to <= 4 months	50	(10.2)	90	215.68	34	(7.0)	46	111.33
4 < to <= 5 months	58	(11.8)	106	263.75	24	(4.9)	33	82.81
5 < to <= 6 months	67	(13.7)	157	379.41	48	(9.9)	71	172.84
6 < to <= 7 months	67	(13.8)	129	323.67	42	(8.7)	65	163.54
7 < to <= 8 months	76	(15.7)	180	439.71	39	(8.1)	55	134.17
8 < to <= 9 months	64	(13.3)	128	323.99	43	(8.9)	68	171.60
9 < to <= 10 months	73	(15.2)	147	361.10	36	(7.5)	54	132.00
10 < to <= 11 months	69	(14.4)	137	348.22	42	(8.7)	66	166.71
11 < to <= 12 months	82	(17.1)	166	408.32	54	(11.2)	76	185.99
12 < to <= 13 months	73	(15.3)	145	370.85	51	(10.6)	62	157.04
13 < to <= 14 months	68	(14.3)	154	383.40	39	(8.1)	59	144.82
14 < to <= 15 months	62	(13.1)	123	317.61	45	(9.4)	70	178.34
15 < to <= 16 months	58	(12.3)	115	288.90	56	(11.8)	81	200.95
16 < to <= 17 months	63	(13.5)	123	319.98	38	(8.0)	55	141.27
17 < to <= 18 months	68	(14.5)	133	335.23	43	(9.1)	73	181.88
> 18 months	32	(6.9)	58	135.82	28	(5.9)	36	85.49
Clinically significant hypoglycaemia (level 2)	61	(12.4)	226	29.52	66	(13.4)	114	14.87
0 < to <= 1 month	2	(0.4)	2	4.95	4	(0.8)	4	9.93
1 < to <= 2 months	5	(1.0)	10	23.95	3	(0.6)	4	9.66
2 < to <= 3 months	5	(1.0)	8	19.80	3	(0.6)	3	7.50
3 < to <= 4 months	5	(1.0)	7	16.78	4	(0.8)	5	12.10
4 < to <= 5 months	10	(2.0)	19	47.28	7	(1.4)	8	20.07
5 < to <= 6 months	12	(2.5)	17	41.08	10	(2.1)	12	29.21
6 < to <= 7 months	7	(1.4)	12	30.11	9	(1.9)	11	27.68
7 < to <= 8 months	9	(1.9)	17	41.53	10	(2.1)	11	26.83
8 < to <= 9 months	16	(3.3)	21	53.15	5	(1.0)	5	12.62
9 < to <= 10 months	7	(1.5)	10	24.56	4	(0.8)	4	9.78
10 < to <= 11 months	9	(1.9)	14	35.58	4	(0.8)	5	12.63
11 < to <= 12 months	8	(1.7)	10	24.60	3	(0.6)	3	7.34
12 < to <= 13 months	9	(1.9)	18	46.04	4	(0.8)	4	10.13
13 < to <= 14 months	6	(1.3)	7	17.43	9	(1.9)	11	27.00
14 < to <= 15 months	4	(0.8)	12	30.99	6	(1.3)	7	17.83
15 < to <= 16 months	7	(1.5)	10	25.12	6	(1.3)	6	14.88
16 < to <= 17 months	3	(0.6)	13	33.82	0			
17 < to <= 18 months	9	(1.9)	12	30.25	6	(1.3)	7	17.44
> 18 months	5	(1.1)	7	16.39	3	(0.6)	4	9.50

%: Percentage of subjects with one or more events, BG: Blood glucose, E: Number of events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. 1 month = 30.5 days. Daily basal insulin: IGlar U100 (ONWARDS 1), IDeg (ONWARDS 6). Data from ONWARDS 1-6.

Hypoglycaemic episodes by trial, classification and month since randomisation - ONWARDS 1 and 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severe hypoglycaemia (level 3)	1	(0.2)	1	0.13	6	(1.2)	7	0.91
0 < to <= 1 month	0				0			
1 < to <= 2 months	0				0			
2 < to <= 3 months	0				0			
3 < to <= 4 months	0				0			
4 < to <= 5 months	0				0			
5 < to <= 6 months	0				0			
6 < to <= 7 months	0				0			
7 < to <= 8 months	0				0			
8 < to <= 9 months	0				2	(0.4)	2	5.05
9 < to <= 10 months	1	(0.2)	1	2.46	0			
10 < to <= 11 months	0				0			
11 < to <= 12 months	0				1	(0.2)	1	2.45
12 < to <= 13 months	0				1	(0.2)	1	2.53
13 < to <= 14 months	0				0			
14 < to <= 15 months	0				1	(0.2)	1	2.55
15 < to <= 16 months	0				0			
16 < to <= 17 months	0				0			
17 < to <= 18 months	0				1	(0.2)	1	2.49
> 18 months	0				1	(0.2)	1	2.37
Severe (level 3) or clinically significant (level 2) hypoglycaemia	61	(12.4)	227	29.65	70	(14.2)	121	15.78
0 < to <= 1 month	2	(0.4)	2	4.95	4	(0.8)	4	9.93
1 < to <= 2 months	5	(1.0)	10	23.95	3	(0.6)	4	9.66
2 < to <= 3 months	5	(1.0)	8	19.80	3	(0.6)	3	7.50
3 < to <= 4 months	5	(1.0)	7	16.78	4	(0.8)	5	12.10
4 < to <= 5 months	10	(2.0)	19	47.28	7	(1.4)	8	20.07
5 < to <= 6 months	12	(2.5)	17	41.08	10	(2.1)	12	29.21
6 < to <= 7 months	7	(1.4)	12	30.11	9	(1.9)	11	27.68
7 < to <= 8 months	9	(1.9)	17	41.53	10	(2.1)	11	26.83
8 < to <= 9 months	16	(3.3)	21	53.15	7	(1.4)	7	17.66
9 < to <= 10 months	8	(1.7)	11	27.02	4	(0.8)	4	9.78
10 < to <= 11 months	9	(1.9)	14	35.58	4	(0.8)	5	12.63
11 < to <= 12 months	8	(1.7)	10	24.60	4	(0.8)	4	9.79
12 < to <= 13 months	9	(1.9)	18	46.04	5	(1.0)	5	12.66
13 < to <= 14 months	6	(1.3)	7	17.43	9	(1.9)	11	27.00
14 < to <= 15 months	4	(0.8)	12	30.99	7	(1.5)	8	20.38
15 < to <= 16 months	7	(1.5)	10	25.12	6	(1.3)	6	14.88
16 < to <= 17 months	3	(0.6)	13	33.82	0			
17 < to <= 18 months	9	(1.9)	12	30.25	7	(1.5)	8	19.93
> 18 months	5	(1.1)	7	16.39	4	(0.8)	5	11.87
ONWARDS 6								
Number of subjects	290				292			
PYE (years)	300.16				309.58			

%: Percentage of subjects with one or more events, BG: Blood glucose, E: Number of events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. 1 month = 30.5 days. Daily basal insulin: IGlar U100 (ONWARDS 1), IDeg (ONWARDS 6). Data from ONWARDS 1-6.

Hypoglycaemic episodes by trial, classification and month since randomisation - ONWARDS 1 and 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hypoglycaemia alert value (level 1)	288	(99.3)	20406	6798.40	289	(99.0)	14819	4786.77
0 < to <= 1 month	262	(90.3)	1891	7979.29	255	(87.3)	1548	6455.89
1 < to <= 2 months	263	(91.3)	2093	8568.35	253	(86.9)	1331	5436.68
2 < to <= 3 months	266	(92.7)	1789	7645.16	247	(86.1)	1153	4891.21
3 < to <= 4 months	260	(91.5)	1733	7223.31	246	(85.7)	1214	5005.80
4 < to <= 5 months	262	(93.2)	1643	7154.34	245	(86.0)	1067	4565.09
5 < to <= 6 months	250	(90.3)	1643	7001.58	242	(85.2)	1079	4483.05
6 < to <= 7 months	243	(88.7)	1517	6767.03	247	(87.3)	1021	4392.46
7 < to <= 8 months	234	(86.0)	1571	6857.17	247	(87.3)	1157	4841.82
8 < to <= 9 months	239	(89.8)	1347	6179.25	234	(83.3)	1080	4679.36
9 < to <= 10 months	232	(87.9)	1461	6520.41	244	(86.8)	1126	4729.43
10 < to <= 11 months	234	(88.6)	1321	6106.76	241	(86.1)	1049	4575.44
11 < to <= 12 months	231	(87.8)	1342	6032.81	229	(82.4)	1069	4530.66
> 12 months	207	(79.0)	1055	4258.83	217	(78.1)	925	3655.27
Clinically significant hypoglycaemia (level 2)	262	(90.3)	5047	1681.44	250	(85.6)	2811	908.00
0 < to <= 1 month	157	(54.1)	467	1970.56	137	(46.9)	354	1476.35
1 < to <= 2 months	169	(58.7)	551	2255.69	123	(42.3)	291	1188.64
2 < to <= 3 months	155	(54.0)	486	2076.89	98	(34.1)	215	912.06
3 < to <= 4 months	145	(51.1)	446	1858.97	111	(38.7)	215	886.53
4 < to <= 5 months	138	(49.1)	382	1663.39	96	(33.7)	186	795.79
5 < to <= 6 months	145	(52.3)	442	1883.57	94	(33.1)	208	864.20
6 < to <= 7 months	145	(52.9)	400	1784.32	106	(37.5)	201	864.73
7 < to <= 8 months	133	(48.9)	367	1601.90	105	(37.1)	219	916.47
8 < to <= 9 months	127	(47.7)	314	1440.45	99	(35.2)	195	844.88
9 < to <= 10 months	123	(46.6)	326	1454.93	97	(34.5)	190	798.04
10 < to <= 11 months	125	(47.3)	326	1507.04	94	(33.6)	190	828.73
11 < to <= 12 months	121	(46.0)	320	1438.52	90	(32.4)	186	788.31
> 12 months	102	(38.9)	220	888.10	94	(33.8)	161	636.21
Severe hypoglycaemia (level 3)	13	(4.5)	56	18.66	12	(4.1)	25	8.08
0 < to <= 1 month	3	(1.0)	11	46.42	5	(1.7)	7	29.19
1 < to <= 2 months	2	(0.7)	21	85.97	2	(0.7)	3	12.25
2 < to <= 3 months	2	(0.7)	4	17.09	1	(0.3)	1	4.24
3 < to <= 4 months	3	(1.1)	5	20.84	1	(0.3)	1	4.12
4 < to <= 5 months	1	(0.4)	1	4.35	1	(0.4)	1	4.28
5 < to <= 6 months	4	(1.4)	5	21.31	3	(1.1)	4	16.62
6 < to <= 7 months	1	(0.4)	1	4.46	0			
7 < to <= 8 months	2	(0.7)	2	8.73	0			
8 < to <= 9 months	2	(0.8)	2	9.17	2	(0.7)	2	8.67
9 < to <= 10 months	0				2	(0.7)	5	21.00
10 < to <= 11 months	0				0			
11 < to <= 12 months	3	(1.1)	3	13.49	1	(0.4)	1	4.24
> 12 months	1	(0.4)	1	4.04	0			

%: Percentage of subjects with one or more events, BG: Blood glucose, E: Number of events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. 1 month = 30.5 days. Daily basal insulin: IGlar U100 (ONWARDS 1), IDeg (ONWARDS 6). Data from ONWARDS 1-6.

Hypoglycaemic episodes by trial, classification and month since randomisation - ONWARDS 1 and 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severe (level 3) or clinically significant (level 2) hypoglycaemia	263	(90.7)	5103	1700.10	250	(85.6)	2836	916.07
0 < to <= 1 month	158	(54.5)	478	2016.98	137	(46.9)	361	1505.54
1 < to <= 2 months	170	(59.0)	572	2341.66	123	(42.3)	294	1200.89
2 < to <= 3 months	156	(54.4)	490	2093.98	98	(34.1)	216	916.31
3 < to <= 4 months	145	(51.1)	451	1879.81	111	(38.7)	216	890.65
4 < to <= 5 months	138	(49.1)	383	1667.75	97	(34.0)	187	800.07
5 < to <= 6 months	146	(52.7)	447	1904.87	95	(33.5)	212	880.82
6 < to <= 7 months	146	(53.3)	401	1788.78	106	(37.5)	201	864.73
7 < to <= 8 months	133	(48.9)	369	1610.63	105	(37.1)	219	916.47
8 < to <= 9 months	127	(47.7)	316	1449.62	99	(35.2)	197	853.55
9 < to <= 10 months	123	(46.6)	326	1454.93	98	(34.9)	195	819.04
10 < to <= 11 months	125	(47.3)	326	1507.04	94	(33.6)	190	828.73
11 < to <= 12 months	122	(46.4)	323	1452.01	90	(32.4)	187	792.55
> 12 months	102	(38.9)	221	892.13	94	(33.8)	161	636.21

%: Percentage of subjects with one or more events, BG: Blood glucose, E: Number of events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. 1 month = 30.5 days. Daily basal insulin: IGlar U100 (ONWARDS 1), IDeg (ONWARDS 6). Data from ONWARDS 1-6.

7.22.2 Nocturnal hypoglycaemic episodes by trial, classification and month since randomisation - ONWARDS 1 and 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
ONWARDS 1								
Number of subjects	492				492			
PYE (years)	765.50				766.76			
Hypoglycaemia alert value (level 1)	89	(18.1)	286	37.36	91	(18.5)	189	24.65
0 < to <= 1 month	3	(0.6)	3	7.42	4	(0.8)	4	9.93
1 < to <= 2 months	7	(1.4)	11	26.34	6	(1.2)	7	16.91
2 < to <= 3 months	12	(2.4)	15	37.12	8	(1.6)	9	22.50
3 < to <= 4 months	12	(2.4)	14	33.55	6	(1.2)	6	14.52
4 < to <= 5 months	9	(1.8)	9	22.39	5	(1.0)	5	12.55
5 < to <= 6 months	11	(2.2)	14	33.83	12	(2.5)	14	34.08
6 < to <= 7 months	8	(1.6)	8	20.07	9	(1.9)	10	25.16
7 < to <= 8 months	16	(3.3)	27	65.96	3	(0.6)	6	14.64
8 < to <= 9 months	10	(2.1)	21	53.15	6	(1.2)	6	15.14
9 < to <= 10 months	14	(2.9)	23	56.50	9	(1.9)	9	22.00
10 < to <= 11 months	13	(2.7)	20	50.84	6	(1.2)	8	20.21
11 < to <= 12 months	15	(3.1)	26	63.95	10	(2.1)	11	26.92
12 < to <= 13 months	8	(1.7)	9	23.02	9	(1.9)	9	22.80
13 < to <= 14 months	12	(2.5)	15	37.34	8	(1.7)	10	24.55
14 < to <= 15 months	9	(1.9)	12	30.99	14	(2.9)	14	35.67
15 < to <= 16 months	14	(3.0)	22	55.27	17	(3.6)	20	49.62
16 < to <= 17 months	11	(2.4)	13	33.82	10	(2.1)	14	35.96
17 < to <= 18 months	10	(2.1)	13	32.77	17	(3.6)	20	49.83
> 18 months	8	(1.7)	11	25.76	5	(1.1)	7	16.62
Clinically significant hypoglycaemia (level 2)	9	(1.8)	26	3.40	15	(3.0)	23	3.00
0 < to <= 1 month	0				1	(0.2)	1	2.48
1 < to <= 2 months	1	(0.2)	1	2.39	0			
2 < to <= 3 months	0				0			
3 < to <= 4 months	2	(0.4)	2	4.79	2	(0.4)	2	4.84
4 < to <= 5 months	2	(0.4)	2	4.98	0			
5 < to <= 6 months	2	(0.4)	2	4.83	3	(0.6)	4	9.74
6 < to <= 7 months	0				3	(0.6)	4	10.06
7 < to <= 8 months	2	(0.4)	5	12.21	2	(0.4)	2	4.88
8 < to <= 9 months	2	(0.4)	2	5.06	0			
9 < to <= 10 months	1	(0.2)	1	2.46	0			
10 < to <= 11 months	2	(0.4)	4	10.17	1	(0.2)	1	2.53
11 < to <= 12 months	1	(0.2)	1	2.46	0			
12 < to <= 13 months	1	(0.2)	1	2.56	1	(0.2)	1	2.53
13 < to <= 14 months	0				1	(0.2)	1	2.45
14 < to <= 15 months	0				2	(0.4)	2	5.10
15 < to <= 16 months	0				3	(0.6)	3	7.44
16 < to <= 17 months	1	(0.2)	4	10.41	0			
17 < to <= 18 months	1	(0.2)	1	2.52	2	(0.4)	2	4.98
> 18 months	0				0			

%: Percentage of subjects with one or more events, BG: Blood glucose, E: Number of events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. 1 month = 30.5 days. Daily basal insulin: IGlar U100 (ONWARDS 1), IDeg (ONWARDS 6). Data from ONWARDS 1-6. Nocturnal: The period between 00:01 and 05:59 (both included).

Nocturnal hypoglycaemic episodes by trial, classification and month since randomisation - ONWARDS 1 and 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severe hypoglycaemia (level 3)	0				1	(0.2)	1	0.13
0 < to <= 1 month	0				0			
1 < to <= 2 months	0				0			
2 < to <= 3 months	0				0			
3 < to <= 4 months	0				0			
4 < to <= 5 months	0				0			
5 < to <= 6 months	0				0			
6 < to <= 7 months	0				0			
7 < to <= 8 months	0				0			
8 < to <= 9 months	0				1	(0.2)	1	2.52
9 < to <= 10 months	0				0			
10 < to <= 11 months	0				0			
11 < to <= 12 months	0				0			
12 < to <= 13 months	0				0			
13 < to <= 14 months	0				0			
14 < to <= 15 months	0				0			
15 < to <= 16 months	0				0			
16 < to <= 17 months	0				0			
17 < to <= 18 months	0				0			
> 18 months	0				0			
Severe (level 3) or clinically significant (level 2) hypoglycaemia	9	(1.8)	26	3.40	16	(3.3)	24	3.13
0 < to <= 1 month	0				1	(0.2)	1	2.48
1 < to <= 2 months	1	(0.2)	1	2.39	0			
2 < to <= 3 months	0				0			
3 < to <= 4 months	2	(0.4)	2	4.79	2	(0.4)	2	4.84
4 < to <= 5 months	2	(0.4)	2	4.98	0			
5 < to <= 6 months	2	(0.4)	2	4.83	3	(0.6)	4	9.74
6 < to <= 7 months	0				3	(0.6)	4	10.06
7 < to <= 8 months	2	(0.4)	5	12.21	2	(0.4)	2	4.88
8 < to <= 9 months	2	(0.4)	2	5.06	1	(0.2)	1	2.52
9 < to <= 10 months	1	(0.2)	1	2.46	0			
10 < to <= 11 months	2	(0.4)	4	10.17	1	(0.2)	1	2.53
11 < to <= 12 months	1	(0.2)	1	2.46	0			
12 < to <= 13 months	1	(0.2)	1	2.56	1	(0.2)	1	2.53
13 < to <= 14 months	0				1	(0.2)	1	2.45
14 < to <= 15 months	0				2	(0.4)	2	5.10
15 < to <= 16 months	0				3	(0.6)	3	7.44
16 < to <= 17 months	1	(0.2)	4	10.41	0			
17 < to <= 18 months	1	(0.2)	1	2.52	2	(0.4)	2	4.98
> 18 months	0				0			
ONWARDS 6								
Number of subjects	290				292			
PYE (years)	300.16				309.58			

%: Percentage of subjects with one or more events, BG: Blood glucose, E: Number of events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. 1 month = 30.5 days. Daily basal insulin: IGlar U100 (ONWARDS 1), IDeg (ONWARDS 6). Data from ONWARDS 1-6. Nocturnal: The period between 00:01 and 05:59 (both included).

Nocturnal hypoglycaemic episodes by trial, classification and month since randomisation - ONWARDS 1 and 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hypoglycaemia alert value (level 1)	237	(81.7)	1953	650.66	211	(72.3)	1523	491.95
0 < to <= 1 month	96	(33.1)	163	687.80	77	(26.4)	138	575.53
1 < to <= 2 months	111	(38.5)	196	802.39	70	(24.1)	126	514.67
2 < to <= 3 months	98	(34.1)	159	679.48	67	(23.3)	112	475.12
3 < to <= 4 months	96	(33.8)	176	733.58	73	(25.4)	136	560.78
4 < to <= 5 months	88	(31.3)	141	613.98	60	(21.1)	96	410.73
5 < to <= 6 months	90	(32.5)	147	626.44	74	(26.1)	122	506.89
6 < to <= 7 months	83	(30.3)	144	642.35	58	(20.5)	99	425.91
7 < to <= 8 months	95	(34.9)	169	737.66	82	(29.0)	134	560.76
8 < to <= 9 months	90	(33.8)	144	660.59	74	(26.3)	123	532.93
9 < to <= 10 months	67	(25.4)	143	638.21	69	(24.6)	113	474.62
10 < to <= 11 months	78	(29.5)	127	587.10	71	(25.4)	120	523.41
11 < to <= 12 months	75	(28.5)	123	552.93	70	(25.2)	113	478.92
> 12 months	73	(27.9)	121	488.45	60	(21.6)	91	359.60
Clinically significant hypoglycaemia (level 2)	171	(59.0)	861	286.85	140	(47.9)	458	147.94
0 < to <= 1 month	50	(17.2)	84	354.45	30	(10.3)	44	183.50
1 < to <= 2 months	50	(17.4)	92	376.63	29	(10.0)	38	155.22
2 < to <= 3 months	46	(16.0)	70	299.14	28	(9.8)	39	165.44
3 < to <= 4 months	55	(19.4)	87	362.62	27	(9.4)	30	123.70
4 < to <= 5 months	44	(15.7)	55	239.49	21	(7.4)	26	111.24
5 < to <= 6 months	47	(17.0)	87	370.75	32	(11.3)	46	191.12
6 < to <= 7 months	38	(13.9)	66	294.41	27	(9.5)	29	124.76
7 < to <= 8 months	40	(14.7)	58	253.16	29	(10.2)	33	138.10
8 < to <= 9 months	41	(15.4)	51	233.96	26	(9.3)	32	138.65
9 < to <= 10 months	37	(14.0)	52	232.07	32	(11.4)	44	184.81
10 < to <= 11 months	43	(16.3)	53	245.01	28	(10.0)	35	152.66
11 < to <= 12 months	33	(12.5)	68	305.69	22	(7.9)	28	118.67
> 12 months	29	(11.1)	38	153.40	30	(10.8)	34	134.36
Severe hypoglycaemia (level 3)	4	(1.4)	9	3.00	4	(1.4)	4	1.29
0 < to <= 1 month	1	(0.3)	1	4.22	3	(1.0)	3	12.51
1 < to <= 2 months	1	(0.3)	1	4.09	0			
2 < to <= 3 months	1	(0.3)	2	8.55	0			
3 < to <= 4 months	0				0			
4 < to <= 5 months	0				0			
5 < to <= 6 months	1	(0.4)	1	4.26	0			
6 < to <= 7 months	1	(0.4)	1	4.46	0			
7 < to <= 8 months	1	(0.4)	1	4.36	0			
8 < to <= 9 months	1	(0.4)	1	4.59	0			
9 < to <= 10 months	0				0			
10 < to <= 11 months	0				0			
11 < to <= 12 months	0				1	(0.4)	1	4.24
> 12 months	1	(0.4)	1	4.04	0			

%: Percentage of subjects with one or more events, BG: Blood glucose, E: Number of events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. 1 month = 30.5 days. Daily basal insulin: IGlar U100 (ONWARDS 1), IDeg (ONWARDS 6). Data from ONWARDS 1-6. Nocturnal: The period between 00:01 and 05:59 (both included).

Nocturnal hypoglycaemic episodes by trial, classification and month since randomisation - ONWARDS 1 and 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severe (level 3) or clinically significant (level 2) hypoglycaemia	171	(59.0)	870	289.85	140	(47.9)	462	149.23
0 < to <= 1 month	51	(17.6)	85	358.67	31	(10.6)	47	196.01
1 < to <= 2 months	51	(17.7)	93	380.72	29	(10.0)	38	155.22
2 < to <= 3 months	47	(16.4)	72	307.69	28	(9.8)	39	165.44
3 < to <= 4 months	55	(19.4)	87	362.62	27	(9.4)	30	123.70
4 < to <= 5 months	44	(15.7)	55	239.49	21	(7.4)	26	111.24
5 < to <= 6 months	47	(17.0)	88	375.01	32	(11.3)	46	191.12
6 < to <= 7 months	39	(14.2)	67	298.87	27	(9.5)	29	124.76
7 < to <= 8 months	41	(15.1)	59	257.53	29	(10.2)	33	138.10
8 < to <= 9 months	42	(15.8)	52	238.55	26	(9.3)	32	138.65
9 < to <= 10 months	37	(14.0)	52	232.07	32	(11.4)	44	184.81
10 < to <= 11 months	43	(16.3)	53	245.01	28	(10.0)	35	152.66
11 < to <= 12 months	33	(12.5)	68	305.69	22	(7.9)	29	122.91
> 12 months	30	(11.5)	39	157.44	30	(10.8)	34	134.36

%: Percentage of subjects with one or more events, BG: Blood glucose, E: Number of events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. 1 month = 30.5 days. Daily basal insulin: IGlar U100 (ONWARDS 1), IDeg (ONWARDS 6). Data from ONWARDS 1-6. Nocturnal: The period between 00:01 and 05:59 (both included).

7.22.3 Hypoglycaemic episodes by trial, classification and baseline renal function - ONWARDS 1 and 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
ONWARDS 1								
Number of subjects	492				492			
Number of subjects (Normal)	224				222			
Number of subjects (Mild)	223				213			
Number of subjects (Moderate)	45				56			
Number of subjects (Severe)	0				1			
PYE	765.50				766.76			
PYE (Normal)	348.90				349.01			
PYE (Mild)	349.01				332.31			
PYE (Moderate)	67.58				83.85			
PYE (Severe)	0				1.59			
Hypoglycaemia alert value (level 1)	278	(56.5)	2308	301.50	239	(48.6)	1067	139.16
Normal	121	(54.0)	973	278.87	113	(50.9)	509	145.84
Mild impairment	128	(57.4)	1131	324.06	105	(49.3)	464	139.63
Moderate impairment	29	(64.4)	204	301.86	21	(37.5)	94	112.11
Severe impairment	0				0			
Clinically significant hypoglycaemia (level 2)	61	(12.4)	226	29.52	66	(13.4)	114	14.87
Normal	31	(13.8)	57	16.34	34	(15.3)	64	18.34
Mild impairment	24	(10.8)	155	44.41	23	(10.8)	41	12.34
Moderate impairment	6	(13.3)	14	20.72	8	(14.3)	8	9.54
Severe impairment	0				1	(100.0)	1	62.87
Severe hypoglycaemia (level 3)	1	(0.2)	1	0.13	6	(1.2)	7	0.91
Normal	1	(0.4)	1	0.29	2	(0.9)	3	0.86
Mild impairment	0				2	(0.9)	2	0.60
Moderate impairment	0				2	(3.6)	2	2.39
Severe impairment	0				0			
Severe (level 3) or clinically significant (level 2) hypoglycaemia	61	(12.4)	227	29.65	70	(14.2)	121	15.78
Normal	31	(13.8)	58	16.62	35	(15.8)	67	19.20
Mild impairment	24	(10.8)	155	44.41	25	(11.7)	43	12.94
Moderate impairment	6	(13.3)	14	20.72	9	(16.1)	10	11.93
Severe impairment	0				1	(100.0)	1	62.87

%: Percentage of subjects with one or more events, BG: Blood glucose, E: Number of events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), moderate impairment (30<=eGFR<60), and severe impairment (eGFR<30). Hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. Daily basal insulin: IGlar U100 (ONWARDS 1), IDeg (ONWARDS 6).

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adhypo.xpt; variable(s): STDNM ACAT4; criteria: SAFFL == "Y" & STUDYID %in% c("NN1436-4477", "NN1436-4625") & ANL02FL == "Y" & ANELFL == "Y"
nn1436/nn1436-japan/submission_ext_20230612_er
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Hypoglycaemic episodes by trial, classification and baseline renal function - ONWARDS 1 and 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
ONWARDS 6								
Number of subjects	290				292			
Number of subjects (Normal)	197				190			
Number of subjects (Mild)	88				93			
Number of subjects (Moderate)	5				9			
Number of subjects (Severe)	0				0			
PYE	300.16				309.58			
PYE (Normal)	205.47				199.83			
PYE (Mild)	89.22				99.88			
PYE (Moderate)	5.46				9.87			
PYE (Severe)	0				0			
Hypoglycaemia alert value (level 1)	288	(99.3)	20406	6798.40	289	(99.0)	14819	4786.77
Normal	197	(100.0)	13725	6679.71	189	(99.5)	9537	4772.49
Mild impairment	87	(98.9)	6246	7000.59	91	(97.8)	4933	4938.95
Moderate impairment	4	(80.0)	435	7960.11	9	(100.0)	349	3535.98
Severe impairment	0				0			
Clinically significant hypoglycaemia (level 2)	262	(90.3)	5047	1681.44	250	(85.6)	2811	908.00
Normal	177	(89.8)	3359	1634.76	165	(86.8)	1808	904.76
Mild impairment	82	(93.2)	1618	1813.47	77	(82.8)	952	953.15
Moderate impairment	3	(60.0)	70	1280.94	8	(88.9)	51	516.72
Severe impairment	0				0			
Severe hypoglycaemia (level 3)	13	(4.5)	56	18.66	12	(4.1)	25	8.08
Normal	10	(5.1)	48	23.36	9	(4.7)	22	11.01
Mild impairment	3	(3.4)	8	8.97	2	(2.2)	2	2.00
Moderate impairment	0				1	(11.1)	1	10.13
Severe impairment	0				0			
Severe (level 3) or clinically significant (level 2) hypoglycaemia	263	(90.7)	5103	1700.10	250	(85.6)	2836	916.07
Normal	178	(90.4)	3407	1658.13	165	(86.8)	1830	915.76
Mild impairment	82	(93.2)	1626	1822.44	77	(82.8)	954	955.15
Moderate impairment	3	(60.0)	70	1280.94	8	(88.9)	52	526.85
Severe impairment	0				0			

%: Percentage of subjects with one or more events, BG: Blood glucose, E: Number of events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), moderate impairment (30<=eGFR<60), and severe impairment (eGFR<30). Hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. Daily basal insulin: IGlar U100 (ONWARDS 1), IDeg (ONWARDS 6).

adsl.xpt; variable(s): STDNM ONTRDURY GFRGR1; criteria: SAFFL == "Y" & STUDYID %in% c("NN1436-4477", "NN1436-4625")
adhypo.xpt; variable(s): STDNM ACAT4; criteria: SAFFL == "Y" & STUDYID %in% c("NN1436-4477", "NN1436-4625") & ANL02FL == "Y" & ANELFL == "Y"
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7.22.4 Hypoglycaemic episodes by trial, classification and baseline BMI group - ONWARDS 1 and 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
ONWARDS 1								
Number of subjects	492				492			
Number of subjects (<25)	87				80			
Number of subjects (>=25 - <30)	164				171			
Number of subjects (>=30 - <35)	162				146			
Number of subjects (>=35)	79				95			
PYE	765.50				766.76			
PYE (<25)	136.15				121.08			
PYE (>=25 - <30)	255.18				269.64			
PYE (>=30 - <35)	252.14				228.71			
PYE (>=35)	122.03				147.32			
Hypoglycaemia alert value (level 1)	278	(56.5)	2308	301.50	239	(48.6)	1067	139.16
<25	64	(73.6)	796	584.65	48	(60.0)	276	227.96
>=25 - <30	96	(58.5)	660	258.64	91	(53.2)	393	145.75
>=30 - <35	83	(51.2)	511	202.66	63	(43.2)	262	114.55
>=35	35	(44.3)	341	279.45	37	(38.9)	136	92.31
Clinically significant hypoglycaemia (level 2)	61	(12.4)	226	29.52	66	(13.4)	114	14.87
<25	9	(10.3)	86	63.17	13	(16.2)	27	22.30
>=25 - <30	22	(13.4)	46	18.03	23	(13.5)	37	13.72
>=30 - <35	23	(14.2)	44	17.45	15	(10.3)	23	10.06
>=35	7	(8.9)	50	40.97	15	(15.8)	27	18.33
Severe hypoglycaemia (level 3)	1	(0.2)	1	0.13	6	(1.2)	7	0.91
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				2	(1.2)	3	1.11
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				3	(3.2)	3	2.04
Severe (level 3) or clinically significant (level 2) hypoglycaemia	61	(12.4)	227	29.65	70	(14.2)	121	15.78
<25	9	(10.3)	87	63.90	13	(16.2)	27	22.30
>=25 - <30	22	(13.4)	46	18.03	24	(14.0)	40	14.83
>=30 - <35	23	(14.2)	44	17.45	16	(11.0)	24	10.49
>=35	7	(8.9)	50	40.97	17	(17.9)	30	20.36

%: Percentage of subjects with one or more events, BG: Blood glucose, BMI: Body mass index (kg/m^2), E: Number of events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. Daily basal insulin: IGlar U100 (ONWARDS 1), IDeg (ONWARDS 6).

Hypoglycaemic episodes by trial, classification and baseline BMI group - ONWARDS 1 and 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
ONWARDS 6								
Number of subjects	290				292			
Number of subjects (<25)	105				135			
Number of subjects (>=25 - <30)	118				102			
Number of subjects (>=30 - <35)	46				41			
Number of subjects (>=35)	21				14			
PYE	300.16				309.58			
PYE (<25)	105.56				145.28			
PYE (>=25 - <30)	122.72				106.74			
PYE (>=30 - <35)	50.00				42.78			
PYE (>=35)	21.89				14.79			
Hypoglycaemia alert value (level 1)	288	(99.3)	20406	6798.40	289	(99.0)	14819	4786.77
<25	105	(100.0)	7999	7577.64	135	(100.0)	7081	4874.08
>=25 - <30	116	(98.3)	8247	6720.40	99	(97.1)	5453	5108.65
>=30 - <35	46	(100.0)	2667	5334.44	41	(100.0)	1675	3915.73
>=35	21	(100.0)	1493	6821.59	14	(100.0)	610	4125.21
Clinically significant hypoglycaemia (level 2)	262	(90.3)	5047	1681.44	250	(85.6)	2811	908.00
<25	96	(91.4)	1904	1803.70	114	(84.4)	1320	908.60
>=25 - <30	106	(89.8)	2223	1811.50	92	(90.2)	1068	1000.56
>=30 - <35	40	(87.0)	637	1274.10	33	(80.5)	344	804.19
>=35	20	(95.2)	283	1293.04	11	(78.6)	79	534.25
Severe hypoglycaemia (level 3)	13	(4.5)	56	18.66	12	(4.1)	25	8.08
<25	4	(3.8)	4	3.79	5	(3.7)	18	12.39
>=25 - <30	5	(4.2)	12	9.78	6	(5.9)	6	5.62
>=30 - <35	1	(2.2)	3	6.00	1	(2.4)	1	2.34
>=35	3	(14.3)	37	169.05	0			
Severe (level 3) or clinically significant (level 2) hypoglycaemia	263	(90.7)	5103	1700.10	250	(85.6)	2836	916.07
<25	96	(91.4)	1908	1807.49	114	(84.4)	1338	920.99
>=25 - <30	107	(90.7)	2235	1821.28	92	(90.2)	1074	1006.18
>=30 - <35	40	(87.0)	640	1280.11	33	(80.5)	345	806.52
>=35	20	(95.2)	320	1462.10	11	(78.6)	79	534.25

%: Percentage of subjects with one or more events, BG: Blood glucose, BMI: Body mass index (kg/m^2), E: Number of events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. Daily basal insulin: IGlar U100 (ONWARDS 1), IDeg (ONWARDS 6).

7.22.5 Hypoglycaemic episodes by trial, classification and age group - ONWARDS 1 and 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
ONWARDS 1								
Number of subjects	492				492			
Number of subjects (>=18 - <65 years)	333				332			
Number of subjects (>=65 - <75 years)	134				144			
Number of subjects (>=75 years)	25				16			
PYE	765.50				766.76			
PYE (>=18 - <65 years)	518.30				522.36			
PYE (>=65 - <75 years)	208.54				220.17			
PYE (>=75 years)	38.66				24.22			
Hypoglycaemia alert value (level 1)	278	(56.5)	2308	301.50	239	(48.6)	1067	139.16
>=18 - <65 years	180	(54.1)	1519	293.07	165	(49.7)	766	146.64
>=65 - <75 years	83	(61.9)	712	341.43	68	(47.2)	269	122.18
>=75 years	15	(60.0)	77	199.18	6	(37.5)	32	132.11
Clinically significant hypoglycaemia (level 2)	61	(12.4)	226	29.52	66	(13.4)	114	14.87
>=18 - <65 years	42	(12.6)	129	24.89	49	(14.8)	90	17.23
>=65 - <75 years	18	(13.4)	93	44.60	16	(11.1)	22	9.99
>=75 years	1	(4.0)	4	10.35	1	(6.2)	2	8.26
Severe hypoglycaemia (level 3)	1	(0.2)	1	0.13	6	(1.2)	7	0.91
>=18 - <65 years	1	(0.3)	1	0.19	4	(1.2)	5	0.96
>=65 - <75 years	0				2	(1.4)	2	0.91
>=75 years	0				0			
Severe (level 3) or clinically significant (level 2) hypoglycaemia	61	(12.4)	227	29.65	70	(14.2)	121	15.78
>=18 - <65 years	42	(12.6)	130	25.08	52	(15.7)	95	18.19
>=65 - <75 years	18	(13.4)	93	44.60	17	(11.8)	24	10.90
>=75 years	1	(4.0)	4	10.35	1	(6.2)	2	8.26

%: Percentage of subjects with one or more events, BG: Blood glucose, E: Number of events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. Daily basal insulin: IGlar U100 (ONWARDS 1), IDeg (ONWARDS 6).

adsl.xpt; variable(s): STDNM ONTRDURY AGEGR1; criteria: SAFFL == "Y" & STUDYID %in% c("NN1436-4477", "NN1436-4625")
adhypo.xpt; variable(s): STDNM ACAT4; criteria: SAFFL == "Y" & STUDYID %in% c("NN1436-4477", "NN1436-4625") & ANL02FL == "Y" & ANELFL == "Y"
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Hypoglycaemic episodes by trial, classification and age group - ONWARDS 1 and 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
ONWARDS 6								
Number of subjects	290				292			
Number of subjects (>=18 - <65 years)	267				271			
Number of subjects (>=65 - <75 years)	20				18			
Number of subjects (>=75 years)	3				3			
PYE	300.16				309.58			
PYE (>=18 - <65 years)	277.22				286.61			
PYE (>=65 - <75 years)	20.28				19.70			
PYE (>=75 years)	2.66				3.28			
Hypoglycaemia alert value (level 1)	288	(99.3)	20406	6798.40	289	(99.0)	14819	4786.77
>=18 - <65 years	266	(99.6)	19067	6877.97	268	(98.9)	13654	4763.98
>=65 - <75 years	19	(95.0)	1209	5960.95	18	(100.0)	919	4665.90
>=75 years	3	(100.0)	130	4890.06	3	(100.0)	246	7506.39
Clinically significant hypoglycaemia (level 2)	262	(90.3)	5047	1681.44	250	(85.6)	2811	908.00
>=18 - <65 years	241	(90.3)	4741	1710.20	234	(86.3)	2540	886.22
>=65 - <75 years	19	(95.0)	299	1474.21	13	(72.2)	236	1198.21
>=75 years	2	(66.7)	7	263.31	3	(100.0)	35	1067.98
Severe hypoglycaemia (level 3)	13	(4.5)	56	18.66	12	(4.1)	25	8.08
>=18 - <65 years	13	(4.9)	56	20.20	10	(3.7)	23	8.02
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	0				1	(33.3)	1	30.51
Severe (level 3) or clinically significant (level 2) hypoglycaemia	263	(90.7)	5103	1700.10	250	(85.6)	2836	916.07
>=18 - <65 years	242	(90.6)	4797	1730.40	234	(86.3)	2563	894.25
>=65 - <75 years	19	(95.0)	299	1474.21	13	(72.2)	237	1203.28
>=75 years	2	(66.7)	7	263.31	3	(100.0)	36	1098.50

%: Percentage of subjects with one or more events, BG: Blood glucose, E: Number of events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. Daily basal insulin: IGlar U100 (ONWARDS 1), IDeg (ONWARDS 6).

adsl.xpt; variable(s): STDNM ONTRDURY AGEGR1; criteria: SAFFL == "Y" & STUDYID %in% c("NN1436-4477", "NN1436-4625")
adhypo.xpt; variable(s): STDNM ACAT4; criteria: SAFFL == "Y" & STUDYID %in% c("NN1436-4477", "NN1436-4625") & ANL02FL == "Y" & ANELFL == "Y"
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7.22.6 Hypoglycaemic episodes by trial, classification and treatment day - ONWARDS 1 and 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
ONWARDS 1								
Number of subjects	492				492			
PYE (years)	765.50				766.76			
Hypoglycaemia alert value (level 1)								
Day 1	82	(16.7)	197	178.58	105	(21.3)	167	151.71
Day 2	158	(32.1)	490	447.97	89	(18.1)	137	124.93
Day 3	177	(36.0)	566	518.01	88	(17.9)	136	124.15
Day 4	155	(31.5)	425	389.27	90	(18.3)	145	132.45
Day 5	122	(24.8)	284	260.19	98	(19.9)	169	154.44
Day 6	101	(20.5)	193	176.86	100	(20.3)	161	147.24
Day 7	69	(14.0)	153	140.27	95	(19.3)	152	139.17
Clinically significant hypoglycaemia (level 2)								
Day 1	12	(2.4)	20	18.13	13	(2.6)	15	13.63
Day 2	23	(4.7)	40	36.57	12	(2.4)	14	12.77
Day 3	21	(4.3)	46	42.10	13	(2.6)	14	12.78
Day 4	25	(5.1)	46	42.13	14	(2.8)	18	16.44
Day 5	18	(3.7)	26	23.82	14	(2.8)	17	15.54
Day 6	12	(2.4)	26	23.83	16	(3.3)	16	14.63
Day 7	11	(2.2)	22	20.17	19	(3.9)	20	18.31
Severe hypoglycaemia (level 3)								
Day 1	0				1	(0.2)	1	0.91
Day 2	0				0			
Day 3	0				0			
Day 4	0				0			
Day 5	0				0			
Day 6	0				4	(0.8)	4	3.66
Day 7	1	(0.2)	1	0.92	1	(0.2)	2	1.83
Severe (level 3) or clinically significant (level 2) hypoglycaemia								
Day 1	12	(2.4)	20	18.13	14	(2.8)	16	14.54
Day 2	23	(4.7)	40	36.57	12	(2.4)	14	12.77
Day 3	21	(4.3)	46	42.10	13	(2.6)	14	12.78
Day 4	25	(5.1)	46	42.13	14	(2.8)	18	16.44
Day 5	18	(3.7)	26	23.82	14	(2.8)	17	15.54
Day 6	12	(2.4)	26	23.83	20	(4.1)	20	18.29
Day 7	12	(2.4)	23	21.09	19	(3.9)	22	20.14

%: Percentage of subjects with one or more events, BG: Blood glucose, E: Number of events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Day represents the relative weekdays with day of start of treatment defined as day 1. Day 1 therefore includes day 1, 8, 15, etc., where day 8 is the day of the 2nd dose of insulin icodec for the insulin icodec arm and day of the 8th dose for the daily basal insulin arm etc. Hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. Daily basal insulin: IGlar U100 (ONWARDS 1), IDeg (ONWARDS 6).

adsl.xpt; variable(s): TRAG1 TRAG1N ONTRDURW ONTRDURD SAFFL STDNM USUBJID; criteria: SAFFL == "Y" & STUDYID %in% c("NN1436-4477", "NN1436-4625")
adhypo.xpt; variable(s): TRAG1 TRAG1N ANL02FL ANELFL SAFFL ACAT4 ACAT4N ASTDY ASTWK STDNM USUBJID; criteria: SAFFL == "Y" & STUDYID %in% c("NN1436-4477", "NN1436-4625") & ANL02FL == "Y" & ANELFL == "Y"

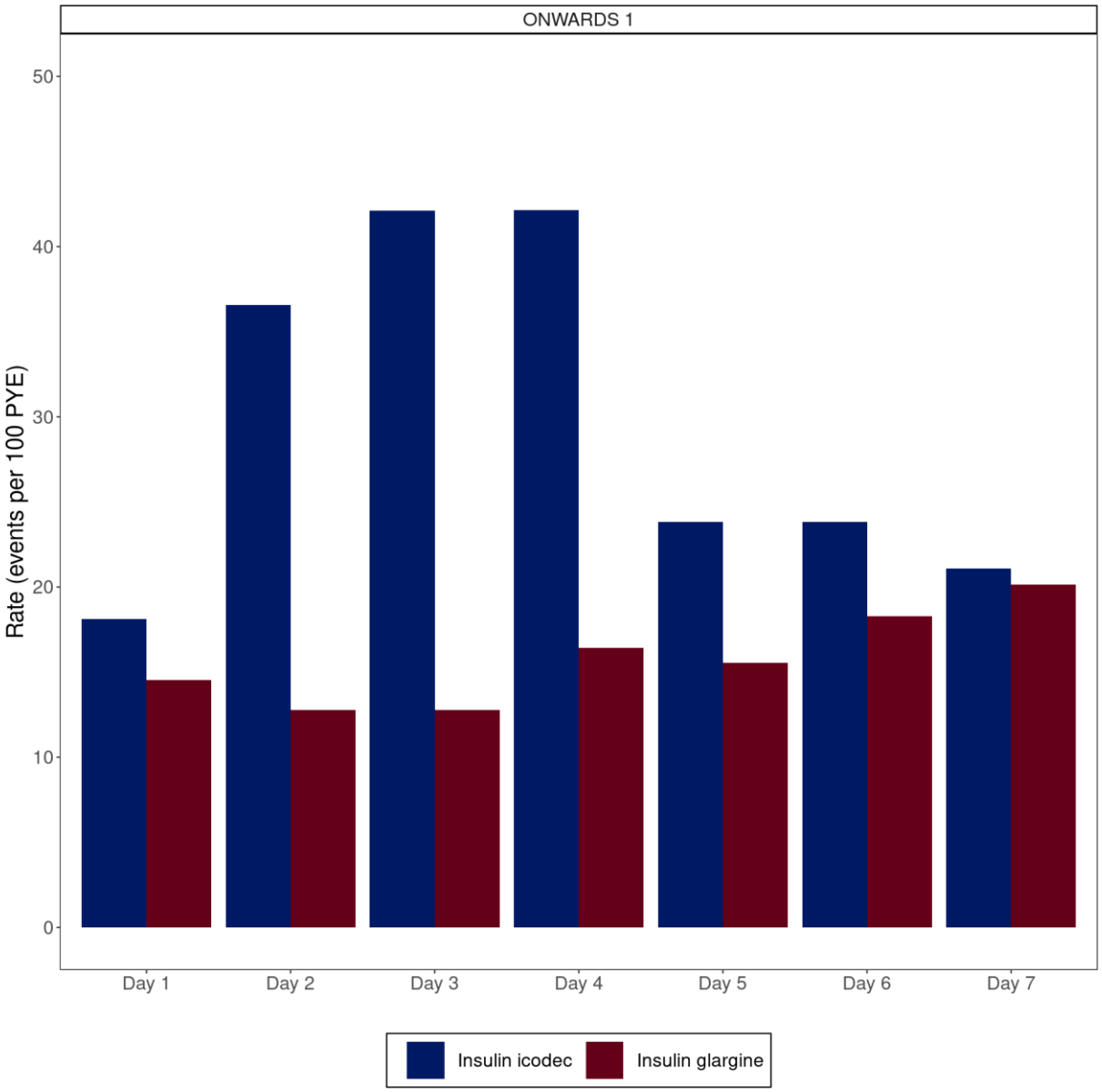
Hypoglycaemic episodes by trial, classification and treatment day - ONWARDS 1 and 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
ONWARDS 6								
Number of subjects	290				292			
PYE (years)	300.16				309.58			
Hypoglycaemia alert value (level 1)								
Day 1	265	(91.4)	2254	5190.55	281	(96.2)	2325	5226.53
Day 2	280	(96.6)	3672	8553.56	276	(94.5)	2215	5000.49
Day 3	274	(94.5)	3843	8975.93	269	(92.1)	2125	4803.84
Day 4	276	(95.2)	3367	7871.20	274	(93.8)	2076	4696.27
Day 5	276	(95.2)	2867	6705.33	274	(93.8)	2001	4527.72
Day 6	272	(93.8)	2322	5432.08	265	(90.8)	1987	4503.02
Day 7	266	(91.7)	2081	4872.34	274	(93.8)	2090	4745.57
Clinically significant hypoglycaemia (level 2)								
Day 1	164	(56.6)	480	1105.35	148	(50.7)	395	887.95
Day 2	205	(70.7)	965	2247.87	160	(54.8)	392	884.96
Day 3	202	(69.7)	1006	2349.67	166	(56.8)	406	917.82
Day 4	196	(67.6)	922	2155.41	156	(53.4)	423	956.90
Day 5	185	(63.8)	668	1562.32	146	(50.0)	401	907.36
Day 6	175	(60.3)	553	1293.69	150	(51.4)	399	904.23
Day 7	156	(53.8)	453	1060.63	149	(51.0)	395	896.89
Severe hypoglycaemia (level 3)								
Day 1	4	(1.4)	9	20.73	4	(1.4)	6	13.49
Day 2	3	(1.0)	9	20.96	1	(0.3)	2	4.52
Day 3	5	(1.7)	16	37.37	2	(0.7)	4	9.04
Day 4	2	(0.7)	7	16.36	4	(1.4)	4	9.05
Day 5	4	(1.4)	8	18.71	2	(0.7)	3	6.79
Day 6	4	(1.4)	4	9.36	4	(1.4)	4	9.06
Day 7	2	(0.7)	3	7.02	2	(0.7)	2	4.54
Severe (level 3) or clinically significant (level 2) hypoglycaemia								
Day 1	165	(56.9)	489	1126.08	149	(51.0)	401	901.44
Day 2	205	(70.7)	974	2268.84	160	(54.8)	394	889.48
Day 3	203	(70.0)	1022	2387.04	166	(56.8)	410	926.86
Day 4	197	(67.9)	929	2171.77	156	(53.4)	427	965.95
Day 5	187	(64.5)	676	1581.03	146	(50.0)	404	914.14
Day 6	176	(60.7)	557	1303.04	151	(51.7)	403	913.29
Day 7	157	(54.1)	456	1067.65	150	(51.4)	397	901.43

%: Percentage of subjects with one or more events, BG: Blood glucose, E: Number of events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Day represents the relative weekdays with day of start of treatment defined as day 1. Day 1 therefore includes day 1, 8, 15, etc., where day 8 is the day of the 2nd dose of insulin icodec for the insulin icodec arm and day of the 8th dose for the daily basal insulin arm etc. Hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. Daily basal insulin: IGlar U100 (ONWARDS 1), IDeg (ONWARDS 6).

adsl.xpt; variable(s): TRAG1 TRAG1N ONTRDURW ONTRDURD SAFFL STDNM USUBJID; criteria: SAFFL == "Y" & STUDYID %in% c("NN1436-4477", "NN1436-4625")
adhypo.xpt; variable(s): TRAG1 TRAG1N ANL02FL ANELFL SAFFL ACAT4 ACAT4N ASTDY ASTWK STDNM USUBJID; criteria: SAFFL == "Y" & STUDYID %in% c("NN1436-4477", "NN1436-4625") & ANL02FL == "Y" & ANELFL == "Y"

7.22.7 Severe (level 3) or clinically significant hypoglycaemia (level 2) by treatment day - ONWARDS 1 (extension part) - on-treatment - bar plot - safety analysis set

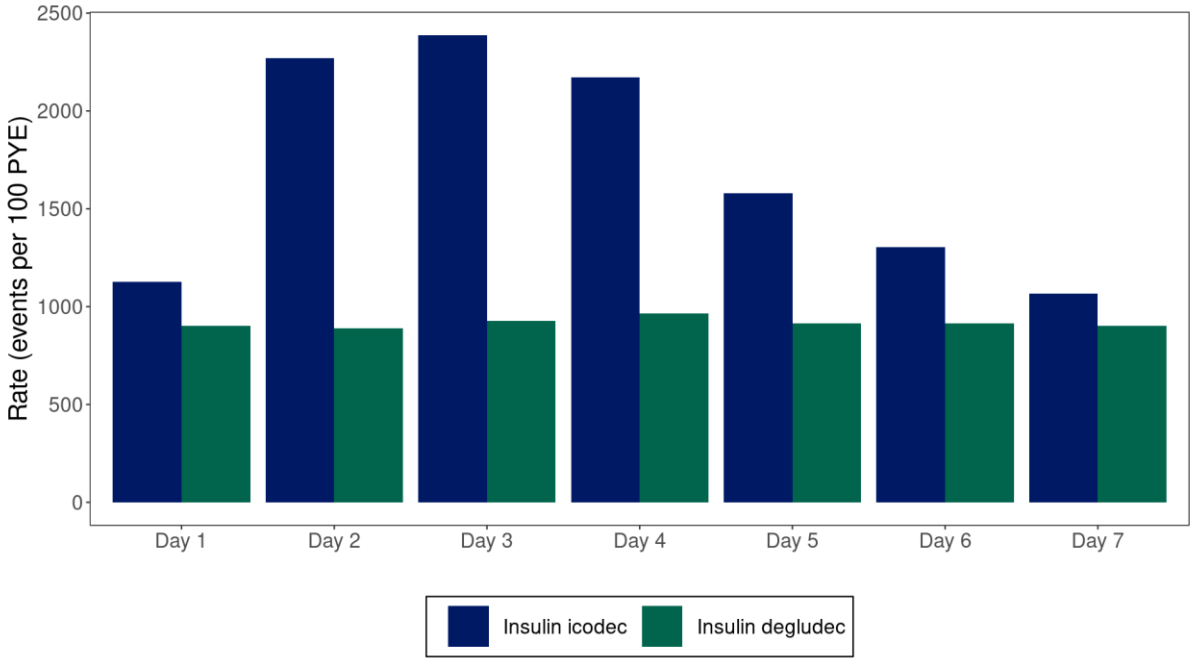


BG: Blood glucose, PYE: Patient years of exposure (1 PYE = 365.25 days). Safety analysis set. Observed data. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): TRTA TRTAN ONTRDURD SAFFL STDNM USUBJID; criteria: SAFFL == "Y" & STDNMN == 1
adhypo.xpt; variable(s): TRTA TRTAN ANL02FL ANELFL SAFFL ACAT4 ACAT4N ASTDY ASTWK STDNM USUBJID; criteria: SAFFL == "Y" & STDNMN == 1 & ANL02FL == "Y" & ANELFL == "Y"

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7.22.8 Severe (level 3) or clinically significant hypoglycaemia (level 2) by treatment day - ONWARDS 6 (extension part) - on-treatment - bar plot - safety analysis set



BG: Blood glucose, PYE: Patient years of exposure (1 PYE = 365.25 days). Safety analysis set. Observed data. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. Daily basal insulin: IDeg.

adsl.xpt; variable(s): TRTA TRTAN ONTRDURW ONTRDURD SAFFL; criteria: SAFFL == "Y" & STDNMN == 6
adhypo.xpt; variable(s): TRTA TRTAN SAFFL ACAT4 ACAT4N ASTDY ASTWK; criteria: SAFFL == "Y" & STDNMN == 6 & ANL02FL == "Y" & ANELFL == "Y"
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7.22.9 Duration of hypoglycaemic episodes in 30-minute intervals by trial and classification based on hypoglycaemic episodes form - ONWARDS 1 and 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec		Daily basal insulin	
	E	(%)	E	(%)
ONWARDS 1				
Number of subjects	492		492	
Hypoglycaemia alert value (level 1)				
Missing duration	1020		496	
Non-missing duration	1288	(100.0)	571	(100.0)
<30 minutes	846	(65.7)	371	(65.0)
30 - <60 minutes	219	(17.0)	100	(17.5)
60 - <90 minutes	95	(7.4)	40	(7.0)
90 - <120 minutes	20	(1.6)	9	(1.6)
120 - <150 minutes	46	(3.6)	16	(2.8)
150 - <180 minutes	12	(0.9)	4	(0.7)
180 - <210 minutes	8	(0.6)	2	(0.4)
210 - <240 minutes	3	(0.2)	0	
240 - <270 minutes	3	(0.2)	1	(0.2)
270 - <300 minutes	0		0	
300 - <330 minutes	2	(0.2)	0	
330 - <360 minutes	0		1	(0.2)
>=360 minutes	34	(2.6)	27	(4.7)
Clinically significant hypoglycaemia (level 2)				
Missing duration	69		49	
Non-missing duration	157	(100.0)	65	(100.0)
<30 minutes	83	(52.9)	45	(69.2)
30 - <60 minutes	29	(18.5)	12	(18.5)
60 - <90 minutes	8	(5.1)	0	
90 - <120 minutes	4	(2.5)	4	(6.2)
120 - <150 minutes	13	(8.3)	2	(3.1)
150 - <180 minutes	1	(0.6)	1	(1.5)
180 - <210 minutes	2	(1.3)	0	
210 - <240 minutes	2	(1.3)	0	
240 - <270 minutes	0		0	
270 - <300 minutes	1	(0.6)	0	
300 - <330 minutes	1	(0.6)	0	
330 - <360 minutes	1	(0.6)	0	
>=360 minutes	12	(7.6)	1	(1.5)
Severe hypoglycaemia (level 3)				
Missing duration	1		2	
Non-missing duration	0		5	(100.0)
<30 minutes	0		2	(40.0)
30 - <60 minutes	0		1	(20.0)
60 - <90 minutes	0		1	(20.0)
90 - <120 minutes	0		0	
120 - <150 minutes	0		0	
150 - <180 minutes	0		1	(20.0)
180 - <210 minutes	0		0	
210 - <240 minutes	0		0	
240 - <270 minutes	0		0	
270 - <300 minutes	0		0	
300 - <330 minutes	0		0	
330 - <360 minutes	0		0	
>=360 minutes	0		0	

%: Percentage of hypoglycaemic episodes, BG: Blood glucose, E: Number of hypoglycaemic episodes. Duration of hypoglycaemic episodes is calculated in minutes with positive durations only contributing to derivations. Hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. Daily basal insulin: IGlar U100 (ONWARDS 1), IDeg (ONWARDS 6).

Duration of hypoglycaemic episodes in 30-minute intervals by trial and classification based on hypoglycaemic episodes form - ONWARDS 1 and 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec		Daily basal insulin	
	E	(%)	E	(%)
Severe (level 3) or clinically significant (level 2) hypoglycaemia				
Missing duration	70		51	
Non-missing duration	157	(100.0)	70	(100.0)
<30 minutes	83	(52.9)	47	(67.1)
30 - <60 minutes	29	(18.5)	13	(18.6)
60 - <90 minutes	8	(5.1)	1	(1.4)
90 - <120 minutes	4	(2.5)	4	(5.7)
120 - <150 minutes	13	(8.3)	2	(2.9)
150 - <180 minutes	1	(0.6)	2	(2.9)
180 - <210 minutes	2	(1.3)	0	
210 - <240 minutes	2	(1.3)	0	
240 - <270 minutes	0		0	
270 - <300 minutes	1	(0.6)	0	
300 - <330 minutes	1	(0.6)	0	
330 - <360 minutes	1	(0.6)	0	
>=360 minutes	12	(7.6)	1	(1.4)
ONWARDS 6				
Number of subjects	290		292	
Hypoglycaemia alert value (level 1)				
Missing duration	7113		5072	
Non-missing duration	13293	(100.0)	9747	(100.0)
<30 minutes	9644	(72.5)	7552	(77.5)
30 - <60 minutes	1866	(14.0)	1350	(13.9)
60 - <90 minutes	1058	(8.0)	514	(5.3)
90 - <120 minutes	155	(1.2)	73	(0.7)
120 - <150 minutes	155	(1.2)	50	(0.5)
150 - <180 minutes	58	(0.4)	18	(0.2)
180 - <210 minutes	67	(0.5)	26	(0.3)
210 - <240 minutes	33	(0.2)	16	(0.2)
240 - <270 minutes	37	(0.3)	18	(0.2)
270 - <300 minutes	31	(0.2)	14	(0.1)
300 - <330 minutes	19	(0.1)	17	(0.2)
330 - <360 minutes	24	(0.2)	10	(0.1)
>=360 minutes	146	(1.1)	89	(0.9)
Clinically significant hypoglycaemia (level 2)				
Missing duration	1759		823	
Non-missing duration	3288	(100.0)	1988	(100.0)
<30 minutes	1952	(59.4)	1363	(68.6)
30 - <60 minutes	495	(15.1)	336	(16.9)
60 - <90 minutes	406	(12.3)	138	(6.9)
90 - <120 minutes	67	(2.0)	25	(1.3)
120 - <150 minutes	81	(2.5)	19	(1.0)
150 - <180 minutes	34	(1.0)	11	(0.6)
180 - <210 minutes	31	(0.9)	11	(0.6)
210 - <240 minutes	20	(0.6)	4	(0.2)
240 - <270 minutes	25	(0.8)	5	(0.3)
270 - <300 minutes	14	(0.4)	5	(0.3)
300 - <330 minutes	14	(0.4)	12	(0.6)
330 - <360 minutes	14	(0.4)	8	(0.4)
>=360 minutes	135	(4.1)	51	(2.6)
Severe hypoglycaemia (level 3)				

%: Percentage of hypoglycaemic episodes, BG: Blood glucose, E: Number of hypoglycaemic episodes. Duration of hypoglycaemic episodes is calculated in minutes with positive durations only contributing to derivations. Hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. Daily basal insulin: IGlar U100 (ONWARDS 1), IDeg (ONWARDS 6).

Duration of hypoglycaemic episodes in 30-minute intervals by trial and classification based on hypoglycaemic episodes form - ONWARDS 1 and 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec		Daily basal insulin	
	E	(%)	E	(%)
Missing duration	3		8	
Non-missing duration	53	(100.0)	17	(100.0)
<30 minutes	38	(71.7)	11	(64.7)
30 - <60 minutes	5	(9.4)	3	(17.6)
60 - <90 minutes	2	(3.8)	1	(5.9)
90 - <120 minutes	2	(3.8)	0	
120 - <150 minutes	2	(3.8)	1	(5.9)
150 - <180 minutes	1	(1.9)	0	
180 - <210 minutes	1	(1.9)	1	(5.9)
210 - <240 minutes	0		0	
240 - <270 minutes	1	(1.9)	0	
270 - <300 minutes	0		0	
300 - <330 minutes	0		0	
330 - <360 minutes	0		0	
>=360 minutes	1	(1.9)	0	
Severe (level 3) or clinically significant (level 2) hypoglycaemia				
Missing duration	1762		831	
Non-missing duration	3341	(100.0)	2005	(100.0)
<30 minutes	1990	(59.6)	1374	(68.5)
30 - <60 minutes	500	(15.0)	339	(16.9)
60 - <90 minutes	408	(12.2)	139	(6.9)
90 - <120 minutes	69	(2.1)	25	(1.2)
120 - <150 minutes	83	(2.5)	20	(1.0)
150 - <180 minutes	35	(1.0)	11	(0.5)
180 - <210 minutes	32	(1.0)	12	(0.6)
210 - <240 minutes	20	(0.6)	4	(0.2)
240 - <270 minutes	26	(0.8)	5	(0.2)
270 - <300 minutes	14	(0.4)	5	(0.2)
300 - <330 minutes	14	(0.4)	12	(0.6)
330 - <360 minutes	14	(0.4)	8	(0.4)
>=360 minutes	136	(4.1)	51	(2.5)

%: Percentage of hypoglycaemic episodes, BG: Blood glucose, E: Number of hypoglycaemic episodes. Duration of hypoglycaemic episodes is calculated in minutes with positive durations only contributing to derivations. Hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. Daily basal insulin: IGlar U100 (ONWARDS 1), IDeg (ONWARDS 6).

7.22.10 Duration of hypoglycaemic episodes by trial and classification - ONWARDS 1 and 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec	Daily basal insulin
ONWARDS 1		
Number of hypoglycaemia alert value (level 1)	2308	1067
Number of clinically significant hypoglycaemia (level 2)	226	114
Number of severe hypoglycaemia (level 3)	1	7
Number of severe (level 3) or clinically significant (level 2) hypoglycaemia	227	121
Hypoglycaemia alert value (level 1)		
E	1288	571
Geom.mean (CV%)	17.9 (255.5)	19.4 (298.0)
Median	19.0	20.0
P25; P75	10.0; 38.2	10.0; 41.0
Min ; Max	1 ; 1440	1 ; 1440
Clinically significant hypoglycaemia (level 2)		
E	157	65
Geom.mean (CV%)	20.4 (736.3)	11.0 (392.5)
Median	27.0	16.0
P25; P75	5.0; 78.0	2.0; 36.0
Min ; Max	1 ; 1436	1 ; 505
Severe hypoglycaemia (level 3)		
E	0	5
Geom.mean (CV%)		42.6 (131.7)
Median		54.0
P25; P75		17.0; 60.0
Min ; Max		15 ; 170
Severe (level 3) or clinically significant (level 2) hypoglycaemia		
E	157	70
Geom.mean (CV%)	20.4 (736.3)	12.2 (388.0)
Median	27.0	16.5
P25; P75	5.0; 78.0	3.2; 38.8
Min ; Max	1 ; 1436	1 ; 505

BG: Blood glucose, CV: Coefficient of variation, E: Number of hypoglycaemic episodes with non-missing duration, P25: 25th percentile, P75: 75th percentile. Duration of hypoglycaemic episodes is calculated in minutes with positive durations only contributing to derivations. Hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. Daily basal insulin: IGlar U100 (ONWARDS 1), IDeg (ONWARDS 6).

Duration of hypoglycaemic episodes by trial and classification - ONWARDS 1 and 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec	Daily basal insulin
ONWARDS 6		
Number of hypoglycaemia alert value (level 1)	20406	14819
Number of clinically significant hypoglycaemia (level 2)	5047	2811
Number of severe hypoglycaemia (level 3)	56	25
Number of severe (level 3) or clinically significant (level 2) hypoglycaemia	5103	2836
Hypoglycaemia alert value (level 1)		
E	13293	9747
Geom.mean (CV%)	19.0 (135.1)	16.8 (127.2)
Median	19.0	17.0
P25; P75	11.0; 31.0	10.0; 28.0
Min ; Max	1 ; 1440	1 ; 1441
Clinically significant hypoglycaemia (level 2)		
E	3288	1988
Geom.mean (CV%)	28.0 (169.8)	21.5 (157.9)
Median	24.0	20.0
P25; P75	15.0; 60.0	13.0; 35.0
Min ; Max	1 ; 1357	1 ; 1343
Severe hypoglycaemia (level 3)		
E	53	17
Geom.mean (CV%)	21.2 (138.9)	25.9 (95.9)
Median	14.0	21.0
P25; P75	11.0; 30.0	14.0; 30.0
Min ; Max	4 ; 360	11 ; 180
Severe (level 3) or clinically significant (level 2) hypoglycaemia		
E	3341	2005
Geom.mean (CV%)	27.9 (169.4)	21.5 (157.3)
Median	23.0	20.0
P25; P75	14.0; 60.0	13.0; 35.0
Min ; Max	1 ; 1357	1 ; 1343

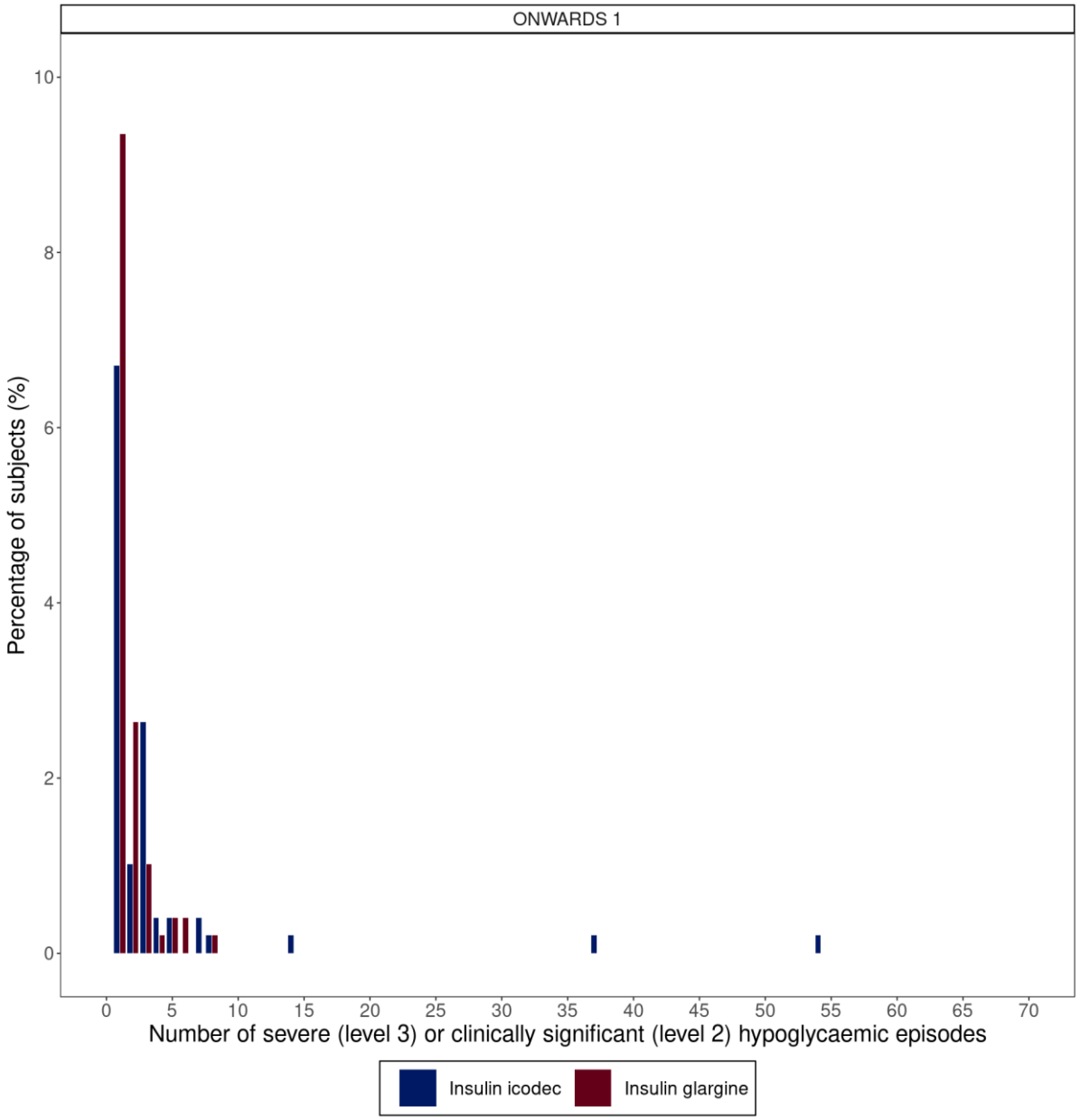
BG: Blood glucose, CV: Coefficient of variation, E: Number of hypoglycaemic episodes with non-missing duration, P25: 25th percentile, P75: 75th percentile. Duration of hypoglycaemic episodes is calculated in minutes with positive durations only contributing to derivations. Hypoglycaemia alert value (level 1): Plasma glucose value of < 3.9 mmol/L (70 mg/dL) and >= 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. Daily basal insulin: IGlar U100 (ONWARDS 1), IDeg (ONWARDS 6).

7.22.11 Severe (level 3) or clinically significant hypoglycaemia (level 2) by trial - ONWARDS 1 and 6 (extension part) - on-treatment - summary of categories of total number of episodes - safety analysis set

	Insulin icodec		Daily basal insulin	
	N	(%)	N	(%)
ONWARDS 1				
Number of subjects	492		492	
Severe (level 3) or clinically significant (level 2) hypoglycaemia				
No episodes	431	(87.6)	422	(85.8)
1-9 episodes	58	(11.8)	70	(14.2)
10-19 episodes	1	(0.2)	0	
>=20 episodes	2	(0.4)	0	
ONWARDS 6				
Number of subjects	290		292	
Severe (level 3) or clinically significant (level 2) hypoglycaemia				
No episodes	27	(9.3)	42	(14.4)
1-9 episodes	108	(37.2)	148	(50.7)
10-19 episodes	63	(21.7)	58	(19.9)
>=20 episodes	92	(31.7)	44	(15.1)

%: Percentage of subjects, BG: Blood glucose, N: Number of subjects. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery. Daily basal insulin: IGlar U100 (ONWARDS 1), IDeg (ONWARDS 6).

7.22.12 Severe (level 3) or clinically significant hypoglycaemia (level 2) - ONWARDS 1 (extension part) - on-treatment - bar plot of total number of episodes - safety analysis set

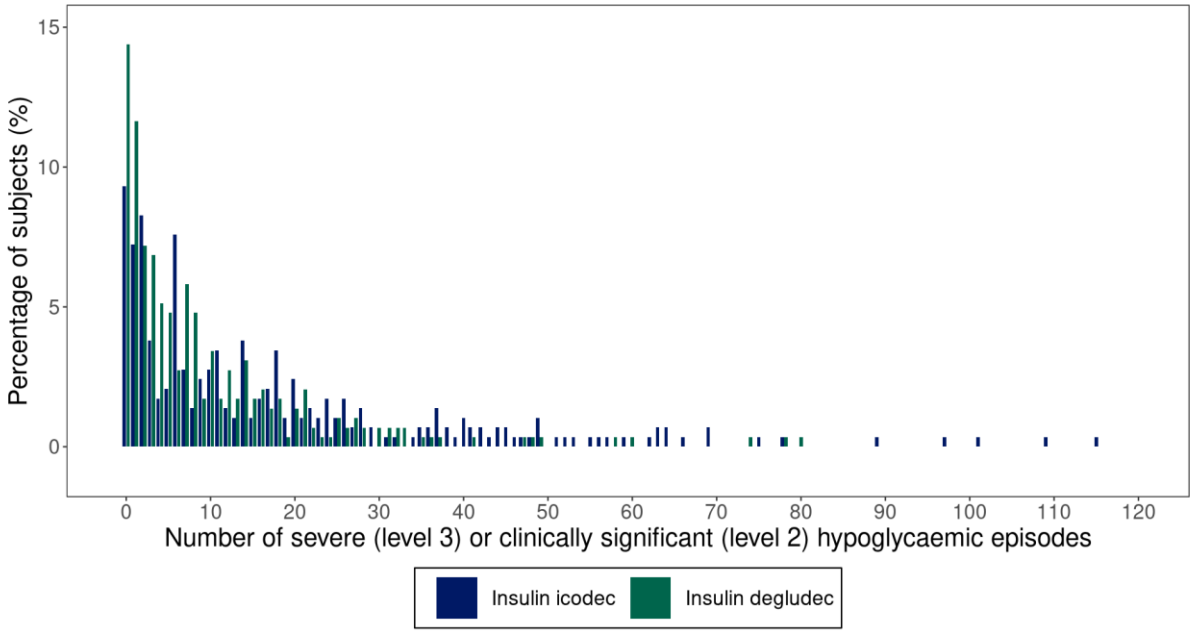


BG: Blood glucose. Safety analysis set. Observed data. Percentage of subjects with no episodes is omitted. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery.

adsl.xpt; variable(s): TRT01A TRT01AN; criteria: STDNMN == 1 & SAFFL == "Y"
adhypo.xpt; variable(s): TRTA TRTAN ACAT4 ACAT4N STDNM; criteria: SAFFL == "Y" & ANL02FL == "Y" & ANELFL == "Y" & STDNMN == 1

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7.22.13 Severe (level 3) or clinically significant hypoglycaemia (level 2) - ONWARDS 6 (extension part) - on-treatment - bar plot of total number of episodes - safety analysis set



BG: Blood glucose. Safety analysis set. Observed data. Clinically significant hypoglycaemia (level 2): Plasma glucose value of < 3.0 mmol/L (54 mg/dL) confirmed by BG meter. Severe hypoglycaemia (level 3): Hypoglycaemia with severe cognitive impairment requiring external assistance for recovery.

adsl.xpt; variable(s): TRT01A TRT01AN; criteria: STDNMN == 6 & SAFFL == "Y"
adhypo.xpt; variable(s): TRTA TRTAN ACAT4 ACAT4N STDNM; criteria: SAFFL == "Y" & ANL02FL == "Y" & ANELFL == "Y" & STDNMN == 6
adhypoen.xpt; variable(s): TRTA TRTAN PARAM AVAL; criteria: SAFFL == "Y"

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7.22.14 Demographics and baseline characteristics by categories of total number of severe (level 3) or clinically significant hypoglycaemia (level 2) in insulin icodec arm - ONWARDS 6 (extension part) - summary of categorical variables - safety analysis set

	No episodes		1-9 episodes		10-19 episodes		>= 20 episodes	
	N	(%)	N	(%)	N	(%)	N	(%)
Number of subjects	27		108		63		92	
Sex								
N	27	(100.0)	108	(100.0)	63	(100.0)	92	(100.0)
Male	20	(74.1)	58	(53.7)	36	(57.1)	51	(55.4)
Female	7	(25.9)	50	(46.3)	27	(42.9)	41	(44.6)
Race								
N	27	(100.0)	108	(100.0)	63	(100.0)	92	(100.0)
White	24	(88.9)	84	(77.8)	49	(77.8)	73	(79.3)
Black or African American	1	(3.7)	5	(4.6)	3	(4.8)	0	
Asian	2	(7.4)	19	(17.6)	11	(17.5)	19	(20.7)
BMI (kg/m^2)								
N	27	(100.0)	108	(100.0)	63	(100.0)	92	(100.0)
<25	9	(33.3)	37	(34.3)	24	(38.1)	35	(38.0)
>=25 - <30	11	(40.7)	44	(40.7)	26	(41.3)	37	(40.2)
>=30 - <35	6	(22.2)	18	(16.7)	9	(14.3)	13	(14.1)
>=35	1	(3.7)	9	(8.3)	4	(6.3)	7	(7.6)
Duration of diabetes								
N	27	(100.0)	108	(100.0)	63	(100.0)	92	(100.0)
<10 years	12	(44.4)	32	(29.6)	15	(23.8)	16	(17.4)
>=10 years	15	(55.6)	76	(70.4)	48	(76.2)	76	(82.6)
HbA1c								
N	27	(100.0)	108	(100.0)	63	(100.0)	92	(100.0)
<8% (<64 mmol/mol)	20	(74.1)	75	(69.4)	37	(58.7)	57	(62.0)
>=8% (>=64 mmol/mol)	7	(25.9)	33	(30.6)	26	(41.3)	35	(38.0)
Renal function (eGFR, mL/min/1.73m^2)								
N	27	(100.0)	108	(100.0)	63	(100.0)	92	(100.0)
Normal (>=90)	19	(70.4)	73	(67.6)	43	(68.3)	62	(67.4)
Mild impairment (>=60 - <90)	6	(22.2)	33	(30.6)	20	(31.7)	29	(31.5)
Moderate impairment (>=30 - <60)	2	(7.4)	2	(1.9)	0		1	(1.1)
Insulin treatment regimen								
N	27	(100.0)	108	(100.0)	63	(100.0)	92	(100.0)
Basal OD + Bolus TID	23	(85.2)	83	(76.9)	47	(74.6)	74	(80.4)
Basal BID + Bolus TID	0		12	(11.1)	11	(17.5)	10	(10.9)
Basal OD + Bolus BID	0		6	(5.6)	1	(1.6)	3	(3.3)
Basal OD + Bolus OTHER	1	(3.7)	3	(2.8)	2	(3.2)	3	(3.3)
Basal BID + Bolus QID	1	(3.7)	0		1	(1.6)	0	
Basal OD + Bolus QID	1	(3.7)	2	(1.9)	0		1	(1.1)
Basal OD + Bolus >QID	0		1	(0.9)	0		0	
Basal BID + Bolus >QID	0		1	(0.9)	0		1	(1.1)
Basal BID + Bolus OTHER	0		0		1	(1.6)	0	
Basal BID + Bolus BID	1	(3.7)	0		0		0	

%: Percentage of subjects, BMI: Body mass index, eGFR: Estimated glomerular filtration rate, N: Number of subjects, OD: Once daily, BID: Bis in die (twice a day), TID: Ter in die (three times a day), QID: Quarter in die (four times a day). Other frequency includes carb counters. Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. The duration of diabetes is calculated as the time from date of diagnosis to the randomisation date.

Demographics and baseline characteristics by categories of total number of severe (level 3) or clinically significant hypoglycaemia (level 2) in insulin icodec arm - ONWARDS 6 (extension part) - summary of categorical variables - safety analysis set

	No episodes		1-9 episodes		10-19 episodes		>= 20 episodes	
	N	(%)	N	(%)	N	(%)	N	(%)
Permanent discontinuation of trial product								
N	27	(100.0)	108	(100.0)	63	(100.0)	92	(100.0)
No	22	(81.5)	92	(85.2)	58	(92.1)	90	(97.8)
Yes	5	(18.5)	16	(14.8)	5	(7.9)	2	(2.2)
Withdrawn from trial								
N	27	(100.0)	108	(100.0)	63	(100.0)	92	(100.0)
No	22	(81.5)	101	(93.5)	60	(95.2)	91	(98.9)
Yes	5	(18.5)	7	(6.5)	3	(4.8)	1	(1.1)

%: Percentage of subjects, BMI: Body mass index, eGFR: Estimated glomerular filtration rate, N: Number of subjects, OD: Once daily, BID: Bis in die (twice a day), TID: Ter in die (three times a day), QID: Quarter in die (four times a day). Other frequency includes carb counters. Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. The duration of diabetes is calculated as the time from date of diagnosis to the randomisation date.

adsl.xpt; variable(s): SEX, RACE2, ETHNIC, BMIG1BL, GFRGR1, CPCLGR1, DIABGR1, HBAGR1; criteria: SAFFL == "Y", TRT01A == "Ico"
adhypo.xpt; variable(s): TOTINSRG; criteria: SAFFL == "Y", ANL02FL == "Y", ANELFL="Y"
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7.22.15 Demographics and baseline characteristics by categories of total number of severe (level 3) or clinically significant hypoglycaemia (level 2) in insulin degludec arm - ONWARDS 6 (extension part) - summary of categorical variables - safety analysis set

	No episodes		1-9 episodes		10-19 episodes		>= 20 episodes	
	N	(%)	N	(%)	N	(%)	N	(%)
Number of subjects	42		148		58		44	
Sex								
N	42	(100.0)	148	(100.0)	58	(100.0)	44	(100.0)
Male	26	(61.9)	88	(59.5)	38	(65.5)	20	(45.5)
Female	16	(38.1)	60	(40.5)	20	(34.5)	24	(54.5)
Race								
N	42	(100.0)	148	(100.0)	58	(100.0)	44	(100.0)
White	25	(59.5)	113	(76.4)	47	(81.0)	33	(75.0)
Black or African American	1	(2.4)	1	(0.7)	0		0	
Asian	16	(38.1)	34	(23.0)	11	(19.0)	11	(25.0)
BMI (kg/m^2)								
N	42	(100.0)	148	(100.0)	58	(100.0)	44	(100.0)
<25	21	(50.0)	68	(45.9)	26	(44.8)	20	(45.5)
>=25 - <30	10	(23.8)	54	(36.5)	21	(36.2)	17	(38.6)
>=30 - <35	8	(19.0)	18	(12.2)	9	(15.5)	6	(13.6)
>=35	3	(7.1)	8	(5.4)	2	(3.4)	1	(2.3)
Duration of diabetes								
N	42	(100.0)	148	(100.0)	58	(100.0)	44	(100.0)
<10 years	12	(28.6)	50	(33.8)	11	(19.0)	9	(20.5)
>=10 years	30	(71.4)	98	(66.2)	47	(81.0)	35	(79.5)
HbA1c								
N	42	(100.0)	148	(100.0)	58	(100.0)	44	(100.0)
<8% (<64 mmol/mol)	26	(61.9)	93	(62.8)	46	(79.3)	24	(54.5)
>=8% (>=64 mmol/mol)	16	(38.1)	55	(37.2)	12	(20.7)	20	(45.5)
Renal function (eGFR, mL/min/1.73m^2)								
N	42	(100.0)	148	(100.0)	58	(100.0)	44	(100.0)
Normal (>=90)	25	(59.5)	99	(66.9)	40	(69.0)	26	(59.1)
Mild impairment (>=60 - <90)	16	(38.1)	42	(28.4)	18	(31.0)	17	(38.6)
Moderate impairment (>=30 - <60)	1	(2.4)	7	(4.7)	0		1	(2.3)
Insulin treatment regimen								
N	42	(100.0)	148	(100.0)	58	(100.0)	44	(100.0)
Basal OD + Bolus TID	33	(78.6)	118	(79.7)	46	(79.3)	37	(84.1)
Basal BID + Bolus TID	3	(7.1)	19	(12.8)	8	(13.8)	4	(9.1)
Basal OD + Bolus BID	1	(2.4)	4	(2.7)	1	(1.7)	1	(2.3)
Basal OD + Bolus OTHER	2	(4.8)	3	(2.0)	2	(3.4)	1	(2.3)
Basal BID + Bolus QID	1	(2.4)	2	(1.4)	0		0	
Basal OD + Bolus QID	0		1	(0.7)	0		0	
Basal OD + Bolus >QID	1	(2.4)	1	(0.7)	1	(1.7)	0	
Basal BID + Bolus OTHER	1	(2.4)	0		0		0	
Basal OD + Bolus OD	0		0		0		1	(2.3)

%: Percentage of subjects, BMI: Body mass index, eGFR: Estimated glomerular filtration rate, N: Number of subjects, OD: Once daily, BID: Bis in die (twice a day), TID: Ter in die (three times a day), QID: Quarter in die (four times a day). Other frequency includes carb counters. Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. The duration of diabetes is calculated as the time from date of diagnosis to the randomisation date.

Demographics and baseline characteristics by categories of total number of severe (level 3) or clinically significant hypoglycaemia (level 2) in insulin degludec arm - ONWARDS 6 (extension part) - summary of categorical variables - safety analysis set

	No episodes		1-9 episodes		10-19 episodes		>= 20 episodes	
	N	(%)	N	(%)	N	(%)	N	(%)
Permanent discontinuation of trial product								
N	42	(100.0)	148	(100.0)	58	(100.0)	44	(100.0)
No	38	(90.5)	140	(94.6)	56	(96.6)	44	(100.0)
Yes	4	(9.5)	8	(5.4)	2	(3.4)	0	
Withdrawn from trial								
N	42	(100.0)	148	(100.0)	58	(100.0)	44	(100.0)
No	39	(92.9)	143	(96.6)	56	(96.6)	43	(97.7)
Yes	3	(7.1)	5	(3.4)	2	(3.4)	1	(2.3)

%: Percentage of subjects, BMI: Body mass index, eGFR: Estimated glomerular filtration rate, N: Number of subjects, OD: Once daily, BID: Bis in die (twice a day), TID: Ter in die (three times a day), QID: Quarter in die (four times a day). Other frequency includes carb counters. Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. The duration of diabetes is calculated as the time from date of diagnosis to the randomisation date.

adsl.xpt; variable(s): SEX, RACE2, ETHNIC, BMIG1BL, GFRGR1, CPCLGR1, DIABGR1, HBAGR1; criteria: SAFFL == "Y", TRT01A == "IDeg"
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7.22.16 Demographics and baseline characteristics by categories of total number of severe (level 3) or clinically significant hypoglycaemia (level 2) in insulin icodec arm - ONWARDS 6 (extension part) - summary of continuous variables - safety analysis set

	No episodes	1-9 episodes	10-19 episodes	>= 20 episodes
Number of subjects	27	108	63	92
Age (years)				
N	27	108	63	92
Mean (SD)	47.81 (13.51)	45.17 (14.85)	44.11 (13.46)	41.47 (13.39)
Median	52.00	42.50	45.00	40.00
Min ; Max	27.00 ; 76.00	19.00 ; 82.00	18.00 ; 73.00	19.00 ; 71.00
Body weight (kg)				
N	27	108	63	92
Mean (SD)	82.47 (15.26)	78.19 (15.83)	80.31 (18.65)	76.93 (19.46)
Median	83.30	77.70	77.20	76.40
Min ; Max	56.50 ; 123.50	41.30 ; 114.90	42.90 ; 135.50	39.60 ; 160.30
BMI (kg/m^2)				
N	27	108	63	92
Mean (SD)	27.29 (4.20)	27.16 (5.14)	26.68 (5.27)	26.46 (4.99)
Median	26.39	26.33	25.87	26.22
Min ; Max	21.30 ; 35.12	17.41 ; 46.61	16.55 ; 42.46	18.40 ; 43.48
Duration of diabetes (years)				
N	27	108	63	92
Mean (SD)	13.75 (12.96)	19.53 (13.69)	19.32 (11.65)	23.00 (13.08)
Median	13.44	17.81	18.59	20.44
Min ; Max	1.13 ; 44.62	1.28 ; 59.57	1.79 ; 47.51	3.08 ; 56.71
HbA1c (%)				
N	27	108	63	92
Mean (SD)	7.27 (1.05)	7.53 (0.97)	7.68 (0.88)	7.69 (0.96)
Median	7.30	7.40	7.60	7.80
Min ; Max	5.40 ; 9.30	5.10 ; 9.60	6.10 ; 9.60	5.70 ; 10.00
FPG (mmol/L)				
N	25	103	60	88
Mean (SD)	8.77 (3.09)	9.64 (3.38)	10.56 (4.65)	10.20 (4.64)
Median	7.70	9.30	9.55	9.70
Min ; Max	3.20 ; 15.90	3.60 ; 19.80	3.50 ; 22.00	2.40 ; 24.50

BMI: Body mass index, FPG: Fasting plasma glucose, N: Number of subjects, SD: Standard deviation.
The duration of diabetes is calculated as the time from date of diagnosis to the randomisation date.

7.22.17 Demographics and baseline characteristics by categories of total number of severe (level 3) or clinically significant hypoglycaemia (level 2) in insulin degludec arm - ONWARDS 6 (extension part) - summary of continuous variables - safety analysis set

	No episodes	1-9 episodes	10-19 episodes	>= 20 episodes
Number of subjects	42	148	58	44
Age (years)				
N	42	148	58	44
Mean (SD)	47.93 (14.21)	44.42 (13.71)	41.69 (12.92)	43.30 (16.04)
Median	48.00	45.00	41.00	43.00
Min ; Max	18.00 ; 74.00	18.00 ; 79.00	19.00 ; 74.00	18.00 ; 76.00
Body weight (kg)				
N	42	148	58	44
Mean (SD)	76.42 (18.25)	77.14 (16.72)	78.42 (16.50)	75.85 (16.38)
Median	74.35	75.20	78.65	75.00
Min ; Max	46.30 ; 124.10	41.30 ; 131.60	44.70 ; 118.40	41.00 ; 116.50
BMI (kg/m^2)				
N	42	148	58	44
Mean (SD)	26.66 (5.24)	26.24 (4.55)	26.07 (4.39)	25.70 (3.99)
Median	25.32	26.09	25.56	25.33
Min ; Max	19.31 ; 39.53	16.21 ; 40.32	18.25 ; 38.12	18.57 ; 35.01
Duration of diabetes (years)				
N	42	148	58	44
Mean (SD)	17.99 (13.41)	17.04 (12.09)	22.25 (13.51)	22.15 (13.09)
Median	15.86	15.29	19.56	20.37
Min ; Max	1.28 ; 56.80	1.11 ; 59.53	2.23 ; 62.46	1.49 ; 53.76
HbA1c (%)				
N	42	148	58	44
Mean (SD)	7.51 (0.94)	7.69 (0.94)	7.41 (0.79)	7.88 (0.98)
Median	7.60	7.60	7.35	7.75
Min ; Max	5.80 ; 9.00	5.60 ; 10.10	5.50 ; 9.40	6.10 ; 10.00
FPG (mmol/L)				
N	42	146	56	43
Mean (SD)	9.27 (3.28)	9.77 (4.15)	8.91 (3.82)	9.98 (4.42)
Median	8.30	9.15	8.25	9.30
Min ; Max	4.50 ; 20.90	3.40 ; 27.70	2.20 ; 16.80	3.40 ; 21.40

BMI: Body mass index, FPG: Fasting plasma glucose, N: Number of subjects, SD: Standard deviation.
The duration of diabetes is calculated as the time from date of diagnosis to the randomisation date.

インスリン イコデク（遺伝子組換え）

2.7.4.7. 付録
23. ONWARDS 1 試験及び ONWARDS 6 試験（延長パートを含む）：注目すべき安全性領域（試験別）

ノボ ノルディスク ファーマ株式会社

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7.23 Safety focus areas by trial (extension part)

7.23.1 Other microvascular diabetic complications (peripheral vascular disease and renal impairment) (predefined MedDRA search) - ONWARDS 1 (extension part) - in-trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects	492				492			
PYO (years)	772.31				773.34			
Events	7	(1.4)	7	0.91	7	(1.4)	7	0.91
Serious								
Yes	0				0			
No	7	(1.4)	7	0.91	7	(1.4)	7	0.91
Missing	0				0			
Severity								
Severe	0				0			
Moderate	0				2	(0.4)	2	0.26
Mild	7	(1.4)	7	0.91	5	(1.0)	5	0.65
Missing	0				0			
Related to basal insulin								
Probable	0				0			
Possible	0				0			
Unlikely	7	(1.4)	7	0.91	7	(1.4)	7	0.91
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	7	(1.4)	7	0.91	7	(1.4)	7	0.91
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	6	(1.2)	6	0.78	5	(1.0)	5	0.65
Recovered/resolved with sequelae	0				0			
Recovering/resolving	0				0			
Recovered/resolved	1	(0.2)	1	0.13	2	(0.4)	2	0.26
Unknown	0				0			
Missing	0				0			

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 22.1. Events found via MedDRA queries. Daily basal insulin: IGlar U100.

adsl.xpt ; variable(s): INTRDURY ; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
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7.23.2 Other microvascular diabetic complications (peripheral vascular disease and renal impairment) (predefined MedDRA search) - ONWARDS 6 (extension part) - in-trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects	290				292			
PYO (years)	307.05				312.83			
Events	2	(0.7)	2	0.65	2	(0.7)	2	0.64
Serious								
Yes	0				0			
No	2	(0.7)	2	0.65	2	(0.7)	2	0.64
Missing	0				0			
Severity								
Severe	0				0			
Moderate	0				0			
Mild	2	(0.7)	2	0.65	2	(0.7)	2	0.64
Missing	0				0			
Related to basal insulin								
Probable	0				0			
Possible	0				0			
Unlikely	2	(0.7)	2	0.65	2	(0.7)	2	0.64
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	2	(0.7)	2	0.65	2	(0.7)	2	0.64
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	1	(0.3)	1	0.33	2	(0.7)	2	0.64
Recovered/resolved with sequelae	0				0			
Recovering/resolving	0				0			
Recovered/resolved	1	(0.3)	1	0.33	0			
Unknown	0				0			
Missing	0				0			

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 22.1. Events found via MedDRA queries. Daily basal insulin: IDeg.

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7.23.3 Other microvascular diabetic complications (peripheral vascular disease and renal impairment) (predefined MedDRA search) by system organ class and preferred term - ONWARDS 1 (extension part) - in-trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects	492				492			
PYO (years)	772.31				773.34			
Events	7	(1.4)	7	0.91	7	(1.4)	7	0.91
Nervous system disorders	3	(0.6)	3	0.39	5	(1.0)	5	0.65
Diabetic neuropathy	3	(0.6)	3	0.39	5	(1.0)	5	0.65
Renal and urinary disorders	3	(0.6)	3	0.39	1	(0.2)	1	0.13
Diabetic nephropathy	2	(0.4)	2	0.26	1	(0.2)	1	0.13
Microalbuminuria	1	(0.2)	1	0.13	0			
Skin and subcutaneous tissue disorders	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Diabetic foot	1	(0.2)	1	0.13	1	(0.2)	1	0.13

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 24.1. Events found via MedDRA queries. Daily basal insulin: IGlar U100.

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7.23.4 Other microvascular diabetic complications (peripheral vascular disease and renal impairment) (predefined MedDRA search) by system organ class and preferred term - ONWARDS 6 (extension part) - in-trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects	290				292			
PYO (years)	307.05				312.83			
Events	2	(0.7)	2	0.65	2	(0.7)	2	0.64
Nervous system disorders	1	(0.3)	1	0.33	0			
Diabetic neuropathy	1	(0.3)	1	0.33	0			
Renal and urinary disorders	1	(0.3)	1	0.33	2	(0.7)	2	0.64
Microalbuminuria	1	(0.3)	1	0.33	0			
Diabetic nephropathy	0				2	(0.7)	2	0.64

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 24.1. Events found via MedDRA queries. Daily basal insulin: IDeg.

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7.23.5 Localized amyloidosis (predefined MedDRA search) - ONWARDS 1 (extension part) - in-trial - summary - safety analysis set

There is no data for this output

adsl.xpt ; variable(s): INTRDURY ; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & ANELFL == "Y" & ANL01FL == "Y" & CQ13NAM != ""
nn1436/nn1436-japan/submission_ext_20230612_er
21JUN2023:08:58:21 - taesum.R/taeamylsumintow1sas.txt

7.23.6 Localized amyloidosis (predefined MedDRA search) - ONWARDS 6 (extension part) - in-trial - summary - safety analysis set

There is no data for this output

adsl.xpt ; variable(s): INTRDURY ; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & ANELFL == "Y" & ANL01FL == "Y" & CQ13NAM != ""
nn1436/nn1436-japan/submission_ext_20230612_er
21JUN2023:08:58:23 - taesum.R/taeamylsumintow6sas.txt

7.23.7 Localized amyloidosis (predefined MedDRA search) by system organ class and preferred term - ONWARDS 1 (extension part) - in-trial - summary - safety analysis set

There is no data for this output

adsl.xpt; variable(s): INTRDURY; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & CQ13NAM != "" & (ANL01FL) == "Y" & (ANELFL) == "Y"
nn1436/nn1436-japan/submission_ext_20230612_er
21JUN2023:08:59:07 - taesocpt.R/taesocptamylsumintow1sas.txt

7.23.8 Localized amyloidosis (predefined MedDRA search) by system organ class and preferred term - ONWARDS 6 (extension part) - in-trial - summary - safety analysis set

There is no data for this output

adsl.xpt; variable(s): INTRDURY; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & CQ13NAM != "" & (ANL01FL) == "Y" & (ANELFL) == "Y"
nn1436/nn1436-japan/submission_ext_20230612_er
21JUN2023:08:59:10 - taesocpt.R/taesocptamylsumintow6sas.txt

7.23.9 Lipodystrophy (predefined MedDRA search) - ONWARDS 1 (extension part) - in-trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects	492				492			
PYO (years)	772.31				773.34			
Events	1	(0.2)	1	0.13	2	(0.4)	2	0.26
Serious								
Yes	0				0			
No	1	(0.2)	1	0.13	2	(0.4)	2	0.26
Missing	0				0			
Severity								
Severe	0				0			
Moderate	0				0			
Mild	1	(0.2)	1	0.13	2	(0.4)	2	0.26
Missing	0				0			
Related to basal insulin								
Probable	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Possible	0				1	(0.2)	1	0.13
Unlikely	0				0			
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	1	(0.2)	1	0.13	2	(0.4)	2	0.26
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	0				1	(0.2)	1	0.13
Recovered/resolved with sequelae	0				0			
Recovering/resolving	1	(0.2)	1	0.13	0			
Recovered/resolved	0				1	(0.2)	1	0.13
Unknown	0				0			
Missing	0				0			

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 22.1. Events found via MedDRA queries. Daily basal insulin: IGlar U100.

adsl.xpt ; variable(s): INTRDURY ; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" &
ANELFL == "Y" & ANL01FL == "Y" & CQ12NAM != ""
nn1436/nn1436-japan/submission_ext_20230612_er
21JUN2023:08:58:17 - taesum.R/taeliposumintow1sas.txt

7.23.10 Lipodystrophy (predefined MedDRA search) - ONWARDS 6 (extension part) - in-trial - summary - safety analysis set

There is no data for this output

adsl.xpt ; variable(s): INTRDURY ; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" &
ANELFL == "Y" & ANL01FL == "Y" & CQ12NAM != ""
nn1436/nn1436-japan/submission_ext_20230612_er
21JUN2023:08:58:19 - taesum.R/taeliposumintow6sas.txt

7.23.11 Lipodystrophy (predefined MedDRA search) by system organ class and preferred term - ONWARDS 1 (extension part) - in-trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects	492				492			
PYO (years)	772.31				773.34			
Events	1	(0.2)	1	0.13	2	(0.4)	2	0.26
Skin and subcutaneous tissue disorders	1	(0.2)	1	0.13	2	(0.4)	2	0.26
Lipodystrophy acquired	1	(0.2)	1	0.13	0			
Lipohypertrophy	0				2	(0.4)	2	0.26

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 24.1. Events found via MedDRA queries. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): INTRDURY; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & CQ12NAM != "" & (ANL01FL) == "Y" & (ANELFL) == "Y"
nn1436/nn1436-japan/submission_ext_20230612_er
21JUN2023:08:58:29 - taesocpt.R/taesocptliposumintow1sas.txt

7.23.12 Lipodystrophy (predefined MedDRA search) by system organ class and preferred term - ONWARDS 6 (extension part) - in-trial - summary - safety analysis set

There is no data for this output

adsl.xpt; variable(s): INTRDURY; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & CQ12NAM != "" & (ANL01FL) == "Y" & (ANELFL) == "Y"
nn1436/nn1436-japan/submission_ext_20230612_er
21JUN2023:08:59:13 - taesocpt.R/taesocptliposumintow6sas.txt

7.23.13 Neoplasms (predefined MedDRA search) - ONWARDS 1 (extension part) - in-trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects	492				492			
PYO (years)	772.31				773.34			
Events	34	(6.9)	39	5.05	23	(4.7)	32	4.14
Serious								
Yes	7	(1.4)	8	1.04	7	(1.4)	9	1.16
No	27	(5.5)	31	4.01	19	(3.9)	23	2.97
Missing	0				0			
Severity								
Severe	3	(0.6)	4	0.52	3	(0.6)	4	0.52
Moderate	8	(1.6)	8	1.04	6	(1.2)	6	0.78
Mild	23	(4.7)	27	3.50	16	(3.3)	22	2.84
Missing	0				0			
Related to basal insulin								
Probable	0				1	(0.2)	1	0.13
Possible	0				0			
Unlikely	33	(6.7)	38	4.92	22	(4.5)	31	4.01
Missing	1	(0.2)	1	0.13	0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	34	(6.9)	39	5.05	23	(4.7)	32	4.14
NA	0				0			
Missing	0				0			
Outcome								
Fatal	2	(0.4)	3	0.39	1	(0.2)	2	0.26
Not recovered/not resolved	16	(3.3)	17	2.20	16	(3.3)	18	2.33
Recovered/resolved with sequelae	0				0			
Recovering/resolving	2	(0.4)	2	0.26	0			
Recovered/resolved	16	(3.3)	17	2.20	9	(1.8)	11	1.42
Unknown	0				1	(0.2)	1	0.13
Missing	0				0			

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 22.1. Events found via MedDRA queries. Daily basal insulin: IGlar U100.

7.23.14 Neoplasms (predefined MedDRA search) - ONWARDS 6 (extension part) - in-trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects	290				292			
PYO (years)	307.05				312.83			
Events	15	(5.2)	15	4.89	14	(4.8)	16	5.11
Serious								
Yes	0				1	(0.3)	1	0.32
No	15	(5.2)	15	4.89	13	(4.5)	15	4.79
Missing	0				0			
Severity								
Severe	0				1	(0.3)	1	0.32
Moderate	0				2	(0.7)	2	0.64
Mild	15	(5.2)	15	4.89	11	(3.8)	13	4.16
Missing	0				0			
Related to basal insulin								
Probable	0				0			
Possible	0				0			
Unlikely	15	(5.2)	15	4.89	14	(4.8)	16	5.11
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	15	(5.2)	15	4.89	14	(4.8)	16	5.11
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	9	(3.1)	9	2.93	7	(2.4)	9	2.88
Recovered/resolved with sequelae	0				0			
Recovering/resolving	0				4	(1.4)	4	1.28
Recovered/resolved	6	(2.1)	6	1.95	3	(1.0)	3	0.96
Unknown	0				0			
Missing	0				0			

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 22.1. Events found via MedDRA queries. Daily basal insulin: IDeg.

7.23.15 Neoplasms (predefined MedDRA search) by system organ class and preferred term - ONWARDS 1 (extension part) - in-trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects	492				492			
PYO (years)	772.31				773.34			
Events	34	(6.9)	39	5.05	23	(4.7)	32	4.14
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	19	(3.9)	21	2.72	10	(2.0)	14	1.81
Basal cell carcinoma	2	(0.4)	2	0.26	2	(0.4)	2	0.26
Colon adenoma	2	(0.4)	2	0.26	0			
Prostate cancer	2	(0.4)	2	0.26	1	(0.2)	1	0.13
Seborrhoeic keratosis	2	(0.4)	3	0.39	1	(0.2)	1	0.13
Acrochordon	1	(0.2)	1	0.13	0			
Glioblastoma multiforme	1	(0.2)	1	0.13	0			
Haemangioma of liver	1	(0.2)	1	0.13	0			
Lipoma	1	(0.2)	1	0.13	0			
Metastases to liver	1	(0.2)	1	0.13	0			
Neoplasm skin	1	(0.2)	1	0.13	0			
Oral fibroma	1	(0.2)	1	0.13	0			
Pancreatic carcinoma metastatic	1	(0.2)	1	0.13	0			
Pancreatic neoplasm	1	(0.2)	1	0.13	0			
Skin papilloma	1	(0.2)	1	0.13	0			
Small cell lung cancer	1	(0.2)	1	0.13	0			
Squamous cell carcinoma	1	(0.2)	1	0.13	0			
Colon cancer	0				1	(0.2)	1	0.13
Dysplastic naevus	0				1	(0.2)	1	0.13
Hepatocellular carcinoma	0				1	(0.2)	1	0.13
Hypergammaglobulinaemia benign monoclonal	0				1	(0.2)	1	0.13
Lung adenocarcinoma	0				1	(0.2)	1	0.13
Malignant melanoma in situ	0				1	(0.2)	1	0.13
Metastatic renal cell carcinoma	0				1	(0.2)	1	0.13
Ovarian cancer metastatic	0				1	(0.2)	1	0.13
Plasma cell myeloma	0				1	(0.2)	1	0.13
Uterine leiomyoma	0				1	(0.2)	1	0.13
Gastrointestinal disorders	5	(1.0)	5	0.65	5	(1.0)	7	0.91
Large intestine polyp	2	(0.4)	2	0.26	3	(0.6)	4	0.52
Barrett's oesophagus	1	(0.2)	1	0.13	0			
Gastric polyps	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Rectal polyp	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Crohn's disease	0				1	(0.2)	1	0.13
Musculoskeletal and connective tissue disorders	3	(0.6)	3	0.39	0			
Synovial cyst	2	(0.4)	2	0.26	0			
Bone cyst	1	(0.2)	1	0.13	0			
Renal and urinary disorders	2	(0.4)	2	0.26	2	(0.4)	2	0.26
Renal cyst	2	(0.4)	2	0.26	2	(0.4)	2	0.26
Reproductive system and breast disorders	2	(0.4)	2	0.26	1	(0.2)	1	0.13
Ovarian cyst	1	(0.2)	1	0.13	0			
Uterine polyp	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Skin and subcutaneous tissue disorders	2	(0.4)	3	0.39	4	(0.8)	4	0.52
Actinic keratosis	1	(0.2)	2	0.26	1	(0.2)	1	0.13
Dermal cyst	1	(0.2)	1	0.13	3	(0.6)	3	0.39

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 24.1. Events found via MedDRA queries. Daily basal insulin: IGlar U100.

Neoplasms (predefined MedDRA search) by system organ class and preferred term - ONWARDS 1 (extension part) - in-trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Investigations	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Prostatic specific antigen increased	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Nervous system disorders	1	(0.2)	1	0.13	0			
Pineal gland cyst	1	(0.2)	1	0.13	0			
Respiratory, thoracic and mediastinal disorders	1	(0.2)	1	0.13	0			
Laryngeal cyst	1	(0.2)	1	0.13	0			
Eye disorders	0				1	(0.2)	1	0.13
Conjunctival cyst	0				1	(0.2)	1	0.13
General disorders and administration site conditions	0				1	(0.2)	1	0.13
Cyst	0				1	(0.2)	1	0.13
Hepatobiliary disorders	0				1	(0.2)	1	0.13
Hepatic cyst	0				1	(0.2)	1	0.13

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 24.1. Events found via MedDRA queries. Daily basal insulin: IGlar U100.

7.23.16 Neoplasms (predefined MedDRA search) by system organ class and preferred term - ONWARDS 6 (extension part) - in-trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects	290				292			
PYO (years)	307.05				312.83			
Events	15	(5.2)	15	4.89	14	(4.8)	16	5.11
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8	(2.8)	8	2.61	5	(1.7)	6	1.92
Benign neoplasm of thyroid gland	1	(0.3)	1	0.33	0			
Colon adenoma	1	(0.3)	1	0.33	0			
Eye naevus	1	(0.3)	1	0.33	2	(0.7)	2	0.64
Haemangioma of liver	1	(0.3)	1	0.33	0			
Lipoma	1	(0.3)	1	0.33	0			
Melanocytic naevus	1	(0.3)	1	0.33	0			
Seborrhoeic keratosis	1	(0.3)	1	0.33	0			
Skin papilloma	1	(0.3)	1	0.33	0			
Uterine leiomyoma	0				2	(0.7)	2	0.64
Benign renal neoplasm	0				1	(0.3)	1	0.32
Myeloproliferative neoplasm	0				1	(0.3)	1	0.32
Reproductive system and breast disorders	2	(0.7)	2	0.65	1	(0.3)	1	0.32
Ovarian cyst	1	(0.3)	1	0.33	0			
Prostatic cyst	1	(0.3)	1	0.33	0			
Fibrocystic breast disease	0				1	(0.3)	1	0.32
General disorders and administration site conditions	1	(0.3)	1	0.33	0			
Cyst	1	(0.3)	1	0.33	0			
Hepatobiliary disorders	1	(0.3)	1	0.33	2	(0.7)	2	0.64
Gallbladder polyp	1	(0.3)	1	0.33	2	(0.7)	2	0.64
Musculoskeletal and connective tissue disorders	1	(0.3)	1	0.33	1	(0.3)	1	0.32
Synovial cyst	1	(0.3)	1	0.33	1	(0.3)	1	0.32
Skin and subcutaneous tissue disorders	1	(0.3)	1	0.33	2	(0.7)	2	0.64
Dermal cyst	1	(0.3)	1	0.33	2	(0.7)	2	0.64
Surgical and medical procedures	1	(0.3)	1	0.33	0			
Skin neoplasm excision	1	(0.3)	1	0.33	0			
Gastrointestinal disorders	0				2	(0.7)	2	0.64
Gastric polyps	0				2	(0.7)	2	0.64
Infections and infestations	0				1	(0.3)	1	0.32
Infected cyst	0				1	(0.3)	1	0.32
Renal and urinary disorders	0				1	(0.3)	1	0.32
Renal cyst	0				1	(0.3)	1	0.32

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 24.1. Events found via MedDRA queries. Daily basal insulin: IDeg.

7.23.17 Diabetic retinopathy or maculopathy (predefined MedDRA search) - ONWARDS 1 (extension part) - in- trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects	492				492			
PYO (years)	772.31				773.34			
Events	48	(9.8)	59	7.64	50	(10.2)	69	8.92
Serious								
Yes	0				1	(0.2)	1	0.13
No	48	(9.8)	59	7.64	50	(10.2)	68	8.79
Missing	0				0			
Severity								
Severe	0				0			
Moderate	7	(1.4)	11	1.42	8	(1.6)	10	1.29
Mild	43	(8.7)	48	6.22	46	(9.3)	59	7.63
Missing	0				0			
Related to basal insulin								
Probable	0				0			
Possible	9	(1.8)	12	1.55	7	(1.4)	8	1.03
Unlikely	40	(8.1)	47	6.09	45	(9.1)	61	7.89
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	48	(9.8)	59	7.64	50	(10.2)	69	8.92
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	46	(9.3)	55	7.12	43	(8.7)	57	7.37
Recovered/resolved with sequelae	0				0			
Recovering/resolving	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Recovered/resolved	3	(0.6)	3	0.39	8	(1.6)	11	1.42
Unknown	0				0			
Missing	0				0			

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 22.1. Events found via MedDRA queries. Daily basal insulin: IGlar U100.

7.23.18 Diabetic retinopathy or maculopathy (predefined MedDRA search) - ONWARDS 6 (extension part) - in- trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects	290				292			
PYO (years)	307.05				312.83			
Events	37	(12.8)	47	15.31	36	(12.3)	47	15.02
Serious								
Yes	0				0			
No	37	(12.8)	47	15.31	36	(12.3)	47	15.02
Missing	0				0			
Severity								
Severe	2	(0.7)	2	0.65	0			
Moderate	4	(1.4)	5	1.63	3	(1.0)	3	0.96
Mild	34	(11.7)	40	13.03	33	(11.3)	44	14.07
Missing	0				0			
Related to basal insulin								
Probable	2	(0.7)	2	0.65	1	(0.3)	1	0.32
Possible	7	(2.4)	7	2.28	3	(1.0)	3	0.96
Unlikely	28	(9.7)	38	12.38	33	(11.3)	43	13.75
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	37	(12.8)	47	15.31	36	(12.3)	47	15.02
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	29	(10)	37	12.05	31	(10.6)	37	11.83
Recovered/resolved with sequelae	0				0			
Recovering/resolving	1	(0.3)	1	0.33	3	(1.0)	4	1.28
Recovered/resolved	9	(3.1)	9	2.93	5	(1.7)	6	1.92
Unknown	0				0			
Missing	0				0			

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 22.1. Events found via MedDRA queries. Daily basal insulin: IDeg.

7.23.19 Diabetic retinopathy or maculopathy (predefined MedDRA search) by system organ class and preferred term - ONWARDS 1 (extension part) - in-trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects	492				492			
PYO (years)	772.31				773.34			
Events	48	(9.8)	59	7.64	50	(10.2)	69	8.92
Eye disorders	48	(9.8)	59	7.64	50	(10.2)	69	8.92
Diabetic retinopathy	36	(7.3)	41	5.31	32	(6.5)	38	4.91
Macular oedema	3	(0.6)	3	0.39	1	(0.2)	1	0.13
Retinopathy hypertensive	2	(0.4)	2	0.26	2	(0.4)	2	0.26
Diabetic retinal oedema	1	(0.2)	1	0.13	6	(1.2)	6	0.78
Non-proliferative retinopathy	1	(0.2)	1	0.13	2	(0.4)	2	0.26
Post thrombotic retinopathy	1	(0.2)	1	0.13	0			
Retinal aneurysm	1	(0.2)	1	0.13	0			
Retinal degeneration	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Retinal haemorrhage	1	(0.2)	1	0.13	0			
Retinal tear	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Retinal vein occlusion	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Retinal vein thrombosis	1	(0.2)	1	0.13	0			
Retinopathy	1	(0.2)	1	0.13	0			
Visual impairment	1	(0.2)	1	0.13	2	(0.4)	2	0.26
Vitreous detachment	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Vitreous floaters	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Age-related macular degeneration	0				2	(0.4)	2	0.26
Vitreous haemorrhage	0				2	(0.4)	2	0.26
Chorioretinal disorder	0				1	(0.2)	1	0.13
Dry age-related macular degeneration	0				1	(0.2)	1	0.13
Retinal artery occlusion	0				1	(0.2)	1	0.13
Retinal detachment	0				1	(0.2)	1	0.13
Retinal drusen	0				1	(0.2)	1	0.13
Retinal vascular disorder	0				1	(0.2)	1	0.13
Retinopathy proliferative	0				1	(0.2)	1	0.13
Scintillating scotoma	0				1	(0.2)	2	0.26

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 24.1. Events found via MedDRA queries. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): INTRDURY; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & CQ08NAM != "" & (ANL01FL) == "Y" & (ANELFL) == "Y"
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7.23.20 Diabetic retinopathy or maculopathy (predefined MedDRA search) by system organ class and preferred term - ONWARDS 6 (extension part) - in-trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects	290				292			
PYO (years)	307.05				312.83			
Events	37	(12.8)	47	15.31	36	(12.3)	47	15.02
Eye disorders	35	(12.1)	45	14.66	35	(12.0)	45	14.38
Diabetic retinopathy	24	(8.3)	28	9.12	26	(8.9)	29	9.27
Macular oedema	4	(1.4)	5	1.63	1	(0.3)	1	0.32
Non-proliferative retinopathy	3	(1.0)	3	0.98	2	(0.7)	2	0.64
Diabetic retinal oedema	2	(0.7)	2	0.65	1	(0.3)	1	0.32
Epiretinal membrane	2	(0.7)	2	0.65	1	(0.3)	1	0.32
Retinopathy hypertensive	2	(0.7)	2	0.65	1	(0.3)	1	0.32
Arteriosclerotic retinopathy	1	(0.3)	1	0.33	0			
Retinal haemorrhage	1	(0.3)	1	0.33	0			
Retinal vascular disorder	1	(0.3)	1	0.33	0			
Vitreous detachment	0				2	(0.7)	2	0.64
Vitreous floaters	0				2	(0.7)	2	0.64
Age-related macular degeneration	0				1	(0.3)	1	0.32
Macular degeneration	0				1	(0.3)	1	0.32
Photopsia	0				1	(0.3)	1	0.32
Retinal drusen	0				1	(0.3)	1	0.32
Retinopathy	0				1	(0.3)	1	0.32
Visual acuity reduced	0				1	(0.3)	1	0.32
Congenital, familial and genetic disorders	1	(0.3)	1	0.33	0			
Colour blindness	1	(0.3)	1	0.33	0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	(0.3)	1	0.33	2	(0.7)	2	0.64
Eye naevus	1	(0.3)	1	0.33	2	(0.7)	2	0.64

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 24.1. Events found via MedDRA queries. Daily basal insulin: IDeg.

7.23.21 Rare events (predefined MedDRA search) - ONWARDS 1 (extension part) - in-trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects	492				492			
PYO (years)	772.31				773.34			
Events	50	(10.2)	62	8.03	45	(9.1)	61	7.89
Serious								
Yes	8	(1.6)	11	1.42	12	(2.4)	15	1.94
No	45	(9.1)	51	6.60	35	(7.1)	46	5.95
Missing	0				0			
Severity								
Severe	2	(0.4)	2	0.26	9	(1.8)	12	1.55
Moderate	16	(3.3)	18	2.33	9	(1.8)	14	1.81
Mild	39	(7.9)	42	5.44	29	(5.9)	35	4.53
Missing	0				0			
Related to basal insulin								
Probable	0				2	(0.4)	2	0.26
Possible	2	(0.4)	2	0.26	1	(0.2)	1	0.13
Unlikely	48	(9.8)	60	7.77	44	(8.9)	58	7.50
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	50	(10.2)	62	8.03	45	(9.1)	61	7.89
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				1	(0.2)	1	0.13
Not recovered/not resolved	29	(5.9)	33	4.27	17	(3.5)	19	2.46
Recovered/resolved with sequelae	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Recovering/resolving	3	(0.6)	3	0.39	2	(0.4)	2	0.26
Recovered/resolved	21	(4.3)	25	3.24	28	(5.7)	38	4.91
Unknown	0				0			
Missing	0				0			

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 22.1. Events found via MedDRA queries. Daily basal insulin: IGlar U100.

adsl.xpt ; variable(s): INTRDURY ; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & ANELFL == "Y" & ANL01FL == "Y" & CQ05NAM != ""
nn1436/nn1436-japan/submission_ext_20230612_er
21JUN2023:08:58:33 - taesum.R/taeraresumintow1sas.txt

7.23.22 Rare events (predefined MedDRA search) - ONWARDS 6 (extension part) - in-trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects	290				292			
PYO (years)	307.05				312.83			
Events	23	(7.9)	23	7.49	13	(4.5)	14	4.48
Serious								
Yes	1	(0.3)	1	0.33	0			
No	22	(7.6)	22	7.16	13	(4.5)	14	4.48
Missing	0				0			
Severity								
Severe	2	(0.7)	2	0.65	0			
Moderate	5	(1.7)	5	1.63	3	(1.0)	3	0.96
Mild	16	(5.5)	16	5.21	11	(3.8)	11	3.52
Missing	0				0			
Related to basal insulin								
Probable	0				0			
Possible	2	(0.7)	2	0.65	1	(0.3)	1	0.32
Unlikely	21	(7.2)	21	6.84	12	(4.1)	13	4.16
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	23	(7.9)	23	7.49	13	(4.5)	14	4.48
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	9	(3.1)	9	2.93	3	(1.0)	3	0.96
Recovered/resolved with sequelae	0				0			
Recovering/resolving	0				1	(0.3)	1	0.32
Recovered/resolved	14	(4.8)	14	4.56	9	(3.1)	10	3.20
Unknown	0				0			
Missing	0				0			

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 22.1. Events found via MedDRA queries. Daily basal insulin: IDeg.

adsl.xpt ; variable(s): INTRDURY ; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & ANELFL == "Y" & ANL01FL == "Y" & CQ05NAM != ""
nn1436/nn1436-japan/submission_ext_20230612_er
21JUN2023:08:58:35 - taesum.R/taeraresumintow6sas.txt

7.23.23 Rare events (predefined MedDRA search) by system organ class and preferred term - ONWARDS 1 (extension part) - in-trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects	492				492			
PYO (years)	772.31				773.34			
Events	50	(10.2)	62	8.03	45	(9.1)	61	7.89
Cardiac disorders	22	(4.5)	27	3.50	28	(5.7)	36	4.66
Atrial fibrillation	8	(1.6)	9	1.17	6	(1.2)	9	1.16
Ventricular extrasystoles	5	(1.0)	5	0.65	1	(0.2)	1	0.13
Palpitations	3	(0.6)	3	0.39	4	(0.8)	5	0.65
Bundle branch block right	2	(0.4)	2	0.26	2	(0.4)	3	0.39
Atrial flutter	1	(0.2)	2	0.26	1	(0.2)	1	0.13
Atrioventricular block first degree	1	(0.2)	1	0.13	0			
Bradycardia	1	(0.2)	1	0.13	3	(0.6)	3	0.39
Bundle branch block left	1	(0.2)	1	0.13	0			
Sinus bradycardia	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Sinus tachycardia	1	(0.2)	1	0.13	2	(0.4)	2	0.26
Supraventricular extrasystoles	1	(0.2)	1	0.13	2	(0.4)	2	0.26
Arrhythmia	0				2	(0.4)	2	0.26
Atrioventricular block complete	0				2	(0.4)	2	0.26
Atrioventricular block second degree	0				1	(0.2)	1	0.13
Cardio-respiratory arrest	0				1	(0.2)	1	0.13
Sinus arrhythmia	0				1	(0.2)	1	0.13
Supraventricular tachycardia	0				1	(0.2)	1	0.13
Tachycardia	0				1	(0.2)	1	0.13
Hepatobiliary disorders	10	(2.0)	11	1.42	7	(1.4)	7	0.91
Hepatic steatosis	8	(1.6)	8	1.04	3	(0.6)	3	0.39
Hepatic cirrhosis	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Liver disorder	1	(0.2)	1	0.13	0			
Non-alcoholic steatohepatitis	1	(0.2)	1	0.13	0			
Hepatitis	0				1	(0.2)	1	0.13
Nonalcoholic fatty liver disease	0				1	(0.2)	1	0.13
Steatohepatitis	0				1	(0.2)	1	0.13
Nervous system disorders	5	(1.0)	7	0.91	1	(0.2)	1	0.13
Syncope	5	(1.0)	7	0.91	1	(0.2)	1	0.13
Gastrointestinal disorders	4	(0.8)	4	0.52	4	(0.8)	6	0.78
Pancreatitis	2	(0.4)	2	0.26	1	(0.2)	1	0.13
Pancreatitis acute	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Varices oesophageal	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Ascites	0				1	(0.2)	1	0.13
Pancreatitis chronic	0				1	(0.2)	1	0.13
Portal hypertensive gastropathy	0				1	(0.2)	1	0.13
Congenital, familial and genetic disorders	3	(0.6)	3	0.39	2	(0.4)	2	0.26
Corneal dystrophy	1	(0.2)	1	0.13	0			
Hydrocele	1	(0.2)	1	0.13	0			
Type V hyperlipidaemia	1	(0.2)	1	0.13	0			
Congenital syphilitic osteochondritis	0				1	(0.2)	1	0.13
Dolichocolon	0				1	(0.2)	1	0.13
Renal and urinary disorders	3	(0.6)	3	0.39	4	(0.8)	5	0.65
Renal impairment	2	(0.4)	2	0.26	3	(0.6)	3	0.39
Acute kidney injury	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Urinary tract obstruction	0				1	(0.2)	1	0.13

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 24.1. Events found via MedDRA queries. Daily basal insulin: IGlar U100.

Rare events (predefined MedDRA search) by system organ class and preferred term - ONWARDS 1 (extension part) - in-trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Respiratory, thoracic and mediastinal disorders	3	(0.6)	4	0.52	0			
Interstitial lung disease	2	(0.4)	2	0.26	0			
Pulmonary fibrosis	1	(0.2)	2	0.26	0			
Blood and lymphatic system disorders	2	(0.4)	2	0.26	1	(0.2)	1	0.13
Pancytopenia	1	(0.2)	1	0.13	0			
Thrombocytopenia	1	(0.2)	1	0.13	1	(0.2)	1	0.13
Investigations	1	(0.2)	1	0.13	2	(0.4)	2	0.26
Electrocardiogram change	1	(0.2)	1	0.13	0			
Electrocardiogram repolarisation abnormality	0				1	(0.2)	1	0.13
White blood cell count decreased	0				1	(0.2)	1	0.13
Infections and infestations	0				1	(0.2)	1	0.13
Clostridium difficile infection	0				1	(0.2)	1	0.13

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 24.1. Events found via MedDRA queries. Daily basal insulin: IGlar U100.

7.23.24 Rare events (predefined MedDRA search) by system organ class and preferred term - ONWARDS 6 (extension part) - in-trial - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects	290				292			
PYO (years)	307.05				312.83			
Events	23	(7.9)	23	7.49	13	(4.5)	14	4.48
Cardiac disorders	9	(3.1)	9	2.93	6	(2.1)	7	2.24
Palpitations	3	(1.0)	3	0.98	4	(1.4)	5	1.60
Ventricular extrasystoles	3	(1.0)	3	0.98	0			
Atrial fibrillation	1	(0.3)	1	0.33	0			
Bundle branch block right	1	(0.3)	1	0.33	1	(0.3)	1	0.32
Conduction disorder	1	(0.3)	1	0.33	0			
Tachycardia	0				1	(0.3)	1	0.32
Hepatobiliary disorders	4	(1.4)	4	1.30	1	(0.3)	1	0.32
Hepatic steatosis	3	(1.0)	3	0.98	1	(0.3)	1	0.32
Hepatic calcification	1	(0.3)	1	0.33	0			
Investigations	4	(1.4)	4	1.30	1	(0.3)	1	0.32
Electrocardiogram abnormal	1	(0.3)	1	0.33	0			
Heart rate increased	1	(0.3)	1	0.33	0			
Platelet count decreased	1	(0.3)	1	0.33	0			
White blood cell count decreased	1	(0.3)	1	0.33	1	(0.3)	1	0.32
Nervous system disorders	4	(1.4)	4	1.30	2	(0.7)	2	0.64
Syncope	3	(1.0)	3	0.98	0			
Loss of consciousness	1	(0.3)	1	0.33	2	(0.7)	2	0.64
Congenital, familial and genetic disorders	1	(0.3)	1	0.33	0			
Arteriovenous malformation	1	(0.3)	1	0.33	0			
Renal and urinary disorders	1	(0.3)	1	0.33	1	(0.3)	1	0.32
Acute kidney injury	1	(0.3)	1	0.33	1	(0.3)	1	0.32
Blood and lymphatic system disorders	0				1	(0.3)	1	0.32
Thrombocytopenia	0				1	(0.3)	1	0.32
Gastrointestinal disorders	0				1	(0.3)	1	0.32
Pancreatitis	0				1	(0.3)	1	0.32

N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events per 100 PYO), PYO: Patient years of observation (1 PYO = 365.25 days). In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. MedDRA version 24.1. Events found via MedDRA queries. Daily basal insulin: IDeg.

インスリン イコデク（遺伝子組換え）

2.7.4.7. 付録
24. ONWARDS 1 試験及び ONWARDS 6 試験（延長パートを含む）：特別な患者集団における安全性（試験別）

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7.24 Safety in special groups by trial (extension part)

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Female	197				229			
Male	295				263			
PYE (years)								
Female	305.11				356.00			
Male	460.39				410.76			
Events								
Female	159	(80.7)	791	259.25	184	(80.3)	943	264.89
Male	238	(80.7)	1091	236.98	205	(77.9)	880	214.24
Serious								
Yes								
Female	20	(10.2)	28	9.18	30	(13.1)	43	12.08
Male	44	(14.9)	67	14.55	41	(15.6)	76	18.50
No								
Female	157	(79.7)	763	250.07	181	(79.0)	900	252.81
Male	230	(78.0)	1024	222.42	199	(75.7)	804	195.73
Missing								
Female	0				0			
Male	0				0			
Severity								
Severe								
Female	8	(4.1)	10	3.28	16	(7.0)	22	6.18
Male	18	(6.1)	28	6.08	20	(7.6)	39	9.49
Moderate								
Female	74	(37.6)	172	56.37	86	(37.6)	212	59.55
Male	118	(40.0)	229	49.74	97	(36.9)	185	45.04
Mild								
Female	142	(72.1)	609	199.60	162	(70.7)	709	199.16
Male	209	(70.8)	834	181.15	178	(67.7)	656	159.70
Missing								
Female	0				0			
Male	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to basal insulin								
Probable								
Female	12	(6.1)	16	5.24	12	(5.2)	22	6.18
Male	18	(6.1)	27	5.86	21	(8.0)	29	7.06
Possible								
Female	24	(12.2)	36	11.80	21	(9.2)	34	9.55
Male	22	(7.5)	31	6.73	18	(6.8)	26	6.33
Unlikely								
Female	158	(80.2)	738	241.88	181	(79.0)	883	248.04
Male	234	(79.3)	1032	224.16	197	(74.9)	823	200.36
Missing								
Female	1	(0.5)	1	0.33	3	(1.3)	4	1.12
Male	1	(0.3)	1	0.22	2	(0.8)	2	0.49
Related to technical complaint for basal insulin								
Yes								
Female	0				0			
Male	0				1	(0.4)	1	0.24
No								
Female	159	(80.7)	790	258.92	183	(79.9)	939	263.77
Male	238	(80.7)	1091	236.98	205	(77.9)	877	213.51
NA								
Female	0				0			
Male	0				0			
Missing								
Female	1	(0.5)	1	0.33	3	(1.3)	4	1.12
Male	0				2	(0.8)	2	0.49

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
Female	0				1	(0.4)	1	0.28
Male	5	(1.7)	7	1.52	2	(0.8)	6	1.46
Not recovered/not resolved								
Female	73	(37.1)	182	59.65	104	(45.4)	229	64.33
Male	140	(47.5)	326	70.81	112	(42.6)	218	53.07
Recovered/resolved with sequelae								
Female	4	(2.0)	4	1.31	3	(1.3)	3	0.84
Male	5	(1.7)	5	1.09	5	(1.9)	5	1.22
Recovering/resolving								
Female	7	(3.6)	13	4.26	15	(6.6)	23	6.46
Male	14	(4.7)	15	3.26	15	(5.7)	16	3.90
Recovered/resolved								
Female	151	(76.6)	592	194.03	175	(76.4)	687	192.98
Male	203	(68.8)	738	160.30	176	(66.9)	635	154.59
Unknown								
Female	0				0			
					0			
Male	0				0			
					0			
Missing								
Female	0				0			
Male	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Female	125				120			
Male	165				172			
PYE (years)								
Female	127.59				126.25			
Male	172.56				183.33			
Events								
Female	109	(87.2)	444	347.98	93	(77.5)	450	356.44
Male	131	(79.4)	521	301.92	143	(83.1)	696	379.63
Serious								
Yes								
Female	10	(8.0)	16	12.54	12	(10.0)	16	12.67
Male	14	(8.5)	23	13.33	8	(4.7)	9	4.91
No								
Female	108	(86.4)	428	335.44	93	(77.5)	434	343.77
Male	129	(78.2)	498	288.59	143	(83.1)	687	374.72
Missing								
Female	0				0			
Male	0				0			
Severity								
Severe								
Female	8	(6.4)	12	9.40	6	(5.0)	7	5.54
Male	12	(7.3)	16	9.27	3	(1.7)	3	1.64
Moderate								
Female	37	(29.6)	90	70.54	34	(28.3)	72	57.03
Male	46	(27.9)	89	51.58	48	(27.9)	87	47.45
Mild								
Female	99	(79.2)	342	268.04	90	(75.0)	371	293.87
Male	120	(72.7)	416	241.07	129	(75.0)	606	330.54
Missing								
Female	0				0			
Male	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to basal insulin								
Probable								
Female	8	(6.4)	9	7.05	3	(2.5)	3	2.38
Male	12	(7.3)	16	9.27	8	(4.7)	9	4.91
Possible								
Female	8	(6.4)	9	7.05	8	(6.7)	11	8.71
Male	22	(13.3)	27	15.65	14	(8.1)	61	33.27
Unlikely								
Female	107	(85.6)	426	333.87	92	(76.7)	436	345.35
Male	127	(77.0)	477	276.42	142	(82.6)	626	341.45
Missing								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Related to technical complaint for basal insulin								
Yes								
Female	0				0			
Male	0				0			
No								
Female	109	(87.2)	444	347.98	93	(77.5)	450	356.44
Male	131	(79.4)	520	301.34	143	(83.1)	696	379.63
NA								
Female	0				0			
Male	0				0			
Missing								
Female	0				0			
Male	1	(0.6)	1	0.58	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Not recovered/not resolved								
Female	47	(37.6)	92	72.10	41	(34.2)	92	72.87
Male	58	(35.2)	103	59.69	63	(36.6)	125	68.18
Recovered/resolved with sequelae								
Female	2	(1.6)	3	2.35	1	(0.8)	1	0.79
Male	0				2	(1.2)	2	1.09
Recovering/resolving								
Female	12	(9.6)	16	12.54	9	(7.5)	10	7.92
Male	8	(4.8)	8	4.64	11	(6.4)	15	8.18
Recovered/resolved								
Female	100	(80.0)	333	260.98	87	(72.5)	347	274.86
Male	121	(73.3)	409	237.01	126	(73.3)	554	302.18
Unknown								
Female	0				0 0			
Male	0				0 0			
Missing								
Female	0				0			
Male	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Female	197				229			
Male	295				263			
PYE (years)								
Female	305.11				356.00			
Male	460.39				410.76			
Events								
Female	159	(80.7)	791	259.25	184	(80.3)	943	264.89
Male	238	(80.7)	1091	236.98	205	(77.9)	880	214.24

Blood and lymphatic system disorders

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
Female	8	(4.1)	8	2.62	10	(4.4)	11	3.09
Male	7	(2.4)	9	1.95	9	(3.4)	9	2.19
Anaemia								
Female	4	(2.0)	4	1.31	6	(2.6)	7	1.97
Male	6	(2.0)	6	1.30	4	(1.5)	4	0.97
Blood loss anaemia								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Eosinophilia								
Female	0				0			
Male	1	(0.3)	1	0.22	2	(0.8)	2	0.49
Hypochromic anaemia								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Iron deficiency anaemia								
Female	3	(1.5)	3	0.98	1	(0.4)	1	0.28
Male	0				0			
Lymphadenopathy								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	0				1	(0.4)	1	0.24
Normochromic normocytic anaemia								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Polycythaemia								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Thrombocytopenia								
Female	0				0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Cardiac disorders								
All								
Female	15	(7.6)	23	7.54	15	(6.6)	24	6.74
Male	29	(9.8)	56	12.16	27	(10.3)	37	9.01
Acute coronary syndrome								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Acute myocardial infarction								
Female	0				2	(0.9)	2	0.56
Male	4	(1.4)	4	0.87	3	(1.1)	3	0.73
Angina pectoris								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	2	(0.8)	2	0.49

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Angina unstable								
Female	1	(0.5)	1	0.33	0			
Male	4	(1.4)	4	0.87	1	(0.4)	1	0.24
Aortic valve calcification								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Aortic valve incompetence								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	0			
Arrhythmia								
Female	0				1	(0.4)	1	0.28
Male	0				1	(0.4)	1	0.24
Arteriosclerosis coronary artery								
Female	0				0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Atrial fibrillation								
Female	2	(1.0)	3	0.98	2	(0.9)	5	1.40
Male	6	(2.0)	6	1.30	4	(1.5)	4	0.97
Atrial flutter								
Female	0				0			
Male	1	(0.3)	2	0.43	1	(0.4)	1	0.24
Atrial thrombosis								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Atrioventricular block complete								
Female	0				1	(0.4)	1	0.28
Male	0				1	(0.4)	1	0.24
Atrioventricular block first degree								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Atrioventricular block second degree								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Bradycardia								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Bundle branch block left								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Bundle branch block right								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	2	(0.8)	3	0.73
Cardiac dysfunction								
Female	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	0				1	(0.4)	1	0.24
Cardiac failure								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	3	(1.0)	3	0.65	0			
Cardiac failure chronic								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	2	(0.7)	2	0.43	0			
Cardiac failure congestive								
Female	0				0			
Male	2	(0.7)	2	0.43	1	(0.4)	1	0.24
Cardiac ventricular thrombosis								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Cardio-respiratory arrest								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Cardiomyopathy								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Chronic coronary syndrome								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Congestive cardiomyopathy								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Coronary artery disease								
Female	3	(1.5)	3	0.98	1	(0.4)	1	0.28
Male	3	(1.0)	3	0.65	2	(0.8)	2	0.49
Coronary artery occlusion								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	0			
Coronary artery stenosis								
Female	0				0			
Male	2	(0.7)	3	0.65	0			
Diastolic dysfunction								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Left atrial dilatation								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	0				0			
Left ventricular dysfunction								
Female	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Left ventricular hypertrophy								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Mitral valve incompetence								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Myocardial infarction								
Female	0				1	(0.4)	1	0.28
Male	3	(1.0)	3	0.65	2	(0.8)	2	0.49
Myocardial ischaemia								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Palpitations								
Female	3	(1.5)	3	0.98	4	(1.7)	5	1.40
Male	0				0			
Pericardial effusion								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Pericarditis								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Sinus arrhythmia								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Sinus bradycardia								
Female	0				0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Sinus tachycardia								
Female	0				0			
Male	1	(0.3)	1	0.22	2	(0.8)	2	0.49
Supraventricular extrasystoles								
Female	0				0			
Male	1	(0.3)	1	0.22	2	(0.8)	2	0.49
Supraventricular tachycardia								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Tachycardia								
Female	0				1	(0.4)	1	0.28
Male	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tricuspid valve incompetence								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	0				0			
Ventricular extrasystoles								
Female	2	(1.0)	2	0.66	0			
Male	3	(1.0)	3	0.65	1	(0.4)	1	0.24
Congenital, familial and genetic disorders								
All								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	2	(0.7)	2	0.43	1	(0.4)	1	0.24
Congenital syphilitic osteochondritis								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Corneal dystrophy								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Dolichocolon								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Hydrocele								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Type V hyperlipidaemia								
Female	0				0			
Male	1	(0.3)	1	0.22	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
Female	4	(2.0)	4	1.31	5	(2.2)	5	1.40
Male	8	(2.7)	9	1.95	8	(3.0)	9	2.19
Cerumen impaction								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Ear discomfort								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Ear inflammation								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Ear pain								
Female	0				0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Eustachian tube dysfunction								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Hypoacusis								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Presbyacusis								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Tinnitus								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Vertigo								
Female	2	(1.0)	2	0.66	3	(1.3)	3	0.84
Male	4	(1.4)	5	1.09	4	(1.5)	5	1.22
Vertigo positional								
Female	0				0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
Female	3	(1.5)	3	0.98	4	(1.7)	4	1.12
Male	1	(0.3)	1	0.22	4	(1.5)	4	0.97
Goitre								
Female	0				1	(0.4)	1	0.28
Male	0				1	(0.4)	1	0.24
Hyperplasia adrenal								
Female	0				1	(0.4)	1	0.28
Male	0				1	(0.4)	1	0.24
Hyperprolactinaemia								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Hyperthyroidism								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Hypothyroidism								
Female	2	(1.0)	2	0.66	0			
Male	0				1	(0.4)	1	0.24
Thyroid mass								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Eye disorders								
All								
Female	29	(14.7)	35	11.47	35	(15.3)	47	13.20
Male	60	(20.3)	92	19.98	41	(15.6)	72	17.53
Acquired epiblepharon								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Age-related macular degeneration								
Female	0				2	(0.9)	2	0.56
Male	0				0			
Asthenopia								
Female	0				0			
Male	2	(0.7)	2	0.43	1	(0.4)	1	0.24
Astigmatism								
Female	0				1	(0.4)	1	0.28
Male	3	(1.0)	3	0.65	0			
Blepharitis								
Female	2	(1.0)	2	0.66	0			
Male	2	(0.7)	2	0.43	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blepharitis allergic								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Cataract								
Female	6	(3.0)	7	2.29	6	(2.6)	8	2.25
Male	12	(4.1)	16	3.48	6	(2.3)	7	1.70
Cataract diabetic								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Cataract nuclear								
Female	0				0			
Male	1	(0.3)	1	0.22	2	(0.8)	2	0.49
Cataract subcapsular								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Chorioretinal disorder								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Conjunctival cyst								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Conjunctival erosion								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Conjunctival haemorrhage								
Female	1	(0.5)	1	0.33	0			
Male	0				2	(0.8)	2	0.49
Conjunctival hyperaemia								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Conjunctivitis allergic								
Female	3	(1.5)	4	1.31	1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Corneal opacity								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Dacryoadenitis acquired								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Dermatochalasis								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Diabetic retinal oedema								
Female	0				3	(1.3)	3	0.84
Male	1	(0.3)	1	0.22	3	(1.1)	3	0.73

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Diabetic retinopathy								
Female	12	(6.1)	14	4.59	14	(6.1)	14	3.93
Male	24	(8.1)	27	5.86	18	(6.8)	24	5.84
Dry age-related macular degeneration								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Dry eye								
Female	1	(0.5)	1	0.33	3	(1.3)	3	0.84
Male	4	(1.4)	4	0.87	2	(0.8)	2	0.49
Eye discharge								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Eye disorder								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Eye inflammation								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Eye irritation								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Eye pain								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Eyelid ptosis								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Giant papillary conjunctivitis								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Glaucoma								
Female	0				0			
Male	2	(0.7)	2	0.43	1	(0.4)	1	0.24
Iritis								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Macular oedema								
Female	0				0			
Male	3	(1.0)	3	0.65	1	(0.4)	1	0.24
Myopia								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Non-proliferative retinopathy								
Female	1	(0.5)	1	0.33	0			
Male	0				2	(0.8)	2	0.49
Normal tension glaucoma								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Ocular hypertension								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Open angle glaucoma								
Female	0				0			
Male	0				1	(0.4)	2	0.49
Optic disc vascular disorder								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Optic ischaemic neuropathy								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Photophobia								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Post thrombotic retinopathy								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Posterior capsule opacification								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Presbyopia								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Pterygium								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Punctate keratitis								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Retinal aneurysm								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Retinal artery occlusion								
Female	0				0			
Male	0				1	(0.4)	1	0.24

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Retinal degeneration								
Female	0				0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Retinal detachment								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Retinal drusen								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Retinal haemorrhage								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Retinal tear								
Female	0				0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Retinal vascular disorder								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Retinal vein occlusion								
Female	0				0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Retinal vein thrombosis								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Retinopathy								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Retinopathy hypertensive								
Female	0				0			
Male	2	(0.7)	2	0.43	2	(0.8)	2	0.49
Retinopathy proliferative								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Scintillating scotoma								
Female	0				0			
Male	0				1	(0.4)	2	0.49
Uveitis								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Vision blurred								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	4	(1.5)	4	0.97

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Visual impairment								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Vitreous detachment								
Female	1	(0.5)	1	0.33	0			
Male	0				1	(0.4)	1	0.24
Vitreous floaters								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Vitreous haemorrhage								
Female	0				1	(0.4)	1	0.28
Male	0				1	(0.4)	1	0.24
Vitreous opacities								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Gastrointestinal disorders								
All								
Female	50	(25.4)	93	30.48	56	(24.5)	99	27.81
Male	62	(21.0)	109	23.68	48	(18.3)	79	19.23
Abdominal discomfort								
Female	2	(1.0)	2	0.66	1	(0.4)	2	0.56
Male	0				2	(0.8)	4	0.97
Abdominal distension								
Female	3	(1.5)	3	0.98	1	(0.4)	1	0.28
Male	5	(1.7)	6	1.30	1	(0.4)	1	0.24
Abdominal hernia								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Abdominal pain								
Female	4	(2.0)	4	1.31	6	(2.6)	6	1.69
Male	4	(1.4)	4	0.87	1	(0.4)	1	0.24
Abdominal pain lower								
Female	1	(0.5)	2	0.66	2	(0.9)	2	0.56
Male	0				0			
Abdominal pain upper								
Female	0				5	(2.2)	6	1.69
Male	3	(1.0)	3	0.65	0			
Abdominal wall haematoma								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Acid peptic disease								
Female	0				0			
Male	0				2	(0.8)	2	0.49

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Anal eczema								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Anal fissure								
Female	1	(0.5)	1	0.33	0			
Male	0				2	(0.8)	2	0.49
Anal pruritus								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Angular cheilitis								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Aphthous ulcer								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Ascites								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Barrett's oesophagus								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Chronic gastritis								
Female	1	(0.5)	1	0.33	4	(1.7)	4	1.12
Male	3	(1.0)	3	0.65	2	(0.8)	2	0.49
Colitis								
Female	1	(0.5)	1	0.33	2	(0.9)	2	0.56
Male	0				1	(0.4)	1	0.24
Colitis ischaemic								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Colitis microscopic								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Constipation								
Female	4	(2.0)	4	1.31	5	(2.2)	5	1.40
Male	4	(1.4)	4	0.87	1	(0.4)	1	0.24
Crohn's disease								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Dental caries								
Female	5	(2.5)	6	1.97	0			
Male	4	(1.4)	5	1.09	1	(0.4)	1	0.24
Diarrhoea								
Female	22	(11.2)	30	9.83	17	(7.4)	19	5.34

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	17	(5.8)	24	5.21	9	(3.4)	10	2.43
Diverticulum								
Female	0				4	(1.7)	4	1.12
Male	0				0			
Diverticulum intestinal								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	0			
Dry mouth								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	0				0			
Duodenal ulcer								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Duodenitis								
Female	0				0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Duodenogastric reflux								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Dyspepsia								
Female	2	(1.0)	2	0.66	3	(1.3)	3	0.84
Male	3	(1.0)	3	0.65	1	(0.4)	1	0.24
Enteritis								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Enterocolitis								
Female	0				0			
Male	3	(1.0)	4	0.87	0			
Epigastric discomfort								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Erosive duodenitis								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Flatulence								
Female	1	(0.5)	1	0.33	0			
Male	2	(0.7)	2	0.43	0			
Food poisoning								
Female	0				3	(1.3)	3	0.84
Male	1	(0.3)	1	0.22	0			
Frequent bowel movements								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Gastric disorder								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	0				0			
Male	0				1	(0.4)	1	0.24
Gastric polyps								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Gastritis								
Female	0				1	(0.4)	1	0.28
Male	2	(0.7)	2	0.43	1	(0.4)	1	0.24
Gastritis erosive								
Female	0				1	(0.4)	1	0.28
Male	0				1	(0.4)	1	0.24
Gastrointestinal disorder								
Female	0				1	(0.4)	1	0.28
Male	0				1	(0.4)	1	0.24
Gastrointestinal haemorrhage								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Gastrointestinal inflammation								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Gastrooesophageal reflux disease								
Female	2	(1.0)	2	0.66	2	(0.9)	2	0.56
Male	6	(2.0)	6	1.30	6	(2.3)	6	1.46
Haematemesis								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Haematochezia								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	0			
Haemorrhoids								
Female	2	(1.0)	2	0.66	3	(1.3)	3	0.84
Male	2	(0.7)	2	0.43	2	(0.8)	2	0.49
Hiatus hernia								
Female	0				1	(0.4)	1	0.28
Male	0				1	(0.4)	1	0.24
Hyperaesthesia teeth								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Hyperchlorhydria								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Ileus								
Female	0				1	(0.4)	1	0.28
Male	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Inguinal hernia								
Female	0				0			
Male	0				1	(0.4)	2	0.49
Intestinal obstruction								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Irritable bowel syndrome								
Female	1	(0.5)	1	0.33	0			
Male	0				1	(0.4)	1	0.24
Large intestine polyp								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	2	(0.8)	3	0.73
Loose tooth								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Melaena								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Nausea								
Female	11	(5.6)	12	3.93	4	(1.7)	5	1.40
Male	9	(3.1)	10	2.17	5	(1.9)	6	1.46
Odynophagia								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Oral discomfort								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Pancreatitis								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Pancreatitis acute								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Pancreatitis chronic								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Periodontal disease								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Periodontal inflammation								
Female	0				0			
Male	0				1	(0.4)	2	0.49
Portal hypertensive gastropathy								
Female	0				0			
Male	0				1	(0.4)	1	0.24

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Rectal polyp								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	0				0			
Rectal prolapse								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Salivary gland calculus								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Stomatitis								
Female	0				1	(0.4)	1	0.28
Male	0				1	(0.4)	1	0.24
Tooth disorder								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Tooth impacted								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Tooth loss								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Toothache								
Female	4	(2.0)	4	1.31	1	(0.4)	1	0.28
Male	7	(2.4)	8	1.74	3	(1.1)	3	0.73
Ulcerative gastritis								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Umbilical hernia								
Female	1	(0.5)	1	0.33	0			
Male	0				2	(0.8)	2	0.49
Varices oesophageal								
Female	0				0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Vomiting								
Female	1	(0.5)	1	0.33	5	(2.2)	7	1.97
Male	6	(2.0)	6	1.30	6	(2.3)	8	1.95
General disorders and administration site conditions								
All								
Female	31	(15.7)	61	19.99	52	(22.7)	75	21.07
Male	60	(20.3)	99	21.50	46	(17.5)	75	18.26
Asthenia								
Female	3	(1.5)	3	0.98	4	(1.7)	4	1.12

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	2	(0.7)	3	0.65	2	(0.8)	2	0.49
Chest discomfort								
Female	3	(1.5)	3	0.98	1	(0.4)	1	0.28
Male	0				1	(0.4)	1	0.24
Chest pain								
Female	1	(0.5)	1	0.33	5	(2.2)	5	1.40
Male	3	(1.0)	3	0.65	2	(0.8)	2	0.49
Chills								
Female	2	(1.0)	2	0.66	0			
Male	0				2	(0.8)	2	0.49
Cyst								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Death								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Discomfort								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	0				0			
Drug intolerance								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	0			
Early satiety								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Effusion								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Fatigue								
Female	6	(3.0)	7	2.29	4	(1.7)	4	1.12
Male	10	(3.4)	11	2.39	3	(1.1)	4	0.97
Feeling abnormal								
Female	0				1	(0.4)	1	0.28
Male	2	(0.7)	7	1.52	0			
Feeling hot								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Gait disturbance								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	0			
Hunger								
Female	2	(1.0)	2	0.66	2	(0.9)	2	0.56
Male	3	(1.0)	4	0.87	0			
Implant site pruritus								

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Inflammation								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	0				0			
Influenza like illness								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Injection site bruising								
Female	0				2	(0.9)	2	0.56
Male	1	(0.3)	1	0.22	0			
Injection site dermatitis								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Injection site erythema								
Female	1	(0.5)	1	0.33	0			
Male	0				4	(1.5)	4	0.97
Injection site haemorrhage								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Injection site hypersensitivity								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	0			
Injection site hypertrophy								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Injection site mass								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Injection site pain								
Female	0				2	(0.9)	2	0.56
Male	0				0			
Injection site reaction								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Injection site urticaria								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Malaise								
Female	2	(1.0)	3	0.98	4	(1.7)	5	1.40
Male	5	(1.7)	6	1.30	6	(2.3)	7	1.70
Mass								
Female	1	(0.5)	1	0.33	0			
Male	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Medical device site bruise								
Female	1	(0.5)	1	0.33	1	(0.4)	2	0.56
Male	4	(1.4)	5	1.09	0			
Medical device site dermatitis								
Female	0				4	(1.7)	4	1.12
Male	2	(0.7)	5	1.09	5	(1.9)	11	2.68
Medical device site discomfort								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Medical device site eczema								
Female	0				0			
Male	1	(0.3)	2	0.43	2	(0.8)	4	0.97
Medical device site erythema								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Medical device site haematoma								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Medical device site haemorrhage								
Female	0				2	(0.9)	2	0.56
Male	4	(1.4)	4	0.87	0			
Medical device site hypersensitivity								
Female	1	(0.5)	2	0.66	0			
Male	1	(0.3)	1	0.22	0			
Medical device site inflammation								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Medical device site pain								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	0				0			
Medical device site pruritus								
Female	1	(0.5)	1	0.33	0			
Male	2	(0.7)	2	0.43	1	(0.4)	1	0.24
Medical device site reaction								
Female	0				0			
Male	1	(0.3)	3	0.65	1	(0.4)	1	0.24
Non-cardiac chest pain								
Female	1	(0.5)	1	0.33	0			
Male	0				1	(0.4)	1	0.24
Oedema								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Oedema peripheral								
Female	5	(2.5)	6	1.97	6	(2.6)	6	1.69
Male	3	(1.0)	3	0.65	5	(1.9)	7	1.70

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pain								
Female	2	(1.0)	2	0.66	4	(1.7)	4	1.12
Male	2	(0.7)	2	0.43	3	(1.1)	4	0.97
Peripheral swelling								
Female	2	(1.0)	2	0.66	2	(0.9)	2	0.56
Male	1	(0.3)	2	0.43	4	(1.5)	4	0.97
Procedural failure								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Pyrexia								
Female	9	(4.6)	9	2.95	12	(5.2)	14	3.93
Male	18	(6.1)	21	4.56	11	(4.2)	13	3.16
Swelling								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	0				0			
Thirst								
Female	2	(1.0)	2	0.66	0			
Male	0				0			
Vaccination site erythema								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Vaccination site pain								
Female	1	(0.5)	2	0.66	2	(0.9)	2	0.56
Male	4	(1.4)	5	1.09	2	(0.8)	2	0.49
Vaccination site reaction								
Female	0				0			
Male	1	(0.3)	1	0.22	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hepatobiliary disorders								
All								
Female	2	(1.0)	2	0.66	5	(2.2)	6	1.69
Male	11	(3.7)	14	3.04	5	(1.9)	5	1.22
Biliary colic								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Cholelithiasis								
Female	0				0			
Male	1	(0.3)	1	0.22	2	(0.8)	2	0.49
Gallbladder cholesterolosis								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Hepatic cirrhosis								
Female	0				0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Hepatic cyst								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Hepatic function abnormal								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Hepatic steatosis								
Female	1	(0.5)	1	0.33	3	(1.3)	3	0.84
Male	7	(2.4)	7	1.52	0			
Hepatitis								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Hypertransaminasaemia								
Female	0				0			
Male	1	(0.3)	2	0.43	0			
Liver disorder								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Non-alcoholic steatohepatitis								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Nonalcoholic fatty liver disease								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Steatohepatitis								
Female	0				1	(0.4)	1	0.28
Male	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
Female	1	(0.5)	1	0.33	5	(2.2)	6	1.69
Male	6	(2.0)	7	1.52	1	(0.4)	1	0.24
Allergy to arthropod bite								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Allergy to arthropod sting								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Immunisation reaction								
Female	0				1	(0.4)	2	0.56
Male	0				0			
Seasonal allergy								
Female	1	(0.5)	1	0.33	3	(1.3)	3	0.84
Male	6	(2.0)	6	1.30	1	(0.4)	1	0.24
Infections and infestations								
All								
Female	106	(53.8)	215	70.47	126	(55.0)	242	67.98
Male	119	(40.3)	200	43.44	126	(47.9)	207	50.39
Abscess								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Acarodermatitis								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Acute sinusitis								
Female	2	(1.0)	2	0.66	0			
Male	2	(0.7)	2	0.43	0			
Anal abscess								
Female	0				1	(0.4)	1	0.28
Male	0				1	(0.4)	1	0.24
Asymptomatic COVID-19								
Female	0				0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Bacterial infection								
Female	1	(0.5)	1	0.33	0			
Male	0				1	(0.4)	1	0.24
Balanitis candida								
Female	0				0			
Male	1	(0.3)	1	0.22	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Body tinea								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Breast abscess								
Female	0				2	(0.9)	2	0.56
Male	0				0			
Breast cellulitis								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Bronchitis								
Female	8	(4.1)	8	2.62	4	(1.7)	4	1.12
Male	4	(1.4)	4	0.87	3	(1.1)	4	0.97
Candida infection								
Female	1	(0.5)	1	0.33	0			
Male	2	(0.7)	2	0.43	0			
Cellulitis								
Female	1	(0.5)	1	0.33	0			
Male	2	(0.7)	2	0.43	3	(1.1)	3	0.73
Chlamydial infection								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Chronic hepatitis C								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Chronic sinusitis								
Female	0				2	(0.9)	2	0.56
Male	0				0			
Chronic tonsillitis								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	0				2	(0.8)	4	0.97
Clostridium difficile infection								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Conjunctivitis								
Female	4	(2.0)	5	1.64	0			
Male	2	(0.7)	2	0.43	3	(1.1)	3	0.73
Conjunctivitis bacterial								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Coronavirus infection								
Female	0				4	(1.7)	4	1.12
Male	6	(2.0)	6	1.30	2	(0.8)	3	0.73
COVID-19								
Female	43	(21.8)	45	14.75	52	(22.7)	55	15.45
Male	48	(16.3)	50	10.86	52	(19.8)	56	13.63

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

adsl.xpt; variable(s): ONTRDURY SEX; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD SEX; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
COVID-19 pneumonia								
Female	4	(2.0)	4	1.31	3	(1.3)	3	0.84
Male	0				0			
Cystitis								
Female	5	(2.5)	6	1.97	6	(2.6)	9	2.53
Male	0				2	(0.8)	2	0.49
Dermatophytosis of nail								
Female	0				0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Diverticulitis								
Female	0				5	(2.2)	5	1.40
Male	0				0			
Ear infection								
Female	2	(1.0)	2	0.66	0			
Male	2	(0.7)	2	0.43	1	(0.4)	1	0.24
Empyema								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Endophthalmitis								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Epididymitis								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Erysipelas								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Escherichia urinary tract infection								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	0				0			
Eye infection bacterial								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Folliculitis								
Female	0				1	(0.4)	1	0.28
Male	2	(0.7)	2	0.43	0			
Fungal balanitis								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Fungal infection								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Furuncle								
Female	0				0			
Male	1	(0.3)	2	0.43	1	(0.4)	1	0.24
Gastroenteritis								
Female	2	(1.0)	2	0.66	3	(1.3)	4	1.12
Male	4	(1.4)	4	0.87	3	(1.1)	3	0.73
Gastroenteritis norovirus								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Gastroenteritis viral								
Female	3	(1.5)	3	0.98	1	(0.4)	1	0.28
Male	2	(0.7)	2	0.43	0			
Gastrointestinal infection								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Genital infection fungal								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Giardiasis								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Gingivitis								
Female	1	(0.5)	1	0.33	2	(0.9)	3	0.84
Male	3	(1.0)	4	0.87	0			
Helicobacter gastritis								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Helicobacter infection								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Hepatitis B								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Herpes dermatitis								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Herpes simplex								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	0				0			
Herpes virus infection								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Herpes zoster								
Female	2	(1.0)	2	0.66	1	(0.4)	1	0.28
Male	4	(1.4)	4	0.87	7	(2.7)	7	1.70
Hordeolum								
Female	2	(1.0)	2	0.66	0			
Male	0				0			
Infected bite								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Infected skin ulcer								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Influenza								
Female	0				1	(0.4)	1	0.28
Male	0				2	(0.8)	2	0.49
Intestinal sepsis								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Labyrinthitis								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Laryngitis								
Female	2	(1.0)	2	0.66	2	(0.9)	2	0.56
Male	0				2	(0.8)	2	0.49
Laryngopharyngitis								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Localised infection								
Female	0				0			
Male	2	(0.7)	2	0.43	0			
Lower respiratory tract infection								
Female	3	(1.5)	5	1.64	1	(0.4)	3	0.84
Male	4	(1.4)	4	0.87	1	(0.4)	1	0.24
Lyme disease								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Lymphangitis								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Mastitis								
Female	1	(0.5)	1	0.33	0			
Male	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mycoplasma infection								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Nail infection								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Nasopharyngitis								
Female	16	(8.1)	21	6.88	21	(9.2)	24	6.74
Male	22	(7.5)	29	6.30	26	(9.9)	32	7.79
Onychomycosis								
Female	0				0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Oophoritis								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Oral candidiasis								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Oral herpes								
Female	3	(1.5)	3	0.98	3	(1.3)	3	0.84
Male	0				0			
Oral infection								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Orchitis								
Female	0				0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Oropharyngeal candidiasis								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Osteomyelitis								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Osteomyelitis chronic								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Otitis externa								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Otitis media								
Female	2	(1.0)	2	0.66	0			
Male	0				1	(0.4)	2	0.49

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Otitis media acute								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Otitis media chronic								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Parotitis								
Female	0				1	(0.4)	3	0.84
Male	0				0			
Peri-implantitis								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Pericoronitis								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Periodontitis								
Female	1	(0.5)	1	0.33	2	(0.9)	2	0.56
Male	1	(0.3)	1	0.22	3	(1.1)	4	0.97
Pharyngitis								
Female	8	(4.1)	10	3.28	2	(0.9)	5	1.40
Male	7	(2.4)	11	2.39	10	(3.8)	12	2.92
Pharyngitis bacterial								
Female	0				2	(0.9)	2	0.56
Male	1	(0.3)	1	0.22	0			
Pharyngotonsillitis								
Female	0				2	(0.9)	2	0.56
Male	0				2	(0.8)	3	0.73
Pneumonia								
Female	2	(1.0)	2	0.66	1	(0.4)	1	0.28
Male	2	(0.7)	2	0.43	2	(0.8)	2	0.49
Post procedural infection								
Female	1	(0.5)	1	0.33	0			
Male	0				1	(0.4)	1	0.24
Pulpitis dental								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Purulence								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Pyelonephritis chronic								
Female	0				1	(0.4)	1	0.28
Male	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Respiratory syncytial virus infection								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Respiratory tract infection								
Female	3	(1.5)	3	0.98	4	(1.7)	4	1.12
Male	1	(0.3)	1	0.22	2	(0.8)	3	0.73
Respiratory tract infection viral								
Female	3	(1.5)	6	1.97	1	(0.4)	1	0.28
Male	2	(0.7)	2	0.43	2	(0.8)	2	0.49
Rhinitis								
Female	3	(1.5)	3	0.98	5	(2.2)	6	1.69
Male	4	(1.4)	5	1.09	4	(1.5)	5	1.22
Rotavirus infection								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Salpingitis								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Sepsis								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Sinusitis								
Female	5	(2.5)	6	1.97	6	(2.6)	9	2.53
Male	0				1	(0.4)	2	0.49
Skin bacterial infection								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Skin infection								
Female	0				0			
Male	2	(0.7)	2	0.43	0			
Staphylococcal infection								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Subcutaneous abscess								
Female	1	(0.5)	1	0.33	0			
Male	0				1	(0.4)	4	0.97
Tinea infection								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Tonsillitis								
Female	1	(0.5)	2	0.66	2	(0.9)	2	0.56
Male	1	(0.3)	1	0.22	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tooth abscess								
Female	2	(1.0)	2	0.66	2	(0.9)	2	0.56
Male	3	(1.0)	3	0.65	2	(0.8)	2	0.49
Tooth infection								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	3	(1.1)	4	0.97
Tracheitis								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	3	0.65	1	(0.4)	1	0.24
Upper respiratory tract infection								
Female	15	(7.6)	22	7.21	13	(5.7)	15	4.21
Male	13	(4.4)	18	3.91	9	(3.4)	9	2.19
Urethritis								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Urinary tract infection								
Female	7	(3.6)	10	3.28	15	(6.6)	19	5.34
Male	2	(0.7)	2	0.43	6	(2.3)	6	1.46
Vaginal infection								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	0				0			
Varicella								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Viral infection								
Female	2	(1.0)	2	0.66	2	(0.9)	2	0.56
Male	2	(0.7)	2	0.43	3	(1.1)	3	0.73
Viral pharyngitis								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Viral upper respiratory tract infection								
Female	0				2	(0.9)	2	0.56
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Vulvovaginal candidiasis								
Female	3	(1.5)	5	1.64	4	(1.7)	4	1.12
Male	0				0			
Vulvovaginal mycotic infection								
Female	1	(0.5)	2	0.66	0			
Male	0				0			
Wound infection								
Female	0				1	(0.4)	1	0.28
Male	0				0			

Injury, poisoning and procedural

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
complications								
All								
Female	37	(18.8)	42	13.77	36	(15.7)	60	16.85
Male	52	(17.6)	60	13.03	31	(11.8)	43	10.47
Accidental overdose								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Alcohol poisoning								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Animal bite								
Female	0				0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Ankle fracture								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Arthropod bite								
Female	0				2	(0.9)	2	0.56
Male	0				0			
Arthropod sting								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Avulsion fracture								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Bone contusion								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Burn oral cavity								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Burns first degree								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Cervical vertebral fracture								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Chillblains								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Concussion								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Contusion								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	2	(1.0)	2	0.66	3	(1.3)	4	1.12
Male	3	(1.0)	4	0.87	10	(3.8)	12	2.92
Deafness traumatic								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Endotracheal intubation complication								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Eye injury								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Fall								
Female	5	(2.5)	7	2.29	4	(1.7)	5	1.40
Male	3	(1.0)	3	0.65	3	(1.1)	3	0.73
Fibula fracture								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Foot fracture								
Female	1	(0.5)	1	0.33	2	(0.9)	2	0.56
Male	0				0			
Hand fracture								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	0			
Head injury								
Female	1	(0.5)	1	0.33	2	(0.9)	2	0.56
Male	0				0			
Heat illness								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	0				2	(0.8)	3	0.73
Hip fracture								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Injury								
Female	0				0			
Male	4	(1.4)	4	0.87	0			
Joint injury								
Female	0				0			
Male	3	(1.0)	3	0.65	1	(0.4)	1	0.24
Ligament sprain								
Female	3	(1.5)	3	0.98	1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	2	(0.8)	2	0.49
Limb fracture								
Female	0				1	(0.4)	1	0.28
Male	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Limb injury								
Female	2	(1.0)	2	0.66	0			
Male	2	(0.7)	2	0.43	0			
Lower limb fracture								
Female	0				2	(0.9)	2	0.56
Male	0				0			
Meniscus injury								
Female	0				0			
Male	3	(1.0)	3	0.65	0			
Muscle strain								
Female	1	(0.5)	1	0.33	3	(1.3)	3	0.84
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Overdose								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Patella fracture								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Periprocedural myocardial infarction								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Post procedural fistula								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Post procedural haemorrhage								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Post procedural hypothyroidism								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Post procedural stroke								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Post procedural swelling								
Female	0				0			
Male	0				1	(0.4)	2	0.49
Post-traumatic neck syndrome								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Procedural pain								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Product administration error								
Female	0				0			
Male	1	(0.3)	1	0.22	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Radius fracture								
Female	1	(0.5)	1	0.33	0			
Male	2	(0.7)	2	0.43	1	(0.4)	1	0.24
Rib fracture								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Road traffic accident								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Scar								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Skin abrasion								
Female	2	(1.0)	2	0.66	0			
Male	2	(0.7)	2	0.43	1	(0.4)	1	0.24
Skin laceration								
Female	0				0			
Male	4	(1.4)	4	0.87	0			
Soft tissue injury								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Spinal column injury								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Spinal cord injury cervical								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Stress fracture								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Subcutaneous haematoma								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Tendon rupture								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Thermal burn								
Female	1	(0.5)	1	0.33	3	(1.3)	3	0.84
Male	0				0			
Tooth fracture								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	2	(0.7)	2	0.43	1	(0.4)	1	0.24
Traumatic arthritis								
Female	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	1	(0.3)	2	0.43	0			
Traumatic haematoma								
Female	1	(0.5)	1	0.33	0			
Male	0				1	(0.4)	1	0.24
Ulna fracture								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Underdose								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Upper limb fracture								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Vaccination complication								
Female	3	(1.5)	4	1.31	13	(5.7)	19	5.34
Male	9	(3.1)	9	1.95	3	(1.1)	5	1.22
Wound								
Female	1	(0.5)	1	0.33	2	(0.9)	2	0.56
Male	3	(1.0)	3	0.65	1	(0.4)	1	0.24
Wrist fracture								
Female	1	(0.5)	1	0.33	0			
Male	0				1	(0.4)	1	0.24
Investigations								
All								
Female	12	(6.1)	15	4.92	15	(6.6)	17	4.78
Male	23	(7.8)	25	5.43	19	(7.2)	19	4.63
Alanine aminotransferase increased								
Female	0				0			
Male	2	(0.7)	2	0.43	1	(0.4)	1	0.24
Aspartate aminotransferase increased								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Blood cholesterol increased								
Female	2	(1.0)	2	0.66	0			
Male	1	(0.3)	1	0.22	0			
Blood creatine increased								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Blood creatine phosphokinase increased								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Blood glucose increased								
Female	0				1	(0.4)	1	0.28

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	0				0			
Blood potassium increased								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Blood pressure decreased								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Blood pressure increased								
Female	2	(1.0)	2	0.66	1	(0.4)	1	0.28
Male	0				1	(0.4)	1	0.24
Blood triglycerides increased								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Body temperature increased								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Cardiac stress test abnormal								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Electrocardiogram change								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Electrocardiogram repolarisation abnormality								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Electrocardiogram T wave inversion								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Glycosylated haemoglobin increased								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Haemoglobin decreased								
Female	0				1	(0.4)	2	0.56
Male	0				0			
Hepatic enzyme abnormal								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Hepatic enzyme increased								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
International normalised ratio abnormal								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
International normalised ratio decreased								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	0				0			
Male	1	(0.3)	1	0.22	0			
International normalised ratio increased								
Female	0				0			
Male	1	(0.3)	2	0.43	0			
Intraocular pressure increased								
Female	1	(0.5)	2	0.66	0			
Male	0				0			
Lipids increased								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Low density lipoprotein increased								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Prostatic specific antigen increased								
Female	0				0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Protein urine present								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Pulse absent								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Red blood cell count decreased								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
SARS-CoV-2 test positive								
Female	1	(0.5)	1	0.33	2	(0.9)	2	0.56
Male	2	(0.7)	2	0.43	1	(0.4)	1	0.24
Serum ferritin decreased								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Transferrin saturation decreased								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Troponin increased								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Weight decreased								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	2	(0.7)	2	0.43	0			
Weight increased								
Female	4	(2.0)	4	1.31	4	(1.7)	4	1.12
Male	5	(1.7)	5	1.09	6	(2.3)	6	1.46

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
White blood cell count decreased								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Metabolism and nutrition disorders								
All								
Female	24	(12.2)	26	8.52	29	(12.7)	48	13.48
Male	35	(11.9)	40	8.69	34	(12.9)	41	9.98
Adult failure to thrive								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Appetite disorder								
Female	0				0			
Male	0				1	(0.4)	2	0.49
Decreased appetite								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	3	(1.0)	3	0.65	0			
Dehydration								
Female	0				2	(0.9)	2	0.56
Male	0				0			
Diabetes mellitus								
Female	0				0			
Male	1	(0.3)	1	0.22	2	(0.8)	2	0.49
Diabetes mellitus inadequate control								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Dyslipidaemia								
Female	5	(2.5)	5	1.64	7	(3.1)	9	2.53
Male	9	(3.1)	10	2.17	2	(0.8)	2	0.49
Electrolyte depletion								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Electrolyte imbalance								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Fluid retention								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Gout								
Female	0				0			
Male	2	(0.7)	3	0.65	2	(0.8)	2	0.49
Hypercalcaemia								
Female	0				1	(0.4)	1	0.28
Male	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hypercholesterolaemia								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	3	(1.1)	3	0.73
Hyperglycaemia								
Female	0				5	(2.2)	5	1.40
Male	1	(0.3)	1	0.22	2	(0.8)	2	0.49
Hyperkalaemia								
Female	3	(1.5)	3	0.98	3	(1.3)	3	0.84
Male	3	(1.0)	3	0.65	1	(0.4)	1	0.24
Hyperlipidaemia								
Female	1	(0.5)	1	0.33	0			
Male	3	(1.0)	3	0.65	3	(1.1)	3	0.73
Hypertriglyceridaemia								
Female	2	(1.0)	2	0.66	1	(0.4)	1	0.28
Male	4	(1.4)	4	0.87	8	(3.0)	8	1.95
Hyperuricaemia								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Hypoglycaemia								
Female	4	(2.0)	5	1.64	6	(2.6)	18	5.06
Male	3	(1.0)	3	0.65	7	(2.7)	8	1.95
Hypokalaemia								
Female	1	(0.5)	1	0.33	2	(0.9)	2	0.56
Male	0				0			
Hypophosphataemia								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Increased appetite								
Female	0				1	(0.4)	1	0.28
Male	2	(0.7)	2	0.43	0			
Iron deficiency								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Lactic acidosis								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Malnutrition								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Metabolic disorder								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Obesity								
Female	1	(0.5)	1	0.33	0			
Male	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Type 2 diabetes mellitus								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Vitamin B12 deficiency								
Female	1	(0.5)	1	0.33	0			
Male	2	(0.7)	2	0.43	0			
Vitamin D deficiency								
Female	2	(1.0)	2	0.66	2	(0.9)	2	0.56
Male	2	(0.7)	3	0.65	1	(0.4)	1	0.24
Zinc deficiency								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Musculoskeletal and connective tissue disorders								
All								
Female	53	(26.9)	98	32.12	67	(29.3)	110	30.90
Male	77	(26.1)	120	26.07	50	(19.0)	74	18.02
Arthralgia								
Female	17	(8.6)	21	6.88	16	(7.0)	20	5.62
Male	13	(4.4)	15	3.26	6	(2.3)	8	1.95
Arthritis								
Female	1	(0.5)	1	0.33	2	(0.9)	3	0.84
Male	1	(0.3)	1	0.22	2	(0.8)	2	0.49
Axillary mass								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Back disorder								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Back pain								
Female	14	(7.1)	15	4.92	12	(5.2)	13	3.65
Male	26	(8.8)	28	6.08	20	(7.6)	21	5.11
Bone cyst								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Bursitis								
Female	2	(1.0)	2	0.66	2	(0.9)	2	0.56
Male	0				1	(0.4)	1	0.24
Cervical spinal stenosis								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Chondrodynia								
Female	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	1	(0.3)	1	0.22	0			
Chondropathy								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Coccydynia								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Costochondritis								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Dupuytren's contracture								
Female	0				1	(0.4)	1	0.28
Male	0				1	(0.4)	1	0.24
Exostosis								
Female	1	(0.5)	1	0.33	0			
Male	0				1	(0.4)	1	0.24
Fibromyalgia								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	0			
Fistula								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Flank pain								
Female	0				1	(0.4)	1	0.28
Male	0				1	(0.4)	1	0.24
Fracture nonunion								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Gouty arthritis								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Groin pain								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Intervertebral disc disorder								
Female	0				0			
Male	2	(0.7)	2	0.43	2	(0.8)	2	0.49
Intervertebral disc protrusion								
Female	2	(1.0)	2	0.66	4	(1.7)	5	1.40
Male	5	(1.7)	6	1.30	1	(0.4)	1	0.24
Intervertebral disc space narrowing								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Joint effusion								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	0				1	(0.4)	1	0.28
Male	0				0			
Joint swelling								
Female	0				0			
Male	0				2	(0.8)	2	0.49
Ligamentitis								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Limb deformity								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Lordosis								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Lumbar spinal stenosis								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Mastication disorder								
Female	0				1	(0.4)	2	0.56
Male	0				0			
Muscle contracture								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Muscle spasms								
Female	6	(3.0)	6	1.97	2	(0.9)	2	0.56
Male	6	(2.0)	6	1.30	2	(0.8)	2	0.49
Muscular weakness								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Musculoskeletal chest pain								
Female	1	(0.5)	1	0.33	0			
Male	3	(1.0)	3	0.65	1	(0.4)	1	0.24
Musculoskeletal pain								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Musculoskeletal stiffness								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Myalgia								
Female	0				1	(0.4)	1	0.28
Male	3	(1.0)	3	0.65	2	(0.8)	2	0.49
Myositis								
Female	1	(0.5)	1	0.33	0			
Male	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neck pain								
Female	5	(2.5)	5	1.64	8	(3.5)	8	2.25
Male	2	(0.7)	2	0.43	0			
Osteoarthritis								
Female	11	(5.6)	13	4.26	9	(3.9)	11	3.09
Male	8	(2.7)	8	1.74	5	(1.9)	6	1.46
Osteochondrosis								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Osteopenia								
Female	0				1	(0.4)	1	0.28
Male	2	(0.7)	2	0.43	0			
Pain in extremity								
Female	8	(4.1)	10	3.28	6	(2.6)	7	1.97
Male	10	(3.4)	13	2.82	8	(3.0)	10	2.43
Periarthritis								
Female	0				4	(1.7)	4	1.12
Male	6	(2.0)	6	1.30	1	(0.4)	1	0.24
Plantar fasciitis								
Female	1	(0.5)	1	0.33	0			
Male	4	(1.4)	5	1.09	1	(0.4)	1	0.24
Polyarthritis								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Rotator cuff syndrome								
Female	2	(1.0)	2	0.66	0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Scoliosis								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Spinal osteoarthritis								
Female	2	(1.0)	2	0.66	0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Spinal pain								
Female	0				3	(1.3)	3	0.84
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Spinal stenosis								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Spondylolisthesis								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Synovial cyst								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tendon calcification								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Tendonitis								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	2	(0.8)	2	0.49
Tenosynovitis								
Female	1	(0.5)	1	0.33	5	(2.2)	5	1.40
Male	0				1	(0.4)	2	0.49
Tenosynovitis stenosans								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Torticollis								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Trigger finger								
Female	2	(1.0)	2	0.66	2	(0.9)	5	1.40
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Vertebral osteophyte								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
Female	5	(2.5)	5	1.64	4	(1.7)	6	1.69
Male	14	(4.7)	16	3.48	5	(1.9)	7	1.70
Acrochordon								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Basal cell carcinoma								
Female	0				1	(0.4)	1	0.28
Male	2	(0.7)	2	0.43	1	(0.4)	1	0.24
Colon adenoma								
Female	0				0			
Male	2	(0.7)	2	0.43	0			
Colon cancer								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Dysplastic naevus								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Glioblastoma multiforme								
Female	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	1	(0.3)	1	0.22	0			
Haemangioma of liver								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Hepatocellular carcinoma								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Hypergammaglobulinaemia benign monoclonal								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Lipoma								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Lung adenocarcinoma								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Malignant melanoma in situ								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Metastases to liver								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Metastatic renal cell carcinoma								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Neoplasm skin								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Oral fibroma								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Ovarian cancer metastatic								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Pancreatic carcinoma metastatic								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Pancreatic neoplasm								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Prostate cancer								
Female	0				0			
Male	2	(0.7)	2	0.43	1	(0.4)	1	0.24
Seborrhoeic keratosis								

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	1	(0.3)	2	0.43	0			
Skin papilloma								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Small cell lung cancer								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Squamous cell carcinoma								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Uterine leiomyoma								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Nervous system disorders								
All								
Female	36	(18.3)	57	18.68	40	(17.5)	55	15.45
Male	48	(16.3)	68	14.77	40	(15.2)	60	14.61
Ageusia								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Anosmia								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Balance disorder								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Brain injury								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Burning sensation								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	2	(0.7)	2	0.43	1	(0.4)	1	0.24
Carotid arteriosclerosis								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Carotid artery stenosis								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Carpal tunnel syndrome								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	3	(1.0)	3	0.65	2	(0.8)	2	0.49
Cerebral arteriosclerosis								

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Cerebral atrophy								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Cerebral haemorrhage								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Cerebral infarction								
Female	0				0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Cerebrovascular accident								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Cerebrovascular disorder								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Cervical radiculopathy								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Cognitive disorder								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Diabetic neuropathy								
Female	2	(1.0)	2	0.66	2	(0.9)	2	0.56
Male	1	(0.3)	1	0.22	3	(1.1)	3	0.73
Dizziness								
Female	4	(2.0)	6	1.97	7	(3.1)	8	2.25
Male	11	(3.7)	15	3.26	8	(3.0)	8	1.95
Dizziness postural								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Dysgeusia								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Essential tremor								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Headache								
Female	13	(6.6)	18	5.90	11	(4.8)	12	3.37
Male	9	(3.1)	10	2.17	10	(3.8)	20	4.87
Hypoaesthesia								
Female	3	(1.5)	3	0.98	3	(1.3)	4	1.12
Male	3	(1.0)	5	1.09	1	(0.4)	1	0.24

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hypoglycaemic unconsciousness								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Ischaemic stroke								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Lethargy								
Female	0				2	(0.9)	2	0.56
Male	0				0			
Lumbar radiculopathy								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	2	(0.8)	2	0.49
Memory impairment								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Mental impairment								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Metabolic encephalopathy								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Migraine								
Female	2	(1.0)	2	0.66	0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Movement disorder								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Muscle tone disorder								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Neuralgia								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Neuroglycopenia								
Female	2	(1.0)	4	1.31	0			
Male	0				1	(0.4)	3	0.73
Neuropathy peripheral								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	2	(0.8)	2	0.49
Paraesthesia								
Female	2	(1.0)	2	0.66	3	(1.3)	3	0.84
Male	2	(0.7)	2	0.43	2	(0.8)	2	0.49
Parkinsonian gait								
Female	0				0			
Male	0				1	(0.4)	1	0.24

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pineal gland cyst								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Post herpetic neuralgia								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Presyncope								
Female	0				2	(0.9)	2	0.56
Male	2	(0.7)	2	0.43	0			
Sciatica								
Female	2	(1.0)	2	0.66	4	(1.7)	7	1.97
Male	1	(0.3)	1	0.22	4	(1.5)	4	0.97
Somnolence								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Stiff leg syndrome								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Syncope								
Female	3	(1.5)	3	0.98	1	(0.4)	1	0.28
Male	2	(0.7)	4	0.87	0			
Tension headache								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	2	0.43	0			
Thrombotic stroke								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Transient ischaemic attack								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	0				1	(0.4)	1	0.24
Tremor								
Female	2	(1.0)	2	0.66	1	(0.4)	1	0.28
Male	4	(1.4)	5	1.09	0			
Trigeminal neuralgia								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Vertebral artery occlusion								
Female	0				1	(0.4)	1	0.28
Male	0				0			
VIth nerve paralysis								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
VIth nerve paresis								
Female	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	1	(0.3)	1	0.22	0			
Psychiatric disorders								
All								
Female	6	(3.0)	6	1.97	9	(3.9)	9	2.53
Male	17	(5.8)	19	4.13	4	(1.5)	4	0.97
Anxiety								
Female	1	(0.5)	1	0.33	2	(0.9)	2	0.56
Male	3	(1.0)	3	0.65	0			
Depressed mood								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Depression								
Female	2	(1.0)	2	0.66	1	(0.4)	1	0.28
Male	5	(1.7)	5	1.09	3	(1.1)	3	0.73
Insomnia								
Female	3	(1.5)	3	0.98	4	(1.7)	4	1.12
Male	6	(2.0)	6	1.30	0			
Mood swings								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Nightmare								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Persistent depressive disorder								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Psychotic disorder								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Schizophrenia								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Sleep disorder								
Female	0				0			
Male	2	(0.7)	2	0.43	0			
Renal and urinary disorders								
All								
Female	12	(6.1)	14	4.59	11	(4.8)	13	3.65
Male	8	(2.7)	10	2.17	17	(6.5)	22	5.36
Acute kidney injury								
Female	0				0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Calculus urinary								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	0				1	(0.4)	1	0.24
Chronic kidney disease								
Female	1	(0.5)	1	0.33	0			
Male	0				4	(1.5)	4	0.97
Diabetic nephropathy								
Female	2	(1.0)	2	0.66	1	(0.4)	1	0.28
Male	0				0			
Dysuria								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	2	(0.7)	2	0.43	3	(1.1)	3	0.73
Haematuria								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	0				3	(1.1)	3	0.73
Hypercalciuria								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Hypertonic bladder								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Ketonuria								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Microalbuminuria								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Nephrolithiasis								
Female	0				1	(0.4)	1	0.28
Male	2	(0.7)	2	0.43	1	(0.4)	1	0.24
Nocturia								
Female	1	(0.5)	1	0.33	0			
Male	0				2	(0.8)	2	0.49
Pollakiuria								
Female	2	(1.0)	2	0.66	1	(0.4)	1	0.28
Male	0				1	(0.4)	1	0.24
Pyelocaliectasis								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Renal colic								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Renal cyst								
Female	0				1	(0.4)	1	0.28

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	2	(0.7)	2	0.43	1	(0.4)	1	0.24
Renal impairment								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	2	(0.8)	2	0.49
Ureterolithiasis								
Female	0				2	(0.9)	2	0.56
Male	1	(0.3)	1	0.22	0			
Urinary incontinence								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Urinary retention								
Female	0				0			
Male	0				1	(0.4)	2	0.49
Urinary tract obstruction								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Urine odour abnormal								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Reproductive system and breast disorders								
All								
Female	8	(4.1)	8	2.62	8	(3.5)	11	3.09
Male	7	(2.4)	7	1.52	8	(3.0)	11	2.68
Adenomyosis								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Atrophic vulvovaginitis								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	0				0			
Balanoposthitis								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Benign prostatic hyperplasia								
Female	0				0			
Male	2	(0.7)	2	0.43	3	(1.1)	3	0.73
Breast mass								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Breast pain								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Erectile dysfunction								
Female	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	3	(1.0)	3	0.65	1	(0.4)	1	0.24
Galactorrhoea								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Hydrometra								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Menopausal symptoms								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Ovarian cyst								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Penile rash								
Female	0				0			
Male	0				1	(0.4)	3	0.73
Prostatism								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Prostatitis								
Female	0				0			
Male	0				1	(0.4)	2	0.49
Pruritus genital								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Uterine haemorrhage								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Uterine polyp								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	0				0			
Uterine prolapse								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Vaginal prolapse								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Vulval eczema								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Vulval leukoplakia								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Vulvovaginal dryness								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	0				1	(0.4)	1	0.28
Male	0				0			
Vulvovaginal pruritus								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	0				0			
Respiratory, thoracic and mediastinal disorders								
All								
Female	20	(10.2)	24	7.87	26	(11.4)	32	8.99
Male	35	(11.9)	52	11.29	22	(8.4)	37	9.01
Acquired diaphragmatic eventration								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Acute pulmonary oedema								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Acute respiratory failure								
Female	1	(0.5)	1	0.33	0			
Male	0				1	(0.4)	1	0.24
Allergic bronchitis								
Female	0				0			
Male	0				1	(0.4)	2	0.49
Asthma								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	2	0.43	0			
Bronchiectasis								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Bronchitis chronic								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Chronic eosinophilic rhinosinusitis								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Chronic obstructive pulmonary disease								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Cough								
Female	3	(1.5)	3	0.98	3	(1.3)	3	0.84
Male	11	(3.7)	12	2.61	5	(1.9)	6	1.46
Dry throat								
Female	0				0			
Male	1	(0.3)	1	0.22	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dyspnoea								
Female	2	(1.0)	2	0.66	4	(1.7)	4	1.12
Male	0				2	(0.8)	2	0.49
Dyspnoea exertional								
Female	0				0			
Male	2	(0.7)	2	0.43	2	(0.8)	2	0.49
Emphysema								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	0				0			
Epistaxis								
Female	0				1	(0.4)	3	0.84
Male	0				0			
Haemoptysis								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Interstitial lung disease								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	0			
Laryngeal cyst								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Nasal congestion								
Female	2	(1.0)	2	0.66	1	(0.4)	1	0.28
Male	3	(1.0)	4	0.87	1	(0.4)	1	0.24
Nasal dryness								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Nasal turbinate hypertrophy								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Oropharyngeal pain								
Female	5	(2.5)	5	1.64	5	(2.2)	6	1.69
Male	8	(2.7)	9	1.95	4	(1.5)	7	1.70
Paranasal sinus discomfort								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Pleural calcification								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Pleural effusion								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Pleuritic pain								
Female	0				0			
Male	0				1	(0.4)	1	0.24

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pneumothorax								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Productive cough								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Pulmonary embolism								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Pulmonary fibrosis								
Female	0				0			
Male	1	(0.3)	2	0.43	0			
Pulmonary mass								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Respiratory disorder								
Female	1	(0.5)	1	0.33	2	(0.9)	2	0.56
Male	0				1	(0.4)	1	0.24
Respiratory failure								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Rhinitis allergic								
Female	0				1	(0.4)	1	0.28
Male	0				1	(0.4)	5	1.22
Rhinorrhoea								
Female	2	(1.0)	2	0.66	1	(0.4)	1	0.28
Male	4	(1.4)	4	0.87	2	(0.8)	2	0.49
Sinus congestion								
Female	0				0			
Male	1	(0.3)	2	0.43	2	(0.8)	2	0.49
Sinus pain								
Female	0				0			
Male	1	(0.3)	2	0.43	0			
Sleep apnoea syndrome								
Female	0				1	(0.4)	1	0.28
Male	3	(1.0)	3	0.65	0			
Sneezing								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Throat irritation								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Upper respiratory tract inflammation								
Female	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	0				1	(0.4)	1	0.24
Upper-airway cough syndrome								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Skin and subcutaneous tissue disorders								
All								
Female	24	(12.2)	35	11.47	28	(12.2)	43	12.08
Male	35	(11.9)	42	9.12	25	(9.5)	32	7.79
Actinic keratosis								
Female	0				0			
Male	1	(0.3)	2	0.43	1	(0.4)	1	0.24
Alopecia								
Female	5	(2.5)	5	1.64	2	(0.9)	2	0.56
Male	1	(0.3)	1	0.22	0			
Alopecia areata								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Angioedema								
Female	1	(0.5)	1	0.33	0			
Male	0				1	(0.4)	1	0.24
Asteatosis								
Female	0				0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Blister								
Female	0				0			
Male	0				2	(0.8)	2	0.49
Cellulite								
Female	0				1	(0.4)	2	0.56
Male	0				0			
Chloasma								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Cold sweat								
Female	1	(0.5)	2	0.66	2	(0.9)	2	0.56
Male	1	(0.3)	1	0.22	0			
Cold urticaria								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Dermal cyst								
Female	1	(0.5)	1	0.33	2	(0.9)	2	0.56
Male	0				1	(0.4)	1	0.24
Dermatitis								
Female	0				3	(1.3)	3	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). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Dermatitis allergic								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Dermatitis contact								
Female	2	(1.0)	3	0.98	5	(2.2)	6	1.69
Male	4	(1.4)	5	1.09	2	(0.8)	2	0.49
Diabetic foot								
Female	0				0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Drug eruption								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Dry skin								
Female	1	(0.5)	1	0.33	0			
Male	2	(0.7)	2	0.43	0			
Ecchymosis								
Female	1	(0.5)	1	0.33	2	(0.9)	2	0.56
Male	0				0			
Eczema								
Female	3	(1.5)	3	0.98	1	(0.4)	1	0.28
Male	5	(1.7)	5	1.09	3	(1.1)	3	0.73
Eczema nummular								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Erythema								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Granuloma annulare								
Female	0				0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Haemorrhage subcutaneous								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	0				0			
Hyperhidrosis								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	3	(1.0)	3	0.65	0			
Hyperkeratosis								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Ingrowing nail								
Female	0				2	(0.9)	2	0.56
Male	1	(0.3)	1	0.22	0			
Lentigo								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	0				0			
Male	0				1	(0.4)	1	0.24
Lipodystrophy acquired								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Lipohypertrophy								
Female	0				1	(0.4)	1	0.28
Male	0				1	(0.4)	1	0.24
Macule								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Miliaria								
Female	2	(1.0)	3	0.98	3	(1.3)	3	0.84
Male	1	(0.3)	1	0.22	2	(0.8)	2	0.49
Myxoid cyst								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Night sweats								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Onychalgia								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Pruritus								
Female	1	(0.5)	3	0.98	2	(0.9)	2	0.56
Male	3	(1.0)	3	0.65	2	(0.8)	2	0.49
Psoriasis								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	0			
Purpura								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Rash								
Female	0				4	(1.7)	4	1.12
Male	2	(0.7)	2	0.43	4	(1.5)	4	0.97
Rosacea								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Skin exfoliation								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Skin fissures								
Female	1	(0.5)	1	0.33	0			
Male	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Skin irritation								
Female	0				0			
Male	2	(0.7)	3	0.65	1	(0.4)	1	0.24
Skin lesion								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	2	(0.8)	2	0.49
Skin ulcer								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Urticaria								
Female	1	(0.5)	2	0.66	3	(1.3)	3	0.84
Male	0				2	(0.8)	2	0.49
Urticaria contact								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Urticaria thermal								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Surgical and medical procedures								
All								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Removal of foreign body								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Vascular disorders								
All								
Female	13	(6.6)	15	4.92	15	(6.6)	19	5.34
Male	27	(9.2)	34	7.39	28	(10.6)	30	7.30
Aneurysm								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Aortic arteriosclerosis								
Female	0				1	(0.4)	1	0.28
Male	3	(1.0)	3	0.65	0			
Aortic stenosis								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Arteriosclerosis								
Female	1	(0.5)	1	0.33	0			
Male	0				2	(0.8)	2	0.49
Blood pressure inadequately controlled								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	0				0			
Male	0				1	(0.4)	1	0.24
Brachiocephalic arteriosclerosis								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	0				2	(0.8)	2	0.49
Diabetic vascular disorder								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Flushing								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Haematoma								
Female	1	(0.5)	1	0.33	1	(0.4)	1	0.28
Male	3	(1.0)	3	0.65	1	(0.4)	1	0.24
Hypertension								
Female	4	(2.0)	4	1.31	5	(2.2)	5	1.40
Male	11	(3.7)	11	2.39	11	(4.2)	12	2.92
Hypertensive angiopathy								
Female	1	(0.5)	1	0.33	0			
Male	1	(0.3)	1	0.22	2	(0.8)	2	0.49
Hypertensive crisis								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Hypertensive urgency								
Female	0				1	(0.4)	1	0.28
Male	1	(0.3)	1	0.22	0			
Hypotension								
Female	1	(0.5)	1	0.33	0			
Male	2	(0.7)	2	0.43	2	(0.8)	2	0.49
Iliac artery stenosis								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Intermittent claudication								
Female	0				0			
Male	1	(0.3)	1	0.22	1	(0.4)	1	0.24
Macroangiopathy								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Peripheral arterial occlusive disease								
Female	0				2	(0.9)	2	0.56
Male	1	(0.3)	2	0.43	3	(1.1)	3	0.73
Peripheral artery occlusion								
Female	1	(0.5)	1	0.33	0			
Male	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Peripheral artery stenosis								
Female	0				0			
Male	1	(0.3)	2	0.43	0			
Peripheral coldness								
Female	2	(1.0)	2	0.66	1	(0.4)	1	0.28
Male	2	(0.7)	2	0.43	0			
Peripheral vascular disorder								
Female	1	(0.5)	1	0.33	0			
Male	0				0			
Peripheral venous disease								
Female	0				2	(0.9)	2	0.56
Male	1	(0.3)	1	0.22	0			
Post thrombotic syndrome								
Female	0				0			
Male	0				1	(0.4)	1	0.24
Secondary hypertension								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Superficial vein thrombosis								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Thrombophlebitis								
Female	0				1	(0.4)	1	0.28
Male	0				0			
Thrombosis								
Female	0				0			
Male	1	(0.3)	1	0.22	0			
Varicose vein								
Female	0				1	(0.4)	1	0.28
Male	2	(0.7)	2	0.43	1	(0.4)	1	0.24

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Female	125				120			
Male	165				172			
PYE (years)								
Female	127.59				126.25			
Male	172.56				183.33			
Events								
Female	109	(87.2)	444	347.98	93	(77.5)	450	356.44
Male	131	(79.4)	521	301.92	143	(83.1)	696	379.63
Blood and lymphatic system disorders								
All								
Female	3	(2.4)	3	2.35	3	(2.5)	4	3.17
Male	4	(2.4)	5	2.90	2	(1.2)	2	1.09
Anaemia								
Female	2	(1.6)	2	1.57	0			
Male	2	(1.2)	2	1.16	0			
Blood loss anaemia								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Iron deficiency anaemia								
Female	0				2	(1.7)	3	2.38
Male	0				0			
Lymphadenitis								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Lymphadenopathy								
Female	0				1	(0.8)	1	0.79
Male	2	(1.2)	2	1.16	0			
Splenomegaly								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Thrombocytopenia								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Cardiac disorders								
All								
Female	9	(7.2)	10	7.84	5	(4.2)	7	5.54
Male	7	(4.2)	8	4.64	6	(3.5)	8	4.36

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Acute myocardial infarction								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Angina pectoris								
Female	1	(0.8)	1	0.78	0			
Male	1	(0.6)	1	0.58	0			
Angina unstable								
Female	0				2	(1.7)	2	1.58
Male	0				0			
Aortic valve incompetence								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Atrial fibrillation								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Bundle branch block right								
Female	0				0			
Male	1	(0.6)	1	0.58	1	(0.6)	1	0.55
Cardiac failure congestive								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Cardiomegaly								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Cardiovascular disorder								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Conduction disorder								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Coronary artery disease								
Female	1	(0.8)	1	0.78	0			
Male	0				1	(0.6)	1	0.55
Left ventricular hypertrophy								
Female	1	(0.8)	1	0.78	1	(0.8)	1	0.79
Male	0				0			
Mitral valve incompetence								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Myocardial infarction								
Female	1	(0.8)	1	0.78	0			
Male	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Myocardial ischaemia								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Palpitations								
Female	3	(2.4)	3	2.35	1	(0.8)	1	0.79
Male	0				3	(1.7)	4	2.18
Tachycardia								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Tricuspid valve incompetence								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Ventricular extrasystoles								
Female	2	(1.6)	2	1.57	0			
Male	1	(0.6)	1	0.58	0			
Congenital, familial and genetic disorders								
All								
Female	1	(0.8)	1	0.78	0			
Male	1	(0.6)	1	0.58	0			
Arteriovenous malformation								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Colour blindness								
Female	0				0			
Male	1	(0.6)	1	0.58	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
Female	2	(1.6)	2	1.57	2	(1.7)	2	1.58
Male	0				2	(1.2)	2	1.09
Deafness neurosensory								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Ear pain								
Female	1	(0.8)	1	0.78	1	(0.8)	1	0.79
Male	0				0			
Tinnitus								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Tympanic membrane perforation								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Vertigo								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Endocrine disorders								
All								
Female	0				2	(1.7)	2	1.58
Male	2	(1.2)	2	1.16	0			
Autoimmune thyroiditis								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Hypogonadism								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Hypothyroidism								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Thyroiditis chronic								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Eye disorders								
All								
Female	16	(12.8)	21	16.46	18	(15.0)	20	15.84
Male	27	(16.4)	41	23.76	28	(16.3)	46	25.09

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Angle closure glaucoma								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Arteriosclerotic retinopathy								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Astigmatism								
Female	1	(0.8)	1	0.78	0			
Male	0				2	(1.2)	2	1.09
Cataract								
Female	3	(2.4)	3	2.35	2	(1.7)	2	1.58
Male	3	(1.8)	3	1.74	2	(1.2)	3	1.64
Cataract nuclear								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Conjunctival haemorrhage								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Corneal erosion								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Diabetic retinal oedema								
Female	0				1	(0.8)	1	0.79
Male	2	(1.2)	2	1.16	0			
Diabetic retinopathy								
Female	8	(6.4)	9	7.05	5	(4.2)	5	3.96
Male	16	(9.7)	19	11.01	21	(12.2)	24	13.09
Dry eye								
Female	0				1	(0.8)	1	0.79
Male	1	(0.6)	1	0.58	0			
Eczema eyelids								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Epiretinal membrane								
Female	0				0			
Male	2	(1.2)	2	1.16	1	(0.6)	1	0.55
Eye pain								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Glaucoma								
Female	0				3	(2.5)	3	2.38
Male	1	(0.6)	1	0.58	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Macular oedema								
Female	3	(2.4)	4	3.13	0			
Male	1	(0.6)	1	0.58	1	(0.6)	1	0.55
Myopia								
Female	0				0			
Male	0				2	(1.2)	2	1.09
Non-proliferative retinopathy								
Female	1	(0.8)	1	0.78	0			
Male	2	(1.2)	2	1.16	2	(1.2)	2	1.09
Ocular hypertension								
Female	0				1	(0.8)	1	0.79
Male	0				1	(0.6)	2	1.09
Photopsia								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Posterior capsule opacification								
Female	0				1	(0.8)	2	1.58
Male	1	(0.6)	1	0.58	0			
Presbyopia								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Pterygium								
Female	0				1	(0.8)	2	1.58
Male	0				0			
Retinal drusen								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Retinal haemorrhage								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Retinal vascular disorder								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Retinopathy								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Retinopathy hypertensive								
Female	0				0			
Male	2	(1.2)	2	1.16	1	(0.6)	1	0.55
Strabismus								
Female	0				0			
Male	1	(0.6)	1	0.58	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vision blurred								
Female	1	(0.8)	1	0.78	0			
Male	1	(0.6)	1	0.58	0			
Visual acuity reduced								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Vitreous detachment								
Female	0				1	(0.8)	1	0.79
Male	0				1	(0.6)	1	0.55
Vitreous floaters								
Female	0				0			
Male	0				2	(1.2)	2	1.09
Gastrointestinal disorders								
All								
Female	28	(22.4)	41	32.13	23	(19.2)	37	29.31
Male	19	(11.5)	40	23.18	19	(11.0)	38	20.73
Abdominal discomfort								
Female	2	(1.6)	2	1.57	1	(0.8)	1	0.79
Male	0				1	(0.6)	1	0.55
Abdominal distension								
Female	1	(0.8)	2	1.57	0			
Male	1	(0.6)	1	0.58	1	(0.6)	1	0.55
Abdominal pain								
Female	4	(3.2)	4	3.13	1	(0.8)	1	0.79
Male	3	(1.8)	3	1.74	0			
Abdominal pain upper								
Female	1	(0.8)	1	0.78	1	(0.8)	1	0.79
Male	2	(1.2)	3	1.74	1	(0.6)	1	0.55
Anal fissure								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Change of bowel habit								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Chronic gastritis								
Female	0				0			
Male	1	(0.6)	1	0.58	3	(1.7)	3	1.64
Constipation								
Female	1	(0.8)	1	0.78	0			
Male	1	(0.6)	2	1.16	2	(1.2)	2	1.09
Dental caries								
Female	1	(0.8)	1	0.78	0			
Male	0				2	(1.2)	2	1.09

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Diarrhoea								
Female	3	(2.4)	4	3.13	4	(3.3)	5	3.96
Male	7	(4.2)	9	5.22	2	(1.2)	2	1.09
Diverticulum intestinal								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Duodenitis								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Dyspepsia								
Female	1	(0.8)	1	0.78	1	(0.8)	1	0.79
Male	2	(1.2)	2	1.16	1	(0.6)	1	0.55
Enteritis								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Faeces soft								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Flatulence								
Female	1	(0.8)	1	0.78	0			
Male	2	(1.2)	2	1.16	0			
Food poisoning								
Female	1	(0.8)	1	0.78	0			
Male	0				2	(1.2)	2	1.09
Gastric polyps								
Female	0				1	(0.8)	1	0.79
Male	0				1	(0.6)	1	0.55
Gastritis								
Female	1	(0.8)	1	0.78	1	(0.8)	1	0.79
Male	1	(0.6)	1	0.58	0			
Gastritis erosive								
Female	0				2	(1.7)	2	1.58
Male	0				0			
Gastrointestinal haemorrhage								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Gastrooesophageal reflux disease								
Female	0				0			
Male	1	(0.6)	1	0.58	2	(1.2)	2	1.09
Gastrooesophageal sphincter insufficiency								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Gingival recession								
Female	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	0				1	(0.6)	2	1.09
Gingival ulceration								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Haematochezia								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Haemorrhoids								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Hiatus hernia								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Impaired gastric emptying								
Female	1	(0.8)	1	0.78	0			
Male	1	(0.6)	2	1.16	0			
Irritable bowel syndrome								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Lumbar hernia								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Mouth ulceration								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Nausea								
Female	6	(4.8)	6	4.70	8	(6.7)	8	6.34
Male	3	(1.8)	3	1.74	2	(1.2)	2	1.09
Odynophagia								
Female	0				1	(0.8)	2	1.58
Male	0				0			
Oesophagitis								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Pancreatic failure								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Pancreatitis								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Pneumatosis intestinalis								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Proctitis ulcerative								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	0				1	(0.8)	2	1.58
Male	0				0			
Toothache								
Female	4	(3.2)	6	4.70	2	(1.7)	3	2.38
Male	0				1	(0.6)	3	1.64
Vomiting								
Female	5	(4.0)	6	4.70	4	(3.3)	4	3.17
Male	6	(3.6)	6	3.48	6	(3.5)	6	3.27
General disorders and administration site conditions								
All								
Female	22	(17.6)	32	25.08	36	(30.0)	58	45.94
Male	33	(20.0)	52	30.13	29	(16.9)	125	68.18
Asthenia								
Female	1	(0.8)	1	0.78	1	(0.8)	1	0.79
Male	0				2	(1.2)	2	1.09
Chest pain								
Female	1	(0.8)	1	0.78	0			
Male	0				2	(1.2)	2	1.09
Chills								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Complication associated with device								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Cyst								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Facial discomfort								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Facial pain								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Fatigue								
Female	6	(4.8)	7	5.49	2	(1.7)	2	1.58
Male	1	(0.6)	1	0.58	3	(1.7)	3	1.64
Hunger								
Female	1	(0.8)	1	0.78	1	(0.8)	2	1.58
Male	0				0			
Hyperthermia								
Female	0				1	(0.8)	1	0.79
Male	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Illness								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Inflammation								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Influenza like illness								
Female	0				2	(1.7)	2	1.58
Male	4	(2.4)	4	2.32	2	(1.2)	2	1.09
Injection site mass								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Injection site pain								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Injection site urticaria								
Female	1	(0.8)	2	1.57	0			
Male	0				0			
Malaise								
Female	1	(0.8)	1	0.78	1	(0.8)	3	2.38
Male	3	(1.8)	3	1.74	4	(2.3)	81	44.18
Medical device site bruise								
Female	0				2	(1.7)	2	1.58
Male	2	(1.2)	2	1.16	0			
Medical device site dermatitis								
Female	1	(0.8)	1	0.78	5	(4.2)	8	6.34
Male	4	(2.4)	5	2.90	1	(0.6)	1	0.55
Medical device site erythema								
Female	0				4	(3.3)	6	4.75
Male	2	(1.2)	3	1.74	1	(0.6)	1	0.55
Medical device site haematoma								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Medical device site haemorrhage								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Medical device site inflammation								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Medical device site irritation								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Medical device site pain								
Female	0				1	(0.8)	1	0.79
Male	1	(0.6)	1	0.58	0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Medical device site pruritus								
Female	0				1	(0.8)	1	0.79
Male	1	(0.6)	1	0.58	4	(2.3)	4	2.18
Medical device site rash								
Female	2	(1.6)	2	1.57	7	(5.8)	7	5.54
Male	5	(3.0)	6	3.48	4	(2.3)	5	2.73
Medical device site reaction								
Female	1	(0.8)	1	0.78	0			
Male	2	(1.2)	2	1.16	2	(1.2)	2	1.09
Medical device site vesicles								
Female	0				0			
Male	1	(0.6)	2	1.16	0			
Nodule								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Non-cardiac chest pain								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Oedema								
Female	0				0			
Male	1	(0.6)	1	0.58	1	(0.6)	1	0.55
Oedema peripheral								
Female	1	(0.8)	1	0.78	1	(0.8)	1	0.79
Male	2	(1.2)	2	1.16	0			
Pain								
Female	1	(0.8)	1	0.78	0			
Male	2	(1.2)	2	1.16	2	(1.2)	2	1.09
Peripheral swelling								
Female	0				1	(0.8)	1	0.79
Male	0				1	(0.6)	1	0.55
Pyrexia								
Female	8	(6.4)	11	8.62	12	(10.0)	15	11.88
Male	8	(4.8)	11	6.37	8	(4.7)	10	5.45
Swelling face								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Vaccination site discomfort								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Vaccination site joint pain								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Vaccination site lymphadenopathy								
Female	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	1	(0.6)	1	0.58	0			
Vaccination site pain								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Vaccination site swelling								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Hepatobiliary disorders								
All								
Female	3	(2.4)	4	3.13	1	(0.8)	1	0.79
Male	2	(1.2)	2	1.16	5	(2.9)	5	2.73
Cholecystitis chronic								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Gallbladder disorder								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Gallbladder polyp								
Female	1	(0.8)	1	0.78	0			
Male	0				2	(1.2)	2	1.09
Hepatic calcification								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Hepatic function abnormal								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Hepatic steatosis								
Female	2	(1.6)	2	1.57	0			
Male	1	(0.6)	1	0.58	1	(0.6)	1	0.55
Hypertransaminasaemia								
Female	1	(0.8)	1	0.78	0			
Male	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
Female	3	(2.4)	3	2.35	1	(0.8)	1	0.79
Male	2	(1.2)	2	1.16	5	(2.9)	5	2.73
Allergy to arthropod bite								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Allergy to arthropod sting								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Hypersensitivity								
Female	2	(1.6)	2	1.57	0			
Male	0				0			
Seasonal allergy								
Female	1	(0.8)	1	0.78	0			
Male	1	(0.6)	1	0.58	5	(2.9)	5	2.73
Infections and infestations								
All								
Female	79	(63.2)	152	119.13	59	(49.2)	127	100.60
Male	80	(48.5)	158	91.56	100	(58.1)	176	96.00
Abscess limb								
Female	1	(0.8)	1	0.78	0			
Male	0				1	(0.6)	2	1.09
Acute sinusitis								
Female	0				1	(0.8)	1	0.79
Male	0				2	(1.2)	2	1.09
Asymptomatic COVID-19								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Beta haemolytic streptococcal infection								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Breast abscess								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Bronchitis								
Female	3	(2.4)	3	2.35	3	(2.5)	4	3.17
Male	2	(1.2)	2	1.16	0			
Conjunctivitis								
Female	2	(1.6)	3	2.35	0			
Male	2	(1.2)	2	1.16	0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Coronavirus infection								
Female	0				1	(0.8)	1	0.79
Male	0				2	(1.2)	2	1.09
COVID-19								
Female	37	(29.6)	38	29.78	27	(22.5)	28	22.18
Male	38	(23.0)	43	24.92	57	(33.1)	61	33.27
COVID-19 pneumonia								
Female	1	(0.8)	1	0.78	1	(0.8)	1	0.79
Male	0				0			
Cystitis								
Female	3	(2.4)	3	2.35	1	(0.8)	1	0.79
Male	0				2	(1.2)	2	1.09
Cystitis escherichia								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Ear infection								
Female	0				0			
Male	1	(0.6)	1	0.58	1	(0.6)	1	0.55
Erythema migrans								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Eye infection								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Febrile infection								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Fungal infection								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Fungal skin infection								
Female	0				1	(0.8)	1	0.79
Male	2	(1.2)	2	1.16	0			
Furuncle								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Gastric infection								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Gastroenteritis								
Female	7	(5.6)	9	7.05	2	(1.7)	2	1.58
Male	6	(3.6)	9	5.22	3	(1.7)	4	2.18
Gastroenteritis viral								
Female	2	(1.6)	2	1.57	2	(1.7)	2	1.58
Male	1	(0.6)	1	0.58	1	(0.6)	1	0.55

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Gastrointestinal infection								
Female	0				0			
Male	1	(0.6)	1	0.58	2	(1.2)	4	2.18
Genital infection fungal								
Female	1	(0.8)	2	1.57	0			
Male	0				0			
Gingival abscess								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Gingivitis								
Female	0				0			
Male	1	(0.6)	1	0.58	2	(1.2)	2	1.09
Herpes zoster								
Female	0				1	(0.8)	1	0.79
Male	1	(0.6)	1	0.58	1	(0.6)	1	0.55
Hordeolum								
Female	0				3	(2.5)	3	2.38
Male	1	(0.6)	1	0.58	0			
Impetigo								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Infected cyst								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Influenza								
Female	2	(1.6)	2	1.57	5	(4.2)	5	3.96
Male	6	(3.6)	7	4.06	3	(1.7)	4	2.18
Laryngitis								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Laryngopharyngitis								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Localised infection								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Lower respiratory tract infection								
Female	0				1	(0.8)	1	0.79
Male	1	(0.6)	1	0.58	0			
Nasopharyngitis								
Female	24	(19.2)	34	26.65	26	(21.7)	37	29.31
Male	24	(14.5)	41	23.76	35	(20.3)	47	25.64

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Norovirus infection								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Oral herpes								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Otitis externa								
Female	0				1	(0.8)	1	0.79
Male	0				2	(1.2)	2	1.09
Otitis media								
Female	0				0			
Male	0				3	(1.7)	3	1.64
Pericoronitis								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Periodontitis								
Female	1	(0.8)	1	0.78	1	(0.8)	1	0.79
Male	0				0			
Pharyngitis								
Female	5	(4.0)	5	3.92	1	(0.8)	1	0.79
Male	3	(1.8)	3	1.74	1	(0.6)	2	1.09
Pneumonia								
Female	2	(1.6)	2	1.57	0			
Male	0				1	(0.6)	1	0.55
Pulpitis dental								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Pyelonephritis acute								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Respiratory tract infection								
Female	1	(0.8)	1	0.78	0			
Male	1	(0.6)	1	0.58	0			
Respiratory tract infection viral								
Female	1	(0.8)	1	0.78	1	(0.8)	1	0.79
Male	3	(1.8)	3	1.74	2	(1.2)	2	1.09
Rhinitis								
Female	1	(0.8)	1	0.78	1	(0.8)	2	1.58
Male	3	(1.8)	3	1.74	4	(2.3)	4	2.18
Sepsis								
Female	1	(0.8)	1	0.78	0			
Male	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severe acute respiratory syndrome								
Female	1	(0.8)	1	0.78	0			
Male	2	(1.2)	2	1.16	1	(0.6)	1	0.55
Sinobronchitis								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Sinusitis								
Female	6	(4.8)	6	4.70	6	(5.0)	6	4.75
Male	8	(4.8)	9	5.22	3	(1.7)	3	1.64
Skin infection								
Female	0				0			
Male	0				2	(1.2)	2	1.09
Tinea cruris								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Tinea pedis								
Female	1	(0.8)	1	0.78	0			
Male	1	(0.6)	2	1.16	1	(0.6)	1	0.55
Tonsillitis								
Female	1	(0.8)	1	0.78	2	(1.7)	3	2.38
Male	1	(0.6)	1	0.58	0			
Tooth abscess								
Female	1	(0.8)	1	0.78	0			
Male	3	(1.8)	3	1.74	0			
Tooth infection								
Female	2	(1.6)	2	1.57	0			
Male	0				0			
Tracheobronchitis								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Trichophytosis								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Upper respiratory tract infection								
Female	9	(7.2)	11	8.62	3	(2.5)	4	3.17
Male	6	(3.6)	7	4.06	8	(4.7)	9	4.91
Urinary tract infection								
Female	11	(8.8)	11	8.62	8	(6.7)	10	7.92
Male	1	(0.6)	1	0.58	0			
Vaginal infection								
Female	1	(0.8)	3	2.35	1	(0.8)	1	0.79
Male	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Varicella								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Viral infection								
Female	0				0			
Male	1	(0.6)	1	0.58	5	(2.9)	6	3.27
Viral rhinitis								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Vulvitis								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Vulvovaginal mycotic infection								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Vulvovaginitis								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Injury, poisoning and procedural complications								
All								
Female	17	(13.6)	28	21.94	20	(16.7)	27	21.39
Male	26	(15.8)	33	19.12	30	(17.4)	37	20.18
Accidental overdose								
Female	2	(1.6)	3	2.35	0			
Male	5	(3.0)	5	2.90	2	(1.2)	2	1.09
Anaemia postoperative								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Animal bite								
Female	1	(0.8)	1	0.78	1	(0.8)	1	0.79
Male	0				0			
Animal scratch								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Ankle fracture								
Female	1	(0.8)	3	2.35	0			
Male	0				0			
Arthropod bite								
Female	1	(0.8)	1	0.78	2	(1.7)	2	1.58
Male	0				1	(0.6)	1	0.55
Back injury								
Female	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	0				1	(0.6)	1	0.55
Burns first degree								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Chest injury								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Clavicle fracture								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Concussion								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Contusion								
Female	1	(0.8)	1	0.78	1	(0.8)	1	0.79
Male	1	(0.6)	1	0.58	2	(1.2)	2	1.09
Corneal abrasion								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Epicondylitis								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Face injury								
Female	1	(0.8)	1	0.78	0			
Male	0				1	(0.6)	1	0.55
Fall								
Female	0				2	(1.7)	5	3.96
Male	2	(1.2)	2	1.16	0			
Fibula fracture								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Hand fracture								
Female	0				0			
Male	1	(0.6)	1	0.58	2	(1.2)	2	1.09
Heat stroke								
Female	0				0			
Male	0				2	(1.2)	2	1.09
Incorrect dose administered								
Female	1	(0.8)	1	0.78	0			
Male	2	(1.2)	2	1.16	0			
Intentional underdose								
Female	0				0			
Male	0				1	(0.6)	2	1.09
Joint injury								

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	0				0			
Male	0				1	(0.6)	1	0.55
Ligament rupture								
Female	1	(0.8)	2	1.57	0			
Male	0				0			
Ligament sprain								
Female	3	(2.4)	3	2.35	2	(1.7)	2	1.58
Male	2	(1.2)	2	1.16	0			
Limb injury								
Female	1	(0.8)	1	0.78	0			
Male	0				1	(0.6)	1	0.55
Medication error								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Meniscus injury								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Muscle rupture								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Muscle strain								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Nerve injury								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Overdose								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Post-traumatic neck syndrome								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Prescribed overdose								
Female	2	(1.6)	2	1.57	0			
Male	3	(1.8)	3	1.74	0			
Procedural pain								
Female	1	(0.8)	2	1.57	0			
Male	0				0			
Product administration error								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Product dispensing error								
Female	0				0			
Male	1	(0.6)	1	0.58	0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Radius fracture								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Road traffic accident								
Female	1	(0.8)	1	0.78	0			
Male	1	(0.6)	2	1.16	1	(0.6)	1	0.55
Skin abrasion								
Female	2	(1.6)	3	2.35	1	(0.8)	1	0.79
Male	1	(0.6)	1	0.58	0			
Skin laceration								
Female	0				1	(0.8)	1	0.79
Male	1	(0.6)	1	0.58	1	(0.6)	1	0.55
Stress fracture								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Tendon rupture								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Thermal burn								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Tooth fracture								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Vaccination complication								
Female	1	(0.8)	1	0.78	3	(2.5)	4	3.17
Male	5	(3.0)	5	2.90	5	(2.9)	8	4.36
Venous injury								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Wound								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Wound dehiscence								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Wrist fracture								
Female	0				2	(1.7)	2	1.58
Male	0				0			
Wrong product administered								
Female	0				1	(0.8)	1	0.79
Male	0				3	(1.7)	3	1.64

Investigations

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
Female	6	(4.8)	6	4.70	9	(7.5)	11	8.71
Male	13	(7.9)	18	10.43	8	(4.7)	8	4.36
Angiogram								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Aspartate aminotransferase increased								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Blood cholesterol increased								
Female	0				1	(0.8)	1	0.79
Male	1	(0.6)	1	0.58	0			
Blood glucose fluctuation								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Blood glucose increased								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Blood pressure increased								
Female	0				0			
Male	2	(1.2)	3	1.74	0			
Blood testosterone decreased								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Blood triglycerides increased								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Blood uric acid increased								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Body temperature increased								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Cardiac murmur								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Electrocardiogram abnormal								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Electrocardiogram T wave abnormal								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Eosinophil count increased								
Female	0				1	(0.8)	2	1.58
Male	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Glomerular filtration rate decreased								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Haemoglobin decreased								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Heart rate increased								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Hepatic enzyme increased								
Female	0				0			
Male	1	(0.6)	1	0.58	1	(0.6)	1	0.55
Hepatitis B virus test positive								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Lipids abnormal								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Low density lipoprotein increased								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Mycobacterium tuberculosis complex test positive								
Female	2	(1.6)	2	1.57	0			
Male	0				0			
Occult blood positive								
Female	0				1	(0.8)	1	0.79
Male	1	(0.6)	1	0.58	0			
Platelet count decreased								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Pulse absent								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
SARS-CoV-2 test positive								
Female	0				3	(2.5)	3	2.38
Male	0				2	(1.2)	2	1.09
Serum ferritin decreased								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Weight decreased								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Weight increased								
Female	2	(1.6)	2	1.57	0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	0				0			
White blood cell count decreased								
Female	0				1	(0.8)	1	0.79
Male	1	(0.6)	1	0.58	0			
Metabolism and nutrition disorders								
All								
Female	8	(6.4)	8	6.27	7	(5.8)	8	6.34
Male	10	(6.1)	16	9.27	9	(5.2)	11	6.00
Decreased appetite								
Female	1	(0.8)	1	0.78	1	(0.8)	1	0.79
Male	0				1	(0.6)	1	0.55
Dehydration								
Female	0				0			
Male	0				1	(0.6)	2	1.09
Diabetic dyslipidaemia								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Diabetic ketoacidosis								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Dyslipidaemia								
Female	0				1	(0.8)	1	0.79
Male	0				1	(0.6)	1	0.55
Hypercholesterolaemia								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Hyperlipidaemia								
Female	1	(0.8)	1	0.78	0			
Male	1	(0.6)	1	0.58	1	(0.6)	1	0.55
Hyperuricaemia								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Hypoglycaemia								
Female	2	(1.6)	2	1.57	2	(1.7)	2	1.58
Male	8	(4.8)	13	7.53	2	(1.2)	3	1.64
Hypokalaemia								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Hyponatraemia								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Insulin resistance								
Female	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	0				1	(0.6)	1	0.55
Iron deficiency								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Obesity								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Vitamin D deficiency								
Female	1	(0.8)	1	0.78	3	(2.5)	3	2.38
Male	0				0			
Musculoskeletal and connective tissue disorders								
All								
Female	24	(19.2)	29	22.73	24	(20.0)	33	26.14
Male	21	(12.7)	29	16.81	32	(18.6)	66	36.00
Acquired claw toe								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Arthralgia								
Female	6	(4.8)	7	5.49	3	(2.5)	3	2.38
Male	6	(3.6)	6	3.48	12	(7.0)	13	7.09
Arthritis								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Back pain								
Female	0				5	(4.2)	5	3.96
Male	5	(3.0)	5	2.90	12	(7.0)	26	14.18
Bursitis								
Female	0				1	(0.8)	1	0.79
Male	1	(0.6)	1	0.58	0			
Chondromalacia								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Flank pain								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Foot deformity								
Female	1	(0.8)	1	0.78	0			
Male	0				1	(0.6)	2	1.09
Groin pain								
Female	0				0			
Male	0				2	(1.2)	2	1.09
Intervertebral disc protrusion								

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	0				1	(0.8)	2	1.58
Male	0				1	(0.6)	1	0.55
Limb discomfort								
Female	0				0			
Male	2	(1.2)	2	1.16	0			
Limb mass								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Muscle spasms								
Female	1	(0.8)	1	0.78	1	(0.8)	1	0.79
Male	3	(1.8)	4	2.32	0			
Muscular weakness								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Musculoskeletal stiffness								
Female	1	(0.8)	1	0.78	1	(0.8)	1	0.79
Male	0				0			
Myalgia								
Female	2	(1.6)	2	1.57	5	(4.2)	5	3.96
Male	1	(0.6)	1	0.58	3	(1.7)	6	3.27
Myopathy								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Neck pain								
Female	2	(1.6)	2	1.57	1	(0.8)	1	0.79
Male	0				1	(0.6)	1	0.55
Nodal osteoarthritis								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Osteoarthritis								
Female	1	(0.8)	1	0.78	2	(1.7)	2	1.58
Male	3	(1.8)	3	1.74	0			
Pain in extremity								
Female	3	(2.4)	3	2.35	7	(5.8)	7	5.54
Male	5	(3.0)	5	2.90	6	(3.5)	6	3.27
Periarthritis								
Female	2	(1.6)	2	1.57	2	(1.7)	2	1.58
Male	0				2	(1.2)	2	1.09
Rheumatoid arthritis								
Female	1	(0.8)	1	0.78	2	(1.7)	2	1.58
Male	0				0			
Rotator cuff syndrome								
Female	0				0			
Male	1	(0.6)	1	0.58	0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Spinal stenosis								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Synovial cyst								
Female	1	(0.8)	1	0.78	0			
Male	0				1	(0.6)	1	0.55
Tendonitis								
Female	1	(0.8)	1	0.78	0			
Male	0				1	(0.6)	1	0.55
Tenosynovitis								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Trigger finger								
Female	2	(1.6)	2	1.57	0			
Male	0				1	(0.6)	1	0.55

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
Female	3	(2.4)	3	2.35	4	(3.3)	5	3.96
Male	5	(3.0)	5	2.90	1	(0.6)	1	0.55
Benign neoplasm of thyroid gland								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Benign renal neoplasm								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Colon adenoma								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Eye naevus								
Female	0				1	(0.8)	1	0.79
Male	1	(0.6)	1	0.58	1	(0.6)	1	0.55
Haemangioma of liver								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Lipoma								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Melanocytic naevus								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Myeloproliferative neoplasm								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Seborrhoeic keratosis								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Skin papilloma								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Uterine leiomyoma								
Female	0				2	(1.7)	2	1.58
Male	0				0			
Nervous system disorders								
All								
Female	15	(12.0)	27	21.16	23	(19.2)	37	29.31
Male	25	(15.2)	45	26.08	16	(9.3)	82	44.73

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ageusia								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Autonomic nervous system imbalance								
Female	0				0			
Male	1	(0.6)	2	1.16	0			
Burning sensation								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Carpal tunnel syndrome								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Cerebral haemorrhage								
Female	1	(0.8)	2	1.57	0			
Male	0				0			
Cerebral infarction								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Cervicobrachial syndrome								
Female	1	(0.8)	1	0.78	0			
Male	1	(0.6)	1	0.58	0			
Diabetic neuropathy								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Disturbance in attention								
Female	0				0			
Male	1	(0.6)	11	6.37	0			
Dizziness								
Female	0				0			
Male	2	(1.2)	3	1.74	5	(2.9)	6	3.27
Dizziness postural								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Encephalopathy								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Haemorrhage intracranial								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Headache								
Female	7	(5.6)	14	10.97	12	(10.0)	18	14.26
Male	10	(6.1)	13	7.53	4	(2.3)	4	2.18

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hemiparesis								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Hypoaesthesia								
Female	1	(0.8)	2	1.57	1	(0.8)	1	0.79
Male	1	(0.6)	1	0.58	1	(0.6)	1	0.55
Hypoglycaemic seizure								
Female	0				1	(0.8)	1	0.79
Male	1	(0.6)	1	0.58	0			
Hypoglycaemic unconsciousness								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Hypotonia								
Female	0				1	(0.8)	1	0.79
Male	0				0			
IIIrd nerve paralysis								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Ischaemic stroke								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Loss of consciousness								
Female	1	(0.8)	1	0.78	1	(0.8)	1	0.79
Male	0				1	(0.6)	1	0.55
Loss of proprioception								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Migraine								
Female	1	(0.8)	1	0.78	2	(1.7)	3	2.38
Male	3	(1.8)	4	2.32	0			
Neuropathy peripheral								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Optic neuritis								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Post herpetic neuralgia								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Presyncope								
Female	0				0			
Male	0				1	(0.6)	1	0.55

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Radiculopathy								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Restless legs syndrome								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Sinus headache								
Female	0				1	(0.8)	1	0.79
Male	1	(0.6)	1	0.58	0			
Somnolence								
Female	1	(0.8)	1	0.78	0			
Male	1	(0.6)	1	0.58	0			
Syncope								
Female	1	(0.8)	1	0.78	0			
Male	2	(1.2)	2	1.16	0			
Tension headache								
Female	0				1	(0.8)	2	1.58
Male	0				0			
Tremor								
Female	0				1	(0.8)	4	3.17
Male	1	(0.6)	1	0.58	3	(1.7)	64	34.91
Pregnancy, puerperium and perinatal conditions								
All								
Female	2	(1.6)	2	1.57	0			
Male	0				0			
Abortion spontaneous								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Abortion threatened								
Female	1	(0.8)	1	0.78	0			
Male	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Psychiatric disorders								
All								
Female	5	(4.0)	5	3.92	6	(5.0)	7	5.54
Male	3	(1.8)	3	1.74	5	(2.9)	7	3.82
Alcohol abuse								
Female	1	(0.8)	1	0.78	0			
Male	0				1	(0.6)	1	0.55
Anxiety								
Female	1	(0.8)	1	0.78	3	(2.5)	3	2.38
Male	0				2	(1.2)	2	1.09
Anxiety disorder								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Attention deficit hyperactivity disorder								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Depressed mood								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Depression								
Female	0				2	(1.7)	2	1.58
Male	0				3	(1.7)	3	1.64
Insomnia								
Female	1	(0.8)	1	0.78	1	(0.8)	1	0.79
Male	0				1	(0.6)	1	0.55
Major depression								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Sleep disorder								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Stress								
Female	0				1	(0.8)	1	0.79
Male	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
Female	3	(2.4)	3	2.35	1	(0.8)	4	3.17
Male	4	(2.4)	4	2.32	4	(2.3)	4	2.18
Acute kidney injury								
Female	0				0			
Male	1	(0.6)	1	0.58	1	(0.6)	1	0.55
Chronic kidney disease								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Diabetic nephropathy								
Female	0				1	(0.8)	1	0.79
Male	0				1	(0.6)	1	0.55
Dysuria								
Female	2	(1.6)	2	1.57	0			
Male	0				0			
Hydrocalyx								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Hypertensive nephropathy								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Microalbuminuria								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Pollakiuria								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Proteinuria								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Renal cyst								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Renal pain								
Female	1	(0.8)	1	0.78	0			
Male	1	(0.6)	1	0.58	0			
Reproductive system and breast disorders								
All								
Female	4	(3.2)	4	3.13	6	(5.0)	8	6.34
Male	5	(3.0)	6	3.48	2	(1.2)	2	1.09

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Atrophic vulvovaginitis								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Benign prostatic hyperplasia								
Female	0				0			
Male	2	(1.2)	2	1.16	1	(0.6)	1	0.55
Dysmenorrhoea								
Female	1	(0.8)	1	0.78	2	(1.7)	2	1.58
Male	0				0			
Ectropion of cervix								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Erectile dysfunction								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Fibrocystic breast disease								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Heavy menstrual bleeding								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Menstruation irregular								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Ovarian cyst								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Ovarian disorder								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Penile pain								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Premenstrual syndrome								
Female	1	(0.8)	1	0.78	1	(0.8)	1	0.79
Male	0				0			
Prostatic cyst								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Prostatitis								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Prostatomegaly								
Female	0				0			
Male	1	(0.6)	1	0.58	0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Respiratory, thoracic and mediastinal disorders								
All								
Female	20	(16.0)	32	25.08	16	(13.3)	24	19.01
Male	16	(9.7)	22	12.75	21	(12.2)	33	18.00
Acute respiratory failure								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Allergic cough								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Asthma								
Female	0				1	(0.8)	1	0.79
Male	1	(0.6)	1	0.58	0			
Bronchial hyperreactivity								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Cough								
Female	7	(5.6)	10	7.84	5	(4.2)	7	5.54
Male	2	(1.2)	2	1.16	6	(3.5)	8	4.36
Cough variant asthma								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Dysphonia								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Dyspnoea								
Female	1	(0.8)	1	0.78	1	(0.8)	1	0.79
Male	1	(0.6)	1	0.58	0			
Dyspnoea exertional								
Female	0				0			
Male	1	(0.6)	1	0.58	1	(0.6)	1	0.55
Epiglottic oedema								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Epistaxis								
Female	2	(1.6)	2	1.57	0			
Male	1	(0.6)	1	0.58	0			
Hiccups								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Nasal congestion								
Female	2	(1.6)	2	1.57	0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Male	0				1	(0.6)	1	0.55
Oropharyngeal discomfort								
Female	0				1	(0.8)	1	0.79
Male	0				1	(0.6)	1	0.55
Oropharyngeal pain								
Female	6	(4.8)	6	4.70	6	(5.0)	7	5.54
Male	2	(1.2)	3	1.74	4	(2.3)	4	2.18
Pleurisy								
Female	1	(0.8)	1	0.78	0			
Male	0				1	(0.6)	1	0.55
Productive cough								
Female	0				0			
Male	0				3	(1.7)	4	2.18
Pulmonary congestion								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Pulmonary mass								
Female	1	(0.8)	1	0.78	0			
Male	0				1	(0.6)	1	0.55
Respiratory disorder								
Female	1	(0.8)	1	0.78	1	(0.8)	1	0.79
Male	3	(1.8)	3	1.74	1	(0.6)	1	0.55
Rhinitis allergic								
Female	1	(0.8)	1	0.78	2	(1.7)	2	1.58
Male	2	(1.2)	3	1.74	0			
Rhinorrhoea								
Female	1	(0.8)	1	0.78	2	(1.7)	2	1.58
Male	2	(1.2)	3	1.74	5	(2.9)	6	3.27
Sinus congestion								
Female	1	(0.8)	1	0.78	0			
Male	1	(0.6)	1	0.58	2	(1.2)	2	1.09
Sleep apnoea syndrome								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Sneezing								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Throat irritation								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Upper-airway cough syndrome								
Female	0				0			
Male	1	(0.6)	1	0.58	1	(0.6)	1	0.55

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Skin and subcutaneous tissue disorders								
All								
Female	18	(14.4)	21	16.46	17	(14.2)	21	16.63
Male	18	(10.9)	21	12.17	23	(13.4)	33	18.00
Alopecia								
Female	2	(1.6)	2	1.57	0			
Male	1	(0.6)	1	0.58	0			
Alopecia areata								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Angioedema								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Chronic spontaneous urticaria								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Cold sweat								
Female	0				2	(1.7)	2	1.58
Male	0				3	(1.7)	8	4.36
Dermal cyst								
Female	0				1	(0.8)	1	0.79
Male	1	(0.6)	1	0.58	1	(0.6)	1	0.55
Dermatitis								
Female	3	(2.4)	4	3.13	2	(1.7)	3	2.38
Male	2	(1.2)	3	1.74	1	(0.6)	1	0.55
Dermatitis allergic								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Dermatitis atopic								
Female	1	(0.8)	1	0.78	1	(0.8)	1	0.79
Male	0				1	(0.6)	1	0.55
Dermatitis contact								
Female	1	(0.8)	1	0.78	4	(3.3)	4	3.17
Male	3	(1.8)	3	1.74	3	(1.7)	3	1.64
Dry skin								
Female	0				0			
Male	1	(0.6)	1	0.58	1	(0.6)	1	0.55
Eczema								
Female	0				1	(0.8)	1	0.79
Male	0				2	(1.2)	2	1.09
Eczema asteatotic								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Erythema								

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Female	0				0			
Male	0				2	(1.2)	2	1.09
Erythema multiforme								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Hidradenitis								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Hyperkeratosis								
Female	0				0			
Male	1	(0.6)	1	0.58	1	(0.6)	1	0.55
Ingrowing nail								
Female	0				1	(0.8)	1	0.79
Male	1	(0.6)	1	0.58	1	(0.6)	1	0.55
Ingrown hair								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Lichen sclerosus								
Female	1	(0.8)	1	0.78	0			
Male	1	(0.6)	1	0.58	0			
Macule								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Miliaria								
Female	0				2	(1.7)	2	1.58
Male	0				0			
Pruritus								
Female	1	(0.8)	1	0.78	1	(0.8)	1	0.79
Male	0				1	(0.6)	1	0.55
Psoriasis								
Female	1	(0.8)	1	0.78	0			
Male	0				1	(0.6)	1	0.55
Rash								
Female	3	(2.4)	3	2.35	1	(0.8)	1	0.79
Male	1	(0.6)	1	0.58	1	(0.6)	1	0.55
Rash erythematous								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Seborrhoeic dermatitis								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Skin fissures								
Female	0				0			
Male	1	(0.6)	1	0.58	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Skin irritation								
Female	1	(0.8)	1	0.78	0			
Male	1	(0.6)	1	0.58	1	(0.6)	1	0.55
Skin lesion								
Female	1	(0.8)	1	0.78	0			
Male	0				1	(0.6)	1	0.55
Skin reaction								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Skin ulcer								
Female	0				0			
Male	0				1	(0.6)	1	0.55
Telangiectasia								
Female	1	(0.8)	1	0.78	1	(0.8)	1	0.79
Male	0				0			
Urticaria								
Female	0				1	(0.8)	1	0.79
Male	0				3	(1.7)	3	1.64
Urticaria papular								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Vitiligo								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Xeroderma								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Surgical and medical procedures								
All								
Female	2	(1.6)	2	1.57	0			
Male	2	(1.2)	2	1.16	0			
Cardiac ablation								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Skin neoplasm excision								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Tooth extraction								
Female	1	(0.8)	1	0.78	0			
Male	0				0			
Wisdom teeth removal								
Female	1	(0.8)	1	0.78	0			
Male	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vascular disorders								
All								
Female	5	(4.0)	5	3.92	5	(4.2)	6	4.75
Male	6	(3.6)	6	3.48	5	(2.9)	5	2.73
Aortic aneurysm								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Arteriosclerosis								
Female	0				0			
Male	1	(0.6)	1	0.58	0			
Brachiocephalic artery stenosis								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Hypertension								
Female	4	(3.2)	4	3.13	2	(1.7)	2	1.58
Male	4	(2.4)	4	2.32	5	(2.9)	5	2.73
Hypertensive crisis								
Female	0				1	(0.8)	1	0.79
Male	0				0			
Hypotension								
Female	1	(0.8)	1	0.78	0			
Male	1	(0.6)	1	0.58	0			
Varicose vein								
Female	0				1	(0.8)	1	0.79
Male	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
>=18 - <65 years	333				332			
>=65 - <75 years	134				144			
>=75 years	25				16			
PYE (years)								
>=18 - <65 years	518.30				522.36			
>=65 - <75 years	208.54				220.17			
>=75 years	38.66				24.22			
Events								
>=18 - <65 years	267	(80.2)	1202	231.91	258	(77.7)	1151	220.34
>=65 - <75 years	106	(79.1)	530	254.15	118	(81.9)	613	278.42
>=75 years	24	(96.0)	150	388.01	13	(81.3)	59	243.58
Serious								
Yes								
>=18 - <65 years	27	(8.1)	37	7.14	41	(12.3)	55	10.53
>=65 - <75 years	29	(21.6)	47	22.54	26	(18.1)	60	27.25
>=75 years	8	(32.0)	11	28.45	4	(25.0)	4	16.51
No								
>=18 - <65 years	265	(79.6)	1165	224.77	253	(76.2)	1096	209.82
>=65 - <75 years	99	(73.9)	483	231.61	114	(79.2)	553	251.17
>=75 years	23	(92.0)	139	359.56	13	(81.3)	55	227.07
Missing								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Severity								
Severe								
>=18 - <65 years	13	(3.9)	17	3.28	21	(6.3)	25	4.79
>=65 - <75 years	10	(7.5)	17	8.15	13	(9.0)	34	15.44
>=75 years	3	(12.0)	4	10.35	2	(12.5)	2	8.26
Moderate								
>=18 - <65 years	121	(36.3)	252	48.62	123	(37.0)	256	49.01
>=65 - <75 years	58	(43.3)	115	55.15	54	(37.5)	133	60.41
>=75 years	13	(52.0)	34	87.95	6	(37.5)	8	33.03
Mild								
>=18 - <65 years	240	(72.1)	933	180.01	223	(67.2)	870	166.55
>=65 - <75 years	90	(67.2)	398	190.85	105	(72.9)	446	202.57
>=75 years	21	(84.0)	112	289.72	12	(75.0)	49	202.30
Missing								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to basal insulin								
Probable								
>=18 - <65 years	23	(6.9)	35	6.75	27	(8.1)	39	7.47
>=65 - <75 years	6	(4.5)	7	3.36	6	(4.2)	12	5.45
>=75 years	1	(4.0)	1	2.59	0			
Possible								
>=18 - <65 years	33	(9.9)	49	9.45	23	(6.9)	31	5.93
>=65 - <75 years	12	(9.0)	17	8.15	15	(10.4)	28	12.72
>=75 years	1	(4.0)	1	2.59	1	(6.3)	1	4.13
Unlikely								
>=18 - <65 years	263	(79.0)	1117	215.51	249	(75.0)	1075	205.80
>=65 - <75 years	105	(78.4)	505	242.16	116	(80.6)	573	260.25
>=75 years	24	(96.0)	148	382.84	13	(81.3)	58	239.45
Missing								
>=18 - <65 years	1	(0.3)	1	0.19	5	(1.5)	6	1.15
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Related to technical complaint for basal insulin								
Yes								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
No								
>=18 - <65 years	267	(80.2)	1201	231.72	257	(77.4)	1144	219.00
>=65 - <75 years	106	(79.1)	530	254.15	118	(81.9)	613	278.42
>=75 years	24	(96.0)	150	388.01	13	(81.3)	59	243.58
NA								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Missing								
>=18 - <65 years	1	(0.3)	1	0.19	5	(1.5)	6	1.15
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
>=18 - <65 years	3	(0.9)	4	0.77	0			
>=65 - <75 years	1	(0.7)	1	0.48	2	(1.4)	6	2.73
>=75 years	1	(4.0)	2	5.17	1	(6.3)	1	4.13
Not recovered/not resolved								
>=18 - <65 years	142	(42.6)	306	59.04	130	(39.2)	263	50.35
>=65 - <75 years	57	(42.5)	154	73.85	78	(54.2)	166	75.40
>=75 years	14	(56.0)	48	124.16	8	(50.0)	18	74.31
Recovered/resolved with sequelae								
>=18 - <65 years	4	(1.2)	4	0.77	5	(1.5)	5	0.96
>=65 - <75 years	3	(2.2)	3	1.44	3	(2.1)	3	1.36
>=75 years	2	(8.0)	2	5.17	0			
Recovering/resolving								
>=18 - <65 years	13	(3.9)	20	3.86	19	(5.7)	22	4.21
>=65 - <75 years	5	(3.7)	5	2.40	11	(7.6)	17	7.72
>=75 years	3	(12.0)	3	7.76	0			
Recovered/resolved								
>=18 - <65 years	238	(71.5)	868	167.47	235	(70.8)	861	164.83
>=65 - <75 years	94	(70.1)	367	175.99	104	(72.2)	421	191.21
>=75 years	22	(88.0)	95	245.74	12	(75.0)	40	165.14
Unknown								
>=18 - <65 years	0				0			
					0			
>=65 - <75 years	0				0			
					0			
>=75 years	0				0			
					0			
Missing								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
>=18 - <65 years	267				271			
>=65 - <75 years	20				18			
>=75 years	3				3			
PYE (years)								
>=18 - <65 years	277.22				286.61			
>=65 - <75 years	20.28				19.70			
>=75 years	2.66				3.28			
Events								
>=18 - <65 years	220	(82.4)	870	313.83	217	(80.1)	1068	372.63
>=65 - <75 years	17	(85.0)	84	414.16	16	(88.9)	59	299.55
>=75 years	3	(100.0)	11	413.77	3	(100.0)	19	579.76
Serious								
Yes								
>=18 - <65 years	21	(7.9)	33	11.90	19	(7.0)	24	8.37
>=65 - <75 years	2	(10.0)	5	24.65	0			
>=75 years	1	(33.3)	1	37.62	1	(33.3)	1	30.51
No								
>=18 - <65 years	218	(81.6)	837	301.93	217	(80.1)	1044	364.26
>=65 - <75 years	17	(85.0)	79	389.51	16	(88.9)	59	299.55
>=75 years	2	(66.7)	10	376.16	3	(100.0)	18	549.25
Missing								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Severity								
Severe								
>=18 - <65 years	17	(6.4)	23	8.30	9	(3.3)	10	3.49
>=65 - <75 years	2	(10.0)	4	19.72	0			
>=75 years	1	(33.3)	1	37.62	0			
Moderate								
>=18 - <65 years	74	(27.7)	155	55.91	75	(27.7)	144	50.24
>=65 - <75 years	8	(40.0)	22	108.47	5	(27.8)	7	35.54
>=75 years	1	(33.3)	2	75.23	2	(66.7)	8	244.11
Mild								
>=18 - <65 years	201	(75.3)	692	249.62	202	(74.5)	914	318.90
>=65 - <75 years	16	(80.0)	58	285.97	15	(83.3)	52	264.01
>=75 years	2	(66.7)	8	300.93	2	(66.7)	11	335.65
Missing								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to basal insulin								
Probable								
>=18 - <65 years	18	(6.7)	23	8.30	11	(4.1)	12	4.19
>=65 - <75 years	2	(10.0)	2	9.86	0			
>=75 years	0				0			
Possible								
>=18 - <65 years	26	(9.7)	32	11.54	20	(7.4)	70	24.42
>=65 - <75 years	3	(15.0)	3	14.79	1	(5.6)	1	5.08
>=75 years	1	(33.3)	1	37.62	1	(33.3)	1	30.51
Unlikely								
>=18 - <65 years	214	(80.1)	814	293.63	216	(79.7)	986	344.02
>=65 - <75 years	17	(85.0)	79	389.51	15	(83.3)	58	294.47
>=75 years	3	(100.0)	10	376.16	3	(100.0)	18	549.25
Missing								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Related to technical complaint for basal insulin								
Yes								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			
No								
>=18 - <65 years	220	(82.4)	869	313.47	217	(80.1)	1068	372.63
>=65 - <75 years	17	(85.0)	84	414.16	16	(88.9)	59	299.55
>=75 years	3	(100.0)	11	413.77	3	(100.0)	19	579.76
NA								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Missing								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(33.3)	1	37.62	0			
Not recovered/not resolved								
>=18 - <65 years	93	(34.8)	166	59.88	95	(35.1)	199	69.43
>=65 - <75 years	11	(55.0)	25	123.26	7	(38.9)	14	71.08
>=75 years	1	(33.3)	4	150.46	2	(66.7)	4	122.06
Recovered/resolved with sequelae								
>=18 - <65 years	2	(0.7)	3	1.08	2	(0.7)	2	0.70
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	0				0			
Recovering/resolving								
>=18 - <65 years	19	(7.1)	23	8.30	16	(5.9)	19	6.63
>=65 - <75 years	1	(5.0)	1	4.93	3	(16.7)	3	15.23
>=75 years	0				1	(33.3)	3	91.54
Recovered/resolved								
>=18 - <65 years	204	(76.4)	678	244.57	196	(72.3)	848	295.87
>=65 - <75 years	15	(75.0)	58	285.97	14	(77.8)	41	208.16
>=75 years	2	(66.7)	6	225.70	3	(100.0)	12	366.17
Unknown								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Missing								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
>=18 - <65 years	333				332			
>=65 - <75 years	134				144			
>=75 years	25				16			
PYE (years)								
>=18 - <65 years	518.30				522.36			
>=65 - <75 years	208.54				220.17			
>=75 years	38.66				24.22			
Events								
>=18 - <65 years	267	(80.2)	1202	231.91	258	(77.7)	1151	220.34
>=65 - <75 years	106	(79.1)	530	254.15	118	(81.9)	613	278.42
>=75 years	24	(96.0)	150	388.01	13	(81.3)	59	243.58

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blood and lymphatic system disorders								
All								
>=18 - <65 years	6	(1.8)	8	1.54	11	(3.3)	11	2.11
>=65 - <75 years	8	(6.0)	8	3.84	7	(4.9)	7	3.18
>=75 years	1	(4.0)	1	2.59	1	(6.3)	2	8.26
Anaemia								
>=18 - <65 years	3	(0.9)	3	0.58	7	(2.1)	7	1.34
>=65 - <75 years	6	(4.5)	6	2.88	2	(1.4)	2	0.91
>=75 years	1	(4.0)	1	2.59	1	(6.3)	2	8.26
Blood loss anaemia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Eosinophilia								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				2	(1.4)	2	0.91
>=75 years	0				0			
Hypochromic anaemia								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Iron deficiency anaemia								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	2	(1.5)	2	0.96	0			
>=75 years	0				0			
Lymphadenopathy								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Normochromic normocytic anaemia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Polycythaemia								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Thrombocytopenia								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Cardiac disorders								
All								
>=18 - <65 years	15	(4.5)	28	5.40	18	(5.4)	27	5.17
>=65 - <75 years	22	(16.4)	37	17.74	22	(15.3)	32	14.53
>=75 years	7	(28.0)	14	36.21	2	(12.5)	2	8.26

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Acute coronary syndrome								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Acute myocardial infarction								
>=18 - <65 years	2	(0.6)	2	0.39	3	(0.9)	3	0.57
>=65 - <75 years	1	(0.7)	1	0.48	2	(1.4)	2	0.91
>=75 years	1	(4.0)	1	2.59	0			
Angina pectoris								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Angina unstable								
>=18 - <65 years	2	(0.6)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	2	(1.5)	2	0.96	0			
>=75 years	1	(4.0)	1	2.59	0			
Aortic valve calcification								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Aortic valve incompetence								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	1	(4.0)	1	2.59	0			
Arrhythmia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				2	(1.4)	2	0.91
>=75 years	0				0			
Arteriosclerosis coronary artery								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Atrial fibrillation								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	4	(3.0)	4	1.92	4	(2.8)	7	3.18
>=75 years	3	(12.0)	4	10.35	1	(6.3)	1	4.13
Atrial flutter								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	2	0.96	0			
>=75 years	0				0			
Atrial thrombosis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Atrioventricular block complete								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				1	(6.3)	1	4.13

%: 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). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Atrioventricular block first degree								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Atrioventricular block second degree								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Bradycardia								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Bundle branch block left								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Bundle branch block right								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	2	0.38
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	1	(4.0)	1	2.59	0			
Cardiac dysfunction								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Cardiac failure								
>=18 - <65 years	2	(0.6)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	2	(1.5)	2	0.96	0			
>=75 years	0				0			
Cardiac failure chronic								
>=18 - <65 years	2	(0.6)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Cardiac failure congestive								
>=18 - <65 years	0				0			
>=65 - <75 years	2	(1.5)	2	0.96	1	(0.7)	1	0.45
>=75 years	0				0			
Cardiac ventricular thrombosis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Cardio-respiratory arrest								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Cardiomyopathy								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Chronic coronary syndrome								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Congestive cardiomyopathy								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Coronary artery disease								
>=18 - <65 years	3	(0.9)	3	0.58	1	(0.3)	1	0.19
>=65 - <75 years	3	(2.2)	3	1.44	2	(1.4)	2	0.91
>=75 years	0				0			
Coronary artery occlusion								
>=18 - <65 years	2	(0.6)	2	0.39	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Coronary artery stenosis								
>=18 - <65 years	1	(0.3)	2	0.39	0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Diastolic dysfunction								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Left atrial dilatation								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Left ventricular dysfunction								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Left ventricular hypertrophy								
>=18 - <65 years	0				0			
>=65 - <75 years	2	(1.5)	2	0.96	1	(0.7)	1	0.45
>=75 years	0				0			
Mitral valve incompetence								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Myocardial infarction								
>=18 - <65 years	2	(0.6)	2	0.39	3	(0.9)	3	0.57
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Myocardial ischaemia								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Palpitations								
>=18 - <65 years	2	(0.6)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	3	(2.1)	4	1.82
>=75 years	0				0			
Pericardial effusion								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Pericarditis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Sinus arrhythmia								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Sinus bradycardia								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Sinus tachycardia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				2	(1.4)	2	0.91
>=75 years	1	(4.0)	1	2.59	0			
Supraventricular extrasystoles								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	2	(1.4)	2	0.91
>=75 years	0				0			
Supraventricular tachycardia								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Tachycardia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Tricuspid valve incompetence								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Ventricular extrasystoles								
>=18 - <65 years	2	(0.6)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	2	(1.5)	2	0.96	0			
>=75 years	1	(4.0)	1	2.59	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Congenital, familial and genetic disorders								
All								
>=18 - <65 years	1	(0.3)	1	0.19	2	(0.6)	2	0.38
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	1	(4.0)	1	2.59	0			
Congenital syphilitic osteochondritis								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Corneal dystrophy								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Dolichocolon								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Hydrocele								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Type V hyperlipidaemia								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
>=18 - <65 years	6	(1.8)	6	1.16	6	(1.8)	6	1.15
>=65 - <75 years	6	(4.5)	7	3.36	7	(4.9)	8	3.63
>=75 years	0				0			
Cerumen impaction								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Ear discomfort								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Ear inflammation								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Ear pain								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Eustachian tube dysfunction								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypoacusis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Presbyacusis								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Tinnitus								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Vertigo								
>=18 - <65 years	1	(0.3)	1	0.19	3	(0.9)	3	0.57
>=65 - <75 years	5	(3.7)	6	2.88	4	(2.8)	5	2.27
>=75 years	0				0			
Vertigo positional								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
>=18 - <65 years	1	(0.3)	1	0.19	4	(1.2)	4	0.77
>=65 - <75 years	3	(2.2)	3	1.44	4	(2.8)	4	1.82
>=75 years	0				0			
Goitre								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Hyperplasia adrenal								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Hyperprolactinaemia								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Hyperthyroidism								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Hypothyroidism								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Thyroid mass								
>=18 - <65 years	0				0			
>=65 - <75 years	2	(1.5)	2	0.96	1	(0.7)	1	0.45
>=75 years	0				0			
Eye disorders								
All								
>=18 - <65 years	65	(19.5)	91	17.56	48	(14.5)	69	13.21
>=65 - <75 years	17	(12.7)	26	12.47	27	(18.8)	46	20.89
>=75 years	7	(28.0)	10	25.87	1	(6.3)	4	16.51
Acquired epiblepharon								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Age-related macular degeneration								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Asthenopia								
>=18 - <65 years	0				0			
>=65 - <75 years	2	(1.5)	2	0.96	1	(0.7)	1	0.45
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Astigmatism								
>=18 - <65 years	2	(0.6)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Blepharitis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	2	(1.5)	2	0.96	0			
>=75 years	1	(4.0)	1	2.59	0			
Blepharitis allergic								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Cataract								
>=18 - <65 years	11	(3.3)	14	2.70	5	(1.5)	6	1.15
>=65 - <75 years	5	(3.7)	6	2.88	7	(4.9)	9	4.09
>=75 years	2	(8.0)	3	7.76	0			
Cataract diabetic								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Cataract nuclear								
>=18 - <65 years	1	(0.3)	1	0.19	2	(0.6)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Cataract subcapsular								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Chorioretinal disorder								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Conjunctival cyst								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Conjunctival erosion								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Conjunctival haemorrhage								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Conjunctival hyperaemia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Conjunctivitis allergic								
>=18 - <65 years	3	(0.9)	4	0.77	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Corneal opacity								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Dacryoadenitis acquired								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Dermatochalasis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Diabetic retinal oedema								
>=18 - <65 years	1	(0.3)	1	0.19	4	(1.2)	4	0.77
>=65 - <75 years	0				2	(1.4)	2	0.91
>=75 years	0				0			
Diabetic retinopathy								
>=18 - <65 years	29	(8.7)	32	6.17	22	(6.6)	25	4.79
>=65 - <75 years	6	(4.5)	7	3.36	10	(6.9)	13	5.90
>=75 years	1	(4.0)	2	5.17	0			
Dry age-related macular degeneration								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	1	4.13
Dry eye								
>=18 - <65 years	3	(0.9)	3	0.58	5	(1.5)	5	0.96
>=65 - <75 years	2	(1.5)	2	0.96	0			
>=75 years	0				0			
Eye discharge								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Eye disorder								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Eye inflammation								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Eye irritation								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Eye pain								
>=18 - <65 years	0				2	(0.6)	2	0.38
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Eyelid ptosis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Giant papillary conjunctivitis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Glaucoma								
>=18 - <65 years	2	(0.6)	2	0.39	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Iritis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Macular oedema								
>=18 - <65 years	2	(0.6)	2	0.39	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	1	(4.0)	1	2.59	0			
Myopia								
>=18 - <65 years	2	(0.6)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Non-proliferative retinopathy								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Normal tension glaucoma								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Ocular hypertension								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Open angle glaucoma								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	2	0.91
>=75 years	0				0			
Optic disc vascular disorder								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Optic ischaemic neuropathy								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Photophobia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Post thrombotic retinopathy								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Posterior capsule opacification								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Presbyopia								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	1	4.13
Pterygium								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Punctate keratitis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Retinal aneurysm								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Retinal artery occlusion								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Retinal degeneration								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Retinal detachment								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Retinal drusen								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Retinal haemorrhage								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Retinal tear								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	1	4.13
Retinal vascular disorder								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Retinal vein occlusion								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Retinal vein thrombosis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Retinopathy								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Retinopathy hypertensive								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	1	(4.0)	1	2.59	0			
Retinopathy proliferative								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Scintillating scotoma								
>=18 - <65 years	0				1	(0.3)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Uveitis								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Vision blurred								
>=18 - <65 years	2	(0.6)	2	0.39	2	(0.6)	2	0.38
>=65 - <75 years	0				2	(1.4)	2	0.91
>=75 years	0				0			
Visual impairment								
>=18 - <65 years	1	(0.3)	1	0.19	2	(0.6)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vitreous detachment								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	1	(4.0)	1	2.59	0			
Vitreous floaters								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Vitreous haemorrhage								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Vitreous opacities								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	1	4.13
Gastrointestinal disorders								
All								
>=18 - <65 years	73	(21.9)	130	25.08	72	(21.7)	113	21.63
>=65 - <75 years	27	(20.1)	49	23.50	30	(20.8)	62	28.16
>=75 years	12	(48.0)	23	59.50	2	(12.5)	3	12.39
Abdominal discomfort								
>=18 - <65 years	2	(0.6)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	0				2	(1.4)	5	2.27
>=75 years	0				0			
Abdominal distension								
>=18 - <65 years	5	(1.5)	6	1.16	2	(0.6)	2	0.38
>=65 - <75 years	2	(1.5)	2	0.96	0			
>=75 years	1	(4.0)	1	2.59	0			
Abdominal hernia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Abdominal pain								
>=18 - <65 years	5	(1.5)	5	0.96	4	(1.2)	4	0.77
>=65 - <75 years	3	(2.2)	3	1.44	2	(1.4)	2	0.91
>=75 years	0				1	(6.3)	1	4.13
Abdominal pain lower								
>=18 - <65 years	1	(0.3)	2	0.39	2	(0.6)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Abdominal pain upper								
>=18 - <65 years	1	(0.3)	1	0.19	4	(1.2)	5	0.96
>=65 - <75 years	2	(1.5)	2	0.96	1	(0.7)	1	0.45
>=75 years	0				0			
Abdominal wall haematoma								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Acid peptic disease								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Anal eczema								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Anal fissure								
>=18 - <65 years	0				2	(0.6)	2	0.38
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Anal pruritus								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Angular cheilitis								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Aphthous ulcer								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Ascites								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Barrett's oesophagus								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Chronic gastritis								
>=18 - <65 years	3	(0.9)	3	0.58	3	(0.9)	3	0.57
>=65 - <75 years	1	(0.7)	1	0.48	3	(2.1)	3	1.36
>=75 years	0				0			
Colitis								
>=18 - <65 years	0				3	(0.9)	3	0.57
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Colitis ischaemic								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Colitis microscopic								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Constipation								
>=18 - <65 years	4	(1.2)	4	0.77	3	(0.9)	3	0.57
>=65 - <75 years	1	(0.7)	1	0.48	2	(1.4)	2	0.91
>=75 years	3	(12.0)	3	7.76	1	(6.3)	1	4.13
Crohn's disease								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Dental caries								
>=18 - <65 years	7	(2.1)	9	1.74	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	2	(8.0)	2	5.17	0			
Diarrhoea								
>=18 - <65 years	19	(5.7)	26	5.02	18	(5.4)	21	4.02
>=65 - <75 years	9	(6.7)	14	6.71	8	(5.6)	8	3.63
>=75 years	11	(44.0)	14	36.21	0			
Diverticulum								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				3	(2.1)	3	1.36
>=75 years	0				0			
Diverticulum intestinal								
>=18 - <65 years	2	(0.6)	2	0.39	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Dry mouth								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Duodenal ulcer								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Duodenitis								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Duodenogastric reflux								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Dyspepsia								
>=18 - <65 years	3	(0.9)	3	0.58	3	(0.9)	3	0.57
>=65 - <75 years	2	(1.5)	2	0.96	1	(0.7)	1	0.45
>=75 years	0				0			
Enteritis								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Enterocolitis								
>=18 - <65 years	3	(0.9)	4	0.77	0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	0				0			
>=75 years	0				0			
Epigastric discomfort								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Erosive duodenitis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Flatulence								
>=18 - <65 years	2	(0.6)	2	0.39	0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Food poisoning								
>=18 - <65 years	1	(0.3)	1	0.19	2	(0.6)	2	0.38
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Frequent bowel movements								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Gastric disorder								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Gastric polyps								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Gastritis								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Gastritis erosive								
>=18 - <65 years	0				0			
>=65 - <75 years	0				2	(1.4)	2	0.91
>=75 years	0				0			
Gastrointestinal disorder								
>=18 - <65 years	0				2	(0.6)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Gastrointestinal haemorrhage								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Gastrointestinal inflammation								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Gastrooesophageal reflux disease								
>=18 - <65 years	7	(2.1)	7	1.35	4	(1.2)	4	0.77
>=65 - <75 years	1	(0.7)	1	0.48	4	(2.8)	4	1.82
>=75 years	0				0			
Haematemesis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Haematochezia								
>=18 - <65 years	0				0			
>=65 - <75 years	2	(1.5)	2	0.96	0			
>=75 years	0				0			
Haemorrhoids								
>=18 - <65 years	3	(0.9)	3	0.58	3	(0.9)	3	0.57
>=65 - <75 years	1	(0.7)	1	0.48	2	(1.4)	2	0.91
>=75 years	0				0			
Hiatus hernia								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Hyperaesthesia teeth								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hyperchlorhydria								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Ileus								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Inguinal hernia								
>=18 - <65 years	0				1	(0.3)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Intestinal obstruction								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Irritable bowel syndrome								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Large intestine polyp								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	2	0.38
>=65 - <75 years	1	(0.7)	1	0.48	2	(1.4)	2	0.91
>=75 years	0				0			
Loose tooth								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Melaena								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Nausea								
>=18 - <65 years	15	(4.5)	17	3.28	6	(1.8)	7	1.34
>=65 - <75 years	3	(2.2)	3	1.44	3	(2.1)	4	1.82
>=75 years	2	(8.0)	2	5.17	0			
Odynophagia								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Oral discomfort								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Pancreatitis								
>=18 - <65 years	2	(0.6)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Pancreatitis acute								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Pancreatitis chronic								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Periodontal disease								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Periodontal inflammation								
>=18 - <65 years	0				1	(0.3)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Portal hypertensive gastropathy								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Rectal polyp								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Rectal prolapse								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				1	(6.3)	1	4.13
Salivary gland calculus								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Stomatitis								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Tooth disorder								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Tooth impacted								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Tooth loss								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Toothache								
>=18 - <65 years	9	(2.7)	10	1.93	3	(0.9)	3	0.57
>=65 - <75 years	2	(1.5)	2	0.96	1	(0.7)	1	0.45
>=75 years	0				0			
Ulcerative gastritis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Umbilical hernia								
>=18 - <65 years	1	(0.3)	1	0.19	2	(0.6)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Varices oesophageal								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Vomiting								
>=18 - <65 years	4	(1.2)	4	0.77	10	(3.0)	12	2.30
>=65 - <75 years	3	(2.2)	3	1.44	1	(0.7)	3	1.36
>=75 years	0				0			
General disorders and administration site conditions								
All								
>=18 - <65 years	62	(18.6)	109	21.03	67	(20.2)	104	19.91
>=65 - <75 years	24	(17.9)	35	16.78	29	(20.1)	44	19.98
>=75 years	5	(20.0)	16	41.39	2	(12.5)	2	8.26
Asthenia								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	4	(1.2)	4	0.77	2	(0.6)	2	0.38
>=65 - <75 years	0				4	(2.8)	4	1.82
>=75 years	1	(4.0)	2	5.17	0			
Chest discomfort								
>=18 - <65 years	2	(0.6)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Chest pain								
>=18 - <65 years	2	(0.6)	2	0.39	6	(1.8)	6	1.15
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	1	(4.0)	1	2.59	0			
Chills								
>=18 - <65 years	1	(0.3)	1	0.19	2	(0.6)	2	0.38
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Cyst								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Death								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	1	4.13
Discomfort								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Drug intolerance								
>=18 - <65 years	2	(0.6)	2	0.39	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Early satiety								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Effusion								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Fatigue								
>=18 - <65 years	9	(2.7)	10	1.93	6	(1.8)	7	1.34
>=65 - <75 years	6	(4.5)	7	3.36	1	(0.7)	1	0.45
>=75 years	1	(4.0)	1	2.59	0			
Feeling abnormal								
>=18 - <65 years	1	(0.3)	5	0.96	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	2	0.96	0			
>=75 years	0				0			
Feeling hot								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Gait disturbance								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Hunger								
>=18 - <65 years	5	(1.5)	6	1.16	1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Implant site pruritus								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Inflammation								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Influenza like illness								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Injection site bruising								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Injection site dermatitis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Injection site erythema								
>=18 - <65 years	1	(0.3)	1	0.19	3	(0.9)	3	0.57
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Injection site haemorrhage								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Injection site hypersensitivity								
>=18 - <65 years	2	(0.6)	2	0.39	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Injection site hypertrophy								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Injection site mass								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Injection site pain								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Injection site reaction								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Injection site urticaria								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Malaise								
>=18 - <65 years	4	(1.2)	6	1.16	5	(1.5)	7	1.34
>=65 - <75 years	3	(2.2)	3	1.44	5	(3.5)	5	2.27
>=75 years	0				0			
Mass								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site bruise								
>=18 - <65 years	3	(0.9)	4	0.77	0			
>=65 - <75 years	2	(1.5)	2	0.96	1	(0.7)	2	0.91
>=75 years	0				0			
Medical device site dermatitis								
>=18 - <65 years	1	(0.3)	4	0.77	9	(2.7)	15	2.87
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Medical device site discomfort								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site eczema								
>=18 - <65 years	1	(0.3)	2	0.39	2	(0.6)	4	0.77
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site erythema								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Medical device site haematoma								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Medical device site haemorrhage								
>=18 - <65 years	2	(0.6)	2	0.39	2	(0.6)	2	0.38
>=65 - <75 years	2	(1.5)	2	0.96	0			
>=75 years	0				0			
Medical device site hypersensitivity								
>=18 - <65 years	2	(0.6)	3	0.58	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site inflammation								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site pain								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site pruritus								
>=18 - <65 years	3	(0.9)	3	0.58	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site reaction								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	3	1.44	1	(0.7)	1	0.45
>=75 years	0				0			
Non-cardiac chest pain								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Oedema								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Oedema peripheral								
>=18 - <65 years	5	(1.5)	6	1.16	7	(2.1)	9	1.72
>=65 - <75 years	2	(1.5)	2	0.96	4	(2.8)	4	1.82
>=75 years	1	(4.0)	1	2.59	0			
Pain								
>=18 - <65 years	3	(0.9)	3	0.58	5	(1.5)	6	1.15
>=65 - <75 years	0				2	(1.4)	2	0.91
>=75 years	1	(4.0)	1	2.59	0			
Peripheral swelling								
>=18 - <65 years	1	(0.3)	1	0.19	2	(0.6)	2	0.38
>=65 - <75 years	2	(1.5)	3	1.44	3	(2.1)	3	1.36
>=75 years	0				1	(6.3)	1	4.13
Procedural failure								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Pyrexia								
>=18 - <65 years	18	(5.4)	21	4.05	16	(4.8)	18	3.45
>=65 - <75 years	5	(3.7)	5	2.40	7	(4.9)	9	4.09
>=75 years	4	(16.0)	4	10.35	0			
Swelling								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Thirst								
>=18 - <65 years	2	(0.6)	2	0.39	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Vaccination site erythema								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Vaccination site pain								
>=18 - <65 years	3	(0.9)	4	0.77	3	(0.9)	3	0.57
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	1	(4.0)	2	5.17	0			
Vaccination site reaction								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hepatobiliary disorders								
All								
>=18 - <65 years	9	(2.7)	11	2.12	9	(2.7)	10	1.91
>=65 - <75 years	3	(2.2)	4	1.92	1	(0.7)	1	0.45
>=75 years	1	(4.0)	1	2.59	0			
Biliary colic								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Cholelithiasis								
>=18 - <65 years	1	(0.3)	1	0.19	2	(0.6)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Gallbladder cholesterolosis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Hepatic cirrhosis								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Hepatic cyst								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Hepatic function abnormal								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Hepatic steatosis								
>=18 - <65 years	6	(1.8)	6	1.16	3	(0.9)	3	0.57
>=65 - <75 years	2	(1.5)	2	0.96	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Hepatitis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Hypertransaminasaemia								
>=18 - <65 years	1	(0.3)	2	0.39	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Liver disorder								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Non-alcoholic steatohepatitis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Nonalcoholic fatty liver disease								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Steatohepatitis								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Immune system disorders								
All								
>=18 - <65 years	5	(1.5)	6	1.16	4	(1.2)	5	0.96
>=65 - <75 years	2	(1.5)	2	0.96	2	(1.4)	2	0.91
>=75 years	0				0			
Allergy to arthropod bite								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Allergy to arthropod sting								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Immunisation reaction								
>=18 - <65 years	0				1	(0.3)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Seasonal allergy								
>=18 - <65 years	5	(1.5)	5	0.96	2	(0.6)	2	0.38
>=65 - <75 years	2	(1.5)	2	0.96	2	(1.4)	2	0.91
>=75 years	0				0			
Infections and infestations								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
>=18 - <65 years	152	(45.6)	283	54.60	175	(52.7)	315	60.30
>=65 - <75 years	59	(44.0)	110	52.75	68	(47.2)	116	52.69
>=75 years	14	(56.0)	22	56.91	9	(56.3)	18	74.31
Abscess								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Acarodermatitis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Acute sinusitis								
>=18 - <65 years	3	(0.9)	3	0.58	0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Anal abscess								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Asymptomatic COVID-19								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Bacterial infection								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Balanitis candida								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Body tinea								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Breast abscess								
>=18 - <65 years	0				2	(0.6)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Breast cellulitis								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Bronchitis								
>=18 - <65 years	7	(2.1)	7	1.35	5	(1.5)	6	1.15
>=65 - <75 years	4	(3.0)	4	1.92	1	(0.7)	1	0.45
>=75 years	1	(4.0)	1	2.59	1	(6.3)	1	4.13
Candida infection								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	2	(0.6)	2	0.39	0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Cellulitis								
>=18 - <65 years	2	(0.6)	2	0.39	2	(0.6)	2	0.38
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Chlamydial infection								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Chronic hepatitis C								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Chronic sinusitis								
>=18 - <65 years	0				2	(0.6)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Chronic tonsillitis								
>=18 - <65 years	1	(0.3)	1	0.19	2	(0.6)	4	0.77
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Clostridium difficile infection								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Conjunctivitis								
>=18 - <65 years	3	(0.9)	4	0.77	1	(0.3)	1	0.19
>=65 - <75 years	3	(2.2)	3	1.44	2	(1.4)	2	0.91
>=75 years	0				0			
Conjunctivitis bacterial								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	1	4.13
Coronavirus infection								
>=18 - <65 years	4	(1.2)	4	0.77	3	(0.9)	4	0.77
>=65 - <75 years	2	(1.5)	2	0.96	3	(2.1)	3	1.36
>=75 years	0				0			
COVID-19								
>=18 - <65 years	65	(19.5)	68	13.12	76	(22.9)	80	15.32
>=65 - <75 years	21	(15.7)	22	10.55	24	(16.7)	26	11.81
>=75 years	5	(20.0)	5	12.93	4	(25.0)	5	20.64
COVID-19 pneumonia								
>=18 - <65 years	1	(0.3)	1	0.19	2	(0.6)	2	0.38
>=65 - <75 years	2	(1.5)	2	0.96	1	(0.7)	1	0.45
>=75 years	1	(4.0)	1	2.59	0			
Cystitis								
>=18 - <65 years	3	(0.9)	3	0.58	5	(1.5)	6	1.15
>=65 - <75 years	2	(1.5)	3	1.44	2	(1.4)	3	1.36

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				1	(6.3)	2	8.26
Dermatophytosis of nail								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Diverticulitis								
>=18 - <65 years	0				2	(0.6)	2	0.38
>=65 - <75 years	0				2	(1.4)	2	0.91
>=75 years	0				1	(6.3)	1	4.13
Ear infection								
>=18 - <65 years	4	(1.2)	4	0.77	0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	1	4.13
Empyema								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Endophthalmitis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Epididymitis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Erysipelas								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Escherichia urinary tract infection								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Eye infection bacterial								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Folliculitis								
>=18 - <65 years	2	(0.6)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Fungal balanitis								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Fungal infection								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Furuncle								
>=18 - <65 years	1	(0.3)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Gastroenteritis								
>=18 - <65 years	6	(1.8)	6	1.16	4	(1.2)	4	0.77
>=65 - <75 years	0				2	(1.4)	3	1.36
>=75 years	0				0			
Gastroenteritis norovirus								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Gastroenteritis viral								
>=18 - <65 years	4	(1.2)	4	0.77	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Gastrointestinal infection								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Genital infection fungal								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Giardiasis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Gingivitis								
>=18 - <65 years	3	(0.9)	3	0.58	1	(0.3)	2	0.38
>=65 - <75 years	1	(0.7)	2	0.96	1	(0.7)	1	0.45
>=75 years	0				0			
Helicobacter gastritis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Helicobacter infection								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Hepatitis B								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Herpes dermatitis								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Herpes simplex								
>=18 - <65 years	0				1	(0.3)	1	0.19

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Herpes virus infection								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Herpes zoster								
>=18 - <65 years	4	(1.2)	4	0.77	4	(1.2)	4	0.77
>=65 - <75 years	2	(1.5)	2	0.96	3	(2.1)	3	1.36
>=75 years	0				1	(6.3)	1	4.13
Hordeolum								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Infected bite								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Infected skin ulcer								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Influenza								
>=18 - <65 years	0				3	(0.9)	3	0.57
>=65 - <75 years	0				0			
>=75 years	0				0			
Intestinal sepsis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Labyrinthitis								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Laryngitis								
>=18 - <65 years	2	(0.6)	2	0.39	4	(1.2)	4	0.77
>=65 - <75 years	0				0			
>=75 years	0				0			
Laryngopharyngitis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Localised infection								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Lower respiratory tract infection								
>=18 - <65 years	5	(1.5)	5	0.96	1	(0.3)	3	0.57
>=65 - <75 years	2	(1.5)	4	1.92	1	(0.7)	1	0.45
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Lyme disease								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Lymphangitis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Mastitis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Mycoplasma infection								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Nail infection								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Nasopharyngitis								
>=18 - <65 years	24	(7.2)	31	5.98	37	(11.1)	45	8.61
>=65 - <75 years	14	(10.4)	19	9.11	9	(6.3)	10	4.54
>=75 years	0				1	(6.3)	1	4.13
Onychomycosis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Oophoritis								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Oral candidiasis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Oral herpes								
>=18 - <65 years	3	(0.9)	3	0.58	3	(0.9)	3	0.57
>=65 - <75 years	0				0			
>=75 years	0				0			
Oral infection								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Orchitis								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Oropharyngeal candidiasis								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Osteomyelitis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Osteomyelitis chronic								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Otitis externa								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Otitis media								
>=18 - <65 years	2	(0.6)	2	0.39	1	(0.3)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Otitis media acute								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Otitis media chronic								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Parotitis								
>=18 - <65 years	0				1	(0.3)	3	0.57
>=65 - <75 years	0				0			
>=75 years	0				0			
Peri-implantitis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	1	4.13
Pericoronitis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Periodontitis								
>=18 - <65 years	1	(0.3)	1	0.19	3	(0.9)	4	0.77
>=65 - <75 years	0				2	(1.4)	2	0.91
>=75 years	1	(4.0)	1	2.59	0			
Pharyngitis								
>=18 - <65 years	11	(3.3)	17	3.28	10	(3.0)	15	2.87
>=65 - <75 years	3	(2.2)	3	1.44	2	(1.4)	2	0.91
>=75 years	1	(4.0)	1	2.59	0			
Pharyngitis bacterial								
>=18 - <65 years	1	(0.3)	1	0.19	2	(0.6)	2	0.38
>=65 - <75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Pharyngotonsillitis								
>=18 - <65 years	0				3	(0.9)	3	0.57
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	2	8.26
Pneumonia								
>=18 - <65 years	1	(0.3)	1	0.19	2	(0.6)	2	0.38
>=65 - <75 years	3	(2.2)	3	1.44	1	(0.7)	1	0.45
>=75 years	0				0			
Post procedural infection								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Pulpitis dental								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Purulence								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Pyelonephritis chronic								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Respiratory syncytial virus infection								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Respiratory tract infection								
>=18 - <65 years	4	(1.2)	4	0.77	2	(0.6)	2	0.38
>=65 - <75 years	0				4	(2.8)	5	2.27
>=75 years	0				0			
Respiratory tract infection viral								
>=18 - <65 years	4	(1.2)	7	1.35	2	(0.6)	2	0.38
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	1	(4.0)	1	2.59	0			
Rhinitis								
>=18 - <65 years	5	(1.5)	6	1.16	5	(1.5)	5	0.96
>=65 - <75 years	2	(1.5)	2	0.96	4	(2.8)	6	2.73
>=75 years	0				0			
Rotavirus infection								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Salpingitis								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Sepsis								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Sinusitis								
>=18 - <65 years	3	(0.9)	4	0.77	5	(1.5)	9	1.72
>=65 - <75 years	1	(0.7)	1	0.48	2	(1.4)	2	0.91
>=75 years	1	(4.0)	1	2.59	0			
Skin bacterial infection								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Skin infection								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Staphylococcal infection								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Subcutaneous abscess								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	4	0.77
>=65 - <75 years	0				0			
>=75 years	0				0			
Tinea infection								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Tonsillitis								
>=18 - <65 years	2	(0.6)	3	0.58	2	(0.6)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Tooth abscess								
>=18 - <65 years	2	(0.6)	2	0.39	2	(0.6)	2	0.38
>=65 - <75 years	3	(2.2)	3	1.44	2	(1.4)	2	0.91
>=75 years	0				0			
Tooth infection								
>=18 - <65 years	1	(0.3)	1	0.19	2	(0.6)	3	0.57
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				1	(6.3)	1	4.13
Tracheitis								
>=18 - <65 years	1	(0.3)	3	0.58	2	(0.6)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Upper respiratory tract infection								
>=18 - <65 years	19	(5.7)	26	5.02	13	(3.9)	14	2.68
>=65 - <75 years	7	(5.2)	11	5.27	9	(6.3)	10	4.54
>=75 years	2	(8.0)	3	7.76	0			
Urethritis								
>=18 - <65 years	1	(0.3)	1	0.19	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	0				0			
>=75 years	0				0			
Urinary tract infection								
>=18 - <65 years	6	(1.8)	9	1.74	14	(4.2)	15	2.87
>=65 - <75 years	1	(0.7)	1	0.48	6	(4.2)	9	4.09
>=75 years	2	(8.0)	2	5.17	1	(6.3)	1	4.13
Vaginal infection								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Varicella								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Viral infection								
>=18 - <65 years	3	(0.9)	3	0.58	3	(0.9)	3	0.57
>=65 - <75 years	1	(0.7)	1	0.48	2	(1.4)	2	0.91
>=75 years	0				0			
Viral pharyngitis								
>=18 - <65 years	1	(0.3)	1	0.19	2	(0.6)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Viral upper respiratory tract infection								
>=18 - <65 years	0				3	(0.9)	3	0.57
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Vulvovaginal candidiasis								
>=18 - <65 years	3	(0.9)	5	0.96	4	(1.2)	4	0.77
>=65 - <75 years	0				0			
>=75 years	0				0			
Vulvovaginal mycotic infection								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	2	5.17	0			
Wound infection								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Injury, poisoning and procedural complications								
All								
>=18 - <65 years	61	(18.3)	72	13.89	43	(13.0)	67	12.83
>=65 - <75 years	23	(17.2)	25	11.99	23	(16.0)	35	15.90
>=75 years	5	(20.0)	5	12.93	1	(6.3)	1	4.13
Accidental overdose								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Alcohol poisoning								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Animal bite								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Ankle fracture								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Arthropod bite								
>=18 - <65 years	0				2	(0.6)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Arthropod sting								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Avulsion fracture								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Bone contusion								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Burn oral cavity								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Burns first degree								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Cervical vertebral fracture								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Chillblains								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Concussion								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Contusion								
>=18 - <65 years	3	(0.9)	4	0.77	10	(3.0)	12	2.30

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	2	(1.5)	2	0.96	3	(2.1)	4	1.82
>=75 years	0				0			
Deafness traumatic								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Endotracheal intubation complication								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Eye injury								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Fall								
>=18 - <65 years	6	(1.8)	7	1.35	4	(1.2)	4	0.77
>=65 - <75 years	1	(0.7)	2	0.96	3	(2.1)	4	1.82
>=75 years	1	(4.0)	1	2.59	0			
Fibula fracture								
>=18 - <65 years	2	(0.6)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Foot fracture								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Hand fracture								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Head injury								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				2	(1.4)	2	0.91
>=75 years	0				0			
Heat illness								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	2	0.38
>=65 - <75 years	0				2	(1.4)	2	0.91
>=75 years	0				0			
Hip fracture								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Injury								
>=18 - <65 years	4	(1.2)	4	0.77	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Joint injury								
>=18 - <65 years	3	(0.9)	3	0.58	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ligament sprain								
>=18 - <65 years	3	(0.9)	3	0.58	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				1	(6.3)	1	4.13
Limb fracture								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Limb injury								
>=18 - <65 years	3	(0.9)	3	0.58	0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Lower limb fracture								
>=18 - <65 years	0				0			
>=65 - <75 years	0				2	(1.4)	2	0.91
>=75 years	0				0			
Meniscus injury								
>=18 - <65 years	3	(0.9)	3	0.58	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Muscle strain								
>=18 - <65 years	2	(0.6)	2	0.39	3	(0.9)	3	0.57
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Overdose								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Patella fracture								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Periprocedural myocardial infarction								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Post procedural fistula								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Post procedural haemorrhage								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Post procedural hypothyroidism								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Post procedural stroke								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Post procedural swelling								
>=18 - <65 years	0				1	(0.3)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Post-traumatic neck syndrome								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Procedural pain								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Product administration error								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Radius fracture								
>=18 - <65 years	2	(0.6)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Rib fracture								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Road traffic accident								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Scar								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Skin abrasion								
>=18 - <65 years	2	(0.6)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	1	(4.0)	1	2.59	0			
Skin laceration								
>=18 - <65 years	3	(0.9)	3	0.58	0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Soft tissue injury								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Spinal column injury								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Spinal cord injury cervical								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Stress fracture								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Subcutaneous haematoma								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Tendon rupture								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Thermal burn								
>=18 - <65 years	1	(0.3)	1	0.19	3	(0.9)	3	0.57
>=65 - <75 years	0				0			
>=75 years	0				0			
Tooth fracture								
>=18 - <65 years	2	(0.6)	2	0.39	2	(0.6)	2	0.38
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Traumatic arthritis								
>=18 - <65 years	1	(0.3)	2	0.39	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Traumatic haematoma								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Ulna fracture								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Underdose								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Upper limb fracture								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Vaccination complication								
>=18 - <65 years	9	(2.7)	10	1.93	11	(3.3)	16	3.06
>=65 - <75 years	2	(1.5)	2	0.96	5	(3.5)	8	3.63
>=75 years	1	(4.0)	1	2.59	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Wound								
>=18 - <65 years	0				2	(0.6)	2	0.38
>=65 - <75 years	4	(3.0)	4	1.92	1	(0.7)	1	0.45
>=75 years	0				0			
Wrist fracture								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Investigations								
All								
>=18 - <65 years	22	(6.6)	25	4.82	24	(7.2)	26	4.98
>=65 - <75 years	11	(8.2)	11	5.27	7	(4.9)	7	3.18
>=75 years	2	(8.0)	4	10.35	3	(18.8)	3	12.39
Alanine aminotransferase increased								
>=18 - <65 years	2	(0.6)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Aspartate aminotransferase increased								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Blood cholesterol increased								
>=18 - <65 years	2	(0.6)	2	0.39	0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Blood creatine increased								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Blood creatine phosphokinase increased								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Blood glucose increased								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	1	4.13
Blood potassium increased								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	1	4.13
Blood pressure decreased								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Blood pressure increased								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blood triglycerides increased								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Body temperature increased								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Cardiac stress test abnormal								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Electrocardiogram change								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Electrocardiogram repolarisation abnormality								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Electrocardiogram T wave inversion								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Glycosylated haemoglobin increased								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Haemoglobin decreased								
>=18 - <65 years	0				1	(0.3)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Hepatic enzyme abnormal								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Hepatic enzyme increased								
>=18 - <65 years	0				2	(0.6)	2	0.38
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
International normalised ratio abnormal								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
International normalised ratio decreased								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
International normalised ratio increased								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	2	5.17	0			
Intraocular pressure increased								
>=18 - <65 years	1	(0.3)	2	0.39	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Lipids increased								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Low density lipoprotein increased								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Prostatic specific antigen increased								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Protein urine present								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	1	4.13
Pulse absent								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Red blood cell count decreased								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
SARS-CoV-2 test positive								
>=18 - <65 years	1	(0.3)	1	0.19	3	(0.9)	3	0.57
>=65 - <75 years	2	(1.5)	2	0.96	0			
>=75 years	0				0			
Serum ferritin decreased								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Transferrin saturation decreased								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Troponin increased								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Weight decreased								
>=18 - <65 years	2	(0.6)	2	0.39	0			
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Weight increased								
>=18 - <65 years	8	(2.4)	8	1.54	8	(2.4)	8	1.53
>=65 - <75 years	1	(0.7)	1	0.48	2	(1.4)	2	0.91
>=75 years	0				0			
White blood cell count decreased								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Metabolism and nutrition disorders								
All								
>=18 - <65 years	39	(11.7)	44	8.49	39	(11.7)	54	10.34
>=65 - <75 years	15	(11.2)	17	8.15	23	(16.0)	34	15.44
>=75 years	5	(20.0)	5	12.93	1	(6.3)	1	4.13
Adult failure to thrive								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Appetite disorder								
>=18 - <65 years	0				1	(0.3)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Decreased appetite								
>=18 - <65 years	2	(0.6)	2	0.39	0			
>=65 - <75 years	2	(1.5)	2	0.96	1	(0.7)	1	0.45
>=75 years	0				0			
Dehydration								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Diabetes mellitus								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Diabetes mellitus inadequate control								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Dyslipidaemia								
>=18 - <65 years	12	(3.6)	13	2.51	8	(2.4)	10	1.91
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	1	(4.0)	1	2.59	0			
Electrolyte depletion								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Electrolyte imbalance								
>=18 - <65 years	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Fluid retention								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Gout								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	1	(0.7)	2	0.96	2	(1.4)	2	0.91
>=75 years	0				0			
Hypercalcaemia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Hypercholesterolaemia								
>=18 - <65 years	0				2	(0.6)	2	0.38
>=65 - <75 years	2	(1.5)	2	0.96	1	(0.7)	1	0.45
>=75 years	0				0			
Hyperglycaemia								
>=18 - <65 years	0				6	(1.8)	6	1.15
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Hyperkalaemia								
>=18 - <65 years	3	(0.9)	3	0.58	3	(0.9)	3	0.57
>=65 - <75 years	2	(1.5)	2	0.96	1	(0.7)	1	0.45
>=75 years	1	(4.0)	1	2.59	0			
Hyperlipidaemia								
>=18 - <65 years	4	(1.2)	4	0.77	1	(0.3)	1	0.19
>=65 - <75 years	0				2	(1.4)	2	0.91
>=75 years	0				0			
Hypertriglyceridaemia								
>=18 - <65 years	4	(1.2)	4	0.77	8	(2.4)	8	1.53
>=65 - <75 years	2	(1.5)	2	0.96	1	(0.7)	1	0.45
>=75 years	0				0			
Hyperuricaemia								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypoglycaemia								
>=18 - <65 years	6	(1.8)	7	1.35	8	(2.4)	15	2.87
>=65 - <75 years	1	(0.7)	1	0.48	5	(3.5)	11	5.00
>=75 years	0				0			
Hypokalaemia								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	1	(4.0)	1	2.59	0			
Hypophosphataemia								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Increased appetite								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Iron deficiency								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Lactic acidosis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Malnutrition								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Metabolic disorder								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	1	4.13
Obesity								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Type 2 diabetes mellitus								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Vitamin B12 deficiency								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	1	(4.0)	1	2.59	0			
Vitamin D deficiency								
>=18 - <65 years	3	(0.9)	4	0.77	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	2	(1.4)	2	0.91
>=75 years	0				0			
Zinc deficiency								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Musculoskeletal and connective tissue disorders								
All								
>=18 - <65 years	89	(26.7)	140	27.01	69	(20.8)	107	20.48
>=65 - <75 years	33	(24.6)	56	26.85	44	(30.6)	69	31.34
>=75 years	8	(32.0)	22	56.91	4	(25.0)	8	33.03
Arthralgia								
>=18 - <65 years	19	(5.7)	22	4.24	10	(3.0)	12	2.30

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	7	(5.2)	10	4.80	9	(6.3)	12	5.45
>=75 years	4	(16.0)	4	10.35	3	(18.8)	4	16.51
Arthritis								
>=18 - <65 years	1	(0.3)	1	0.19	2	(0.6)	3	0.57
>=65 - <75 years	1	(0.7)	1	0.48	2	(1.4)	2	0.91
>=75 years	0				0			
Axillary mass								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Back disorder								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Back pain								
>=18 - <65 years	24	(7.2)	25	4.82	21	(6.3)	23	4.40
>=65 - <75 years	13	(9.7)	15	7.19	9	(6.3)	9	4.09
>=75 years	3	(12.0)	3	7.76	2	(12.5)	2	8.26
Bone cyst								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Bursitis								
>=18 - <65 years	2	(0.6)	2	0.39	3	(0.9)	3	0.57
>=65 - <75 years	0				0			
>=75 years	0				0			
Cervical spinal stenosis								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Chondrodynia								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Chondropathy								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Coccydynia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Costochondritis								
>=18 - <65 years	2	(0.6)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Dupuytren's contracture								
>=18 - <65 years	0				0			
>=65 - <75 years	0				2	(1.4)	2	0.91
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Exostosis								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Fibromyalgia								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Fistula								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Flank pain								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Fracture nonunion								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Gouty arthritis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Groin pain								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Intervertebral disc disorder								
>=18 - <65 years	2	(0.6)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	1	4.13
Intervertebral disc protrusion								
>=18 - <65 years	2	(0.6)	2	0.39	5	(1.5)	6	1.15
>=65 - <75 years	4	(3.0)	4	1.92	0			
>=75 years	1	(4.0)	2	5.17	0			
Intervertebral disc space narrowing								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Joint effusion								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Joint swelling								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Ligamentitis								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Limb deformity								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Lordosis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Lumbar spinal stenosis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Mastication disorder								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	2	0.91
>=75 years	0				0			
Muscle contracture								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Muscle spasms								
>=18 - <65 years	6	(1.8)	6	1.16	4	(1.2)	4	0.77
>=65 - <75 years	5	(3.7)	5	2.40	0			
>=75 years	1	(4.0)	1	2.59	0			
Muscular weakness								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Musculoskeletal chest pain								
>=18 - <65 years	3	(0.9)	3	0.58	0			
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Musculoskeletal pain								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Musculoskeletal stiffness								
>=18 - <65 years	2	(0.6)	2	0.39	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Myalgia								
>=18 - <65 years	2	(0.6)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	2	(1.4)	2	0.91
>=75 years	0				0			
Myositis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Neck pain								
>=18 - <65 years	5	(1.5)	5	0.96	7	(2.1)	7	1.34
>=65 - <75 years	2	(1.5)	2	0.96	1	(0.7)	1	0.45
>=75 years	0				0			
Osteoarthritis								
>=18 - <65 years	13	(3.9)	15	2.89	6	(1.8)	8	1.53
>=65 - <75 years	3	(2.2)	3	1.44	8	(5.6)	9	4.09
>=75 years	3	(12.0)	3	7.76	0			
Osteochondrosis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Osteopenia								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	1	(4.0)	1	2.59	0			
Pain in extremity								
>=18 - <65 years	11	(3.3)	14	2.70	8	(2.4)	9	1.72
>=65 - <75 years	7	(5.2)	9	4.32	6	(4.2)	8	3.63
>=75 years	0				0			
Periarthritis								
>=18 - <65 years	6	(1.8)	6	1.16	3	(0.9)	3	0.57
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				1	(6.3)	1	4.13
Plantar fasciitis								
>=18 - <65 years	5	(1.5)	6	1.16	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Polyarthritis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Rotator cuff syndrome								
>=18 - <65 years	3	(0.9)	3	0.58	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Scoliosis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Spinal osteoarthritis								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	1	(4.0)	1	2.59	0			
Spinal pain								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				3	(2.1)	3	1.36
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Spinal stenosis								
>=18 - <65 years	2	(0.6)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Spondylolisthesis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Synovial cyst								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Tendon calcification								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Tendonitis								
>=18 - <65 years	1	(0.3)	1	0.19	2	(0.6)	2	0.38
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Tenosynovitis								
>=18 - <65 years	1	(0.3)	1	0.19	2	(0.6)	3	0.57
>=65 - <75 years	0				4	(2.8)	4	1.82
>=75 years	0				0			
Tenosynovitis stenosans								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Torticollis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Trigger finger								
>=18 - <65 years	1	(0.3)	1	0.19	3	(0.9)	6	1.15
>=65 - <75 years	0				0			
>=75 years	2	(8.0)	2	5.17	0			
Vertebral osteophyte								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
>=18 - <65 years	8	(2.4)	8	1.54	5	(1.5)	6	1.15
>=65 - <75 years	6	(4.5)	6	2.88	3	(2.1)	6	2.73
>=75 years	5	(20.0)	7	18.11	1	(6.3)	1	4.13
Acrochordon								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Basal cell carcinoma								
>=18 - <65 years	2	(0.6)	2	0.39	2	(0.6)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Colon adenoma								
>=18 - <65 years	2	(0.6)	2	0.39	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Colon cancer								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Dysplastic naevus								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Glioblastoma multiforme								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Haemangioma of liver								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hepatocellular carcinoma								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Hypergammaglobulinaemia benign monoclonal								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	1	4.13
Lipoma								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Lung adenocarcinoma								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Malignant melanoma in situ								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Metastases to liver								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Metastatic renal cell carcinoma								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Neoplasm skin								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Oral fibroma								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Ovarian cancer metastatic								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Pancreatic carcinoma metastatic								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Pancreatic neoplasm								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Prostate cancer								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	1	(4.0)	1	2.59	0			
Seborrhoeic keratosis								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	1	(4.0)	2	5.17	0			
Skin papilloma								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Small cell lung cancer								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Squamous cell carcinoma								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Uterine leiomyoma								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			

Nervous system disorders

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
>=18 - <65 years	54	(16.2)	78	15.05	49	(14.8)	77	14.74
>=65 - <75 years	24	(17.9)	41	19.66	27	(18.8)	34	15.44
>=75 years	6	(24.0)	6	15.52	4	(25.0)	4	16.51
Ageusia								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Anosmia								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Balance disorder								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Brain injury								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Burning sensation								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	1	(4.0)	1	2.59	1	(6.3)	1	4.13
Carotid arteriosclerosis								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Carotid artery stenosis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Carpal tunnel syndrome								
>=18 - <65 years	3	(0.9)	3	0.58	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	2	(1.4)	2	0.91
>=75 years	0				0			
Cerebral arteriosclerosis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Cerebral atrophy								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Cerebral haemorrhage								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Cerebral 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). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Cerebrovascular accident								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Cerebrovascular disorder								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Cervical radiculopathy								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Cognitive disorder								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Diabetic neuropathy								
>=18 - <65 years	2	(0.6)	2	0.39	3	(0.9)	3	0.57
>=65 - <75 years	1	(0.7)	1	0.48	2	(1.4)	2	0.91
>=75 years	0				0			
Dizziness								
>=18 - <65 years	10	(3.0)	10	1.93	9	(2.7)	10	1.91
>=65 - <75 years	5	(3.7)	11	5.27	6	(4.2)	6	2.73
>=75 years	0				0			
Dizziness postural								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Dysgeusia								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Essential tremor								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Headache								
>=18 - <65 years	15	(4.5)	21	4.05	16	(4.8)	25	4.79
>=65 - <75 years	5	(3.7)	5	2.40	2	(1.4)	4	1.82
>=75 years	2	(8.0)	2	5.17	3	(18.8)	3	12.39
Hypoaesthesia								
>=18 - <65 years	4	(1.2)	6	1.16	3	(0.9)	3	0.57
>=65 - <75 years	2	(1.5)	2	0.96	1	(0.7)	2	0.91
>=75 years	0				0			
Hypoglycaemic unconsciousness								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Ischaemic stroke								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Lethargy								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Lumbar radiculopathy								
>=18 - <65 years	2	(0.6)	2	0.39	3	(0.9)	3	0.57
>=65 - <75 years	0				0			
>=75 years	0				0			
Memory impairment								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Mental impairment								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Metabolic encephalopathy								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Migraine								
>=18 - <65 years	2	(0.6)	2	0.39	0			
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Movement disorder								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Muscle tone disorder								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Neuralgia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Neuroglycopenia								
>=18 - <65 years	1	(0.3)	3	0.58	1	(0.3)	3	0.57
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Neuropathy peripheral								
>=18 - <65 years	2	(0.6)	2	0.39	2	(0.6)	2	0.38
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Paraesthesia								
>=18 - <65 years	3	(0.9)	3	0.58	4	(1.2)	4	0.77
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Parkinsonian gait								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Pineal gland cyst								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Post herpetic neuralgia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Presyncope								
>=18 - <65 years	2	(0.6)	2	0.39	0			
>=65 - <75 years	0				2	(1.4)	2	0.91
>=75 years	0				0			
Sciatica								
>=18 - <65 years	2	(0.6)	2	0.39	6	(1.8)	9	1.72
>=65 - <75 years	1	(0.7)	1	0.48	2	(1.4)	2	0.91
>=75 years	0				0			
Somnolence								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Stiff leg syndrome								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Syncope								
>=18 - <65 years	4	(1.2)	6	1.16	0			
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Tension headache								
>=18 - <65 years	1	(0.3)	2	0.39	0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Thrombotic stroke								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Transient ischaemic attack								
>=18 - <65 years	0				2	(0.6)	2	0.38
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Tremor								
>=18 - <65 years	4	(1.2)	4	0.77	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	2	(1.5)	3	1.44	1	(0.7)	1	0.45
>=75 years	0				0			
Trigeminal neuralgia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Vertebral artery occlusion								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
VIth nerve paralysis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
VIth nerve paresis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Psychiatric disorders								
All								
>=18 - <65 years	13	(3.9)	14	2.70	9	(2.7)	9	1.72
>=65 - <75 years	9	(6.7)	10	4.80	4	(2.8)	4	1.82
>=75 years	1	(4.0)	1	2.59	0			
Anxiety								
>=18 - <65 years	3	(0.9)	3	0.58	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Depressed mood								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Depression								
>=18 - <65 years	5	(1.5)	5	0.96	3	(0.9)	3	0.57
>=65 - <75 years	2	(1.5)	2	0.96	1	(0.7)	1	0.45
>=75 years	0				0			
Insomnia								
>=18 - <65 years	3	(0.9)	3	0.58	3	(0.9)	3	0.57
>=65 - <75 years	5	(3.7)	5	2.40	1	(0.7)	1	0.45
>=75 years	1	(4.0)	1	2.59	0			
Mood swings								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Nightmare								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Persistent depressive disorder								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Psychotic disorder								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Schizophrenia								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Sleep disorder								
>=18 - <65 years	0				0			
>=65 - <75 years	2	(1.5)	2	0.96	0			
>=75 years	0				0			
Renal and urinary disorders								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
>=18 - <65 years	10	(3.0)	12	2.32	13	(3.9)	19	3.64
>=65 - <75 years	7	(5.2)	9	4.32	11	(7.6)	12	5.45
>=75 years	3	(12.0)	3	7.76	4	(25.0)	4	16.51
Acute kidney injury								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Calculus urinary								
>=18 - <65 years	0				2	(0.6)	2	0.38
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Chronic kidney disease								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	3	(2.1)	3	1.36
>=75 years	0				0			
Diabetic nephropathy								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	1	(4.0)	1	2.59	0			
Dysuria								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	2	(1.5)	2	0.96	3	(2.1)	3	1.36
>=75 years	0				1	(6.3)	1	4.13
Haematuria								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				3	(2.1)	3	1.36
>=75 years	0				0			
Hypercalciuria								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypertonic bladder								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Ketonuria								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Microalbuminuria								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Nephrolithiasis								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Nocturia								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	1	(4.0)	1	2.59	0			
Pollakiuria								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	1	(6.3)	1	4.13
Pyelocaliectasis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Renal colic								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Renal cyst								
>=18 - <65 years	2	(0.6)	2	0.39	2	(0.6)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Renal impairment								
>=18 - <65 years	2	(0.6)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				2	(12.5)	2	8.26
Ureterolithiasis								
>=18 - <65 years	0				2	(0.6)	2	0.38
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Urinary incontinence								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Urinary retention								
>=18 - <65 years	0				1	(0.3)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Urinary tract obstruction								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Urine odour abnormal								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Reproductive system and breast disorders								

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
>=18 - <65 years	9	(2.7)	9	1.74	8	(2.4)	10	1.91
>=65 - <75 years	6	(4.5)	6	2.88	7	(4.9)	11	5.00
>=75 years	0				1	(6.3)	1	4.13
Adenomyosis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Atrophic vulvovaginitis								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Balanoposthitis								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Benign prostatic hyperplasia								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	2	(1.4)	2	0.91
>=75 years	0				0			
Breast mass								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Breast pain								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Erectile dysfunction								
>=18 - <65 years	3	(0.9)	3	0.58	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Galactorrhoea								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Hydrometra								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Menopausal symptoms								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Ovarian cyst								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Penile rash								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	3	1.36
>=75 years	0				0			
Prostatism								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Prostatitis								
>=18 - <65 years	0				1	(0.3)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Pruritus genital								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Uterine haemorrhage								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Uterine polyp								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Uterine prolapse								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Vaginal prolapse								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	1	4.13
Vulval eczema								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Vulval leukoplakia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Vulvovaginal dryness								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Vulvovaginal pruritus								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Respiratory, thoracic and mediastinal disorders								
All								
>=18 - <65 years	35	(10.5)	47	9.07	33	(9.9)	45	8.61
>=65 - <75 years	18	(13.4)	26	12.47	15	(10.4)	24	10.90
>=75 years	2	(8.0)	3	7.76	0			
Acquired diaphragmatic eventration								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Acute pulmonary oedema								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Acute respiratory failure								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Allergic bronchitis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	2	0.91
>=75 years	0				0			
Asthma								
>=18 - <65 years	1	(0.3)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Bronchiectasis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Bronchitis chronic								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Chronic eosinophilic rhinosinusitis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Chronic obstructive pulmonary disease								
>=18 - <65 years	0				0			
>=65 - <75 years	2	(1.5)	2	0.96	1	(0.7)	1	0.45
>=75 years	0				0			
Cough								
>=18 - <65 years	11	(3.3)	12	2.32	4	(1.2)	4	0.77
>=65 - <75 years	3	(2.2)	3	1.44	4	(2.8)	5	2.27
>=75 years	0				0			
Dry throat								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dyspnoea								
>=18 - <65 years	2	(0.6)	2	0.39	3	(0.9)	3	0.57
>=65 - <75 years	0				3	(2.1)	3	1.36
>=75 years	0				0			
Dyspnoea exertional								
>=18 - <65 years	2	(0.6)	2	0.39	2	(0.6)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Emphysema								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Epistaxis								
>=18 - <65 years	0				1	(0.3)	3	0.57
>=65 - <75 years	0				0			
>=75 years	0				0			
Haemoptysis								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Interstitial lung disease								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Laryngeal cyst								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Nasal congestion								
>=18 - <65 years	2	(0.6)	2	0.39	2	(0.6)	2	0.38
>=65 - <75 years	2	(1.5)	3	1.44	0			
>=75 years	1	(4.0)	1	2.59	0			
Nasal dryness								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Nasal turbinate hypertrophy								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Oropharyngeal pain								
>=18 - <65 years	8	(2.4)	8	1.54	6	(1.8)	9	1.72
>=65 - <75 years	5	(3.7)	6	2.88	3	(2.1)	4	1.82
>=75 years	0				0			
Paranasal sinus discomfort								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Pleural calcification								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Pleural effusion								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Pleuritic pain								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Pneumothorax								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Productive cough								
>=18 - <65 years	1	(0.3)	1	0.19	2	(0.6)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Pulmonary embolism								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Pulmonary fibrosis								
>=18 - <65 years	1	(0.3)	2	0.39	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Pulmonary mass								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Respiratory disorder								
>=18 - <65 years	1	(0.3)	1	0.19	3	(0.9)	3	0.57
>=65 - <75 years	0				0			
>=75 years	0				0			
Respiratory failure								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Rhinitis allergic								
>=18 - <65 years	0				2	(0.6)	6	1.15
>=65 - <75 years	0				0			
>=75 years	0				0			
Rhinorrhoea								
>=18 - <65 years	5	(1.5)	5	0.96	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	2	(1.4)	2	0.91
>=75 years	0				0			
Sinus congestion								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	2	0.96	1	(0.7)	1	0.45

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Sinus pain								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	2	0.96	0			
>=75 years	0				0			
Sleep apnoea syndrome								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	2	(1.5)	2	0.96	0			
>=75 years	0				0			
Sneezing								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Throat irritation								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Upper respiratory tract inflammation								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Upper-airway cough syndrome								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Skin and subcutaneous tissue disorders								
All								
>=18 - <65 years	36	(10.8)	48	9.26	27	(8.1)	41	7.85
>=65 - <75 years	20	(14.9)	25	11.99	24	(16.7)	31	14.08
>=75 years	3	(12.0)	4	10.35	2	(12.5)	3	12.39
Actinic keratosis								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	2	0.96	0			
>=75 years	0				0			
Alopecia								
>=18 - <65 years	2	(0.6)	2	0.39	2	(0.6)	2	0.38
>=65 - <75 years	3	(2.2)	3	1.44	0			
>=75 years	1	(4.0)	1	2.59	0			
Alopecia areata								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Angioedema								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Asteatosis								
>=18 - <65 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Blister								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Cellulite								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(6.3)	2	8.26
Chloasma								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Cold sweat								
>=18 - <65 years	2	(0.6)	3	0.58	1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Cold urticaria								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Dermal cyst								
>=18 - <65 years	1	(0.3)	1	0.19	2	(0.6)	2	0.38
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Dermatitis								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				3	(2.1)	3	1.36
>=75 years	0				0			
Dermatitis allergic								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Dermatitis contact								
>=18 - <65 years	4	(1.2)	6	1.16	4	(1.2)	5	0.96
>=65 - <75 years	2	(1.5)	2	0.96	3	(2.1)	3	1.36
>=75 years	0				0			
Diabetic foot								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Drug eruption								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Dry skin								
>=18 - <65 years	2	(0.6)	2	0.39	0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ecchymosis								
>=18 - <65 years	1	(0.3)	1	0.19	2	(0.6)	2	0.38
>=65 - <75 years	0				0			
>=75 years	0				0			
Eczema								
>=18 - <65 years	7	(2.1)	7	1.35	2	(0.6)	2	0.38
>=65 - <75 years	1	(0.7)	1	0.48	2	(1.4)	2	0.91
>=75 years	0				0			
Eczema nummular								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Erythema								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Granuloma annulare								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Haemorrhage subcutaneous								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Hyperhidrosis								
>=18 - <65 years	2	(0.6)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	2	(1.5)	2	0.96	0			
>=75 years	0				0			
Hyperkeratosis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Ingrowing nail								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Lentigo								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Lipodystrophy acquired								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Lipohypertrophy								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Macule								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Miliaria								
>=18 - <65 years	2	(0.6)	3	0.58	5	(1.5)	5	0.96
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Myxoid cyst								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Night sweats								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Onychalgia								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Pruritus								
>=18 - <65 years	2	(0.6)	4	0.77	1	(0.3)	1	0.19
>=65 - <75 years	2	(1.5)	2	0.96	3	(2.1)	3	1.36
>=75 years	0				0			
Psoriasis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Purpura								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Rash								
>=18 - <65 years	1	(0.3)	1	0.19	5	(1.5)	5	0.96
>=65 - <75 years	1	(0.7)	1	0.48	3	(2.1)	3	1.36
>=75 years	0				0			
Rosacea								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Skin exfoliation								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Skin fissures								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Skin irritation								
>=18 - <65 years	1	(0.3)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Skin lesion								
>=18 - <65 years	2	(0.6)	2	0.39	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				1	(6.3)	1	4.13
Skin ulcer								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Urticaria								
>=18 - <65 years	1	(0.3)	2	0.39	2	(0.6)	2	0.38
>=65 - <75 years	0				3	(2.1)	3	1.36
>=75 years	0				0			
Urticaria contact								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Urticaria thermal								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Surgical and medical procedures								
All								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Removal of foreign body								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Vascular disorders								
All								
>=18 - <65 years	27	(8.1)	31	5.98	19	(5.7)	23	4.40
>=65 - <75 years	11	(8.2)	16	7.67	22	(15.3)	24	10.90
>=75 years	2	(8.0)	2	5.17	2	(12.5)	2	8.26
Aneurysm								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Aortic arteriosclerosis								
>=18 - <65 years	2	(0.6)	2	0.39	1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	1	(4.0)	1	2.59	0			
Aortic stenosis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Arteriosclerosis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	2	(1.4)	2	0.91
>=75 years	0				0			
Blood pressure inadequately controlled								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Brachiocephalic arteriosclerosis								
>=18 - <65 years	0				2	(0.6)	2	0.38
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Diabetic vascular disorder								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Flushing								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Haematoma								
>=18 - <65 years	4	(1.2)	4	0.77	1	(0.3)	1	0.19
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Hypertension								
>=18 - <65 years	10	(3.0)	10	1.93	7	(2.1)	8	1.53
>=65 - <75 years	4	(3.0)	4	1.92	8	(5.6)	8	3.63
>=75 years	1	(4.0)	1	2.59	1	(6.3)	1	4.13
Hypertensive angiopathy								
>=18 - <65 years	1	(0.3)	1	0.19	1	(0.3)	1	0.19
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Hypertensive crisis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Hypertensive urgency								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				0			
Hypotension								
>=18 - <65 years	2	(0.6)	2	0.39	2	(0.6)	2	0.38
>=65 - <75 years	1	(0.7)	1	0.48	0			
>=75 years	0				0			
Iliac artery stenosis								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Intermittent claudication								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Macroangiopathy								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Peripheral arterial occlusive disease								
>=18 - <65 years	1	(0.3)	2	0.39	4	(1.2)	4	0.77
>=65 - <75 years	0				1	(0.7)	1	0.45
>=75 years	0				0			
Peripheral artery occlusion								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Peripheral artery stenosis								
>=18 - <65 years	1	(0.3)	2	0.39	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Peripheral coldness								
>=18 - <65 years	2	(0.6)	2	0.39	0			
>=65 - <75 years	2	(1.5)	2	0.96	1	(0.7)	1	0.45
>=75 years	0				0			
Peripheral vascular disorder								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Peripheral venous disease								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	1	(0.7)	1	0.45
>=75 years	0				1	(6.3)	1	4.13
Post thrombotic syndrome								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Secondary hypertension								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Superficial vein thrombosis								
>=18 - <65 years	1	(0.3)	1	0.19	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Thrombophlebitis								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	0				0			
>=75 years	0				0			
Thrombosis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(0.7)	1	0.48	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Varicose vein								
>=18 - <65 years	0				1	(0.3)	1	0.19
>=65 - <75 years	2	(1.5)	2	0.96	1	(0.7)	1	0.45
>=75 years	0				0			

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

7.24.8 Adverse events by age group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
>=18 - <65 years	267				271			
>=65 - <75 years	20				18			
>=75 years	3				3			
PYE (years)								
>=18 - <65 years	277.22				286.61			
>=65 - <75 years	20.28				19.70			
>=75 years	2.66				3.28			
Events								
>=18 - <65 years	220	(82.4)	870	313.83	217	(80.1)	1068	372.63
>=65 - <75 years	17	(85.0)	84	414.16	16	(88.9)	59	299.55
>=75 years	3	(100.0)	11	413.77	3	(100.0)	19	579.76

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blood and lymphatic system disorders								
All								
>=18 - <65 years	5	(1.9)	6	2.16	5	(1.8)	6	2.09
>=65 - <75 years	2	(10.0)	2	9.86	0			
>=75 years	0				0			
Anaemia								
>=18 - <65 years	3	(1.1)	3	1.08	0			
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Blood loss anaemia								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Iron deficiency anaemia								
>=18 - <65 years	0				2	(0.7)	3	1.05
>=65 - <75 years	0				0			
>=75 years	0				0			
Lymphadenitis								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Lymphadenopathy								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Splenomegaly								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Thrombocytopenia								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Cardiac disorders								
All								
>=18 - <65 years	11	(4.1)	12	4.33	9	(3.3)	12	4.19
>=65 - <75 years	4	(20.0)	5	24.65	1	(5.6)	2	10.15
>=75 years	1	(33.3)	1	37.62	1	(33.3)	1	30.51
Acute myocardial infarction								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Angina pectoris								
>=18 - <65 years	2	(0.7)	2	0.72	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Angina unstable								
>=18 - <65 years	0				2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Aortic valve incompetence								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Atrial fibrillation								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Bundle branch block right								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Cardiac failure congestive								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Cardiomegaly								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Cardiovascular disorder								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Conduction disorder								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(33.3)	1	37.62	0			
Coronary artery disease								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Left ventricular hypertrophy								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mitral valve incompetence								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	0				0			
Myocardial infarction								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Myocardial ischaemia								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Palpitations								
>=18 - <65 years	3	(1.1)	3	1.08	3	(1.1)	4	1.40
>=65 - <75 years	0				0			
>=75 years	0				1	(33.3)	1	30.51
Tachycardia								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Tricuspid valve incompetence								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	0				0			
Ventricular extrasystoles								
>=18 - <65 years	2	(0.7)	2	0.72	0			
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Congenital, familial and genetic disorders								
All								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Arteriovenous malformation								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Colour blindness								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
>=18 - <65 years	2	(0.7)	2	0.72	4	(1.5)	4	1.40
>=65 - <75 years	0				0			
>=75 years	0				0			
Deafness neurosensory								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Ear pain								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Tinnitus								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Tympanic membrane perforation								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Vertigo								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
>=18 - <65 years	1	(0.4)	1	0.36	2	(0.7)	2	0.70
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Autoimmune thyroiditis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Hypogonadism								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypothyroidism								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Thyroiditis chronic								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Eye disorders								
All								
>=18 - <65 years	39	(14.6)	55	19.84	39	(14.4)	55	19.19
>=65 - <75 years	3	(15.0)	6	29.58	6	(33.3)	10	50.77
>=75 years	1	(33.3)	1	37.62	1	(33.3)	1	30.51
Angle closure glaucoma								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Arteriosclerotic retinopathy								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Astigmatism								
>=18 - <65 years	1	(0.4)	1	0.36	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Cataract								
>=18 - <65 years	6	(2.2)	6	2.16	4	(1.5)	5	1.74
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cataract nuclear								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Conjunctival haemorrhage								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Corneal erosion								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Diabetic retinal oedema								
>=18 - <65 years	2	(0.7)	2	0.72	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Diabetic retinopathy								
>=18 - <65 years	21	(7.9)	25	9.02	24	(8.9)	27	9.42
>=65 - <75 years	2	(10.0)	2	9.86	1	(5.6)	1	5.08
>=75 years	1	(33.3)	1	37.62	1	(33.3)	1	30.51
Dry eye								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Eczema eyelids								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Epiretinal membrane								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Eye pain								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Glaucoma								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				3	(16.7)	3	15.23
>=75 years	0				0			
Macular oedema								
>=18 - <65 years	4	(1.5)	5	1.80	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Myopia								
>=18 - <65 years	0				2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Non-proliferative retinopathy								
>=18 - <65 years	2	(0.7)	2	0.72	2	(0.7)	2	0.70
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Ocular hypertension								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				1	(5.6)	2	10.15
>=75 years	0				0			
Photopsia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	0				0			
Posterior capsule opacification								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	4.93	1	(5.6)	2	10.15
>=75 years	0				0			
Presbyopia								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Pterygium								
>=18 - <65 years	0				1	(0.4)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Retinal drusen								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Retinal haemorrhage								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Retinal vascular disorder								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Retinopathy								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Retinopathy hypertensive								
>=18 - <65 years	2	(0.7)	2	0.72	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Strabismus								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Vision blurred								
>=18 - <65 years	2	(0.7)	2	0.72	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Visual acuity reduced								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Vitreous detachment								
>=18 - <65 years	0				2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Vitreous floaters								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	0				0			
Gastrointestinal disorders								
All								
>=18 - <65 years	39	(14.6)	68	24.53	41	(15.1)	74	25.82
>=65 - <75 years	7	(35.0)	12	59.17	1	(5.6)	1	5.08
>=75 years	1	(33.3)	1	37.62	0			
Abdominal discomfort								
>=18 - <65 years	2	(0.7)	2	0.72	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Abdominal distension								
>=18 - <65 years	2	(0.7)	3	1.08	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Abdominal pain								
>=18 - <65 years	6	(2.2)	6	2.16	1	(0.4)	1	0.35
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Abdominal pain upper								
>=18 - <65 years	3	(1.1)	4	1.44	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Anal fissure								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Change of bowel habit								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Chronic gastritis								
>=18 - <65 years	0				3	(1.1)	3	1.05
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Constipation								
>=18 - <65 years	2	(0.7)	3	1.08	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Dental caries								
>=18 - <65 years	1	(0.4)	1	0.36	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Diarrhoea								
>=18 - <65 years	8	(3.0)	11	3.97	6	(2.2)	7	2.44
>=65 - <75 years	2	(10.0)	2	9.86	0			
>=75 years	0				0			
Diverticulum intestinal								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Duodenitis								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Dyspepsia								
>=18 - <65 years	2	(0.7)	2	0.72	1	(0.4)	1	0.35
>=65 - <75 years	1	(5.0)	1	4.93	1	(5.6)	1	5.08
>=75 years	0				0			
Enteritis								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Faeces soft								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Flatulence								
>=18 - <65 years	3	(1.1)	3	1.08	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Food poisoning								
>=18 - <65 years	0				2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	1	(33.3)	1	37.62	0			
Gastric polyps								
>=18 - <65 years	0				2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Gastritis								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Gastritis erosive								
>=18 - <65 years	0				2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Gastrointestinal haemorrhage								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Gastrooesophageal reflux disease								
>=18 - <65 years	0				2	(0.7)	2	0.70
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Gastrooesophageal sphincter insufficiency								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Gingival recession								
>=18 - <65 years	0				1	(0.4)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Gingival ulceration								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Haematochezia								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Haemorrhoids								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Hiatus hernia								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Impaired gastric emptying								
>=18 - <65 years	2	(0.7)	3	1.08	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Irritable bowel syndrome								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Lumbar hernia								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Mouth ulceration								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Nausea								
>=18 - <65 years	9	(3.4)	9	3.25	10	(3.7)	10	3.49
>=65 - <75 years	0				0			
>=75 years	0				0			
Odynophagia								
>=18 - <65 years	0				1	(0.4)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Oesophagitis								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Pancreatic failure								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Pancreatitis								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Pneumatosis intestinalis								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Proctitis ulcerative								
>=18 - <65 years	0				1	(0.4)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Toothache								
>=18 - <65 years	3	(1.1)	4	1.44	3	(1.1)	6	2.09

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	1	(5.0)	2	9.86	0			
>=75 years	0				0			
Vomiting								
>=18 - <65 years	10	(3.7)	11	3.97	10	(3.7)	10	3.49
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
General disorders and administration site conditions								
All								
>=18 - <65 years	47	(17.6)	73	26.33	60	(22.1)	173	60.36
>=65 - <75 years	7	(35.0)	10	49.30	4	(22.2)	8	40.62
>=75 years	1	(33.3)	1	37.62	1	(33.3)	2	61.03
Asthenia								
>=18 - <65 years	1	(0.4)	1	0.36	3	(1.1)	3	1.05
>=65 - <75 years	0				0			
>=75 years	0				0			
Chest pain								
>=18 - <65 years	1	(0.4)	1	0.36	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Chills								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Complication associated with device								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Cyst								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Facial discomfort								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Facial pain								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Fatigue								
>=18 - <65 years	5	(1.9)	5	1.80	4	(1.5)	4	1.40
>=65 - <75 years	1	(5.0)	2	9.86	0			
>=75 years	1	(33.3)	1	37.62	1	(33.3)	1	30.51
Hunger								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	2	0.70

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	0				0			
>=75 years	0				0			
Hyperthermia								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Illness								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Inflammation								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Influenza like illness								
>=18 - <65 years	3	(1.1)	3	1.08	4	(1.5)	4	1.40
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Injection site mass								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Injection site pain								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Injection site urticaria								
>=18 - <65 years	1	(0.4)	2	0.72	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Malaise								
>=18 - <65 years	3	(1.1)	3	1.08	5	(1.8)	84	29.31
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Medical device site bruise								
>=18 - <65 years	2	(0.7)	2	0.72	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site dermatitis								
>=18 - <65 years	4	(1.5)	5	1.80	3	(1.1)	4	1.40
>=65 - <75 years	1	(5.0)	1	4.93	3	(16.7)	5	25.39
>=75 years	0				0			
Medical device site erythema								
>=18 - <65 years	2	(0.7)	3	1.08	5	(1.8)	7	2.44
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site haematoma								

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site haemorrhage								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	0				0			
Medical device site inflammation								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site irritation								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Medical device site pain								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site pruritus								
>=18 - <65 years	1	(0.4)	1	0.36	5	(1.8)	5	1.74
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site rash								
>=18 - <65 years	6	(2.2)	6	2.16	11	(4.1)	12	4.19
>=65 - <75 years	1	(5.0)	2	9.86	0			
>=75 years	0				0			
Medical device site reaction								
>=18 - <65 years	3	(1.1)	3	1.08	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Medical device site vesicles								
>=18 - <65 years	1	(0.4)	2	0.72	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Nodule								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Non-cardiac chest pain								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Oedema								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Oedema peripheral								
>=18 - <65 years	3	(1.1)	3	1.08	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Pain								
>=18 - <65 years	3	(1.1)	3	1.08	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				1	(33.3)	1	30.51
Peripheral swelling								
>=18 - <65 years	0				2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Pyrexia								
>=18 - <65 years	15	(5.6)	21	7.58	19	(7.0)	23	8.02
>=65 - <75 years	1	(5.0)	1	4.93	1	(5.6)	2	10.15
>=75 years	0				0			
Swelling face								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Vaccination site discomfort								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Vaccination site joint pain								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Vaccination site lymphadenopathy								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Vaccination site pain								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Vaccination site swelling								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hepatobiliary disorders								
All								
>=18 - <65 years	4	(1.5)	5	1.80	5	(1.8)	5	1.74
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				1	(33.3)	1	30.51
Cholecystitis chronic								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Gallbladder disorder								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Gallbladder polyp								
>=18 - <65 years	1	(0.4)	1	0.36	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Hepatic calcification								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Hepatic function abnormal								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Hepatic steatosis								
>=18 - <65 years	3	(1.1)	3	1.08	0			
>=65 - <75 years	0				0			
>=75 years	0				1	(33.3)	1	30.51
Hypertransaminasaemia								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
>=18 - <65 years	4	(1.5)	4	1.44	5	(1.8)	5	1.74
>=65 - <75 years	1	(5.0)	1	4.93	1	(5.6)	1	5.08
>=75 years	0				0			
Allergy to arthropod bite								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Allergy to arthropod sting								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypersensitivity								
>=18 - <65 years	2	(0.7)	2	0.72	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Seasonal allergy								
>=18 - <65 years	1	(0.4)	1	0.36	4	(1.5)	4	1.40
>=65 - <75 years	1	(5.0)	1	4.93	1	(5.6)	1	5.08
>=75 years	0				0			
Infections and infestations								
All								
>=18 - <65 years	153	(57.3)	295	106.41	148	(54.6)	281	98.04
>=65 - <75 years	6	(30.0)	15	73.96	9	(50.0)	17	86.31
>=75 years	0				2	(66.7)	5	152.57
Abscess limb								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Acute sinusitis								
>=18 - <65 years	0				3	(1.1)	3	1.05
>=65 - <75 years	0				0			
>=75 years	0				0			
Asymptomatic COVID-19								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Beta haemolytic streptococcal infection								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Breast abscess								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Bronchitis								
>=18 - <65 years	4	(1.5)	4	1.44	2	(0.7)	2	0.70
>=65 - <75 years	1	(5.0)	1	4.93	1	(5.6)	2	10.15
>=75 years	0				0			
Conjunctivitis								
>=18 - <65 years	4	(1.5)	5	1.80	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Coronavirus infection								
>=18 - <65 years	0				2	(0.7)	2	0.70
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	0				0			
COVID-19								
>=18 - <65 years	72	(27.0)	78	28.14	80	(29.5)	85	29.66
>=65 - <75 years	3	(15.0)	3	14.79	4	(22.2)	4	20.31
>=75 years	0				0			
COVID-19 pneumonia								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Cystitis								
>=18 - <65 years	2	(0.7)	2	0.72	3	(1.1)	3	1.05
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Cystitis escherichia								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Ear infection								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Erythema migrans								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Eye infection								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Febrile infection								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Fungal infection								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Fungal skin infection								
>=18 - <65 years	2	(0.7)	2	0.72	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Furuncle								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	0				0			
Gastric infection								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Gastroenteritis								
>=18 - <65 years	12	(4.5)	17	6.13	4	(1.5)	5	1.74
>=65 - <75 years	1	(5.0)	1	4.93	1	(5.6)	1	5.08
>=75 years	0				0			
Gastroenteritis viral								
>=18 - <65 years	3	(1.1)	3	1.08	3	(1.1)	3	1.05
>=65 - <75 years	0				0			
>=75 years	0				0			
Gastrointestinal infection								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				1	(33.3)	3	91.54
Genital infection fungal								
>=18 - <65 years	1	(0.4)	2	0.72	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Gingival abscess								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Gingivitis								
>=18 - <65 years	1	(0.4)	1	0.36	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Herpes zoster								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	0				0			
Hordeolum								
>=18 - <65 years	1	(0.4)	1	0.36	3	(1.1)	3	1.05
>=65 - <75 years	0				0			
>=75 years	0				0			
Impetigo								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Infected cyst								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Influenza								
>=18 - <65 years	8	(3.0)	9	3.25	8	(3.0)	9	3.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Laryngitis								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Laryngopharyngitis								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Localised infection								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Lower respiratory tract infection								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Nasopharyngitis								
>=18 - <65 years	46	(17.2)	69	24.89	57	(21.0)	77	26.87
>=65 - <75 years	2	(10.0)	6	29.58	3	(16.7)	6	30.46
>=75 years	0				1	(33.3)	1	30.51
Norovirus infection								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Oral herpes								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Otitis externa								
>=18 - <65 years	0				3	(1.1)	3	1.05
>=65 - <75 years	0				0			
>=75 years	0				0			
Otitis media								
>=18 - <65 years	0				3	(1.1)	3	1.05
>=65 - <75 years	0				0			
>=75 years	0				0			
Pericoronitis								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Periodontitis								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Pharyngitis								
>=18 - <65 years	8	(3.0)	8	2.89	2	(0.7)	3	1.05
>=65 - <75 years	0				0			
>=75 years	0				0			
Pneumonia								
>=18 - <65 years	2	(0.7)	2	0.72	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Pulpitis dental								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Pyelonephritis acute								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Respiratory tract infection								
>=18 - <65 years	2	(0.7)	2	0.72	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Respiratory tract infection viral								
>=18 - <65 years	4	(1.5)	4	1.44	3	(1.1)	3	1.05
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Rhinitis								
>=18 - <65 years	3	(1.1)	3	1.08	5	(1.8)	6	2.09
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Sepsis								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Severe acute respiratory syndrome								
>=18 - <65 years	3	(1.1)	3	1.08	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Sinobronchitis								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Sinusitis								
>=18 - <65 years	14	(5.2)	15	5.41	9	(3.3)	9	3.14
>=65 - <75 years	0				0			
>=75 years	0				0			
Skin infection								
>=18 - <65 years	0				2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Tinea cruris								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Tinea pedis								
>=18 - <65 years	2	(0.7)	3	1.08	0			
>=65 - <75 years	0				0			
>=75 years	0				1	(33.3)	1	30.51
Tonsillitis								
>=18 - <65 years	2	(0.7)	2	0.72	2	(0.7)	3	1.05
>=65 - <75 years	0				0			
>=75 years	0				0			
Tooth abscess								
>=18 - <65 years	4	(1.5)	4	1.44	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Tooth infection								
>=18 - <65 years	2	(0.7)	2	0.72	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tracheobronchitis								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Trichophytosis								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Upper respiratory tract infection								
>=18 - <65 years	14	(5.2)	17	6.13	10	(3.7)	12	4.19
>=65 - <75 years	1	(5.0)	1	4.93	1	(5.6)	1	5.08
>=75 years	0				0			
Urinary tract infection								
>=18 - <65 years	11	(4.1)	11	3.97	8	(3.0)	10	3.49
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Vaginal infection								
>=18 - <65 years	1	(0.4)	3	1.08	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Varicella								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Viral infection								
>=18 - <65 years	1	(0.4)	1	0.36	5	(1.8)	6	2.09
>=65 - <75 years	0				0			
>=75 years	0				0			
Viral rhinitis								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Vulvitis								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Vulvovaginal mycotic infection								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Vulvovaginitis								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

Injury, poisoning and procedural complications

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
>=18 - <65 years	40	(15.0)	58	20.92	46	(17.0)	60	20.93
>=65 - <75 years	3	(15.0)	3	14.79	3	(16.7)	3	15.23
>=75 years	0				1	(33.3)	1	30.51
Accidental overdose								
>=18 - <65 years	6	(2.2)	7	2.53	2	(0.7)	2	0.70
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Anaemia postoperative								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Animal bite								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Animal scratch								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Ankle fracture								
>=18 - <65 years	1	(0.4)	3	1.08	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Arthropod bite								
>=18 - <65 years	1	(0.4)	1	0.36	3	(1.1)	3	1.05
>=65 - <75 years	0				0			
>=75 years	0				0			
Back injury								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Burns first degree								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Chest injury								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Clavicle fracture								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Concussion								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Contusion								
>=18 - <65 years	1	(0.4)	1	0.36	2	(0.7)	2	0.70
>=65 - <75 years	1	(5.0)	1	4.93	1	(5.6)	1	5.08
>=75 years	0				0			
Corneal abrasion								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	0				0			
Epicondylitis								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Face injury								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Fall								
>=18 - <65 years	2	(0.7)	2	0.72	2	(0.7)	5	1.74
>=65 - <75 years	0				0			
>=75 years	0				0			
Fibula fracture								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Hand fracture								
>=18 - <65 years	1	(0.4)	1	0.36	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Heat stroke								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	0				1	(33.3)	1	30.51
Incorrect dose administered								
>=18 - <65 years	3	(1.1)	3	1.08	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Intentional underdose								
>=18 - <65 years	0				1	(0.4)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Joint injury								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Ligament rupture								
>=18 - <65 years	1	(0.4)	2	0.72	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	0				0			
>=75 years	0				0			
Ligament sprain								
>=18 - <65 years	5	(1.9)	5	1.80	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Limb injury								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Medication error								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Meniscus injury								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Muscle rupture								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Muscle strain								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Nerve injury								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Overdose								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Post-traumatic neck syndrome								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Prescribed overdose								
>=18 - <65 years	5	(1.9)	5	1.80	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Procedural pain								
>=18 - <65 years	1	(0.4)	2	0.72	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Product administration error								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Product dispensing error								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Radius fracture								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Road traffic accident								
>=18 - <65 years	2	(0.7)	3	1.08	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Skin abrasion								
>=18 - <65 years	3	(1.1)	4	1.44	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Skin laceration								
>=18 - <65 years	1	(0.4)	1	0.36	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Stress fracture								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Tendon rupture								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Thermal burn								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Tooth fracture								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Vaccination complication								
>=18 - <65 years	5	(1.9)	5	1.80	8	(3.0)	12	4.19
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Venous injury								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Wound								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Wound dehiscence								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Wrist fracture								
>=18 - <65 years	0				2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Wrong product administered								
>=18 - <65 years	0				4	(1.5)	4	1.40
>=65 - <75 years	0				0			
>=75 years	0				0			
Investigations								
All								
>=18 - <65 years	16	(6.0)	19	6.85	14	(5.2)	16	5.58
>=65 - <75 years	3	(15.0)	5	24.65	3	(16.7)	3	15.23
>=75 years	0				0			
Angiogram								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Aspartate aminotransferase increased								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Blood cholesterol increased								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Blood glucose fluctuation								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Blood glucose increased								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Blood pressure increased								
>=18 - <65 years	2	(0.7)	3	1.08	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Blood testosterone decreased								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Blood triglycerides increased								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Blood uric acid increased								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	0				0			
Body temperature increased								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Cardiac murmur								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Electrocardiogram abnormal								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Electrocardiogram T wave abnormal								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Eosinophil count increased								
>=18 - <65 years	0				1	(0.4)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Glomerular filtration rate decreased								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Haemoglobin decreased								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Heart rate increased								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hepatic enzyme increased								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hepatitis B virus test positive								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Lipids abnormal								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Low density lipoprotein increased								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Mycobacterium tuberculosis complex test positive								
>=18 - <65 years	2	(0.7)	2	0.72	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Occult blood positive								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	4.93	1	(5.6)	1	5.08
>=75 years	0				0			
Platelet count decreased								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Pulse absent								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
SARS-CoV-2 test positive								
>=18 - <65 years	0				4	(1.5)	4	1.40
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	0				0			
Serum ferritin decreased								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Weight decreased								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Weight increased								
>=18 - <65 years	2	(0.7)	2	0.72	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
White blood cell count decreased								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Metabolism and nutrition disorders								
All								
>=18 - <65 years	18	(6.7)	24	8.66	16	(5.9)	19	6.63
>=65 - <75 years	0				0			
>=75 years	0				0			
Decreased appetite								
>=18 - <65 years	1	(0.4)	1	0.36	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Dehydration								
>=18 - <65 years	0				1	(0.4)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Diabetic dyslipidaemia								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Diabetic ketoacidosis								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Dyslipidaemia								
>=18 - <65 years	0				2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypercholesterolaemia								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Hyperlipidaemia								
>=18 - <65 years	2	(0.7)	2	0.72	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Hyperuricaemia								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypoglycaemia								
>=18 - <65 years	10	(3.7)	15	5.41	4	(1.5)	5	1.74
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypokalaemia								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hyponatraemia								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Insulin resistance								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Iron deficiency								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Obesity								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Vitamin D deficiency								
>=18 - <65 years	1	(0.4)	1	0.36	3	(1.1)	3	1.05
>=65 - <75 years	0				0			
>=75 years	0				0			
Musculoskeletal and connective tissue disorders								
All								
>=18 - <65 years	39	(14.6)	51	18.40	52	(19.2)	93	32.45
>=65 - <75 years	5	(25.0)	6	29.58	3	(16.7)	4	20.31
>=75 years	1	(33.3)	1	37.62	1	(33.3)	2	61.03
Acquired claw toe								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Arthralgia								
>=18 - <65 years	10	(3.7)	11	3.97	14	(5.2)	15	5.23
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	1	(33.3)	1	37.62	1	(33.3)	1	30.51
Arthritis								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Back pain								
>=18 - <65 years	4	(1.5)	4	1.44	15	(5.5)	29	10.12
>=65 - <75 years	1	(5.0)	1	4.93	2	(11.1)	2	10.15
>=75 years	0				0			
Bursitis								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Chondromalacia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	0				0			
Flank pain								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Foot deformity								
>=18 - <65 years	0				1	(0.4)	2	0.70
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Groin pain								
>=18 - <65 years	0				2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Intervertebral disc protrusion								
>=18 - <65 years	0				2	(0.7)	3	1.05
>=65 - <75 years	0				0			
>=75 years	0				0			
Limb discomfort								
>=18 - <65 years	2	(0.7)	2	0.72	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Limb mass								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Muscle spasms								
>=18 - <65 years	2	(0.7)	3	1.08	1	(0.4)	1	0.35
>=65 - <75 years	2	(10.0)	2	9.86	0			
>=75 years	0				0			
Muscular weakness								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Musculoskeletal stiffness								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Myalgia								
>=18 - <65 years	3	(1.1)	3	1.08	7	(2.6)	10	3.49
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	0				0			
Myopathy								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neck pain								
>=18 - <65 years	2	(0.7)	2	0.72	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Nodal osteoarthritis								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Osteoarthritis								
>=18 - <65 years	4	(1.5)	4	1.44	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Pain in extremity								
>=18 - <65 years	7	(2.6)	7	2.53	13	(4.8)	13	4.54
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Periarthritis								
>=18 - <65 years	2	(0.7)	2	0.72	4	(1.5)	4	1.40
>=65 - <75 years	0				0			
>=75 years	0				0			
Rheumatoid arthritis								
>=18 - <65 years	1	(0.4)	1	0.36	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Rotator cuff syndrome								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Spinal stenosis								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Synovial cyst								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				1	(33.3)	1	30.51
Tendonitis								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Tenosynovitis								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Trigger finger								
>=18 - <65 years	2	(0.7)	2	0.72	1	(0.4)	1	0.35
>=65 - <75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
>=18 - <65 years	6	(2.2)	6	2.16	5	(1.8)	6	2.09
>=65 - <75 years	2	(10.0)	2	9.86	0			
>=75 years	0				0			
Benign neoplasm of thyroid gland								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Benign renal neoplasm								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Colon adenoma								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Eye naevus								
>=18 - <65 years	1	(0.4)	1	0.36	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Haemangioma of liver								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Lipoma								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Melanocytic naevus								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Myeloproliferative neoplasm								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Seborrhoeic keratosis								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Skin papilloma								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Uterine leiomyoma								
>=18 - <65 years	0				2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Nervous system disorders								
All								
>=18 - <65 years	34	(12.7)	66	23.81	34	(12.5)	114	39.78
>=65 - <75 years	4	(20.0)	4	19.72	3	(16.7)	3	15.23
>=75 years	2	(66.7)	2	75.23	2	(66.7)	2	61.03
Ageusia								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Autonomic nervous system imbalance								
>=18 - <65 years	1	(0.4)	2	0.72	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Burning sensation								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Carpal tunnel syndrome								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Cerebral haemorrhage								
>=18 - <65 years	1	(0.4)	2	0.72	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Cerebral infarction								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Cervicobrachial syndrome								
>=18 - <65 years	2	(0.7)	2	0.72	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Diabetic neuropathy								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Disturbance in attention								
>=18 - <65 years	1	(0.4)	11	3.97	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dizziness								
>=18 - <65 years	1	(0.4)	2	0.72	4	(1.5)	5	1.74
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				1	(33.3)	1	30.51
Dizziness postural								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Encephalopathy								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Haemorrhage intracranial								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(33.3)	1	37.62	0			
Headache								
>=18 - <65 years	16	(6.0)	26	9.38	15	(5.5)	21	7.33
>=65 - <75 years	1	(5.0)	1	4.93	1	(5.6)	1	5.08
>=75 years	0				0			
Hemiparesis								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypoaesthesia								
>=18 - <65 years	2	(0.7)	3	1.08	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypoglycaemic seizure								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypoglycaemic unconsciousness								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(33.3)	1	30.51
Hypotonia								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
IIIrd nerve paralysis								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Ischaemic stroke								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Loss of consciousness								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	0				0			
Loss of proprioception								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Migraine								
>=18 - <65 years	4	(1.5)	5	1.80	2	(0.7)	3	1.05
>=65 - <75 years	0				0			
>=75 years	0				0			
Neuropathy peripheral								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Optic neuritis								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Post herpetic neuralgia								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	0				0			
Presyncope								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Radiculopathy								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Restless legs syndrome								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Sinus headache								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Somnolence								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	1	(33.3)	1	37.62	0			
Syncope								
>=18 - <65 years	2	(0.7)	2	0.72	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Tension headache								
>=18 - <65 years	0				1	(0.4)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Tremor								
>=18 - <65 years	1	(0.4)	1	0.36	4	(1.5)	68	23.73
>=65 - <75 years	0				0			
>=75 years	0				0			
Pregnancy, puerperium and perinatal conditions								
All								
>=18 - <65 years	2	(0.7)	2	0.72	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Abortion spontaneous								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Abortion threatened								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Psychiatric disorders								
All								
>=18 - <65 years	7	(2.6)	7	2.53	11	(4.1)	14	4.88
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Alcohol abuse								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Anxiety								
>=18 - <65 years	1	(0.4)	1	0.36	5	(1.8)	5	1.74
>=65 - <75 years	0				0			
>=75 years	0				0			
Anxiety disorder								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Attention deficit hyperactivity disorder								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Depressed mood								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Depression								
>=18 - <65 years	0				5	(1.8)	5	1.74
>=65 - <75 years	0				0			
>=75 years	0				0			
Insomnia								
>=18 - <65 years	1	(0.4)	1	0.36	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Major depression								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Sleep disorder								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Stress								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
>=18 - <65 years	6	(2.2)	6	2.16	5	(1.8)	8	2.79
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Acute kidney injury								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Chronic kidney disease								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Diabetic nephropathy								
>=18 - <65 years	0				2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Dysuria								
>=18 - <65 years	2	(0.7)	2	0.72	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hydrocalyx								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypertensive nephropathy								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Microalbuminuria								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Pollakiuria								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Proteinuria								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Renal cyst								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal pain								
>=18 - <65 years	2	(0.7)	2	0.72	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Reproductive system and breast disorders								
All								
>=18 - <65 years	8	(3.0)	9	3.25	7	(2.6)	9	3.14
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	1	(33.3)	1	37.62	0			
Atrophic vulvovaginitis								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Benign prostatic hyperplasia								
>=18 - <65 years	2	(0.7)	2	0.72	0			
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	0				0			
Dysmenorrhoea								
>=18 - <65 years	1	(0.4)	1	0.36	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Ectropion of cervix								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Erectile dysfunction								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Fibrocystic breast disease								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Heavy menstrual bleeding								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Menstruation irregular								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Ovarian cyst								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ovarian disorder								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Penile pain								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Premenstrual syndrome								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Prostatic cyst								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Prostatitis								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Prostatomegaly								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(33.3)	1	37.62	0			
Respiratory, thoracic and mediastinal disorders								
All								
>=18 - <65 years	33	(12.4)	48	17.31	35	(12.9)	54	18.84
>=65 - <75 years	2	(10.0)	4	19.72	1	(5.6)	1	5.08
>=75 years	1	(33.3)	2	75.23	1	(33.3)	2	61.03
Acute respiratory failure								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Allergic cough								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Asthma								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	0				0			
Bronchial hyperreactivity								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cough								
>=18 - <65 years	8	(3.0)	10	3.61	11	(4.1)	15	5.23
>=65 - <75 years	1	(5.0)	2	9.86	0			
>=75 years	0				0			
Cough variant asthma								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Dysphonia								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Dyspnoea								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Dyspnoea exertional								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	1	(33.3)	1	37.62	0			
Epiglottic oedema								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Epistaxis								
>=18 - <65 years	3	(1.1)	3	1.08	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hiccups								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	1	(33.3)	1	37.62	0			
Nasal congestion								
>=18 - <65 years	2	(0.7)	2	0.72	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Oropharyngeal discomfort								
>=18 - <65 years	0				2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Oropharyngeal pain								
>=18 - <65 years	8	(3.0)	9	3.25	10	(3.7)	11	3.84
>=65 - <75 years	0				0			
>=75 years	0				0			
Pleurisy								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Productive cough								
>=18 - <65 years	0				2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				1	(33.3)	2	61.03
Pulmonary congestion								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Pulmonary mass								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Respiratory disorder								
>=18 - <65 years	4	(1.5)	4	1.44	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Rhinitis allergic								
>=18 - <65 years	3	(1.1)	4	1.44	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Rhinorrhoea								
>=18 - <65 years	3	(1.1)	4	1.44	7	(2.6)	8	2.79
>=65 - <75 years	0				0			
>=75 years	0				0			
Sinus congestion								
>=18 - <65 years	2	(0.7)	2	0.72	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Sleep apnoea syndrome								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Sneezing								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Throat irritation								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Upper-airway cough syndrome								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	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). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
>=18 - <65 years	33	(12.4)	39	14.07	36	(13.3)	49	17.10
>=65 - <75 years	2	(10.0)	2	9.86	3	(16.7)	3	15.23
>=75 years	1	(33.3)	1	37.62	1	(33.3)	2	61.03
Alopecia								
>=18 - <65 years	3	(1.1)	3	1.08	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Alopecia areata								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Angioedema								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Chronic spontaneous urticaria								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Cold sweat								
>=18 - <65 years	0				4	(1.5)	9	3.14
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	0				0			
Dermal cyst								
>=18 - <65 years	1	(0.4)	1	0.36	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Dermatitis								
>=18 - <65 years	5	(1.9)	7	2.53	3	(1.1)	4	1.40
>=65 - <75 years	0				0			
>=75 years	0				0			
Dermatitis allergic								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Dermatitis atopic								
>=18 - <65 years	1	(0.4)	1	0.36	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Dermatitis contact								
>=18 - <65 years	4	(1.5)	4	1.44	5	(1.8)	5	1.74
>=65 - <75 years	0				2	(11.1)	2	10.15
>=75 years	0				0			
Dry skin								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Eczema								
>=18 - <65 years	0				3	(1.1)	3	1.05
>=65 - <75 years	0				0			
>=75 years	0				0			
Eczema asteatotic								
>=18 - <65 years	0				0			
>=65 - <75 years	0				0			
>=75 years	0				1	(33.3)	1	30.51
Erythema								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				1	(33.3)	1	30.51
Erythema multiforme								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hidradenitis								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Hyperkeratosis								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Ingrowing nail								
>=18 - <65 years	1	(0.4)	1	0.36	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Ingrown hair								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Lichen sclerosus								
>=18 - <65 years	2	(0.7)	2	0.72	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Macule								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Miliaria								
>=18 - <65 years	0				2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Pruritus								
>=18 - <65 years	1	(0.4)	1	0.36	2	(0.7)	2	0.70
>=65 - <75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=75 years	0				0			
Psoriasis								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Rash								
>=18 - <65 years	4	(1.5)	4	1.44	2	(0.7)	2	0.70
>=65 - <75 years	0				0			
>=75 years	0				0			
Rash erythematous								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Seborrhoeic dermatitis								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Skin fissures								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Skin irritation								
>=18 - <65 years	1	(0.4)	1	0.36	1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	1	(33.3)	1	37.62	0			
Skin lesion								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Skin reaction								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Skin ulcer								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Telangiectasia								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Urticaria								
>=18 - <65 years	0				4	(1.5)	4	1.40
>=65 - <75 years	0				0			
>=75 years	0				0			
Urticaria papular								
>=18 - <65 years	0				1	(0.4)	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). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=65 - <75 years	0				0			
>=75 years	0				0			
Vitiligo								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Xeroderma								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Surgical and medical procedures								
All								
>=18 - <65 years	2	(0.7)	2	0.72	0			
>=65 - <75 years	2	(10.0)	2	9.86	0			
>=75 years	0				0			
Cardiac ablation								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Skin neoplasm excision								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Tooth extraction								
>=18 - <65 years	0				0			
>=65 - <75 years	1	(5.0)	1	4.93	0			
>=75 years	0				0			
Wisdom teeth removal								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vascular disorders								
All								
>=18 - <65 years	11	(4.1)	11	3.97	8	(3.0)	9	3.14
>=65 - <75 years	0				2	(11.1)	2	10.15
>=75 years	0				0			
Aortic aneurysm								
>=18 - <65 years	0				0			
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	0				0			
Arteriosclerosis								
>=18 - <65 years	1	(0.4)	1	0.36	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Brachiocephalic artery stenosis								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypertension								
>=18 - <65 years	8	(3.0)	8	2.89	6	(2.2)	6	2.09
>=65 - <75 years	0				1	(5.6)	1	5.08
>=75 years	0				0			
Hypertensive crisis								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			
Hypotension								
>=18 - <65 years	2	(0.7)	2	0.72	0			
>=65 - <75 years	0				0			
>=75 years	0				0			
Varicose vein								
>=18 - <65 years	0				1	(0.4)	1	0.35
>=65 - <75 years	0				0			
>=75 years	0				0			

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

7.24.9 Adverse events by baseline HbA1c group - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<8% (<64 mmol/mol)	170				188			
>=8% (>=64 mmol/mol)	322				304			
PYE (years)								
<8% (<64 mmol/mol)	265.19				296.04			
>=8% (>=64 mmol/mol)	500.31				470.71			
Events								
<8% (<64 mmol/mol)	139	(81.8)	659	248.50	150	(79.8)	770	260.10
>=8% (>=64 mmol/mol)	258	(80.1)	1223	244.45	239	(78.6)	1053	223.70
Serious								
Yes								
<8% (<64 mmol/mol)	23	(13.5)	33	12.44	25	(13.3)	42	14.19
>=8% (>=64 mmol/mol)	41	(12.7)	62	12.39	46	(15.1)	77	16.36
No								
<8% (<64 mmol/mol)	137	(80.6)	626	236.06	146	(77.7)	728	245.91
>=8% (>=64 mmol/mol)	250	(77.6)	1161	232.06	234	(77.0)	976	207.34
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			
Severity								
Severe								
<8% (<64 mmol/mol)	8	(4.7)	11	4.15	9	(4.8)	18	6.08
>=8% (>=64 mmol/mol)	18	(5.6)	27	5.40	27	(8.9)	43	9.14
Moderate								
<8% (<64 mmol/mol)	57	(33.5)	137	51.66	68	(36.2)	165	55.73
>=8% (>=64 mmol/mol)	135	(41.9)	264	52.77	115	(37.8)	232	49.29
Mild								
<8% (<64 mmol/mol)	127	(74.7)	511	192.69	138	(73.4)	587	198.28
>=8% (>=64 mmol/mol)	224	(69.6)	932	186.29	202	(66.4)	778	165.28
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to basal insulin								
Probable								
<8% (<64 mmol/mol)	7	(4.1)	15	5.66	13	(6.9)	16	5.40
>=8% (>=64 mmol/mol)	23	(7.1)	28	5.60	20	(6.6)	35	7.44
Possible								
<8% (<64 mmol/mol)	19	(11.2)	24	9.05	16	(8.5)	31	10.47
>=8% (>=64 mmol/mol)	27	(8.4)	43	8.59	23	(7.6)	29	6.16
Unlikely								
<8% (<64 mmol/mol)	138	(81.2)	620	233.79	147	(78.2)	718	242.53
>=8% (>=64 mmol/mol)	254	(78.9)	1150	229.86	231	(76.0)	988	209.89
Missing								
<8% (<64 mmol/mol)	0				4	(2.1)	5	1.69
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Related to technical complaint for basal insulin								
Yes								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
No								
<8% (<64 mmol/mol)	139	(81.8)	659	248.50	149	(79.3)	765	258.41
>=8% (>=64 mmol/mol)	258	(80.1)	1222	244.25	239	(78.6)	1051	223.28
NA								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			
Missing								
<8% (<64 mmol/mol)	0				4	(2.1)	5	1.69
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21

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

Adverse events by baseline HbA1c group - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	4	1.35
>=8% (>=64 mmol/mol)	4	(1.2)	6	1.20	2	(0.7)	3	0.64
Not recovered/not resolved								
<8% (<64 mmol/mol)	67	(39.4)	173	65.24	79	(42.0)	166	56.07
>=8% (>=64 mmol/mol)	146	(45.3)	335	66.96	137	(45.1)	281	59.70
Recovered/resolved with sequelae								
<8% (<64 mmol/mol)	5	(2.9)	5	1.89	4	(2.1)	4	1.35
>=8% (>=64 mmol/mol)	4	(1.2)	4	0.80	4	(1.3)	4	0.85
Recovering/resolving								
<8% (<64 mmol/mol)	7	(4.1)	13	4.90	8	(4.3)	8	2.70
>=8% (>=64 mmol/mol)	14	(4.3)	15	3.00	22	(7.2)	31	6.59
Recovered/resolved								
<8% (<64 mmol/mol)	125	(73.5)	467	176.10	143	(76.1)	588	198.62
>=8% (>=64 mmol/mol)	229	(71.1)	863	172.49	208	(68.4)	734	155.93
Unknown								
<8% (<64 mmol/mol)	0				0			
					0			
>=8% (>=64 mmol/mol)	0				0			
					0			
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			

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

7.24.10 Adverse events by baseline HbA1c group - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<8% (<64 mmol/mol)	189				189			
>=8% (>=64 mmol/mol)	101				103			
PYE (years)								
<8% (<64 mmol/mol)	194.57				202.05			
>=8% (>=64 mmol/mol)	105.59				107.53			
Events								
<8% (<64 mmol/mol)	154	(81.5)	608	312.48	156	(82.5)	689	341.00
>=8% (>=64 mmol/mol)	86	(85.1)	357	338.11	80	(77.7)	457	424.99
Serious								
Yes								
<8% (<64 mmol/mol)	12	(6.3)	18	9.25	12	(6.3)	14	6.93
>=8% (>=64 mmol/mol)	12	(11.9)	21	19.89	8	(7.8)	11	10.23
No								
<8% (<64 mmol/mol)	152	(80.4)	590	303.23	156	(82.5)	675	334.07
>=8% (>=64 mmol/mol)	85	(84.2)	336	318.22	80	(77.7)	446	414.76
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			
Severity								
Severe								
<8% (<64 mmol/mol)	11	(5.8)	12	6.17	5	(2.6)	5	2.47
>=8% (>=64 mmol/mol)	9	(8.9)	16	15.15	4	(3.9)	5	4.65
Moderate								
<8% (<64 mmol/mol)	49	(25.9)	119	61.16	51	(27.0)	108	53.45
>=8% (>=64 mmol/mol)	34	(33.7)	60	56.82	31	(30.1)	51	47.43
Mild								
<8% (<64 mmol/mol)	140	(74.1)	477	245.15	141	(74.6)	576	285.08
>=8% (>=64 mmol/mol)	79	(78.2)	281	266.13	78	(75.7)	401	372.91
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to basal insulin								
Probable								
<8% (<64 mmol/mol)	11	(5.8)	12	6.17	9	(4.8)	10	4.95
>=8% (>=64 mmol/mol)	9	(8.9)	13	12.31	2	(1.9)	2	1.86
Possible								
<8% (<64 mmol/mol)	16	(8.5)	19	9.77	11	(5.8)	50	24.75
>=8% (>=64 mmol/mol)	14	(13.9)	17	16.10	11	(10.7)	22	20.46
Unlikely								
<8% (<64 mmol/mol)	153	(81.0)	576	296.04	156	(82.5)	629	311.31
>=8% (>=64 mmol/mol)	81	(80.2)	327	309.69	78	(75.7)	433	402.67
Missing								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Related to technical complaint for basal insulin								
Yes								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			
No								
<8% (<64 mmol/mol)	154	(81.5)	607	311.97	156	(82.5)	689	341.00
>=8% (>=64 mmol/mol)	86	(85.1)	357	338.11	80	(77.7)	457	424.99
NA								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			
Missing								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Not recovered/not resolved								
<8% (<64 mmol/mol)	67	(35.4)	130	66.81	65	(34.4)	143	70.77
>=8% (>=64 mmol/mol)	38	(37.6)	65	61.56	39	(37.9)	74	68.82
Recovered/resolved with sequelae								
<8% (<64 mmol/mol)	1	(0.5)	2	1.03	2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	1	(1.0)	1	0.93
Recovering/resolving								
<8% (<64 mmol/mol)	13	(6.9)	13	6.68	11	(5.8)	14	6.93
>=8% (>=64 mmol/mol)	7	(6.9)	11	10.42	9	(8.7)	11	10.23
Recovered/resolved								
<8% (<64 mmol/mol)	142	(75.1)	462	237.45	137	(72.5)	530	262.31
>=8% (>=64 mmol/mol)	79	(78.2)	280	265.18	76	(73.8)	371	345.01
Unknown								
<8% (<64 mmol/mol)	0				0 0			
>=8% (>=64 mmol/mol)	0				0 0			
Missing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				0			

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

7.24.11 Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<8% (<64 mmol/mol)	170				188			
>=8% (>=64 mmol/mol)	322				304			
PYE (years)								
<8% (<64 mmol/mol)	265.19				296.04			
>=8% (>=64 mmol/mol)	500.31				470.71			
Events								
<8% (<64 mmol/mol)	139	(81.8)	659	248.50	150	(79.8)	770	260.10
>=8% (>=64 mmol/mol)	258	(80.1)	1223	244.45	239	(78.6)	1053	223.70

Blood and lymphatic system disorders

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
<8% (<64 mmol/mol)	3	(1.8)	4	1.51	7	(3.7)	7	2.36
>=8% (>=64 mmol/mol)	12	(3.7)	13	2.60	12	(3.9)	13	2.76
Anaemia								
<8% (<64 mmol/mol)	3	(1.8)	3	1.13	3	(1.6)	3	1.01
>=8% (>=64 mmol/mol)	7	(2.2)	7	1.40	7	(2.3)	8	1.70
Blood loss anaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Eosinophilia								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	0				0			
Hypochromic anaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Iron deficiency anaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	1	(0.3)	1	0.21
Lymphadenopathy								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Normochromic normocytic anaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Polycythaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Thrombocytopenia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Cardiac disorders								
All								
<8% (<64 mmol/mol)	17	(10.0)	29	10.94	19	(10.1)	23	7.77
>=8% (>=64 mmol/mol)	27	(8.4)	50	9.99	23	(7.6)	38	8.07
Acute coronary syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Acute myocardial infarction								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	4	(1.3)	4	0.85
Angina pectoris								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Angina unstable								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	4	(1.2)	4	0.80	1	(0.3)	1	0.21
Aortic valve calcification								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Aortic valve incompetence								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Arrhythmia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Arteriosclerosis coronary artery								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Atrial fibrillation								
<8% (<64 mmol/mol)	4	(2.4)	4	1.51	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	4	(1.2)	5	1.00	5	(1.6)	8	1.70
Atrial flutter								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.40	1	(0.3)	1	0.21
Atrial thrombosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Atrioventricular block complete								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.42
Atrioventricular block first degree								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Atrioventricular block second degree								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Bradycardia								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Bundle branch block left								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Bundle branch block right								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	2	(1.1)	3	1.01
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Cardiac dysfunction								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	0				0			
Cardiac failure								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	1	(0.3)	1	0.21
Cardiac failure chronic								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Cardiac failure congestive								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Cardiac ventricular thrombosis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Cardio-respiratory arrest								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Cardiomyopathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Chronic coronary syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Congestive cardiomyopathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Coronary artery disease								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	5	(1.6)	5	1.00	3	(1.0)	3	0.64
Coronary artery occlusion								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Coronary artery stenosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	3	0.60	0			
Diastolic dysfunction								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Left atrial dilatation								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Left ventricular dysfunction								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Left ventricular hypertrophy								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Mitral valve incompetence								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Myocardial infarction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	3	(1.0)	3	0.64
Myocardial ischaemia								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Palpitations								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	3	(1.6)	4	1.35
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Pericardial effusion								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Pericarditis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Sinus arrhythmia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Sinus bradycardia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Sinus tachycardia								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Supraventricular extrasystoles								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Supraventricular tachycardia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Tachycardia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tricuspid valve incompetence								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Ventricular extrasystoles								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	0			
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	1	(0.3)	1	0.21
Congenital, familial and genetic disorders								
All								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Congenital syphilitic osteochondritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Corneal dystrophy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Dolichocolon								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Hydrocele								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Type V hyperlipidaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
<8% (<64 mmol/mol)	4	(2.4)	5	1.89	6	(3.2)	6	2.03
>=8% (>=64 mmol/mol)	8	(2.5)	8	1.60	7	(2.3)	8	1.70
Cerumen impaction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Ear discomfort								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Ear inflammation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Ear pain								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Eustachian tube dysfunction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Hypoacusis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Presbyacusis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Tinnitus								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Vertigo								
<8% (<64 mmol/mol)	4	(2.4)	5	1.89	3	(1.6)	3	1.01
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	4	(1.3)	5	1.06
Vertigo positional								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	6	(2.0)	6	1.27
Goitre								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Hyperplasia adrenal								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Hyperprolactinaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Hyperthyroidism								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Hypothyroidism								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Thyroid mass								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Eye disorders								
All								
<8% (<64 mmol/mol)	23	(13.5)	35	13.20	34	(18.1)	56	18.92
>=8% (>=64 mmol/mol)	66	(20.5)	92	18.39	42	(13.8)	63	13.38
Acquired epiblepharon								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Age-related macular degeneration								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	0				0			
Asthenopia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Astigmatism								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Blepharitis								
<8% (<64 mmol/mol)	3	(1.8)	3	1.13	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			

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Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blepharitis allergic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Cataract								
<8% (<64 mmol/mol)	7	(4.1)	10	3.77	4	(2.1)	7	2.36
>=8% (>=64 mmol/mol)	11	(3.4)	13	2.60	8	(2.6)	8	1.70
Cataract diabetic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Cataract nuclear								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Cataract subcapsular								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Chorioretinal disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Conjunctival cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Conjunctival erosion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Conjunctival haemorrhage								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Conjunctival hyperaemia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Conjunctivitis allergic								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	2	(0.6)	3	0.60	0			
Corneal opacity								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Dacryoadenitis acquired								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Dermatochalasis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Diabetic retinal oedema								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	4	(1.3)	4	0.85

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Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Diabetic retinopathy								
<8% (<64 mmol/mol)	6	(3.5)	6	2.26	11	(5.9)	14	4.73
>=8% (>=64 mmol/mol)	30	(9.3)	35	7.00	21	(6.9)	24	5.10
Dry age-related macular degeneration								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Dry eye								
<8% (<64 mmol/mol)	0				3	(1.6)	3	1.01
>=8% (>=64 mmol/mol)	5	(1.6)	5	1.00	2	(0.7)	2	0.42
Eye discharge								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Eye disorder								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Eye inflammation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Eye irritation								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Eye pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	2	(0.7)	2	0.42
Eyelid ptosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Giant papillary conjunctivitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Glaucoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Iritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Macular oedema								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Myopia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21

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Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Non-proliferative retinopathy								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Normal tension glaucoma								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Ocular hypertension								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Open angle glaucoma								
<8% (<64 mmol/mol)	0				1	(0.5)	2	0.68
>=8% (>=64 mmol/mol)	0				0			
Optic disc vascular disorder								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Optic ischaemic neuropathy								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Photophobia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Post thrombotic retinopathy								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Posterior capsule opacification								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Presbyopia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Pterygium								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Punctate keratitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Retinal aneurysm								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Retinal artery occlusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Retinal degeneration								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Retinal detachment								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Retinal drusen								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Retinal haemorrhage								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Retinal tear								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Retinal vascular disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Retinal vein occlusion								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Retinal vein thrombosis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Retinopathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Retinopathy hypertensive								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	0				0			
Retinopathy proliferative								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Scintillating scotoma								
<8% (<64 mmol/mol)	0				1	(0.5)	2	0.68
>=8% (>=64 mmol/mol)	0				0			
Uveitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Vision blurred								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	3	(1.0)	3	0.64

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	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Visual impairment								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Vitreous detachment								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Vitreous floaters								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Vitreous haemorrhage								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.42
Vitreous opacities								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Gastrointestinal disorders								
All								
<8% (<64 mmol/mol)	42	(24.7)	69	26.02	47	(25.0)	78	26.35
>=8% (>=64 mmol/mol)	70	(21.7)	133	26.58	57	(18.8)	100	21.24
Abdominal discomfort								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	2	(1.1)	4	1.35
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	2	0.42
Abdominal distension								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	7	(2.2)	8	1.60	1	(0.3)	1	0.21
Abdominal hernia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Abdominal pain								
<8% (<64 mmol/mol)	3	(1.8)	3	1.13	3	(1.6)	3	1.01
>=8% (>=64 mmol/mol)	5	(1.6)	5	1.00	4	(1.3)	4	0.85
Abdominal pain lower								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.40	2	(0.7)	2	0.42
Abdominal pain upper								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	4	(1.3)	5	1.06
Abdominal wall haematoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Acid peptic disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.42

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Anal eczema								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Anal fissure								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Anal pruritus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Angular cheilitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Aphthous ulcer								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Ascites								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Barrett's oesophagus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Chronic gastritis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	5	(1.6)	5	1.06
Colitis								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Colitis ischaemic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Colitis microscopic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Constipation								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	3	(1.6)	3	1.01
>=8% (>=64 mmol/mol)	6	(1.9)	6	1.20	3	(1.0)	3	0.64
Crohn's disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Dental caries								
<8% (<64 mmol/mol)	6	(3.5)	7	2.64	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	3	(0.9)	4	0.80	0			
Diarrhoea								
<8% (<64 mmol/mol)	19	(11.2)	24	9.05	11	(5.9)	13	4.39

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	20	(6.2)	30	6.00	15	(4.9)	16	3.40
Diverticulum								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				3	(1.0)	3	0.64
Diverticulum intestinal								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	0			
>=8% (>=64 mmol/mol)	0				0			
Dry mouth								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Duodenal ulcer								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Duodenitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Duodenogastric reflux								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Dyspepsia								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	3	(1.0)	3	0.64
Enteritis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Enterocolitis								
<8% (<64 mmol/mol)	2	(1.2)	3	1.13	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Epigastric discomfort								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Erosive duodenitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Flatulence								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Food poisoning								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Frequent bowel movements								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Gastric disorder								

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Gastric polyps								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Gastritis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	2	(0.7)	2	0.42
Gastritis erosive								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Gastrointestinal disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.42
Gastrointestinal haemorrhage								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Gastrointestinal inflammation								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Gastrooesophageal reflux disease								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	6	(3.2)	6	2.03
>=8% (>=64 mmol/mol)	6	(1.9)	6	1.20	2	(0.7)	2	0.42
Haematemesis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Haematochezia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Haemorrhoids								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	3	(1.6)	3	1.01
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	2	(0.7)	2	0.42
Hiatus hernia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.42
Hyperaesthesia teeth								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Hyperchlorhydria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Ileus								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Inguinal hernia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	2	0.42
Intestinal obstruction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Irritable bowel syndrome								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Large intestine polyp								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	2	(1.1)	3	1.01
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Loose tooth								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Melaena								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Nausea								
<8% (<64 mmol/mol)	7	(4.1)	9	3.39	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	13	(4.0)	13	2.60	7	(2.3)	9	1.91
Odynophagia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Oral discomfort								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Pancreatitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Pancreatitis acute								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Pancreatitis chronic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Periodontal disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Periodontal inflammation								
<8% (<64 mmol/mol)	0				1	(0.5)	2	0.68
>=8% (>=64 mmol/mol)	0				0			
Portal hypertensive gastropathy								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Rectal polyp								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Rectal prolapse								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Salivary gland calculus								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Stomatitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Tooth disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Tooth impacted								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Tooth loss								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Toothache								
<8% (<64 mmol/mol)	3	(1.8)	3	1.13	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	8	(2.5)	9	1.80	3	(1.0)	3	0.64
Ulcerative gastritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Umbilical hernia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	2	(0.7)	2	0.42
Varices oesophageal								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Vomiting								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	7	(3.7)	7	2.36
>=8% (>=64 mmol/mol)	5	(1.6)	5	1.00	4	(1.3)	8	1.70
General disorders and administration site conditions								
All								
<8% (<64 mmol/mol)	28	(16.5)	46	17.35	51	(27.1)	85	28.71
>=8% (>=64 mmol/mol)	63	(19.6)	114	22.79	47	(15.5)	65	13.81
Asthenia								
<8% (<64 mmol/mol)	1	(0.6)	2	0.75	5	(2.7)	5	1.69

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	4	(1.2)	4	0.80	1	(0.3)	1	0.21
Chest discomfort								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Chest pain								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	3	(1.6)	3	1.01
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	4	(1.3)	4	0.85
Chills								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Death								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Discomfort								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Drug intolerance								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Early satiety								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Effusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Fatigue								
<8% (<64 mmol/mol)	3	(1.8)	4	1.51	4	(2.1)	5	1.69
>=8% (>=64 mmol/mol)	13	(4.0)	14	2.80	3	(1.0)	3	0.64
Feeling abnormal								
<8% (<64 mmol/mol)	1	(0.6)	5	1.89	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.40	0			
Feeling hot								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Gait disturbance								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Hunger								
<8% (<64 mmol/mol)	5	(2.9)	6	2.26	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Implant site pruritus								

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Inflammation								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Influenza like illness								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Injection site bruising								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Injection site dermatitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Injection site erythema								
<8% (<64 mmol/mol)	0				3	(1.6)	3	1.01
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Injection site haemorrhage								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Injection site hypersensitivity								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Injection site hypertrophy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Injection site mass								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Injection site pain								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Injection site reaction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Injection site urticaria								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Malaise								
<8% (<64 mmol/mol)	4	(2.4)	5	1.89	6	(3.2)	8	2.70
>=8% (>=64 mmol/mol)	3	(0.9)	4	0.80	4	(1.3)	4	0.85
Mass								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Medical device site bruise								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	2	0.68
>=8% (>=64 mmol/mol)	4	(1.2)	5	1.00	0			
Medical device site dermatitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	5	(2.7)	11	3.72
>=8% (>=64 mmol/mol)	1	(0.3)	4	0.80	4	(1.3)	4	0.85
Medical device site discomfort								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Medical device site eczema								
<8% (<64 mmol/mol)	0				2	(1.1)	4	1.35
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.40	0			
Medical device site erythema								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Medical device site haematoma								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Medical device site haemorrhage								
<8% (<64 mmol/mol)	3	(1.8)	3	1.13	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Medical device site hypersensitivity								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	3	0.60	0			
Medical device site inflammation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Medical device site pain								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Medical device site pruritus								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Medical device site reaction								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	3	0.60	0			
Non-cardiac chest pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Oedema								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Oedema peripheral								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	5	(2.7)	5	1.69
>=8% (>=64 mmol/mol)	6	(1.9)	7	1.40	6	(2.0)	8	1.70

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pain								
<8% (<64 mmol/mol)	0				3	(1.6)	4	1.35
>=8% (>=64 mmol/mol)	4	(1.2)	4	0.80	4	(1.3)	4	0.85
Peripheral swelling								
<8% (<64 mmol/mol)	0				3	(1.6)	3	1.01
>=8% (>=64 mmol/mol)	3	(0.9)	4	0.80	3	(1.0)	3	0.64
Procedural failure								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Pyrexia								
<8% (<64 mmol/mol)	6	(3.5)	6	2.26	9	(4.8)	9	3.04
>=8% (>=64 mmol/mol)	21	(6.5)	24	4.80	14	(4.6)	18	3.82
Swelling								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Thirst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Vaccination site erythema								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Vaccination site pain								
<8% (<64 mmol/mol)	1	(0.6)	2	0.75	4	(2.1)	4	1.35
>=8% (>=64 mmol/mol)	4	(1.2)	5	1.00	0			
Vaccination site reaction								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hepatobiliary disorders								
All								
<8% (<64 mmol/mol)	5	(2.9)	6	2.26	4	(2.1)	4	1.35
>=8% (>=64 mmol/mol)	8	(2.5)	10	2.00	6	(2.0)	7	1.49
Biliary colic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Cholelithiasis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Gallbladder cholesterolosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Hepatic cirrhosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Hepatic cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Hepatic function abnormal								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Hepatic steatosis								
<8% (<64 mmol/mol)	3	(1.8)	3	1.13	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	5	(1.6)	5	1.00	2	(0.7)	2	0.42
Hepatitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Hypertransaminasaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.40	0			
Liver disorder								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Non-alcoholic steatohepatitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Nonalcoholic fatty liver disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Steatohepatitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
<8% (<64 mmol/mol)	4	(2.4)	5	1.89	2	(1.1)	3	1.01
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	4	(1.3)	4	0.85
Allergy to arthropod bite								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Allergy to arthropod sting								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Immunisation reaction								
<8% (<64 mmol/mol)	0				1	(0.5)	2	0.68
>=8% (>=64 mmol/mol)	0				0			
Seasonal allergy								
<8% (<64 mmol/mol)	4	(2.4)	4	1.51	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	3	(1.0)	3	0.64
Infections and infestations								
All								
<8% (<64 mmol/mol)	78	(45.9)	145	54.68	100	(53.2)	190	64.18
>=8% (>=64 mmol/mol)	147	(45.7)	270	53.97	152	(50.0)	259	55.02
Abscess								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Acarodermatitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Acute sinusitis								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Anal abscess								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	0				0			
Asymptomatic COVID-19								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Bacterial infection								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Balanitis candida								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Body tinea								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Breast abscess								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.42
Breast cellulitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Bronchitis								
<8% (<64 mmol/mol)	4	(2.4)	4	1.51	6	(3.2)	7	2.36
>=8% (>=64 mmol/mol)	8	(2.5)	8	1.60	1	(0.3)	1	0.21
Candida infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	0			
Cellulitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	3	(1.0)	3	0.64
Chlamydial infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Chronic hepatitis C								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Chronic sinusitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Chronic tonsillitis								
<8% (<64 mmol/mol)	0				1	(0.5)	3	1.01
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	2	(0.7)	2	0.42
Clostridium difficile infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Conjunctivitis								
<8% (<64 mmol/mol)	1	(0.6)	2	0.75	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	5	(1.6)	5	1.00	1	(0.3)	1	0.21
Conjunctivitis bacterial								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Coronavirus infection								
<8% (<64 mmol/mol)	3	(1.8)	3	1.13	4	(2.1)	5	1.69
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	2	(0.7)	2	0.42
COVID-19								
<8% (<64 mmol/mol)	31	(18.2)	33	12.44	35	(18.6)	36	12.16
>=8% (>=64 mmol/mol)	60	(18.6)	62	12.39	69	(22.7)	75	15.93

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Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
COVID-19 pneumonia								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	1	(0.3)	1	0.21
Cystitis								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	6	(3.2)	9	3.04
>=8% (>=64 mmol/mol)	3	(0.9)	4	0.80	2	(0.7)	2	0.42
Dermatophytosis of nail								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Diverticulitis								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	0				3	(1.0)	3	0.64
Ear infection								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	0			
Empyema								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Endophthalmitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Epididymitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Erysipelas								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Escherichia urinary tract infection								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Eye infection bacterial								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Folliculitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Fungal balanitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Fungal infection								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Furuncle								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.40	1	(0.3)	1	0.21
Gastroenteritis								
<8% (<64 mmol/mol)	3	(1.8)	3	1.13	3	(1.6)	4	1.35
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	3	(1.0)	3	0.64
Gastroenteritis norovirus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Gastroenteritis viral								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	0			
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	1	(0.3)	1	0.21
Gastrointestinal infection								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Genital infection fungal								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Giardiasis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Gingivitis								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	1	(0.5)	2	0.68
>=8% (>=64 mmol/mol)	2	(0.6)	3	0.60	1	(0.3)	1	0.21
Helicobacter gastritis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Helicobacter infection								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Hepatitis B								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Herpes dermatitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Herpes simplex								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Herpes virus infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Herpes zoster								
<8% (<64 mmol/mol)	3	(1.8)	3	1.13	4	(2.1)	4	1.35
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	4	(1.3)	4	0.85
Hordeolum								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Infected bite								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Infected skin ulcer								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Influenza								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.42
Intestinal sepsis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Labyrinthitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Laryngitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	3	(1.0)	3	0.64
Laryngopharyngitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Localised infection								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Lower respiratory tract infection								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	6	(1.9)	8	1.60	2	(0.7)	4	0.85
Lyme disease								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Lymphangitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Mastitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mycoplasma infection								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Nail infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Nasopharyngitis								
<8% (<64 mmol/mol)	14	(8.2)	16	6.03	19	(10.1)	22	7.43
>=8% (>=64 mmol/mol)	24	(7.5)	34	6.80	28	(9.2)	34	7.22
Onychomycosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Oophoritis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Oral candidiasis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Oral herpes								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Oral infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Orchitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Oropharyngeal candidiasis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Osteomyelitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Osteomyelitis chronic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Otitis externa								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Otitis media								
<8% (<64 mmol/mol)	0				1	(0.5)	2	0.68
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Otitis media acute								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Otitis media chronic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Parotitis								
<8% (<64 mmol/mol)	0				1	(0.5)	3	1.01
>=8% (>=64 mmol/mol)	0				0			
Peri-implantitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Pericoronitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Periodontitis								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	5	(2.7)	6	2.03
>=8% (>=64 mmol/mol)	0				0			
Pharyngitis								
<8% (<64 mmol/mol)	6	(3.5)	11	4.15	5	(2.7)	5	1.69
>=8% (>=64 mmol/mol)	9	(2.8)	10	2.00	7	(2.3)	12	2.55
Pharyngitis bacterial								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Pharyngotonsillitis								
<8% (<64 mmol/mol)	0				1	(0.5)	2	0.68
>=8% (>=64 mmol/mol)	0				3	(1.0)	3	0.64
Pneumonia								
<8% (<64 mmol/mol)	3	(1.8)	3	1.13	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Post procedural infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Pulpitis dental								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Purulence								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Pyelonephritis chronic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Respiratory syncytial virus infection								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Respiratory tract infection								
<8% (<64 mmol/mol)	3	(1.8)	3	1.13	3	(1.6)	4	1.35
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	3	(1.0)	3	0.64
Respiratory tract infection viral								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	4	(1.2)	7	1.40	1	(0.3)	1	0.21
Rhinitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	6	(1.9)	7	1.40	9	(3.0)	11	2.34
Rotavirus infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Salpingitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Sepsis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Sinusitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	3	(1.6)	5	1.69
>=8% (>=64 mmol/mol)	4	(1.2)	5	1.00	4	(1.3)	6	1.27
Skin bacterial infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Skin infection								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Staphylococcal infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Subcutaneous abscess								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	4	0.85
Tinea infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Tonsillitis								
<8% (<64 mmol/mol)	2	(1.2)	3	1.13	0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.42

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tooth abscess								
<8% (<64 mmol/mol)	0				4	(2.1)	4	1.35
>=8% (>=64 mmol/mol)	5	(1.6)	5	1.00	0			
Tooth infection								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	2	(0.7)	3	0.64
Tracheitis								
<8% (<64 mmol/mol)	1	(0.6)	3	1.13	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Upper respiratory tract infection								
<8% (<64 mmol/mol)	11	(6.5)	18	6.79	10	(5.3)	11	3.72
>=8% (>=64 mmol/mol)	17	(5.3)	22	4.40	12	(3.9)	13	2.76
Urethritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Urinary tract infection								
<8% (<64 mmol/mol)	3	(1.8)	5	1.89	10	(5.3)	13	4.39
>=8% (>=64 mmol/mol)	6	(1.9)	7	1.40	11	(3.6)	12	2.55
Vaginal infection								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Varicella								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Viral infection								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	3	(1.0)	3	0.64
Viral pharyngitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	0				0			
Viral upper respiratory tract infection								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	2	(0.7)	2	0.42
Vulvovaginal candidiasis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.9)	5	1.00	4	(1.3)	4	0.85
Vulvovaginal mycotic infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.40	0			
Wound infection								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			

Injury, poisoning and procedural

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
complications								
All								
<8% (<64 mmol/mol)	36	(21.2)	39	14.71	31	(16.5)	43	14.52
>=8% (>=64 mmol/mol)	53	(16.5)	63	12.59	36	(11.8)	60	12.75
Accidental overdose								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Alcohol poisoning								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Animal bite								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Ankle fracture								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Arthropod bite								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	0				0			
Arthropod sting								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Avulsion fracture								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Bone contusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Burn oral cavity								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Burns first degree								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Cervical vertebral fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Chillblains								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Concussion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Contusion								

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	2	(1.2)	3	1.13	6	(3.2)	7	2.36
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	7	(2.3)	9	1.91
Deafness traumatic								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Endotracheal intubation complication								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Eye injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Fall								
<8% (<64 mmol/mol)	5	(2.9)	6	2.26	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	3	(0.9)	4	0.80	5	(1.6)	6	1.27
Fibula fracture								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Foot fracture								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Hand fracture								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	0			
>=8% (>=64 mmol/mol)	0				0			
Head injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	2	(0.7)	2	0.42
Heat illness								
<8% (<64 mmol/mol)	0				1	(0.5)	2	0.68
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	2	(0.7)	2	0.42
Hip fracture								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Injury								
<8% (<64 mmol/mol)	3	(1.8)	3	1.13	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Joint injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	1	(0.3)	1	0.21
Ligament sprain								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Limb fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Limb injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	4	(1.2)	4	0.80	0			
Lower limb fracture								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Meniscus injury								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Muscle strain								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	0			
>=8% (>=64 mmol/mol)	0				4	(1.3)	4	0.85
Overdose								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Patella fracture								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Periprocedural myocardial infarction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Post procedural fistula								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Post procedural haemorrhage								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Post procedural hypothyroidism								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Post procedural stroke								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Post procedural swelling								
<8% (<64 mmol/mol)	0				1	(0.5)	2	0.68
>=8% (>=64 mmol/mol)	0				0			
Post-traumatic neck syndrome								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Procedural pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Product administration error								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Radius fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	1	(0.3)	1	0.21
Rib fracture								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Road traffic accident								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Scar								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Skin abrasion								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Skin laceration								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Soft tissue injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Spinal column injury								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Spinal cord injury cervical								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Stress fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Subcutaneous haematoma								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Tendon rupture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Thermal burn								
<8% (<64 mmol/mol)	0				3	(1.6)	3	1.01
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Tooth fracture								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Traumatic arthritis								
<8% (<64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.40	0			
Traumatic haematoma								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Ulna fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Underdose								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Upper limb fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Vaccination complication								
<8% (<64 mmol/mol)	6	(3.5)	6	2.26	9	(4.8)	11	3.72
>=8% (>=64 mmol/mol)	6	(1.9)	7	1.40	7	(2.3)	13	2.76
Wound								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	1	(0.3)	1	0.21
Wrist fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Investigations								
All								
<8% (<64 mmol/mol)	12	(7.1)	15	5.66	11	(5.9)	11	3.72
>=8% (>=64 mmol/mol)	23	(7.1)	25	5.00	23	(7.6)	25	5.31
Alanine aminotransferase increased								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Aspartate aminotransferase increased								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Blood cholesterol increased								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Blood creatine increased								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Blood creatine phosphokinase increased								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Blood glucose increased								
<8% (<64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Blood potassium increased								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Blood pressure decreased								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Blood pressure increased								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Blood triglycerides increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Body temperature increased								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Cardiac stress test abnormal								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Electrocardiogram change								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Electrocardiogram repolarisation abnormality								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Electrocardiogram T wave inversion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Glycosylated haemoglobin increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Haemoglobin decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	2	0.42
Hepatic enzyme abnormal								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Hepatic enzyme increased								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
International normalised ratio abnormal								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
International normalised ratio decreased								

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
International normalised ratio increased								
<8% (<64 mmol/mol)	1	(0.6)	2	0.75	0			
>=8% (>=64 mmol/mol)	0				0			
Intraocular pressure increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.40	0			
Lipids increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Low density lipoprotein increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Prostatic specific antigen increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Protein urine present								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Pulse absent								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Red blood cell count decreased								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
SARS-CoV-2 test positive								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	3	(1.0)	3	0.64
Serum ferritin decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Transferrin saturation decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Troponin increased								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Weight decreased								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Weight increased								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	7	(2.2)	7	1.40	9	(3.0)	9	1.91

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
White blood cell count decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Metabolism and nutrition disorders								
All								
<8% (<64 mmol/mol)	20	(11.8)	23	8.67	22	(11.7)	27	9.12
>=8% (>=64 mmol/mol)	39	(12.1)	43	8.59	41	(13.5)	62	13.17
Adult failure to thrive								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Appetite disorder								
<8% (<64 mmol/mol)	0				1	(0.5)	2	0.68
>=8% (>=64 mmol/mol)	0				0			
Decreased appetite								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	4	(1.2)	4	0.80	0			
Dehydration								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.42
Diabetes mellitus								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Diabetes mellitus inadequate control								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Dyslipidaemia								
<8% (<64 mmol/mol)	5	(2.9)	6	2.26	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	9	(2.8)	9	1.80	7	(2.3)	9	1.91
Electrolyte depletion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Electrolyte imbalance								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Fluid retention								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Gout								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.40	1	(0.3)	1	0.21
Hypercalcaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hypercholesterolaemia								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Hyperglycaemia								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				6	(2.0)	6	1.27
Hyperkalaemia								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	0			
>=8% (>=64 mmol/mol)	4	(1.2)	4	0.80	4	(1.3)	4	0.85
Hyperlipidaemia								
<8% (<64 mmol/mol)	3	(1.8)	3	1.13	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	3	(1.0)	3	0.64
Hypertriglyceridaemia								
<8% (<64 mmol/mol)	0				3	(1.6)	3	1.01
>=8% (>=64 mmol/mol)	6	(1.9)	6	1.20	6	(2.0)	6	1.27
Hyperuricaemia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Hypoglycaemia								
<8% (<64 mmol/mol)	3	(1.8)	3	1.13	5	(2.7)	5	1.69
>=8% (>=64 mmol/mol)	4	(1.2)	5	1.00	8	(2.6)	21	4.46
Hypokalaemia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Hypophosphataemia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Increased appetite								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Iron deficiency								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Lactic acidosis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Malnutrition								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Metabolic disorder								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Obesity								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Type 2 diabetes mellitus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Vitamin B12 deficiency								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Vitamin D deficiency								
<8% (<64 mmol/mol)	2	(1.2)	3	1.13	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Zinc deficiency								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Musculoskeletal and connective tissue disorders								
All								
<8% (<64 mmol/mol)	52	(30.6)	95	35.82	41	(21.8)	66	22.29
>=8% (>=64 mmol/mol)	78	(24.2)	123	24.58	76	(25.0)	118	25.07
Arthralgia								
<8% (<64 mmol/mol)	15	(8.8)	18	6.79	7	(3.7)	10	3.38
>=8% (>=64 mmol/mol)	15	(4.7)	18	3.60	15	(4.9)	18	3.82
Arthritis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	2	(1.1)	3	1.01
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	2	(0.7)	2	0.42
Axillary mass								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Back disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Back pain								
<8% (<64 mmol/mol)	20	(11.8)	21	7.92	9	(4.8)	10	3.38
>=8% (>=64 mmol/mol)	20	(6.2)	22	4.40	23	(7.6)	24	5.10
Bone cyst								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Bursitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	2	(0.7)	2	0.42
Cervical spinal stenosis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Chondrodynia								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	0				0			
Chondropathy								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Coccydynia								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Costochondritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Dupuytren's contracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.42
Exostosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Fibromyalgia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Fistula								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Flank pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.42
Fracture nonunion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Gouty arthritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Groin pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Intervertebral disc disorder								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Intervertebral disc protrusion								
<8% (<64 mmol/mol)	3	(1.8)	4	1.51	2	(1.1)	3	1.01
>=8% (>=64 mmol/mol)	4	(1.2)	4	0.80	3	(1.0)	3	0.64
Intervertebral disc space narrowing								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Joint effusion								

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Joint swelling								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.42
Ligamentitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Limb deformity								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Lordosis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Lumbar spinal stenosis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Mastication disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	2	0.42
Muscle contracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Muscle spasms								
<8% (<64 mmol/mol)	5	(2.9)	5	1.89	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	7	(2.2)	7	1.40	2	(0.7)	2	0.42
Muscular weakness								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Musculoskeletal chest pain								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	0			
Musculoskeletal pain								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Musculoskeletal stiffness								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Myalgia								
<8% (<64 mmol/mol)	3	(1.8)	3	1.13	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.42
Myositis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neck pain								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	3	(1.6)	3	1.01
>=8% (>=64 mmol/mol)	5	(1.6)	5	1.00	5	(1.6)	5	1.06
Osteoarthritis								
<8% (<64 mmol/mol)	8	(4.7)	9	3.39	4	(2.1)	5	1.69
>=8% (>=64 mmol/mol)	11	(3.4)	12	2.40	10	(3.3)	12	2.55
Osteochondrosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Osteopenia								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Pain in extremity								
<8% (<64 mmol/mol)	3	(1.8)	3	1.13	5	(2.7)	5	1.69
>=8% (>=64 mmol/mol)	15	(4.7)	20	4.00	9	(3.0)	12	2.55
Periarthritis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	5	(1.6)	5	1.00	3	(1.0)	3	0.64
Plantar fasciitis								
<8% (<64 mmol/mol)	2	(1.2)	3	1.13	0			
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	1	(0.3)	1	0.21
Polyarthritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Rotator cuff syndrome								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Scoliosis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Spinal osteoarthritis								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Spinal pain								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	2	(0.7)	2	0.42
Spinal stenosis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Spondylolisthesis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Synovial cyst								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tendon calcification								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Tendonitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Tenosynovitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	4	(2.1)	5	1.69
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.42
Tenosynovitis stenosans								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Torticollis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Trigger finger								
<8% (<64 mmol/mol)	3	(1.8)	3	1.13	0			
>=8% (>=64 mmol/mol)	0				3	(1.0)	6	1.27
Vertebral osteophyte								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
<8% (<64 mmol/mol)	7	(4.1)	8	3.02	5	(2.7)	7	2.36
>=8% (>=64 mmol/mol)	12	(3.7)	13	2.60	4	(1.3)	6	1.27
Acrochordon								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Basal cell carcinoma								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	0				0			
Colon adenoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Colon cancer								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Dysplastic naevus								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Glioblastoma multiforme								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	0				0			
Haemangioma of liver								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Hepatocellular carcinoma								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Hypergammaglobulinaemia benign monoclonal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Lipoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Lung adenocarcinoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Malignant melanoma in situ								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Metastases to liver								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Metastatic renal cell carcinoma								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Neoplasm skin								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Oral fibroma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Ovarian cancer metastatic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Pancreatic carcinoma metastatic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Pancreatic neoplasm								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Prostate cancer								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Seborrhoeic keratosis								

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	1	(0.6)	2	0.75	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Skin papilloma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Small cell lung cancer								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Squamous cell carcinoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Uterine leiomyoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Nervous system disorders								
All								
<8% (<64 mmol/mol)	28	(16.5)	39	14.71	36	(19.1)	54	18.24
>=8% (>=64 mmol/mol)	56	(17.4)	86	17.19	44	(14.5)	61	12.96
Ageusia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Anosmia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Balance disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Brain injury								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Burning sensation								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Carotid arteriosclerosis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Carotid artery stenosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Carpal tunnel syndrome								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	4	(1.2)	4	0.80	2	(0.7)	2	0.42
Cerebral arteriosclerosis								

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Cerebral atrophy								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Cerebral haemorrhage								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Cerebral infarction								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Cerebrovascular accident								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Cerebrovascular disorder								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Cervical radiculopathy								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Cognitive disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Diabetic neuropathy								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	4	(1.3)	4	0.85
Dizziness								
<8% (<64 mmol/mol)	4	(2.4)	6	2.26	3	(1.6)	3	1.01
>=8% (>=64 mmol/mol)	11	(3.4)	15	3.00	12	(3.9)	13	2.76
Dizziness postural								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Dysgeusia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Essential tremor								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Headache								
<8% (<64 mmol/mol)	9	(5.3)	10	3.77	14	(7.4)	24	8.11
>=8% (>=64 mmol/mol)	13	(4.0)	18	3.60	7	(2.3)	8	1.70
Hypoaesthesia								
<8% (<64 mmol/mol)	2	(1.2)	4	1.51	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	4	(1.2)	4	0.80	3	(1.0)	4	0.85

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hypoglycaemic unconsciousness								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Ischaemic stroke								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Lethargy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.42
Lumbar radiculopathy								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	3	(1.0)	3	0.64
Memory impairment								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Mental impairment								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Metabolic encephalopathy								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Migraine								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	1	(0.3)	1	0.21
Movement disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Muscle tone disorder								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Neuralgia								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Neuroglycopenia								
<8% (<64 mmol/mol)	0				1	(0.5)	3	1.01
>=8% (>=64 mmol/mol)	2	(0.6)	4	0.80	0			
Neuropathy peripheral								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Paraesthesia								
<8% (<64 mmol/mol)	0				3	(1.6)	3	1.01
>=8% (>=64 mmol/mol)	4	(1.2)	4	0.80	2	(0.7)	2	0.42
Parkinsonian gait								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pineal gland cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Post herpetic neuralgia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Presyncope								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.42
Sciatica								
<8% (<64 mmol/mol)	0				3	(1.6)	3	1.01
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	5	(1.6)	8	1.70
Somnolence								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Stiff leg syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Syncope								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	4	(1.2)	6	1.20	1	(0.3)	1	0.21
Tension headache								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.40	0			
Thrombotic stroke								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Transient ischaemic attack								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	0				0			
Tremor								
<8% (<64 mmol/mol)	3	(1.8)	4	1.51	0			
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	1	(0.3)	1	0.21
Trigeminal neuralgia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Vertebral artery occlusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
VIth nerve paralysis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
VIth nerve paresis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	0				0			
Psychiatric disorders								
All								
<8% (<64 mmol/mol)	8	(4.7)	9	3.39	3	(1.6)	3	1.01
>=8% (>=64 mmol/mol)	15	(4.7)	16	3.20	10	(3.3)	10	2.12
Anxiety								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	1	(0.3)	1	0.21
Depressed mood								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Depression								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	5	(1.6)	5	1.00	3	(1.0)	3	0.64
Insomnia								
<8% (<64 mmol/mol)	5	(2.9)	5	1.89	0			
>=8% (>=64 mmol/mol)	4	(1.2)	4	0.80	4	(1.3)	4	0.85
Mood swings								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Nightmare								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Persistent depressive disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Psychotic disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Schizophrenia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Sleep disorder								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Renal and urinary disorders								
All								
<8% (<64 mmol/mol)	5	(2.9)	7	2.64	12	(6.4)	12	4.05
>=8% (>=64 mmol/mol)	15	(4.7)	17	3.40	16	(5.3)	23	4.89
Acute kidney injury								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Calculus urinary								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Chronic kidney disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	4	(1.3)	4	0.85
Diabetic nephropathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Dysuria								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	2	(0.7)	2	0.42
Haematuria								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	2	(0.7)	2	0.42
Hypercalciuria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Hypertonic bladder								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Ketonuria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Microalbuminuria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Nephrolithiasis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	2	(0.7)	2	0.42
Nocturia								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Pollakiuria								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Pyelocaliectasis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Renal colic								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Renal cyst								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	1	(0.5)	1	0.34

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Renal impairment								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	2	(0.7)	2	0.42
Ureterolithiasis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Urinary incontinence								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Urinary retention								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	2	0.42
Urinary tract obstruction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Urine odour abnormal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Reproductive system and breast disorders								
All								
<8% (<64 mmol/mol)	3	(1.8)	3	1.13	5	(2.7)	9	3.04
>=8% (>=64 mmol/mol)	12	(3.7)	12	2.40	11	(3.6)	13	2.76
Adenomyosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Atrophic vulvovaginitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Balanoposthitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Benign prostatic hyperplasia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	3	(1.0)	3	0.64
Breast mass								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Breast pain								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Erectile dysfunction								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Galactorrhoea								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Hydrometra								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Menopausal symptoms								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Ovarian cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Penile rash								
<8% (<64 mmol/mol)	0				1	(0.5)	3	1.01
>=8% (>=64 mmol/mol)	0				0			
Prostatism								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Prostatitis								
<8% (<64 mmol/mol)	0				1	(0.5)	2	0.68
>=8% (>=64 mmol/mol)	0				0			
Pruritus genital								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Uterine haemorrhage								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Uterine polyp								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Uterine prolapse								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Vaginal prolapse								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Vulval eczema								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Vulval leukoplakia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Vulvovaginal dryness								

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Vulvovaginal pruritus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Respiratory, thoracic and mediastinal disorders								
All								
<8% (<64 mmol/mol)	20	(11.8)	29	10.94	21	(11.2)	33	11.15
>=8% (>=64 mmol/mol)	35	(10.9)	47	9.39	27	(8.9)	36	7.65
Acquired diaphragmatic eventration								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Acute pulmonary oedema								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Acute respiratory failure								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Allergic bronchitis								
<8% (<64 mmol/mol)	0				1	(0.5)	2	0.68
>=8% (>=64 mmol/mol)	0				0			
Asthma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.40	1	(0.3)	1	0.21
Bronchiectasis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Bronchitis chronic								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Chronic eosinophilic rhinosinusitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Chronic obstructive pulmonary disease								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Cough								
<8% (<64 mmol/mol)	3	(1.8)	3	1.13	3	(1.6)	4	1.35
>=8% (>=64 mmol/mol)	11	(3.4)	12	2.40	5	(1.6)	5	1.06
Dry throat								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dyspnoea								
<8% (<64 mmol/mol)	0				3	(1.6)	3	1.01
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	3	(1.0)	3	0.64
Dyspnoea exertional								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	2	(0.7)	2	0.42
Emphysema								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Epistaxis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	3	0.64
Haemoptysis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Interstitial lung disease								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Laryngeal cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Nasal congestion								
<8% (<64 mmol/mol)	2	(1.2)	3	1.13	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	1	(0.3)	1	0.21
Nasal dryness								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Nasal turbinate hypertrophy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Oropharyngeal pain								
<8% (<64 mmol/mol)	5	(2.9)	6	2.26	3	(1.6)	5	1.69
>=8% (>=64 mmol/mol)	8	(2.5)	8	1.60	6	(2.0)	8	1.70
Paranasal sinus discomfort								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Pleural calcification								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Pleural effusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Pleuritic pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pneumothorax								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Productive cough								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Pulmonary embolism								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Pulmonary fibrosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.40	0			
Pulmonary mass								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Respiratory disorder								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	3	(1.6)	3	1.01
>=8% (>=64 mmol/mol)	0				0			
Respiratory failure								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Rhinitis allergic								
<8% (<64 mmol/mol)	0				2	(1.1)	6	2.03
>=8% (>=64 mmol/mol)	0				0			
Rhinorrhoea								
<8% (<64 mmol/mol)	3	(1.8)	3	1.13	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	2	(0.7)	2	0.42
Sinus congestion								
<8% (<64 mmol/mol)	1	(0.6)	2	0.75	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Sinus pain								
<8% (<64 mmol/mol)	1	(0.6)	2	0.75	0			
>=8% (>=64 mmol/mol)	0				0			
Sleep apnoea syndrome								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Sneezing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Throat irritation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Upper respiratory tract inflammation								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	0				0			
Upper-airway cough syndrome								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Skin and subcutaneous tissue disorders								
All								
<8% (<64 mmol/mol)	22	(12.9)	29	10.94	20	(10.6)	32	10.81
>=8% (>=64 mmol/mol)	37	(11.5)	48	9.59	33	(10.9)	43	9.14
Actinic keratosis								
<8% (<64 mmol/mol)	1	(0.6)	2	0.75	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Alopecia								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	5	(1.6)	5	1.00	1	(0.3)	1	0.21
Alopecia areata								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Angioedema								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Asteatosis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Blister								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.42
Cellulite								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	2	0.42
Chloasma								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Cold sweat								
<8% (<64 mmol/mol)	2	(1.2)	3	1.13	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	0				0			
Cold urticaria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Dermal cyst								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				3	(1.0)	3	0.64
Dermatitis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	2	(1.1)	2	0.68

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.42
Dermatitis allergic								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Dermatitis contact								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	2	(1.1)	3	1.01
>=8% (>=64 mmol/mol)	5	(1.6)	7	1.40	5	(1.6)	5	1.06
Diabetic foot								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Drug eruption								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Dry skin								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	0			
Ecchymosis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Eczema								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	6	(1.9)	6	1.20	2	(0.7)	2	0.42
Eczema nummular								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Erythema								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Granuloma annulare								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Haemorrhage subcutaneous								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Hyperhidrosis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	1	(0.3)	1	0.21
Hyperkeratosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Ingrowing nail								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Lentigo								

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Lipodystrophy acquired								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Lipohypertrophy								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	0				0			
Macule								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Miliaria								
<8% (<64 mmol/mol)	1	(0.6)	2	0.75	4	(2.1)	4	1.35
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Myxoid cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Night sweats								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Onychalgia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Pruritus								
<8% (<64 mmol/mol)	1	(0.6)	3	1.13	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	2	(0.7)	2	0.42
Psoriasis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Purpura								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Rash								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	6	(2.0)	6	1.27
Rosacea								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Skin exfoliation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Skin fissures								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Skin irritation								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.40	1	(0.3)	1	0.21
Skin lesion								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	2	(0.6)	2	0.40	1	(0.3)	1	0.21
Skin ulcer								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Urticaria								
<8% (<64 mmol/mol)	1	(0.6)	2	0.75	2	(1.1)	2	0.68
>=8% (>=64 mmol/mol)	0				3	(1.0)	3	0.64
Urticaria contact								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Urticaria thermal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Surgical and medical procedures								
All								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Removal of foreign body								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Vascular disorders								
All								
<8% (<64 mmol/mol)	12	(7.1)	17	6.41	16	(8.5)	18	6.08
>=8% (>=64 mmol/mol)	28	(8.7)	32	6.40	27	(8.9)	31	6.59
Aneurysm								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Aortic arteriosclerosis								
<8% (<64 mmol/mol)	2	(1.2)	2	0.75	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Aortic stenosis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Arteriosclerosis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Blood pressure inadequately controlled								

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Brachiocephalic arteriosclerosis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				2	(0.7)	2	0.42
Diabetic vascular disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Flushing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Haematoma								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	1	(0.3)	1	0.21
Hypertension								
<8% (<64 mmol/mol)	3	(1.8)	3	1.13	6	(3.2)	7	2.36
>=8% (>=64 mmol/mol)	12	(3.7)	12	2.40	10	(3.3)	10	2.12
Hypertensive angiopathy								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	1	(0.3)	1	0.21
Hypertensive crisis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Hypertensive urgency								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Hypotension								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	1	(0.3)	1	0.21
Iliac artery stenosis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				0			
Intermittent claudication								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Macroangiopathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Peripheral arterial occlusive disease								
<8% (<64 mmol/mol)	1	(0.6)	2	0.75	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	0				4	(1.3)	4	0.85
Peripheral artery occlusion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Peripheral artery stenosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	2	0.40	0			
Peripheral coldness								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	1	(0.5)	1	0.34
>=8% (>=64 mmol/mol)	3	(0.9)	3	0.60	0			
Peripheral vascular disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Peripheral venous disease								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	2	(0.7)	2	0.42
Post thrombotic syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Secondary hypertension								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Superficial vein thrombosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	0			
Thrombophlebitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(0.3)	1	0.21
Thrombosis								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	0				0			
Varicose vein								
<8% (<64 mmol/mol)	1	(0.6)	1	0.38	0			
>=8% (>=64 mmol/mol)	1	(0.3)	1	0.20	2	(0.7)	2	0.42

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

adsl.xpt; variable(s): ONTRDURY HBAGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD HBAGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"
nn1436/nn1436-japan/submission_ext_20230612_er
21JUN2023:08:58:30 - taesocptgrptrl.R/taesocptgrphba1csumontow1sas.txt

7.24.12 Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<8% (<64 mmol/mol)	189				189			
>=8% (>=64 mmol/mol)	101				103			
PYE (years)								
<8% (<64 mmol/mol)	194.57				202.05			
>=8% (>=64 mmol/mol)	105.59				107.53			
Events								
<8% (<64 mmol/mol)	154	(81.5)	608	312.48	156	(82.5)	689	341.00
>=8% (>=64 mmol/mol)	86	(85.1)	357	338.11	80	(77.7)	457	424.99
Blood and lymphatic system disorders								
All								
<8% (<64 mmol/mol)	4	(2.1)	4	2.06	2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	3	(3.0)	4	3.79	3	(2.9)	4	3.72
Anaemia								
<8% (<64 mmol/mol)	3	(1.6)	3	1.54	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Blood loss anaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Iron deficiency anaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(1.9)	3	2.79
Lymphadenitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Lymphadenopathy								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	1	(1.0)	1	0.93
Splenomegaly								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Thrombocytopenia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Cardiac disorders								
All								
<8% (<64 mmol/mol)	12	(6.3)	13	6.68	6	(3.2)	8	3.96
>=8% (>=64 mmol/mol)	4	(4.0)	5	4.74	5	(4.9)	7	6.51

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Acute myocardial infarction								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Angina pectoris								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	0			
>=8% (>=64 mmol/mol)	0				0			
Angina unstable								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(1.9)	2	1.86
Aortic valve incompetence								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Atrial fibrillation								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Bundle branch block right								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Cardiac failure congestive								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Cardiomegaly								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Cardiovascular disorder								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Conduction disorder								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Coronary artery disease								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Left ventricular hypertrophy								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Mitral valve incompetence								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Myocardial infarction								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Myocardial ischaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Palpitations								
<8% (<64 mmol/mol)	3	(1.6)	3	1.54	3	(1.6)	4	1.98
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Tachycardia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Tricuspid valve incompetence								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Ventricular extrasystoles								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Congenital, familial and genetic disorders								
All								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Arteriovenous malformation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Colour blindness								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	3	(1.6)	3	1.48
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Deafness neurosensory								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Ear pain								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Tinnitus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Tympanic membrane perforation								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Vertigo								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Endocrine disorders								
All								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	0				0			
Autoimmune thyroiditis								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Hypogonadism								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Hypothyroidism								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Thyroiditis chronic								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Eye disorders								
All								
<8% (<64 mmol/mol)	27	(14.3)	43	22.10	26	(13.8)	37	18.31
>=8% (>=64 mmol/mol)	16	(15.8)	19	17.99	20	(19.4)	29	26.97

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Angle closure glaucoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Arteriosclerotic retinopathy								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Astigmatism								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Cataract								
<8% (<64 mmol/mol)	4	(2.1)	4	2.06	4	(2.1)	5	2.47
>=8% (>=64 mmol/mol)	2	(2.0)	2	1.89	0			
Cataract nuclear								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Conjunctival haemorrhage								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Corneal erosion								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Diabetic retinal oedema								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Diabetic retinopathy								
<8% (<64 mmol/mol)	14	(7.4)	16	8.22	14	(7.4)	15	7.42
>=8% (>=64 mmol/mol)	10	(9.9)	12	11.36	12	(11.7)	14	13.02
Dry eye								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Eczema eyelids								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Epiretinal membrane								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Eye pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Glaucoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	3	(2.9)	3	2.79

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Macular oedema								
<8% (<64 mmol/mol)	3	(1.6)	4	2.06	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Myopia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Non-proliferative retinopathy								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	1	(1.0)	1	0.93
Ocular hypertension								
<8% (<64 mmol/mol)	0				2	(1.1)	3	1.48
>=8% (>=64 mmol/mol)	0				0			
Photopsia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Posterior capsule opacification								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	2	1.86
Presbyopia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Pterygium								
<8% (<64 mmol/mol)	0				1	(0.5)	2	0.99
>=8% (>=64 mmol/mol)	0				0			
Retinal drusen								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Retinal haemorrhage								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Retinal vascular disorder								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Retinopathy								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Retinopathy hypertensive								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Strabismus								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			

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Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vision blurred								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Visual acuity reduced								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Vitreous detachment								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	0				0			
Vitreous floaters								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Gastrointestinal disorders								
All								
<8% (<64 mmol/mol)	32	(16.9)	48	24.67	29	(15.3)	47	23.26
>=8% (>=64 mmol/mol)	15	(14.9)	33	31.25	13	(12.6)	28	26.04
Abdominal discomfort								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(2.0)	2	1.89	2	(1.9)	2	1.86
Abdominal distension								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	2	(2.0)	3	2.84	0			
Abdominal pain								
<8% (<64 mmol/mol)	7	(3.7)	7	3.60	0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Abdominal pain upper								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	2	(2.0)	3	2.84	2	(1.9)	2	1.86
Anal fissure								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Change of bowel habit								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Chronic gastritis								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Constipation								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	2	(2.0)	3	2.84	0			
Dental caries								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Diarrhoea								
<8% (<64 mmol/mol)	7	(3.7)	8	4.11	2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	3	(3.0)	5	4.74	4	(3.9)	5	4.65
Diverticulum intestinal								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Duodenitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Dyspepsia								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	1	(1.0)	1	0.93
Enteritis								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Faeces soft								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Flatulence								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Food poisoning								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Gastric polyps								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Gastritis								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Gastritis erosive								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	0				0			
Gastrointestinal haemorrhage								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Gastrooesophageal reflux disease								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	0				0			
Gastrooesophageal sphincter insufficiency								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Gingival recession								
<8% (<64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	0				1	(1.0)	2	1.86
Gingival ulceration								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Haematochezia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Haemorrhoids								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Hiatus hernia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Impaired gastric emptying								
<8% (<64 mmol/mol)	1	(0.5)	2	1.03	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Irritable bowel syndrome								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Lumbar hernia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Mouth ulceration								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Nausea								
<8% (<64 mmol/mol)	4	(2.1)	4	2.06	8	(4.2)	8	3.96
>=8% (>=64 mmol/mol)	5	(5.0)	5	4.74	2	(1.9)	2	1.86
Odynophagia								
<8% (<64 mmol/mol)	0				1	(0.5)	2	0.99
>=8% (>=64 mmol/mol)	0				0			
Oesophagitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Pancreatic failure								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Pancreatitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Pneumatosis intestinalis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Proctitis ulcerative								

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	2	1.86
Toothache								
<8% (<64 mmol/mol)	3	(1.6)	5	2.57	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	2	(1.9)	5	4.65
Vomiting								
<8% (<64 mmol/mol)	7	(3.7)	8	4.11	10	(5.3)	10	4.95
>=8% (>=64 mmol/mol)	4	(4.0)	4	3.79	0			
General disorders and administration site conditions								
All								
<8% (<64 mmol/mol)	40	(21.2)	55	28.27	41	(21.7)	138	68.30
>=8% (>=64 mmol/mol)	15	(14.9)	29	27.47	24	(23.3)	45	41.85
Asthenia								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Chest pain								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Chills								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Complication associated with device								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Facial discomfort								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Facial pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Fatigue								
<8% (<64 mmol/mol)	4	(2.1)	5	2.57	4	(2.1)	4	1.98
>=8% (>=64 mmol/mol)	3	(3.0)	3	2.84	1	(1.0)	1	0.93
Hunger								
<8% (<64 mmol/mol)	0				1	(0.5)	2	0.99
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Hyperthermia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Illness								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Inflammation								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Influenza like illness								
<8% (<64 mmol/mol)	4	(2.1)	4	2.06	3	(1.6)	3	1.48
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Injection site mass								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Injection site pain								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Injection site urticaria								
<8% (<64 mmol/mol)	1	(0.5)	2	1.03	0			
>=8% (>=64 mmol/mol)	0				0			
Malaise								
<8% (<64 mmol/mol)	3	(1.6)	3	1.54	3	(1.6)	75	37.12
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	2	(1.9)	9	8.37
Medical device site bruise								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	2	(2.0)	2	1.89	0			
Medical device site dermatitis								
<8% (<64 mmol/mol)	3	(1.6)	4	2.06	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	2	(2.0)	2	1.89	5	(4.9)	8	7.44
Medical device site erythema								
<8% (<64 mmol/mol)	0				4	(2.1)	5	2.47
>=8% (>=64 mmol/mol)	2	(2.0)	3	2.84	1	(1.0)	2	1.86
Medical device site haematoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Medical device site haemorrhage								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Medical device site inflammation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Medical device site irritation								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Medical device site pain								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Medical device site pruritus								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	4	(2.1)	4	1.98
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Medical device site rash								
<8% (<64 mmol/mol)	4	(2.1)	4	2.06	8	(4.2)	9	4.45
>=8% (>=64 mmol/mol)	3	(3.0)	4	3.79	3	(2.9)	3	2.79
Medical device site reaction								
<8% (<64 mmol/mol)	3	(1.6)	3	1.54	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Medical device site vesicles								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	2	1.89	0			
Nodule								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Non-cardiac chest pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Oedema								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Oedema peripheral								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	1	(1.0)	1	0.93
Pain								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	1	(1.0)	1	0.93
Peripheral swelling								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	0				0			
Pyrexia								
<8% (<64 mmol/mol)	12	(6.3)	16	8.22	15	(7.9)	18	8.91
>=8% (>=64 mmol/mol)	4	(4.0)	6	5.68	5	(4.9)	7	6.51
Swelling face								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Vaccination site discomfort								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Vaccination site joint pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Vaccination site lymphadenopathy								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	0				0			
Vaccination site pain								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Vaccination site swelling								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Hepatobiliary disorders								
All								
<8% (<64 mmol/mol)	5	(2.6)	6	3.08	5	(2.6)	5	2.47
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Cholecystitis chronic								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Gallbladder disorder								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Gallbladder polyp								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	0				0			
Hepatic calcification								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Hepatic function abnormal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Hepatic steatosis								
<8% (<64 mmol/mol)	3	(1.6)	3	1.54	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Hypertransaminasaemia								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
<8% (<64 mmol/mol)	4	(2.1)	4	2.06	4	(2.1)	4	1.98
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	2	(1.9)	2	1.86
Allergy to arthropod bite								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Allergy to arthropod sting								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Hypersensitivity								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Seasonal allergy								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	4	(2.1)	4	1.98
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Infections and infestations								
All								
<8% (<64 mmol/mol)	102	(54.0)	196	100.73	106	(56.1)	201	99.48
>=8% (>=64 mmol/mol)	57	(56.4)	114	107.97	53	(51.5)	102	94.86
Abscess limb								
<8% (<64 mmol/mol)	0				1	(0.5)	2	0.99
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Acute sinusitis								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Asymptomatic COVID-19								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Beta haemolytic streptococcal infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Breast abscess								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Bronchitis								
<8% (<64 mmol/mol)	3	(1.6)	3	1.54	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	2	(2.0)	2	1.89	2	(1.9)	3	2.79
Conjunctivitis								
<8% (<64 mmol/mol)	3	(1.6)	4	2.06	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Coronavirus infection								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
COVID-19								
<8% (<64 mmol/mol)	53	(28.0)	57	29.30	54	(28.6)	58	28.71
>=8% (>=64 mmol/mol)	22	(21.8)	24	22.73	30	(29.1)	31	28.83
COVID-19 pneumonia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	1	(1.0)	1	0.93
Cystitis								
<8% (<64 mmol/mol)	3	(1.6)	3	1.54	3	(1.6)	3	1.48
>=8% (>=64 mmol/mol)	0				0			
Cystitis escherichia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Ear infection								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Erythema migrans								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Eye infection								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Febrile infection								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Fungal infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Fungal skin infection								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Furuncle								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Gastric infection								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Gastroenteritis								
<8% (<64 mmol/mol)	11	(5.8)	16	8.22	2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	2	(2.0)	2	1.89	3	(2.9)	4	3.72
Gastroenteritis viral								
<8% (<64 mmol/mol)	3	(1.6)	3	1.54	2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Gastrointestinal infection								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	2	(1.1)	4	1.98
>=8% (>=64 mmol/mol)	0				0			
Genital infection fungal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	2	1.89	0			
Gingival abscess								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Gingivitis								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Herpes zoster								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Hordeolum								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Impetigo								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Infected cyst								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Influenza								
<8% (<64 mmol/mol)	5	(2.6)	5	2.57	4	(2.1)	4	1.98
>=8% (>=64 mmol/mol)	3	(3.0)	4	3.79	4	(3.9)	5	4.65
Laryngitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Laryngopharyngitis								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Localised infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Lower respiratory tract infection								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Nasopharyngitis								
<8% (<64 mmol/mol)	31	(16.4)	45	23.13	42	(22.2)	59	29.20
>=8% (>=64 mmol/mol)	17	(16.8)	30	28.41	19	(18.4)	25	23.25

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Norovirus infection								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Oral herpes								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Otitis externa								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Otitis media								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Pericoronitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Periodontitis								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Pharyngitis								
<8% (<64 mmol/mol)	4	(2.1)	4	2.06	2	(1.1)	3	1.48
>=8% (>=64 mmol/mol)	4	(4.0)	4	3.79	0			
Pneumonia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	2	(2.0)	2	1.89	0			
Pulpitis dental								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Pyelonephritis acute								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Respiratory tract infection								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Respiratory tract infection viral								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	3	(1.6)	3	1.48
>=8% (>=64 mmol/mol)	2	(2.0)	2	1.89	0			
Rhinitis								
<8% (<64 mmol/mol)	3	(1.6)	3	1.54	3	(1.6)	3	1.48
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	2	(1.9)	3	2.79
Sepsis								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severe acute respiratory syndrome								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Sinobronchitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Sinusitis								
<8% (<64 mmol/mol)	10	(5.3)	10	5.14	4	(2.1)	4	1.98
>=8% (>=64 mmol/mol)	4	(4.0)	5	4.74	5	(4.9)	5	4.65
Skin infection								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	0				0			
Tinea cruris								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Tinea pedis								
<8% (<64 mmol/mol)	2	(1.1)	3	1.54	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Tonsillitis								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	2	(1.1)	3	1.48
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Tooth abscess								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	3	(3.0)	3	2.84	0			
Tooth infection								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	0			
>=8% (>=64 mmol/mol)	0				0			
Tracheobronchitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Trichophytosis								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Upper respiratory tract infection								
<8% (<64 mmol/mol)	8	(4.2)	9	4.63	4	(2.1)	5	2.47
>=8% (>=64 mmol/mol)	7	(6.9)	9	8.52	7	(6.8)	8	7.44
Urinary tract infection								
<8% (<64 mmol/mol)	6	(3.2)	6	3.08	5	(2.6)	7	3.46
>=8% (>=64 mmol/mol)	6	(5.9)	6	5.68	3	(2.9)	3	2.79
Vaginal infection								
<8% (<64 mmol/mol)	1	(0.5)	3	1.54	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Varicella								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Viral infection								
<8% (<64 mmol/mol)	0				4	(2.1)	5	2.47
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	1	(1.0)	1	0.93
Viral rhinitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Vulvitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Vulvovaginal mycotic infection								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Vulvovaginitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Injury, poisoning and procedural complications								
All								
<8% (<64 mmol/mol)	25	(13.2)	38	19.53	32	(16.9)	38	18.81
>=8% (>=64 mmol/mol)	18	(17.8)	23	21.78	18	(17.5)	26	24.18
Accidental overdose								
<8% (<64 mmol/mol)	3	(1.6)	3	1.54	2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	4	(4.0)	5	4.74	0			
Anaemia postoperative								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Animal bite								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Animal scratch								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Ankle fracture								
<8% (<64 mmol/mol)	1	(0.5)	3	1.54	0			
>=8% (>=64 mmol/mol)	0				0			
Arthropod bite								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	3	(1.6)	3	1.48
>=8% (>=64 mmol/mol)	0				0			
Back injury								
<8% (<64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Burns first degree								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Chest injury								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Clavicle fracture								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Concussion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Contusion								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	3	(1.6)	3	1.48
>=8% (>=64 mmol/mol)	0				0			
Corneal abrasion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Epicondylitis								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Face injury								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Fall								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	1	(1.0)	4	3.72
Fibula fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Hand fracture								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Heat stroke								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	0				0			
Incorrect dose administered								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	2	(2.0)	2	1.89	0			
Intentional underdose								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	2	1.86
Joint injury								

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Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Ligament rupture								
<8% (<64 mmol/mol)	1	(0.5)	2	1.03	0			
>=8% (>=64 mmol/mol)	0				0			
Ligament sprain								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	5	(5.0)	5	4.74	1	(1.0)	1	0.93
Limb injury								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Medication error								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Meniscus injury								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Muscle rupture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Muscle strain								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Nerve injury								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Overdose								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Post-traumatic neck syndrome								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Prescribed overdose								
<8% (<64 mmol/mol)	4	(2.1)	4	2.06	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Procedural pain								
<8% (<64 mmol/mol)	1	(0.5)	2	1.03	0			
>=8% (>=64 mmol/mol)	0				0			
Product administration error								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Product dispensing error								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Radius fracture								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Road traffic accident								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	2	(2.0)	3	2.84	0			
Skin abrasion								
<8% (<64 mmol/mol)	3	(1.6)	4	2.06	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Skin laceration								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	1	(1.0)	1	0.93
Stress fracture								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Tendon rupture								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Thermal burn								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Tooth fracture								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Vaccination complication								
<8% (<64 mmol/mol)	4	(2.1)	4	2.06	6	(3.2)	9	4.45
>=8% (>=64 mmol/mol)	2	(2.0)	2	1.89	2	(1.9)	3	2.79
Venous injury								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Wound								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Wound dehiscence								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Wrist fracture								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				2	(1.9)	2	1.86
Wrong product administered								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	0				2	(1.9)	2	1.86

Investigations

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
<8% (<64 mmol/mol)	15	(7.9)	20	10.28	10	(5.3)	12	5.94
>=8% (>=64 mmol/mol)	4	(4.0)	4	3.79	7	(6.8)	7	6.51
Angiogram								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Aspartate aminotransferase increased								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Blood cholesterol increased								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Blood glucose fluctuation								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Blood glucose increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Blood pressure increased								
<8% (<64 mmol/mol)	2	(1.1)	3	1.54	0			
>=8% (>=64 mmol/mol)	0				0			
Blood testosterone decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Blood triglycerides increased								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Blood uric acid increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Body temperature increased								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Cardiac murmur								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Electrocardiogram abnormal								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Electrocardiogram T wave abnormal								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Eosinophil count increased								
<8% (<64 mmol/mol)	0				1	(0.5)	2	0.99
>=8% (>=64 mmol/mol)	0				0			

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Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Glomerular filtration rate decreased								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Haemoglobin decreased								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Heart rate increased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Hepatic enzyme increased								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Hepatitis B virus test positive								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Lipids abnormal								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Low density lipoprotein increased								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Mycobacterium tuberculosis complex test positive								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	0			
>=8% (>=64 mmol/mol)	0				0			
Occult blood positive								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Platelet count decreased								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Pulse absent								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
SARS-CoV-2 test positive								
<8% (<64 mmol/mol)	0				4	(2.1)	4	1.98
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Serum ferritin decreased								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Weight decreased								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Weight increased								
<8% (<64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	2	(2.0)	2	1.89	0			
White blood cell count decreased								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Metabolism and nutrition disorders								
All								
<8% (<64 mmol/mol)	10	(5.3)	13	6.68	9	(4.8)	11	5.44
>=8% (>=64 mmol/mol)	8	(7.9)	11	10.42	7	(6.8)	8	7.44
Decreased appetite								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	0				0			
Dehydration								
<8% (<64 mmol/mol)	0				1	(0.5)	2	0.99
>=8% (>=64 mmol/mol)	0				0			
Diabetic dyslipidaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Diabetic ketoacidosis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Dyslipidaemia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Hypercholesterolaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Hyperlipidaemia								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Hyperuricaemia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Hypoglycaemia								
<8% (<64 mmol/mol)	5	(2.6)	7	3.60	3	(1.6)	4	1.98
>=8% (>=64 mmol/mol)	5	(5.0)	8	7.58	1	(1.0)	1	0.93
Hypokalaemia								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Hyponatraemia								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Insulin resistance								
<8% (<64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Iron deficiency								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Obesity								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Vitamin D deficiency								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				2	(1.9)	2	1.86
Musculoskeletal and connective tissue disorders								
All								
<8% (<64 mmol/mol)	29	(15.3)	35	17.99	34	(18.0)	53	26.23
>=8% (>=64 mmol/mol)	16	(15.8)	23	21.78	22	(21.4)	46	42.78
Acquired claw toe								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Arthralgia								
<8% (<64 mmol/mol)	5	(2.6)	6	3.08	10	(5.3)	11	5.44
>=8% (>=64 mmol/mol)	7	(6.9)	7	6.63	5	(4.9)	5	4.65
Arthritis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Back pain								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	10	(5.3)	11	5.44
>=8% (>=64 mmol/mol)	3	(3.0)	3	2.84	7	(6.8)	20	18.60
Bursitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Chondromalacia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Flank pain								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Foot deformity								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	2	1.86
Groin pain								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Intervertebral disc protrusion								

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	0				2	(1.1)	3	1.48
>=8% (>=64 mmol/mol)	0				0			
Limb discomfort								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Limb mass								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Muscle spasms								
<8% (<64 mmol/mol)	3	(1.6)	3	1.54	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	1	(1.0)	2	1.89	0			
Muscular weakness								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Musculoskeletal stiffness								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Myalgia								
<8% (<64 mmol/mol)	3	(1.6)	3	1.54	3	(1.6)	3	1.48
>=8% (>=64 mmol/mol)	0				5	(4.9)	8	7.44
Myopathy								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Neck pain								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	0				0			
Nodal osteoarthritis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Osteoarthritis								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	2	(2.0)	2	1.89	1	(1.0)	1	0.93
Pain in extremity								
<8% (<64 mmol/mol)	6	(3.2)	6	3.08	10	(5.3)	10	4.95
>=8% (>=64 mmol/mol)	2	(2.0)	2	1.89	3	(2.9)	3	2.79
Periarthritis								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	0				2	(1.9)	2	1.86
Rheumatoid arthritis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	1	(1.0)	1	0.93
Rotator cuff syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Spinal stenosis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Synovial cyst								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Tendonitis								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Tenosynovitis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Trigger finger								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
<8% (<64 mmol/mol)	4	(2.1)	4	2.06	3	(1.6)	4	1.98
>=8% (>=64 mmol/mol)	4	(4.0)	4	3.79	2	(1.9)	2	1.86
Benign neoplasm of thyroid gland								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Benign renal neoplasm								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Colon adenoma								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Eye naevus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	2	(1.9)	2	1.86
Haemangioma of liver								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Lipoma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Melanocytic naevus								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Myeloproliferative neoplasm								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Seborrhoeic keratosis								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Skin papilloma								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Uterine leiomyoma								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	0				0			
Nervous system disorders								
All								
<8% (<64 mmol/mol)	24	(12.7)	39	20.04	27	(14.3)	41	20.29
>=8% (>=64 mmol/mol)	16	(15.8)	33	31.25	12	(11.7)	78	72.54

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ageusia								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Autonomic nervous system imbalance								
<8% (<64 mmol/mol)	1	(0.5)	2	1.03	0			
>=8% (>=64 mmol/mol)	0				0			
Burning sensation								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Carpal tunnel syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Cerebral haemorrhage								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	2	1.89	0			
Cerebral infarction								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Cervicobrachial syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(2.0)	2	1.89	0			
Diabetic neuropathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Disturbance in attention								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	11	10.42	0			
Dizziness								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	4	(2.1)	5	2.47
>=8% (>=64 mmol/mol)	1	(1.0)	2	1.89	1	(1.0)	1	0.93
Dizziness postural								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Encephalopathy								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Haemorrhage intracranial								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Headache								
<8% (<64 mmol/mol)	13	(6.9)	22	11.31	11	(5.8)	14	6.93
>=8% (>=64 mmol/mol)	4	(4.0)	5	4.74	5	(4.9)	8	7.44

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hemiparesis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Hypoaesthesia								
<8% (<64 mmol/mol)	2	(1.1)	3	1.54	2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	0				0			
Hypoglycaemic seizure								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Hypoglycaemic unconsciousness								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Hypotonia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
IIIrd nerve paralysis								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Ischaemic stroke								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Loss of consciousness								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	1	(1.0)	1	0.93
Loss of proprioception								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Migraine								
<8% (<64 mmol/mol)	4	(2.1)	5	2.57	2	(1.1)	3	1.48
>=8% (>=64 mmol/mol)	0				0			
Neuropathy peripheral								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Optic neuritis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Post herpetic neuralgia								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Presyncope								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Radiculopathy								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Restless legs syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Sinus headache								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	1	(1.0)	1	0.93
Somnolence								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Syncope								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	2	(2.0)	2	1.89	0			
Tension headache								
<8% (<64 mmol/mol)	0				1	(0.5)	2	0.99
>=8% (>=64 mmol/mol)	0				0			
Tremor								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	2	(1.1)	5	2.47
>=8% (>=64 mmol/mol)	0				2	(1.9)	63	58.59
Pregnancy, puerperium and perinatal conditions								
All								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Abortion spontaneous								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Abortion threatened								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Psychiatric disorders								
All								
<8% (<64 mmol/mol)	7	(3.7)	7	3.60	9	(4.8)	11	5.44
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	2	(1.9)	3	2.79
Alcohol abuse								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Anxiety								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	4	(2.1)	4	1.98
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Anxiety disorder								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Attention deficit hyperactivity disorder								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Depressed mood								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Depression								
<8% (<64 mmol/mol)	0				4	(2.1)	4	1.98
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Insomnia								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Major depression								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Sleep disorder								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Stress								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	3	(1.6)	6	2.97
>=8% (>=64 mmol/mol)	5	(5.0)	5	4.74	2	(1.9)	2	1.86
Acute kidney injury								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Chronic kidney disease								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Diabetic nephropathy								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Dysuria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(2.0)	2	1.89	0			
Hydrocalyx								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Hypertensive nephropathy								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Microalbuminuria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Pollakiuria								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Proteinuria								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Renal cyst								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Renal pain								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Reproductive system and breast disorders								
All								
<8% (<64 mmol/mol)	8	(4.2)	9	4.63	5	(2.6)	7	3.46
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	3	(2.9)	3	2.79

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Atrophic vulvovaginitis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Benign prostatic hyperplasia								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Dysmenorrhoea								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Ectropion of cervix								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Erectile dysfunction								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Fibrocystic breast disease								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Heavy menstrual bleeding								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Menstruation irregular								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Ovarian cyst								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Ovarian disorder								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Penile pain								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Premenstrual syndrome								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Prostatic cyst								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Prostatitis								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Prostatomegaly								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Respiratory, thoracic and mediastinal disorders								
All								
<8% (<64 mmol/mol)	21	(11.1)	28	14.39	20	(10.6)	27	13.36
>=8% (>=64 mmol/mol)	15	(14.9)	26	24.62	17	(16.5)	30	27.90
Acute respiratory failure								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Allergic cough								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Asthma								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Bronchial hyperreactivity								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Cough								
<8% (<64 mmol/mol)	5	(2.6)	7	3.60	5	(2.6)	6	2.97
>=8% (>=64 mmol/mol)	4	(4.0)	5	4.74	6	(5.8)	9	8.37
Cough variant asthma								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Dysphonia								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Dyspnoea								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	2	(2.0)	2	1.89	1	(1.0)	1	0.93
Dyspnoea exertional								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	1	(1.0)	1	0.93
Epiglottic oedema								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Epistaxis								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Hiccups								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Nasal congestion								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	1	(1.0)	1	0.93
Oropharyngeal discomfort								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Oropharyngeal pain								
<8% (<64 mmol/mol)	4	(2.1)	4	2.06	6	(3.2)	6	2.97
>=8% (>=64 mmol/mol)	4	(4.0)	5	4.74	4	(3.9)	5	4.65
Pleurisy								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Productive cough								
<8% (<64 mmol/mol)	0				1	(0.5)	2	0.99
>=8% (>=64 mmol/mol)	0				2	(1.9)	2	1.86
Pulmonary congestion								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Pulmonary mass								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	1	(1.0)	1	0.93
Respiratory disorder								
<8% (<64 mmol/mol)	3	(1.6)	3	1.54	2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Rhinitis allergic								
<8% (<64 mmol/mol)	2	(1.1)	3	1.54	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	1	(1.0)	1	0.93
Rhinorrhoea								
<8% (<64 mmol/mol)	2	(1.1)	3	1.54	2	(1.1)	3	1.48
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	5	(4.9)	5	4.65
Sinus congestion								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	1	(1.0)	1	0.93
Sleep apnoea syndrome								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Sneezing								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Throat irritation								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Upper-airway cough syndrome								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Skin and subcutaneous tissue disorders								
All								
<8% (<64 mmol/mol)	23	(12.2)	26	13.36	25	(13.2)	28	13.86
>=8% (>=64 mmol/mol)	13	(12.9)	16	15.15	15	(14.6)	26	24.18
Alopecia								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	2	(2.0)	2	1.89	0			
Alopecia areata								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Angioedema								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Chronic spontaneous urticaria								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Cold sweat								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				4	(3.9)	9	8.37
Dermal cyst								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Dermatitis								
<8% (<64 mmol/mol)	3	(1.6)	4	2.06	2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	2	(2.0)	3	2.84	1	(1.0)	2	1.86
Dermatitis allergic								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Dermatitis atopic								
<8% (<64 mmol/mol)	0				2	(1.1)	2	0.99
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Dermatitis contact								
<8% (<64 mmol/mol)	3	(1.6)	3	1.54	4	(2.1)	4	1.98
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	3	(2.9)	3	2.79
Dry skin								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Eczema								
<8% (<64 mmol/mol)	0				3	(1.6)	3	1.48
>=8% (>=64 mmol/mol)	0				0			
Eczema asteatotic								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Erythema								

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Erythema multiforme								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Hidradenitis								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Hyperkeratosis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Ingrowing nail								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	2	(1.9)	2	1.86
Ingrown hair								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Lichen sclerosus								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Macule								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Miliaria								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Pruritus								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				2	(1.9)	2	1.86
Psoriasis								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Rash								
<8% (<64 mmol/mol)	3	(1.6)	3	1.54	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	2	(1.9)	2	1.86
Rash erythematous								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Seborrhoeic dermatitis								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Skin fissures								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Skin irritation								
<8% (<64 mmol/mol)	2	(1.1)	2	1.03	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Skin lesion								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Skin reaction								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Skin ulcer								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Telangiectasia								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Urticaria								
<8% (<64 mmol/mol)	0				3	(1.6)	3	1.48
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Urticaria papular								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Vitiligo								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Xeroderma								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Surgical and medical procedures								
All								
<8% (<64 mmol/mol)	4	(2.1)	4	2.06	0			
>=8% (>=64 mmol/mol)	0				0			
Cardiac ablation								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Skin neoplasm excision								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Tooth extraction								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Wisdom teeth removal								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			

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

Adverse events by baseline HbA1c group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vascular disorders								
All								
<8% (<64 mmol/mol)	8	(4.2)	8	4.11	3	(1.6)	4	1.98
>=8% (>=64 mmol/mol)	3	(3.0)	3	2.84	7	(6.8)	7	6.51
Aortic aneurysm								
<8% (<64 mmol/mol)	0				0			
>=8% (>=64 mmol/mol)	0				1	(1.0)	1	0.93
Arteriosclerosis								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	0				0			
Brachiocephalic artery stenosis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Hypertension								
<8% (<64 mmol/mol)	6	(3.2)	6	3.08	1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	2	(2.0)	2	1.89	6	(5.8)	6	5.58
Hypertensive crisis								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			
Hypotension								
<8% (<64 mmol/mol)	1	(0.5)	1	0.51	0			
>=8% (>=64 mmol/mol)	1	(1.0)	1	0.95	0			
Varicose vein								
<8% (<64 mmol/mol)	0				1	(0.5)	1	0.49
>=8% (>=64 mmol/mol)	0				0			

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

adsl.xpt; variable(s): ONTRDURY HBAGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD HBAGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL02FL) == "Y" & (ANELFL) == "Y"
nn1436/nn1436-japan/submission_ext_20230612_er
21JUN2023:08:58:34 - taesocptgrptrl.R/taesocptgrphba1csumontow6sas.txt

7.24.13 Adverse events by diabetes duration - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<10 years	211				230			
>=10 years	281				262			
PYE (years)								
<10 years	328.31				356.86			
>=10 years	437.19				409.89			
Events								
<10 years	164	(77.7)	727	221.44	172	(74.8)	821	230.06
>=10 years	233	(82.9)	1155	264.19	217	(82.8)	1002	244.45
Serious								
Yes								
<10 years	19	(9.0)	25	7.61	24	(10.4)	35	9.81
>=10 years	45	(16.0)	70	16.01	47	(17.9)	84	20.49
No								
<10 years	160	(75.8)	702	213.82	170	(73.9)	786	220.25
>=10 years	227	(80.8)	1085	248.18	210	(80.2)	918	223.96
Missing								
<10 years	0				0			
>=10 years	0				0			
Severity								
Severe								
<10 years	7	(3.3)	9	2.74	12	(5.2)	19	5.32
>=10 years	19	(6.8)	29	6.63	24	(9.2)	42	10.25
Moderate								
<10 years	69	(32.7)	138	42.03	82	(35.7)	186	52.12
>=10 years	123	(43.8)	263	60.16	101	(38.5)	211	51.48
Mild								
<10 years	149	(70.6)	580	176.66	148	(64.3)	616	172.62
>=10 years	202	(71.9)	863	197.40	192	(73.3)	749	182.73
Missing								
<10 years	0				0			
>=10 years	0				0			

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

adsl.xpt ; variable(s): ONTRDURY DIABGR1 ; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & ANELFL == "Y" & ANL02FL == "Y"
nn1436/nn1436-japan/submission_ext_20230612_er
21JUN2023:08:59:25 - taesumgrptrl.R/taegrpdiadursumontow1sas.txt

Adverse events by diabetes duration - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to basal insulin								
Probable								
<10 years	12	(5.7)	21	6.40	14	(6.1)	24	6.73
>=10 years	18	(6.4)	22	5.03	19	(7.3)	27	6.59
Possible								
<10 years	19	(9.0)	26	7.92	16	(7.0)	24	6.73
>=10 years	27	(9.6)	41	9.38	23	(8.8)	36	8.78
Unlikely								
<10 years	163	(77.3)	680	207.12	167	(72.6)	771	216.05
>=10 years	229	(81.5)	1090	249.32	211	(80.5)	935	228.11
Missing								
<10 years	0				2	(0.9)	2	0.56
>=10 years	2	(0.7)	2	0.46	3	(1.1)	4	0.98
Related to technical complaint for basal insulin								
Yes								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
No								
<10 years	164	(77.7)	727	221.44	172	(74.8)	818	229.22
>=10 years	233	(82.9)	1154	263.96	216	(82.4)	998	243.48
NA								
<10 years	0				0			
>=10 years	0				0			
Missing								
<10 years	0				2	(0.9)	2	0.56
>=10 years	1	(0.4)	1	0.23	3	(1.1)	4	0.98

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

Adverse events by diabetes duration - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	4	(1.4)	6	1.37	3	(1.1)	7	1.71
Not recovered/not resolved								
<10 years	79	(37.4)	166	50.56	95	(41.3)	195	54.64
>=10 years	134	(47.7)	342	78.23	121	(46.2)	252	61.48
Recovered/resolved with sequelae								
<10 years	4	(1.9)	4	1.22	4	(1.7)	4	1.12
>=10 years	5	(1.8)	5	1.14	4	(1.5)	4	0.98
Recovering/resolving								
<10 years	10	(4.7)	16	4.87	12	(5.2)	19	5.32
>=10 years	11	(3.9)	12	2.74	18	(6.9)	20	4.88
Recovered/resolved								
<10 years	143	(67.8)	540	164.48	159	(69.1)	603	168.97
>=10 years	211	(75.1)	790	180.70	192	(73.3)	719	175.41
Unknown								
<10 years	0				0			
					0			
>=10 years	0				0			
					0			
Missing								
<10 years	0				0			
>=10 years	0				0			

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

7.24.14 Adverse events by diabetes duration - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<10 years	75				82			
>=10 years	215				210			
PYE (years)								
<10 years	77.55				87.29			
>=10 years	222.61				222.29			
Events								
<10 years	58	(77.3)	270	348.15	64	(78.0)	267	305.87
>=10 years	182	(84.7)	695	312.21	172	(81.9)	879	395.43
Serious								
Yes								
<10 years	8	(10.7)	8	10.32	4	(4.9)	4	4.58
>=10 years	16	(7.4)	31	13.93	16	(7.6)	21	9.45
No								
<10 years	56	(74.7)	262	337.84	64	(78.0)	263	301.29
>=10 years	181	(84.2)	664	298.28	172	(81.9)	858	385.98
Missing								
<10 years	0				0			
>=10 years	0				0			
Severity								
Severe								
<10 years	9	(12.0)	12	15.47	0			
>=10 years	11	(5.1)	16	7.19	9	(4.3)	10	4.50
Moderate								
<10 years	23	(30.7)	52	67.05	18	(22.0)	31	35.51
>=10 years	60	(27.9)	127	57.05	64	(30.5)	128	57.58
Mild								
<10 years	52	(69.3)	206	265.63	60	(73.2)	236	270.36
>=10 years	167	(77.7)	552	247.97	159	(75.7)	741	333.35
Missing								
<10 years	0				0			
>=10 years	0				0			

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

Adverse events by diabetes duration - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to basal insulin								
Probable								
<10 years	6	(8.0)	6	7.74	5	(6.1)	5	5.73
>=10 years	14	(6.5)	19	8.54	6	(2.9)	7	3.15
Possible								
<10 years	5	(6.7)	8	10.32	5	(6.1)	5	5.73
>=10 years	25	(11.6)	28	12.58	17	(8.1)	67	30.14
Unlikely								
<10 years	56	(74.7)	255	328.81	64	(78.0)	257	294.42
>=10 years	178	(82.8)	648	291.10	170	(81.0)	805	362.14
Missing								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Related to technical complaint for basal insulin								
Yes								
<10 years	0				0			
>=10 years	0				0			
No								
<10 years	58	(77.3)	269	346.86	64	(78.0)	267	305.87
>=10 years	182	(84.7)	695	312.21	172	(81.9)	879	395.43
NA								
<10 years	0				0			
>=10 years	0				0			
Missing								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			

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

Adverse events by diabetes duration - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Not recovered/not resolved								
<10 years	30	(40.0)	43	55.45	27	(32.9)	56	64.15
>=10 years	75	(34.9)	152	68.28	77	(36.7)	161	72.43
Recovered/resolved with sequelae								
<10 years	1	(1.3)	1	1.29	1	(1.2)	1	1.15
>=10 years	1	(0.5)	2	0.90	2	(1.0)	2	0.90
Recovering/resolving								
<10 years	5	(6.7)	5	6.45	3	(3.7)	4	4.58
>=10 years	15	(7.0)	19	8.54	17	(8.1)	21	9.45
Recovered/resolved								
<10 years	54	(72.0)	220	283.68	59	(72.0)	206	235.99
>=10 years	167	(77.7)	522	234.49	154	(73.3)	695	312.65
Unknown								
<10 years	0				0 0			
>=10 years	0				0 0			
Missing								
<10 years	0				0			
>=10 years	0				0			

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

7.24.15 Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<10 years	211				230			
>=10 years	281				262			
PYE (years)								
<10 years	328.31				356.86			
>=10 years	437.19				409.89			
Events								
<10 years	164	(77.7)	727	221.44	172	(74.8)	821	230.06
>=10 years	233	(82.9)	1155	264.19	217	(82.8)	1002	244.45
Blood and lymphatic system disorders								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
<10 years	4	(1.9)	5	1.52	7	(3.0)	7	1.96
>=10 years	11	(3.9)	12	2.74	12	(4.6)	13	3.17
Anaemia								
<10 years	3	(1.4)	3	0.91	3	(1.3)	3	0.84
>=10 years	7	(2.5)	7	1.60	7	(2.7)	8	1.95
Blood loss anaemia								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Eosinophilia								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Hypochromic anaemia								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Iron deficiency anaemia								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	2	(0.7)	2	0.46	1	(0.4)	1	0.24
Lymphadenopathy								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Normochromic normocytic anaemia								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Polycythaemia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Thrombocytopenia								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Cardiac disorders								
All								
<10 years	16	(7.6)	25	7.61	11	(4.8)	20	5.60
>=10 years	28	(10.0)	54	12.35	31	(11.8)	41	10.00
Acute coronary syndrome								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Acute myocardial infarction								
<10 years	2	(0.9)	2	0.61	0			
>=10 years	2	(0.7)	2	0.46	5	(1.9)	5	1.22
Angina pectoris								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.46	2	(0.8)	2	0.49

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

adsl.xpt; variable(s): ONTRDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Angina unstable								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	4	(1.4)	4	0.91	1	(0.4)	1	0.24
Aortic valve calcification								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Aortic valve incompetence								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	1	(0.4)	1	0.23	0			
Arrhythmia								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Arteriosclerosis coronary artery								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Atrial fibrillation								
<10 years	3	(1.4)	3	0.91	3	(1.3)	6	1.68
>=10 years	5	(1.8)	6	1.37	3	(1.1)	3	0.73
Atrial flutter								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	2	0.46	0			
Atrial thrombosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Atrioventricular block complete								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Atrioventricular block first degree								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Atrioventricular block second degree								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Bradycardia								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Bundle branch block left								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Bundle branch block right								
<10 years	1	(0.5)	1	0.30	2	(0.9)	3	0.84
>=10 years	1	(0.4)	1	0.23	0			
Cardiac dysfunction								
<10 years	0				1	(0.4)	1	0.28

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

adsl.xpt; variable(s): ONTRDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	0				0			
Cardiac failure								
<10 years	2	(0.9)	2	0.61	0			
>=10 years	2	(0.7)	2	0.46	1	(0.4)	1	0.24
Cardiac failure chronic								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	2	(0.7)	2	0.46	1	(0.4)	1	0.24
Cardiac failure congestive								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.46	1	(0.4)	1	0.24
Cardiac ventricular thrombosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Cardio-respiratory arrest								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Cardiomyopathy								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Chronic coronary syndrome								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Congestive cardiomyopathy								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Coronary artery disease								
<10 years	2	(0.9)	2	0.61	0			
>=10 years	4	(1.4)	4	0.91	3	(1.1)	3	0.73
Coronary artery occlusion								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.46	0			
Coronary artery stenosis								
<10 years	0				0			
>=10 years	2	(0.7)	3	0.69	0			
Diastolic dysfunction								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Left atrial dilatation								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Left ventricular dysfunction								
<10 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Left ventricular hypertrophy								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.46	1	(0.4)	1	0.24
Mitral valve incompetence								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Myocardial infarction								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	2	(0.7)	2	0.46	2	(0.8)	2	0.49
Myocardial ischaemia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Palpitations								
<10 years	2	(0.9)	2	0.61	1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	3	(1.1)	4	0.98
Pericardial effusion								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Pericarditis								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Sinus arrhythmia								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Sinus bradycardia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Sinus tachycardia								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				2	(0.8)	2	0.49
Supraventricular extrasystoles								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				2	(0.8)	2	0.49
Supraventricular tachycardia								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Tachycardia								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tricuspid valve incompetence								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Ventricular extrasystoles								
<10 years	3	(1.4)	3	0.91	0			
>=10 years	2	(0.7)	2	0.46	1	(0.4)	1	0.24
Congenital, familial and genetic disorders								
All								
<10 years	0				1	(0.4)	1	0.28
>=10 years	3	(1.1)	3	0.69	1	(0.4)	1	0.24
Congenital syphilitic osteochondritis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Corneal dystrophy								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Dolichocolon								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Hydrocele								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Type V hyperlipidaemia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
<10 years	6	(2.8)	7	2.13	4	(1.7)	4	1.12
>=10 years	6	(2.1)	6	1.37	9	(3.4)	10	2.44
Cerumen impaction								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Ear discomfort								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Ear inflammation								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Ear pain								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				1	(0.4)	1	0.24
Eustachian tube dysfunction								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Hypoacusis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Presbyacusis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Tinnitus								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Vertigo								
<10 years	4	(1.9)	5	1.52	2	(0.9)	2	0.56
>=10 years	2	(0.7)	2	0.46	5	(1.9)	6	1.46
Vertigo positional								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
<10 years	0				6	(2.6)	6	1.68
>=10 years	4	(1.4)	4	0.91	2	(0.8)	2	0.49
Goitre								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Hyperplasia adrenal								
<10 years	0				2	(0.9)	2	0.56
>=10 years	0				0			
Hyperprolactinaemia								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Hyperthyroidism								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Hypothyroidism								
<10 years	0				1	(0.4)	1	0.28
>=10 years	2	(0.7)	2	0.46	0			
Thyroid mass								
<10 years	0				1	(0.4)	1	0.28
>=10 years	2	(0.7)	2	0.46	0			
Eye disorders								
All								
<10 years	30	(14.2)	36	10.97	35	(15.2)	54	15.13
>=10 years	59	(21.0)	91	20.81	41	(15.6)	65	15.86
Acquired epiblepharon								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Age-related macular degeneration								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Asthenopia								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.46	1	(0.4)	1	0.24
Astigmatism								
<10 years	2	(0.9)	2	0.61	0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Blepharitis								
<10 years	0				0			
>=10 years	4	(1.4)	4	0.91	0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blepharitis allergic								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Cataract								
<10 years	6	(2.8)	7	2.13	4	(1.7)	5	1.40
>=10 years	12	(4.3)	16	3.66	8	(3.1)	10	2.44
Cataract diabetic								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Cataract nuclear								
<10 years	1	(0.5)	1	0.30	2	(0.9)	2	0.56
>=10 years	0				0			
Cataract subcapsular								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Chorioretinal disorder								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Conjunctival cyst								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Conjunctival erosion								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Conjunctival haemorrhage								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				2	(0.8)	2	0.49
Conjunctival hyperaemia								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Conjunctivitis allergic								
<10 years	0				1	(0.4)	1	0.28
>=10 years	4	(1.4)	5	1.14	0			
Corneal opacity								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Dacryoadenitis acquired								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Dermatochalasis								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Diabetic retinal oedema								
<10 years	0				4	(1.7)	4	1.12
>=10 years	1	(0.4)	1	0.23	2	(0.8)	2	0.49

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Diabetic retinopathy								
<10 years	13	(6.2)	14	4.26	15	(6.5)	20	5.60
>=10 years	23	(8.2)	27	6.18	17	(6.5)	18	4.39
Dry age-related macular degeneration								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Dry eye								
<10 years	0				3	(1.3)	3	0.84
>=10 years	5	(1.8)	5	1.14	2	(0.8)	2	0.49
Eye discharge								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Eye disorder								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Eye inflammation								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Eye irritation								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Eye pain								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Eyelid ptosis								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Giant papillary conjunctivitis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Glaucoma								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.46	1	(0.4)	1	0.24
Iritis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Macular oedema								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	2	(0.7)	2	0.46	1	(0.4)	1	0.24
Myopia								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Non-proliferative retinopathy								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Normal tension glaucoma								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Ocular hypertension								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Open angle glaucoma								
<10 years	0				1	(0.4)	2	0.56
>=10 years	0				0			
Optic disc vascular disorder								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Optic ischaemic neuropathy								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Photophobia								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Post thrombotic retinopathy								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Posterior capsule opacification								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Presbyopia								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Pterygium								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Punctate keratitis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Retinal aneurysm								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Retinal artery occlusion								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Retinal degeneration								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	0				0			
Retinal detachment								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Retinal drusen								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Retinal haemorrhage								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Retinal tear								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Retinal vascular disorder								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Retinal vein occlusion								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Retinal vein thrombosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Retinopathy								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Retinopathy hypertensive								
<10 years	1	(0.5)	1	0.30	2	(0.9)	2	0.56
>=10 years	1	(0.4)	1	0.23	0			
Retinopathy proliferative								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Scintillating scotoma								
<10 years	0				1	(0.4)	2	0.56
>=10 years	0				0			
Uveitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Vision blurred								
<10 years	1	(0.5)	1	0.30	2	(0.9)	2	0.56
>=10 years	1	(0.4)	1	0.23	2	(0.8)	2	0.49

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Visual impairment								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	2	(0.8)	2	0.49
Vitreous detachment								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Vitreous floaters								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Vitreous haemorrhage								
<10 years	0				0			
>=10 years	0				2	(0.8)	2	0.49
Vitreous opacities								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Gastrointestinal disorders								
All								
<10 years	43	(20.4)	80	24.37	38	(16.5)	65	18.21
>=10 years	69	(24.6)	122	27.91	66	(25.2)	113	27.57
Abdominal discomfort								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	1	(0.4)	1	0.23	3	(1.1)	6	1.46
Abdominal distension								
<10 years	4	(1.9)	5	1.52	0			
>=10 years	4	(1.4)	4	0.91	2	(0.8)	2	0.49
Abdominal hernia								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Abdominal pain								
<10 years	3	(1.4)	3	0.91	6	(2.6)	6	1.68
>=10 years	5	(1.8)	5	1.14	1	(0.4)	1	0.24
Abdominal pain lower								
<10 years	1	(0.5)	2	0.61	1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Abdominal pain upper								
<10 years	0				3	(1.3)	4	1.12
>=10 years	3	(1.1)	3	0.69	2	(0.8)	2	0.49
Abdominal wall haematoma								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Acid peptic disease								
<10 years	0				0			
>=10 years	0				2	(0.8)	2	0.49

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Anal eczema								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Anal fissure								
<10 years	0				2	(0.9)	2	0.56
>=10 years	1	(0.4)	1	0.23	0			
Anal pruritus								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Angular cheilitis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Aphthous ulcer								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Ascites								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Barrett's oesophagus								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Chronic gastritis								
<10 years	0				3	(1.3)	3	0.84
>=10 years	4	(1.4)	4	0.91	3	(1.1)	3	0.73
Colitis								
<10 years	1	(0.5)	1	0.30	2	(0.9)	2	0.56
>=10 years	0				1	(0.4)	1	0.24
Colitis ischaemic								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Colitis microscopic								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Constipation								
<10 years	3	(1.4)	3	0.91	0			
>=10 years	5	(1.8)	5	1.14	6	(2.3)	6	1.46
Crohn's disease								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Dental caries								
<10 years	2	(0.9)	2	0.61	1	(0.4)	1	0.28
>=10 years	7	(2.5)	9	2.06	0			
Diarrhoea								
<10 years	12	(5.7)	15	4.57	9	(3.9)	10	2.80

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

adsl.xpt; variable(s): ONTRDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	27	(9.6)	39	8.92	17	(6.5)	19	4.64
Diverticulum								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				3	(1.1)	3	0.73
Diverticulum intestinal								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.46	0			
Dry mouth								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Duodenal ulcer								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Duodenitis								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				1	(0.4)	1	0.24
Duodenogastric reflux								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Dyspepsia								
<10 years	4	(1.9)	4	1.22	1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	3	(1.1)	3	0.73
Enteritis								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				1	(0.4)	1	0.24
Enterocolitis								
<10 years	2	(0.9)	3	0.91	0			
>=10 years	1	(0.4)	1	0.23	0			
Epigastric discomfort								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Erosive duodenitis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Flatulence								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	2	(0.7)	2	0.46	0			
Food poisoning								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	0				2	(0.8)	2	0.49
Frequent bowel movements								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Gastric disorder								

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

adsl.xpt; variable(s): ONTRDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Gastric polyps								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				1	(0.4)	1	0.24
Gastritis								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	1	(0.4)	1	0.23	2	(0.8)	2	0.49
Gastritis erosive								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Gastrointestinal disorder								
<10 years	0				0			
>=10 years	0				2	(0.8)	2	0.49
Gastrointestinal haemorrhage								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Gastrointestinal inflammation								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Gastrooesophageal reflux disease								
<10 years	3	(1.4)	3	0.91	3	(1.3)	3	0.84
>=10 years	5	(1.8)	5	1.14	5	(1.9)	5	1.22
Haematemesis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Haematochezia								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.46	0			
Haemorrhoids								
<10 years	3	(1.4)	3	0.91	2	(0.9)	2	0.56
>=10 years	1	(0.4)	1	0.23	3	(1.1)	3	0.73
Hiatus hernia								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Hyperaesthesia teeth								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Hyperchlorhydria								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Ileus								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			

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

adsl.xpt; variable(s): ONTRDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Inguinal hernia								
<10 years	0				0			
>=10 years	0				1	(0.4)	2	0.49
Intestinal obstruction								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Irritable bowel syndrome								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Large intestine polyp								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.46	3	(1.1)	4	0.98
Loose tooth								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Melaena								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Nausea								
<10 years	8	(3.8)	9	2.74	3	(1.3)	3	0.84
>=10 years	12	(4.3)	13	2.97	6	(2.3)	8	1.95
Odynophagia								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Oral discomfort								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Pancreatitis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	2	(0.7)	2	0.46	0			
Pancreatitis acute								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Pancreatitis chronic								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Periodontal disease								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Periodontal inflammation								
<10 years	0				0			
>=10 years	0				1	(0.4)	2	0.49
Portal hypertensive gastropathy								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Rectal polyp								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	0				0			
Rectal prolapse								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Salivary gland calculus								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Stomatitis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Tooth disorder								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Tooth impacted								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Tooth loss								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Toothache								
<10 years	7	(3.3)	7	2.13	3	(1.3)	3	0.84
>=10 years	4	(1.4)	5	1.14	1	(0.4)	1	0.24
Ulcerative gastritis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Umbilical hernia								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				2	(0.8)	2	0.49
Varices oesophageal								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Vomiting								
<10 years	5	(2.4)	5	1.52	4	(1.7)	6	1.68
>=10 years	2	(0.7)	2	0.46	7	(2.7)	9	2.20
General disorders and administration site conditions								
All								
<10 years	33	(15.6)	70	21.32	43	(18.7)	69	19.34
>=10 years	58	(20.6)	90	20.59	55	(21.0)	81	19.76
Asthenia								
<10 years	2	(0.9)	2	0.61	1	(0.4)	1	0.28

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

adsl.xpt; variable(s): ONTRDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	3	(1.1)	4	0.91	5	(1.9)	5	1.22
Chest discomfort								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	2	(0.7)	2	0.46	2	(0.8)	2	0.49
Chest pain								
<10 years	1	(0.5)	1	0.30	4	(1.7)	4	1.12
>=10 years	3	(1.1)	3	0.69	3	(1.1)	3	0.73
Chills								
<10 years	1	(0.5)	1	0.30	2	(0.9)	2	0.56
>=10 years	1	(0.4)	1	0.23	0			
Cyst								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Death								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Discomfort								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				1	(0.4)	1	0.24
Drug intolerance								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	1	(0.4)	1	0.23	0			
Early satiety								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Effusion								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Fatigue								
<10 years	8	(3.8)	9	2.74	2	(0.9)	2	0.56
>=10 years	8	(2.8)	9	2.06	5	(1.9)	6	1.46
Feeling abnormal								
<10 years	1	(0.5)	5	1.52	1	(0.4)	1	0.28
>=10 years	1	(0.4)	2	0.46	0			
Feeling hot								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Gait disturbance								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.46	0			
Hunger								
<10 years	3	(1.4)	4	1.22	1	(0.4)	1	0.28
>=10 years	2	(0.7)	2	0.46	1	(0.4)	1	0.24
Implant site pruritus								

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

adsl.xpt; variable(s): ONTRDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Inflammation								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Influenza like illness								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Injection site bruising								
<10 years	0				2	(0.9)	2	0.56
>=10 years	1	(0.4)	1	0.23	0			
Injection site dermatitis								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Injection site erythema								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				4	(1.5)	4	0.98
Injection site haemorrhage								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Injection site hypersensitivity								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	1	(0.4)	1	0.23	0			
Injection site hypertrophy								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Injection site mass								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Injection site pain								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Injection site reaction								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				1	(0.4)	1	0.24
Injection site urticaria								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Malaise								
<10 years	3	(1.4)	4	1.22	4	(1.7)	5	1.40
>=10 years	4	(1.4)	5	1.14	6	(2.3)	7	1.71
Mass								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Medical device site bruise								
<10 years	4	(1.9)	5	1.52	1	(0.4)	2	0.56
>=10 years	1	(0.4)	1	0.23	0			
Medical device site dermatitis								
<10 years	1	(0.5)	4	1.22	5	(2.2)	11	3.08
>=10 years	1	(0.4)	1	0.23	4	(1.5)	4	0.98
Medical device site discomfort								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Medical device site eczema								
<10 years	0				1	(0.4)	2	0.56
>=10 years	1	(0.4)	2	0.46	1	(0.4)	2	0.49
Medical device site erythema								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Medical device site haematoma								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Medical device site haemorrhage								
<10 years	2	(0.9)	2	0.61	1	(0.4)	1	0.28
>=10 years	2	(0.7)	2	0.46	1	(0.4)	1	0.24
Medical device site hypersensitivity								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	1	(0.4)	2	0.46	0			
Medical device site inflammation								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Medical device site pain								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	0				0			
Medical device site pruritus								
<10 years	2	(0.9)	2	0.61	1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Medical device site reaction								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	3	0.69	0			
Non-cardiac chest pain								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	0				0			
Oedema								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Oedema peripheral								
<10 years	1	(0.5)	1	0.30	4	(1.7)	4	1.12
>=10 years	7	(2.5)	8	1.83	7	(2.7)	9	2.20

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

adsl.xpt; variable(s): ONTRDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pain								
<10 years	1	(0.5)	1	0.30	2	(0.9)	2	0.56
>=10 years	3	(1.1)	3	0.69	5	(1.9)	6	1.46
Peripheral swelling								
<10 years	2	(0.9)	3	0.91	4	(1.7)	4	1.12
>=10 years	1	(0.4)	1	0.23	2	(0.8)	2	0.49
Procedural failure								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Pyrexia								
<10 years	7	(3.3)	9	2.74	10	(4.3)	13	3.64
>=10 years	20	(7.1)	21	4.80	13	(5.0)	14	3.42
Swelling								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Thirst								
<10 years	2	(0.9)	2	0.61	0			
>=10 years	0				0			
Vaccination site erythema								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Vaccination site pain								
<10 years	3	(1.4)	4	1.22	2	(0.9)	2	0.56
>=10 years	2	(0.7)	3	0.69	2	(0.8)	2	0.49
Vaccination site reaction								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hepatobiliary disorders								
All								
<10 years	6	(2.8)	8	2.44	7	(3.0)	8	2.24
>=10 years	7	(2.5)	8	1.83	3	(1.1)	3	0.73
Biliary colic								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Cholelithiasis								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Gallbladder cholesterolosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Hepatic cirrhosis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Hepatic cyst								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Hepatic function abnormal								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Hepatic steatosis								
<10 years	3	(1.4)	3	0.91	2	(0.9)	2	0.56
>=10 years	5	(1.8)	5	1.14	1	(0.4)	1	0.24
Hepatitis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Hypertransaminasaemia								
<10 years	1	(0.5)	2	0.61	0			
>=10 years	0				0			
Liver disorder								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Non-alcoholic steatohepatitis								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Nonalcoholic fatty liver disease								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Steatohepatitis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
<10 years	3	(1.4)	4	1.22	3	(1.3)	4	1.12
>=10 years	4	(1.4)	4	0.91	3	(1.1)	3	0.73
Allergy to arthropod bite								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Allergy to arthropod sting								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Immunisation reaction								
<10 years	0				1	(0.4)	2	0.56
>=10 years	0				0			
Seasonal allergy								
<10 years	3	(1.4)	3	0.91	2	(0.9)	2	0.56
>=10 years	4	(1.4)	4	0.91	2	(0.8)	2	0.49
Infections and infestations								
All								
<10 years	95	(45.0)	182	55.44	113	(49.1)	215	60.25
>=10 years	130	(46.3)	233	53.30	139	(53.1)	234	57.09
Abscess								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Acarodermatitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Acute sinusitis								
<10 years	2	(0.9)	2	0.61	0			
>=10 years	2	(0.7)	2	0.46	0			
Anal abscess								
<10 years	0				0			
>=10 years	0				2	(0.8)	2	0.49
Asymptomatic COVID-19								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Bacterial infection								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				1	(0.4)	1	0.24
Balanitis candida								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Body tinea								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Breast abscess								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Breast cellulitis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Bronchitis								
<10 years	7	(3.3)	7	2.13	5	(2.2)	6	1.68
>=10 years	5	(1.8)	5	1.14	2	(0.8)	2	0.49
Candida infection								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	2	(0.7)	2	0.46	0			
Cellulitis								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	2	(0.7)	2	0.46	2	(0.8)	2	0.49
Chlamydial infection								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Chronic hepatitis C								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Chronic sinusitis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Chronic tonsillitis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	2	(0.8)	4	0.98
Clostridium difficile infection								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Conjunctivitis								
<10 years	2	(0.9)	2	0.61	1	(0.4)	1	0.28
>=10 years	4	(1.4)	5	1.14	2	(0.8)	2	0.49
Conjunctivitis bacterial								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Coronavirus infection								
<10 years	2	(0.9)	2	0.61	3	(1.3)	4	1.12
>=10 years	4	(1.4)	4	0.91	3	(1.1)	3	0.73
COVID-19								
<10 years	38	(18.0)	40	12.18	42	(18.3)	45	12.61
>=10 years	53	(18.9)	55	12.58	62	(23.7)	66	16.10

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
COVID-19 pneumonia								
<10 years	1	(0.5)	1	0.30	3	(1.3)	3	0.84
>=10 years	3	(1.1)	3	0.69	0			
Cystitis								
<10 years	1	(0.5)	1	0.30	4	(1.7)	6	1.68
>=10 years	4	(1.4)	5	1.14	4	(1.5)	5	1.22
Dermatophytosis of nail								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Diverticulitis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				4	(1.5)	4	0.98
Ear infection								
<10 years	3	(1.4)	3	0.91	0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Empyema								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Endophthalmitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Epididymitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Erysipelas								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Escherichia urinary tract infection								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				1	(0.4)	1	0.24
Eye infection bacterial								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Folliculitis								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Fungal balanitis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Fungal infection								
<10 years	2	(0.9)	2	0.61	0			
>=10 years	0				1	(0.4)	1	0.24

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Furuncle								
<10 years	1	(0.5)	2	0.61	1	(0.4)	1	0.28
>=10 years	0				0			
Gastroenteritis								
<10 years	4	(1.9)	4	1.22	4	(1.7)	4	1.12
>=10 years	2	(0.7)	2	0.46	2	(0.8)	3	0.73
Gastroenteritis norovirus								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Gastroenteritis viral								
<10 years	2	(0.9)	2	0.61	1	(0.4)	1	0.28
>=10 years	3	(1.1)	3	0.69	0			
Gastrointestinal infection								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Genital infection fungal								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				1	(0.4)	1	0.24
Giardiasis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Gingivitis								
<10 years	2	(0.9)	2	0.61	1	(0.4)	2	0.56
>=10 years	2	(0.7)	3	0.69	1	(0.4)	1	0.24
Helicobacter gastritis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Helicobacter infection								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Hepatitis B								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Herpes dermatitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Herpes simplex								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	0				0			
Herpes virus infection								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.46	0			

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

adsl.xpt; variable(s): ONTRDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Herpes zoster								
<10 years	3	(1.4)	3	0.91	4	(1.7)	4	1.12
>=10 years	3	(1.1)	3	0.69	4	(1.5)	4	0.98
Hordeolum								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.46	0			
Infected bite								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Infected skin ulcer								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Influenza								
<10 years	0				2	(0.9)	2	0.56
>=10 years	0				1	(0.4)	1	0.24
Intestinal sepsis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Labyrinthitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Laryngitis								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	1	(0.4)	1	0.23	4	(1.5)	4	0.98
Laryngopharyngitis								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Localised infection								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.46	0			
Lower respiratory tract infection								
<10 years	3	(1.4)	3	0.91	0			
>=10 years	4	(1.4)	6	1.37	2	(0.8)	4	0.98
Lyme disease								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Lymphangitis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Mastitis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mycoplasma infection								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Nail infection								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Nasopharyngitis								
<10 years	14	(6.6)	18	5.48	21	(9.1)	28	7.85
>=10 years	24	(8.5)	32	7.32	26	(9.9)	28	6.83
Onychomycosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Oophoritis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Oral candidiasis								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Oral herpes								
<10 years	2	(0.9)	2	0.61	3	(1.3)	3	0.84
>=10 years	1	(0.4)	1	0.23	0			
Oral infection								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Orchitis								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				1	(0.4)	1	0.24
Oropharyngeal candidiasis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Osteomyelitis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Osteomyelitis chronic								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Otitis externa								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Otitis media								
<10 years	2	(0.9)	2	0.61	1	(0.4)	2	0.56
>=10 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Otitis media acute								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Otitis media chronic								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Parotitis								
<10 years	0				1	(0.4)	3	0.84
>=10 years	0				0			
Peri-implantitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Pericoronitis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Periodontitis								
<10 years	0				5	(2.2)	6	1.68
>=10 years	2	(0.7)	2	0.46	0			
Pharyngitis								
<10 years	7	(3.3)	10	3.05	6	(2.6)	11	3.08
>=10 years	8	(2.8)	11	2.52	6	(2.3)	6	1.46
Pharyngitis bacterial								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Pharyngotonsillitis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				3	(1.1)	4	0.98
Pneumonia								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	3	(1.1)	3	0.69	2	(0.8)	2	0.49
Post procedural infection								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Pulpitis dental								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Purulence								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Pyelonephritis chronic								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Respiratory syncytial virus infection								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Respiratory tract infection								
<10 years	3	(1.4)	3	0.91	4	(1.7)	5	1.40
>=10 years	1	(0.4)	1	0.23	2	(0.8)	2	0.49
Respiratory tract infection viral								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	4	(1.4)	7	1.60	2	(0.8)	2	0.49
Rhinitis								
<10 years	3	(1.4)	3	0.91	6	(2.6)	8	2.24
>=10 years	4	(1.4)	5	1.14	3	(1.1)	3	0.73
Rotavirus infection								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Salpingitis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Sepsis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Sinusitis								
<10 years	1	(0.5)	2	0.61	3	(1.3)	5	1.40
>=10 years	4	(1.4)	4	0.91	4	(1.5)	6	1.46
Skin bacterial infection								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Skin infection								
<10 years	2	(0.9)	2	0.61	0			
>=10 years	0				0			
Staphylococcal infection								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Subcutaneous abscess								
<10 years	1	(0.5)	1	0.30	1	(0.4)	4	1.12
>=10 years	0				0			
Tinea infection								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Tonsillitis								
<10 years	2	(0.9)	3	0.91	2	(0.9)	2	0.56
>=10 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tooth abscess								
<10 years	2	(0.9)	2	0.61	2	(0.9)	2	0.56
>=10 years	3	(1.1)	3	0.69	2	(0.8)	2	0.49
Tooth infection								
<10 years	1	(0.5)	1	0.30	1	(0.4)	2	0.56
>=10 years	1	(0.4)	1	0.23	2	(0.8)	2	0.49
Tracheitis								
<10 years	1	(0.5)	3	0.91	2	(0.9)	2	0.56
>=10 years	0				0			
Upper respiratory tract infection								
<10 years	15	(7.1)	21	6.40	8	(3.5)	10	2.80
>=10 years	13	(4.6)	19	4.35	14	(5.3)	14	3.42
Urethritis								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Urinary tract infection								
<10 years	4	(1.9)	6	1.83	8	(3.5)	8	2.24
>=10 years	5	(1.8)	6	1.37	13	(5.0)	17	4.15
Vaginal infection								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Varicella								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Viral infection								
<10 years	2	(0.9)	2	0.61	4	(1.7)	4	1.12
>=10 years	2	(0.7)	2	0.46	1	(0.4)	1	0.24
Viral pharyngitis								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Viral upper respiratory tract infection								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	0				2	(0.8)	2	0.49
Vulvovaginal candidiasis								
<10 years	3	(1.4)	5	1.52	2	(0.9)	2	0.56
>=10 years	0				2	(0.8)	2	0.49
Vulvovaginal mycotic infection								
<10 years	0				0			
>=10 years	1	(0.4)	2	0.46	0			
Wound infection								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			

Injury, poisoning and procedural

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
complications								
All								
<10 years	34	(16.1)	41	12.49	36	(15.7)	59	16.53
>=10 years	55	(19.6)	61	13.95	31	(11.8)	44	10.73
Accidental overdose								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Alcohol poisoning								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Animal bite								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				1	(0.4)	1	0.24
Ankle fracture								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Arthropod bite								
<10 years	0				2	(0.9)	2	0.56
>=10 years	0				0			
Arthropod sting								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Avulsion fracture								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Bone contusion								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Burn oral cavity								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Burns first degree								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Cervical vertebral fracture								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Chillblains								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Concussion								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Contusion								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				8	(3.5)	10	2.80
>=10 years	5	(1.8)	6	1.37	5	(1.9)	6	1.46
Deafness traumatic								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Endotracheal intubation complication								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Eye injury								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Fall								
<10 years	2	(0.9)	2	0.61	4	(1.7)	4	1.12
>=10 years	6	(2.1)	8	1.83	3	(1.1)	4	0.98
Fibula fracture								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Foot fracture								
<10 years	0				2	(0.9)	2	0.56
>=10 years	1	(0.4)	1	0.23	0			
Hand fracture								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.46	0			
Head injury								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				2	(0.8)	2	0.49
Heat illness								
<10 years	0				1	(0.4)	2	0.56
>=10 years	1	(0.4)	1	0.23	2	(0.8)	2	0.49
Hip fracture								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Injury								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	3	(1.1)	3	0.69	0			
Joint injury								
<10 years	2	(0.9)	2	0.61	1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Ligament sprain								
<10 years	3	(1.4)	3	0.91	1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	2	(0.8)	2	0.49
Limb fracture								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Limb injury								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	3	(1.1)	3	0.69	0			
Lower limb fracture								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Meniscus injury								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	2	(0.7)	2	0.46	0			
Muscle strain								
<10 years	1	(0.5)	1	0.30	2	(0.9)	2	0.56
>=10 years	1	(0.4)	1	0.23	2	(0.8)	2	0.49
Overdose								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Patella fracture								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Periprocedural myocardial infarction								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Post procedural fistula								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Post procedural haemorrhage								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Post procedural hypothyroidism								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Post procedural stroke								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Post procedural swelling								
<10 years	0				1	(0.4)	2	0.56
>=10 years	0				0			
Post-traumatic neck syndrome								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Procedural pain								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Product administration error								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Radius fracture								
<10 years	3	(1.4)	3	0.91	1	(0.4)	1	0.28
>=10 years	0				0			
Rib fracture								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	0				0			
Road traffic accident								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Scar								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Skin abrasion								
<10 years	2	(0.9)	2	0.61	0			
>=10 years	2	(0.7)	2	0.46	1	(0.4)	1	0.24
Skin laceration								
<10 years	2	(0.9)	2	0.61	0			
>=10 years	2	(0.7)	2	0.46	0			
Soft tissue injury								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Spinal column injury								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Spinal cord injury cervical								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Stress fracture								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Subcutaneous haematoma								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Tendon rupture								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Thermal burn								
<10 years	1	(0.5)	1	0.30	2	(0.9)	2	0.56
>=10 years	0				1	(0.4)	1	0.24
Tooth fracture								
<10 years	2	(0.9)	2	0.61	1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Traumatic arthritis								
<10 years	1	(0.5)	2	0.61	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	0				0			
Traumatic haematoma								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Ulna fracture								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Underdose								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Upper limb fracture								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Vaccination complication								
<10 years	5	(2.4)	6	1.83	9	(3.9)	14	3.92
>=10 years	7	(2.5)	7	1.60	7	(2.7)	10	2.44
Wound								
<10 years	0				1	(0.4)	1	0.28
>=10 years	4	(1.4)	4	0.91	2	(0.8)	2	0.49
Wrist fracture								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Investigations								
All								
<10 years	15	(7.1)	16	4.87	20	(8.7)	22	6.16
>=10 years	20	(7.1)	24	5.49	14	(5.3)	14	3.42
Alanine aminotransferase increased								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Aspartate aminotransferase increased								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Blood cholesterol increased								
<10 years	0				0			
>=10 years	3	(1.1)	3	0.69	0			
Blood creatine increased								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Blood creatine phosphokinase increased								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Blood glucose increased								
<10 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	0				1	(0.4)	1	0.24
Blood potassium increased								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Blood pressure decreased								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Blood pressure increased								
<10 years	0				1	(0.4)	1	0.28
>=10 years	2	(0.7)	2	0.46	1	(0.4)	1	0.24
Blood triglycerides increased								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	0				0			
Body temperature increased								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Cardiac stress test abnormal								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Electrocardiogram change								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Electrocardiogram repolarisation abnormality								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Electrocardiogram T wave inversion								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Glycosylated haemoglobin increased								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Haemoglobin decreased								
<10 years	0				1	(0.4)	2	0.56
>=10 years	0				0			
Hepatic enzyme abnormal								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Hepatic enzyme increased								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
International normalised ratio abnormal								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
International normalised ratio decreased								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
International normalised ratio increased								
<10 years	0				0			
>=10 years	1	(0.4)	2	0.46	0			
Intraocular pressure increased								
<10 years	1	(0.5)	2	0.61	0			
>=10 years	0				0			
Lipids increased								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Low density lipoprotein increased								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Prostatic specific antigen increased								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				1	(0.4)	1	0.24
Protein urine present								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Pulse absent								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Red blood cell count decreased								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
SARS-CoV-2 test positive								
<10 years	2	(0.9)	2	0.61	1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	2	(0.8)	2	0.49
Serum ferritin decreased								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Transferrin saturation decreased								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Troponin increased								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Weight decreased								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	2	(0.7)	2	0.46	0			
Weight increased								
<10 years	3	(1.4)	3	0.91	9	(3.9)	9	2.52
>=10 years	6	(2.1)	6	1.37	1	(0.4)	1	0.24

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
White blood cell count decreased								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Metabolism and nutrition disorders								
All								
<10 years	23	(10.9)	27	8.22	30	(13.0)	47	13.17
>=10 years	36	(12.8)	39	8.92	33	(12.6)	42	10.25
Adult failure to thrive								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Appetite disorder								
<10 years	0				0			
>=10 years	0				1	(0.4)	2	0.49
Decreased appetite								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	3	(1.1)	3	0.69	1	(0.4)	1	0.24
Dehydration								
<10 years	0				0			
>=10 years	0				2	(0.8)	2	0.49
Diabetes mellitus								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Diabetes mellitus inadequate control								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Dyslipidaemia								
<10 years	7	(3.3)	8	2.44	5	(2.2)	7	1.96
>=10 years	7	(2.5)	7	1.60	4	(1.5)	4	0.98
Electrolyte depletion								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Electrolyte imbalance								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Fluid retention								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Gout								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	1	(0.4)	2	0.46	1	(0.4)	1	0.24
Hypercalcaemia								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hypercholesterolaemia								
<10 years	0				3	(1.3)	3	0.84
>=10 years	2	(0.7)	2	0.46	0			
Hyperglycaemia								
<10 years	0				4	(1.7)	4	1.12
>=10 years	1	(0.4)	1	0.23	3	(1.1)	3	0.73
Hyperkalaemia								
<10 years	2	(0.9)	2	0.61	1	(0.4)	1	0.28
>=10 years	4	(1.4)	4	0.91	3	(1.1)	3	0.73
Hyperlipidaemia								
<10 years	2	(0.9)	2	0.61	1	(0.4)	1	0.28
>=10 years	2	(0.7)	2	0.46	2	(0.8)	2	0.49
Hypertriglyceridaemia								
<10 years	4	(1.9)	4	1.22	8	(3.5)	8	2.24
>=10 years	2	(0.7)	2	0.46	1	(0.4)	1	0.24
Hyperuricaemia								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Hypoglycaemia								
<10 years	1	(0.5)	2	0.61	8	(3.5)	18	5.04
>=10 years	6	(2.1)	6	1.37	5	(1.9)	8	1.95
Hypokalaemia								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Hypophosphataemia								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Increased appetite								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Iron deficiency								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				1	(0.4)	1	0.24
Lactic acidosis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Malnutrition								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Metabolic disorder								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Obesity								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Type 2 diabetes mellitus								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Vitamin B12 deficiency								
<10 years	2	(0.9)	2	0.61	0			
>=10 years	1	(0.4)	1	0.23	0			
Vitamin D deficiency								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	3	(1.1)	4	0.91	3	(1.1)	3	0.73
Zinc deficiency								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Musculoskeletal and connective tissue disorders								
All								
<10 years	46	(21.8)	78	23.76	46	(20.0)	70	19.62
>=10 years	84	(29.9)	140	32.02	71	(27.1)	114	27.81
Arthralgia								
<10 years	13	(6.2)	16	4.87	7	(3.0)	8	2.24
>=10 years	17	(6.0)	20	4.57	15	(5.7)	20	4.88
Arthritis								
<10 years	1	(0.5)	1	0.30	3	(1.3)	3	0.84
>=10 years	1	(0.4)	1	0.23	1	(0.4)	2	0.49
Axillary mass								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Back disorder								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Back pain								
<10 years	14	(6.6)	15	4.57	9	(3.9)	10	2.80
>=10 years	26	(9.3)	28	6.40	23	(8.8)	24	5.86
Bone cyst								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Bursitis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	2	(0.7)	2	0.46	2	(0.8)	2	0.49
Cervical spinal stenosis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Chondrodynia								
<10 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	1	(0.4)	1	0.23	0			
Chondropathy								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Coccydynia								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Costochondritis								
<10 years	2	(0.9)	2	0.61	0			
>=10 years	0				1	(0.4)	1	0.24
Dupuytren's contracture								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Exostosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Fibromyalgia								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	1	(0.4)	1	0.23	0			
Fistula								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Flank pain								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Fracture nonunion								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Gouty arthritis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Groin pain								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.46	1	(0.4)	1	0.24
Intervertebral disc disorder								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Intervertebral disc protrusion								
<10 years	1	(0.5)	1	0.30	3	(1.3)	4	1.12
>=10 years	6	(2.1)	7	1.60	2	(0.8)	2	0.49
Intervertebral disc space narrowing								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Joint effusion								

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Joint swelling								
<10 years	0				0			
>=10 years	0				2	(0.8)	2	0.49
Ligamentitis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Limb deformity								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Lordosis								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Lumbar spinal stenosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Mastication disorder								
<10 years	0				1	(0.4)	2	0.56
>=10 years	0				0			
Muscle contracture								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Muscle spasms								
<10 years	3	(1.4)	3	0.91	3	(1.3)	3	0.84
>=10 years	9	(3.2)	9	2.06	1	(0.4)	1	0.24
Muscular weakness								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Musculoskeletal chest pain								
<10 years	2	(0.9)	2	0.61	1	(0.4)	1	0.28
>=10 years	2	(0.7)	2	0.46	0			
Musculoskeletal pain								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				1	(0.4)	1	0.24
Musculoskeletal stiffness								
<10 years	2	(0.9)	2	0.61	1	(0.4)	1	0.28
>=10 years	0				0			
Myalgia								
<10 years	1	(0.5)	1	0.30	2	(0.9)	2	0.56
>=10 years	2	(0.7)	2	0.46	1	(0.4)	1	0.24
Myositis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neck pain								
<10 years	2	(0.9)	2	0.61	3	(1.3)	3	0.84
>=10 years	5	(1.8)	5	1.14	5	(1.9)	5	1.22
Osteoarthritis								
<10 years	5	(2.4)	6	1.83	3	(1.3)	5	1.40
>=10 years	14	(5.0)	15	3.43	11	(4.2)	12	2.93
Osteochondrosis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Osteopenia								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.46	1	(0.4)	1	0.24
Pain in extremity								
<10 years	5	(2.4)	6	1.83	3	(1.3)	3	0.84
>=10 years	13	(4.6)	17	3.89	11	(4.2)	14	3.42
Periarthritis								
<10 years	2	(0.9)	2	0.61	4	(1.7)	4	1.12
>=10 years	4	(1.4)	4	0.91	1	(0.4)	1	0.24
Plantar fasciitis								
<10 years	3	(1.4)	3	0.91	0			
>=10 years	2	(0.7)	3	0.69	1	(0.4)	1	0.24
Polyarthritis								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Rotator cuff syndrome								
<10 years	0				0			
>=10 years	3	(1.1)	3	0.69	1	(0.4)	1	0.24
Scoliosis								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Spinal osteoarthritis								
<10 years	2	(0.9)	2	0.61	1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Spinal pain								
<10 years	0				2	(0.9)	2	0.56
>=10 years	1	(0.4)	1	0.23	2	(0.8)	2	0.49
Spinal stenosis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	2	(0.7)	2	0.46	0			
Spondylolisthesis								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Synovial cyst								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	1	(0.4)	1	0.23	0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tendon calcification								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Tendonitis								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	1	(0.4)	1	0.23	2	(0.8)	2	0.49
Tenosynovitis								
<10 years	1	(0.5)	1	0.30	3	(1.3)	4	1.12
>=10 years	0				3	(1.1)	3	0.73
Tenosynovitis stenosans								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Torticollis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Trigger finger								
<10 years	0				1	(0.4)	4	1.12
>=10 years	3	(1.1)	3	0.69	2	(0.8)	2	0.49
Vertebral osteophyte								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
<10 years	9	(4.3)	10	3.05	2	(0.9)	3	0.84
>=10 years	10	(3.6)	11	2.52	7	(2.7)	10	2.44
Acrochordon								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Basal cell carcinoma								
<10 years	1	(0.5)	1	0.30	2	(0.9)	2	0.56
>=10 years	1	(0.4)	1	0.23	0			
Colon adenoma								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	1	(0.4)	1	0.23	0			
Colon cancer								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Dysplastic naevus								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Glioblastoma multiforme								
<10 years	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	1	(0.4)	1	0.23	0			
Haemangioma of liver								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Hepatocellular carcinoma								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Hypergammaglobulinaemia benign monoclonal								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Lipoma								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Lung adenocarcinoma								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Malignant melanoma in situ								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Metastases to liver								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Metastatic renal cell carcinoma								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Neoplasm skin								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Oral fibroma								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Ovarian cancer metastatic								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Pancreatic carcinoma metastatic								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Pancreatic neoplasm								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Prostate cancer								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Seborrhoeic keratosis								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	1	(0.5)	2	0.61	0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Skin papilloma								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Small cell lung cancer								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Squamous cell carcinoma								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Uterine leiomyoma								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Nervous system disorders								
All								
<10 years	27	(12.8)	43	13.10	34	(14.8)	52	14.57
>=10 years	57	(20.3)	82	18.76	46	(17.6)	63	15.37
Ageusia								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Anosmia								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Balance disorder								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Brain injury								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Burning sensation								
<10 years	0				0			
>=10 years	3	(1.1)	3	0.69	2	(0.8)	2	0.49
Carotid arteriosclerosis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Carotid artery stenosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Carpal tunnel syndrome								
<10 years	0				0			
>=10 years	4	(1.4)	4	0.91	3	(1.1)	3	0.73
Cerebral arteriosclerosis								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Cerebral atrophy								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Cerebral haemorrhage								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Cerebral infarction								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Cerebrovascular accident								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Cerebrovascular disorder								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Cervical radiculopathy								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Cognitive disorder								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Diabetic neuropathy								
<10 years	0				3	(1.3)	3	0.84
>=10 years	3	(1.1)	3	0.69	2	(0.8)	2	0.49
Dizziness								
<10 years	6	(2.8)	8	2.44	6	(2.6)	6	1.68
>=10 years	9	(3.2)	13	2.97	9	(3.4)	10	2.44
Dizziness postural								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Dysgeusia								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Essential tremor								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Headache								
<10 years	12	(5.7)	16	4.87	11	(4.8)	19	5.32
>=10 years	10	(3.6)	12	2.74	10	(3.8)	13	3.17
Hypoaesthesia								
<10 years	1	(0.5)	1	0.30	4	(1.7)	5	1.40
>=10 years	5	(1.8)	7	1.60	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hypoglycaemic unconsciousness								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Ischaemic stroke								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Lethargy								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Lumbar radiculopathy								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	2	(0.8)	2	0.49
Memory impairment								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Mental impairment								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Metabolic encephalopathy								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Migraine								
<10 years	0				0			
>=10 years	3	(1.1)	3	0.69	1	(0.4)	1	0.24
Movement disorder								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Muscle tone disorder								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Neuralgia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Neuroglycopenia								
<10 years	0				0			
>=10 years	2	(0.7)	4	0.91	1	(0.4)	3	0.73
Neuropathy peripheral								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	2	(0.8)	2	0.49
Paraesthesia								
<10 years	2	(0.9)	2	0.61	2	(0.9)	2	0.56
>=10 years	2	(0.7)	2	0.46	3	(1.1)	3	0.73
Parkinsonian gait								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pineal gland cyst								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Post herpetic neuralgia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Presyncope								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.46	2	(0.8)	2	0.49
Sciatica								
<10 years	0				4	(1.7)	6	1.68
>=10 years	3	(1.1)	3	0.69	4	(1.5)	5	1.22
Somnolence								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Stiff leg syndrome								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Syncope								
<10 years	2	(0.9)	4	1.22	1	(0.4)	1	0.28
>=10 years	3	(1.1)	3	0.69	0			
Tension headache								
<10 years	0				0			
>=10 years	2	(0.7)	3	0.69	0			
Thrombotic stroke								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Transient ischaemic attack								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Tremor								
<10 years	3	(1.4)	3	0.91	0			
>=10 years	3	(1.1)	4	0.91	1	(0.4)	1	0.24
Trigeminal neuralgia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Vertebral artery occlusion								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
VIth nerve paralysis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
VIth nerve paresis								
<10 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	1	(0.4)	1	0.23	0			
Psychiatric disorders								
All								
<10 years	8	(3.8)	9	2.74	5	(2.2)	5	1.40
>=10 years	15	(5.3)	16	3.66	8	(3.1)	8	1.95
Anxiety								
<10 years	2	(0.9)	2	0.61	0			
>=10 years	2	(0.7)	2	0.46	2	(0.8)	2	0.49
Depressed mood								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Depression								
<10 years	4	(1.9)	4	1.22	1	(0.4)	1	0.28
>=10 years	3	(1.1)	3	0.69	3	(1.1)	3	0.73
Insomnia								
<10 years	2	(0.9)	2	0.61	1	(0.4)	1	0.28
>=10 years	7	(2.5)	7	1.60	3	(1.1)	3	0.73
Mood swings								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Nightmare								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Persistent depressive disorder								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Psychotic disorder								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Schizophrenia								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Sleep disorder								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.46	0			
Renal and urinary disorders								
All								
<10 years	4	(1.9)	6	1.83	8	(3.5)	10	2.80
>=10 years	16	(5.7)	18	4.12	20	(7.6)	25	6.10
Acute kidney injury								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24

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

adsl.xpt; variable(s): ONTRDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Calculus urinary								
<10 years	1	(0.5)	1	0.30	2	(0.9)	2	0.56
>=10 years	0				0			
Chronic kidney disease								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				4	(1.5)	4	0.98
Diabetic nephropathy								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Dysuria								
<10 years	0				1	(0.4)	1	0.28
>=10 years	3	(1.1)	3	0.69	3	(1.1)	3	0.73
Haematuria								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	3	(1.1)	3	0.73
Hypercalciuria								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Hypertonic bladder								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Ketonuria								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Microalbuminuria								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Nephrolithiasis								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.46	2	(0.8)	2	0.49
Nocturia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	2	(0.8)	2	0.49
Pollakiuria								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	1	(0.4)	1	0.23	2	(0.8)	2	0.49
Pyelocaliectasis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Renal colic								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Renal cyst								
<10 years	1	(0.5)	1	0.30	2	(0.9)	2	0.56

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	1	(0.4)	1	0.23	0			
Renal impairment								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.46	3	(1.1)	3	0.73
Ureterolithiasis								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Urinary incontinence								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Urinary retention								
<10 years	0				0			
>=10 years	0				1	(0.4)	2	0.49
Urinary tract obstruction								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Urine odour abnormal								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Reproductive system and breast disorders								
All								
<10 years	2	(0.9)	2	0.61	6	(2.6)	9	2.52
>=10 years	13	(4.6)	13	2.97	10	(3.8)	13	3.17
Adenomyosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Atrophic vulvovaginitis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Balanoposthitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Benign prostatic hyperplasia								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.46	3	(1.1)	3	0.73
Breast mass								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Breast pain								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Erectile dysfunction								
<10 years	2	(0.9)	2	0.61	1	(0.4)	1	0.28

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	1	(0.4)	1	0.23	0			
Galactorrhoea								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Hydrometra								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Menopausal symptoms								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Ovarian cyst								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Penile rash								
<10 years	0				0			
>=10 years	0				1	(0.4)	3	0.73
Prostatism								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Prostatitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	2	0.49
Pruritus genital								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Uterine haemorrhage								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Uterine polyp								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Uterine prolapse								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Vaginal prolapse								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Vulval eczema								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Vulval leukoplakia								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Vulvovaginal dryness								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Vulvovaginal pruritus								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Respiratory, thoracic and mediastinal disorders								
All								
<10 years	24	(11.4)	37	11.27	25	(10.9)	32	8.97
>=10 years	31	(11.0)	39	8.92	23	(8.8)	37	9.03
Acquired diaphragmatic eventration								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Acute pulmonary oedema								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Acute respiratory failure								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				1	(0.4)	1	0.24
Allergic bronchitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	2	0.49
Asthma								
<10 years	1	(0.5)	2	0.61	0			
>=10 years	0				1	(0.4)	1	0.24
Bronchiectasis								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Bronchitis chronic								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Chronic eosinophilic rhinosinusitis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Chronic obstructive pulmonary disease								
<10 years	0				0			
>=10 years	2	(0.7)	2	0.46	1	(0.4)	1	0.24
Cough								
<10 years	7	(3.3)	7	2.13	6	(2.6)	6	1.68
>=10 years	7	(2.5)	8	1.83	2	(0.8)	3	0.73
Dry throat								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dyspnoea								
<10 years	2	(0.9)	2	0.61	1	(0.4)	1	0.28
>=10 years	0				5	(1.9)	5	1.22
Dyspnoea exertional								
<10 years	0				1	(0.4)	1	0.28
>=10 years	2	(0.7)	2	0.46	1	(0.4)	1	0.24
Emphysema								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	0				0			
Epistaxis								
<10 years	0				1	(0.4)	3	0.84
>=10 years	0				0			
Haemoptysis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Interstitial lung disease								
<10 years	2	(0.9)	2	0.61	0			
>=10 years	0				0			
Laryngeal cyst								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Nasal congestion								
<10 years	2	(0.9)	3	0.91	2	(0.9)	2	0.56
>=10 years	3	(1.1)	3	0.69	0			
Nasal dryness								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Nasal turbinate hypertrophy								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Oropharyngeal pain								
<10 years	8	(3.8)	8	2.44	4	(1.7)	8	2.24
>=10 years	5	(1.8)	6	1.37	5	(1.9)	5	1.22
Paranasal sinus discomfort								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Pleural calcification								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Pleural effusion								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Pleuritic pain								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pneumothorax								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Productive cough								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Pulmonary embolism								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Pulmonary fibrosis								
<10 years	0				0			
>=10 years	1	(0.4)	2	0.46	0			
Pulmonary mass								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Respiratory disorder								
<10 years	0				2	(0.9)	2	0.56
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Respiratory failure								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Rhinitis allergic								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	5	1.22
Rhinorrhoea								
<10 years	2	(0.9)	2	0.61	1	(0.4)	1	0.28
>=10 years	4	(1.4)	4	0.91	2	(0.8)	2	0.49
Sinus congestion								
<10 years	1	(0.5)	2	0.61	0			
>=10 years	0				2	(0.8)	2	0.49
Sinus pain								
<10 years	1	(0.5)	2	0.61	0			
>=10 years	0				0			
Sleep apnoea syndrome								
<10 years	0				0			
>=10 years	3	(1.1)	3	0.69	1	(0.4)	1	0.24
Sneezing								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Throat irritation								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Upper respiratory tract inflammation								
<10 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	0				1	(0.4)	1	0.24
Upper-airway cough syndrome								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Skin and subcutaneous tissue disorders								
All								
<10 years	18	(8.5)	25	7.61	22	(9.6)	31	8.69
>=10 years	41	(14.6)	52	11.89	31	(11.8)	44	10.73
Actinic keratosis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	2	0.46	0			
Alopecia								
<10 years	2	(0.9)	2	0.61	1	(0.4)	1	0.28
>=10 years	4	(1.4)	4	0.91	1	(0.4)	1	0.24
Alopecia areata								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Angioedema								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Asteatosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Blister								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				1	(0.4)	1	0.24
Cellulite								
<10 years	0				0			
>=10 years	0				1	(0.4)	2	0.49
Chloasma								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Cold sweat								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	1	(0.4)	2	0.46	1	(0.4)	1	0.24
Cold urticaria								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Dermal cyst								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	2	(0.8)	2	0.49
Dermatitis								
<10 years	0				1	(0.4)	1	0.28

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	1	(0.4)	1	0.23	3	(1.1)	3	0.73
Dermatitis allergic								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Dermatitis contact								
<10 years	2	(0.9)	3	0.91	3	(1.3)	4	1.12
>=10 years	4	(1.4)	5	1.14	4	(1.5)	4	0.98
Diabetic foot								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				1	(0.4)	1	0.24
Drug eruption								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	0				0			
Dry skin								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	2	(0.7)	2	0.46	0			
Ecchymosis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Eczema								
<10 years	4	(1.9)	4	1.22	3	(1.3)	3	0.84
>=10 years	4	(1.4)	4	0.91	1	(0.4)	1	0.24
Eczema nummular								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Erythema								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Granuloma annulare								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				1	(0.4)	1	0.24
Haemorrhage subcutaneous								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Hyperhidrosis								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	3	(1.1)	3	0.69	1	(0.4)	1	0.24
Hyperkeratosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Ingrowing nail								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	2	(0.8)	2	0.49
Lentigo								

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

adsl.xpt; variable(s): ONTRDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Lipodystrophy acquired								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Lipohypertrophy								
<10 years	0				0			
>=10 years	0				2	(0.8)	2	0.49
Macule								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Miliaria								
<10 years	0				3	(1.3)	3	0.84
>=10 years	3	(1.1)	4	0.91	2	(0.8)	2	0.49
Myxoid cyst								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Night sweats								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Onychalgia								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Pruritus								
<10 years	1	(0.5)	3	0.91	1	(0.4)	1	0.28
>=10 years	3	(1.1)	3	0.69	3	(1.1)	3	0.73
Psoriasis								
<10 years	2	(0.9)	2	0.61	0			
>=10 years	0				0			
Purpura								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Rash								
<10 years	1	(0.5)	1	0.30	3	(1.3)	3	0.84
>=10 years	1	(0.4)	1	0.23	5	(1.9)	5	1.22
Rosacea								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Skin exfoliation								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	0				0			
Skin fissures								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Skin irritation								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	1	(0.4)	2	0.46	1	(0.4)	1	0.24
Skin lesion								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Skin ulcer								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Urticaria								
<10 years	0				2	(0.9)	2	0.56
>=10 years	1	(0.4)	2	0.46	3	(1.1)	3	0.73
Urticaria contact								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Urticaria thermal								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Surgical and medical procedures								
All								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Removal of foreign body								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Vascular disorders								
All								
<10 years	15	(7.1)	16	4.87	25	(10.9)	27	7.57
>=10 years	25	(8.9)	33	7.55	18	(6.9)	22	5.37
Aneurysm								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Aortic arteriosclerosis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	3	(1.1)	3	0.69	0			
Aortic stenosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Arteriosclerosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	2	(0.8)	2	0.49
Blood pressure inadequately controlled								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Brachiocephalic arteriosclerosis								
<10 years	0				2	(0.9)	2	0.56
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Diabetic vascular disorder								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Flushing								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Haematoma								
<10 years	2	(0.9)	2	0.61	0			
>=10 years	2	(0.7)	2	0.46	2	(0.8)	2	0.49
Hypertension								
<10 years	5	(2.4)	5	1.52	10	(4.3)	10	2.80
>=10 years	10	(3.6)	10	2.29	6	(2.3)	7	1.71
Hypertensive angiopathy								
<10 years	2	(0.9)	2	0.61	2	(0.9)	2	0.56
>=10 years	0				0			
Hypertensive crisis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Hypertensive urgency								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	0			
Hypotension								
<10 years	2	(0.9)	2	0.61	2	(0.9)	2	0.56
>=10 years	1	(0.4)	1	0.23	0			
Iliac artery stenosis								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Intermittent claudication								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Macroangiopathy								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Peripheral arterial occlusive disease								
<10 years	0				2	(0.9)	2	0.56
>=10 years	1	(0.4)	2	0.46	3	(1.1)	3	0.73
Peripheral artery occlusion								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Peripheral artery stenosis								
<10 years	0				0			
>=10 years	1	(0.4)	2	0.46	0			
Peripheral coldness								
<10 years	2	(0.9)	2	0.61	0			
>=10 years	2	(0.7)	2	0.46	1	(0.4)	1	0.24
Peripheral vascular disorder								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Peripheral venous disease								
<10 years	0				1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24
Post thrombotic syndrome								
<10 years	0				0			
>=10 years	0				1	(0.4)	1	0.24
Secondary hypertension								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Superficial vein thrombosis								
<10 years	0				0			
>=10 years	1	(0.4)	1	0.23	0			
Thrombophlebitis								
<10 years	0				1	(0.4)	1	0.28
>=10 years	0				0			
Thrombosis								
<10 years	1	(0.5)	1	0.30	0			
>=10 years	0				0			
Varicose vein								
<10 years	1	(0.5)	1	0.30	1	(0.4)	1	0.28
>=10 years	1	(0.4)	1	0.23	1	(0.4)	1	0.24

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

7.24.16 Adverse events by diabetes duration, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<10 years	75				82			
>=10 years	215				210			
PYE (years)								
<10 years	77.55				87.29			
>=10 years	222.61				222.29			
Events								
<10 years	58	(77.3)	270	348.15	64	(78.0)	267	305.87
>=10 years	182	(84.7)	695	312.21	172	(81.9)	879	395.43
Blood and lymphatic system disorders								
All								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	6	(2.8)	7	3.14	5	(2.4)	6	2.70
Anaemia								
<10 years	0				0			
>=10 years	4	(1.9)	4	1.80	0			
Blood loss anaemia								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Iron deficiency anaemia								
<10 years	0				0			
>=10 years	0				2	(1.0)	3	1.35
Lymphadenitis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Lymphadenopathy								
<10 years	0				0			
>=10 years	2	(0.9)	2	0.90	1	(0.5)	1	0.45
Splenomegaly								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Thrombocytopenia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Cardiac disorders								
All								
<10 years	3	(4.0)	3	3.87	2	(2.4)	3	3.44
>=10 years	13	(6.0)	15	6.74	9	(4.3)	12	5.40

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

adsl.xpt; variable(s): ONTRDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL02FL) == "Y" & (ANELFL) == "Y"

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Acute myocardial infarction								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Angina pectoris								
<10 years	0				0			
>=10 years	2	(0.9)	2	0.90	0			
Angina unstable								
<10 years	0				0			
>=10 years	0				2	(1.0)	2	0.90
Aortic valve incompetence								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Atrial fibrillation								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Bundle branch block right								
<10 years	1	(1.3)	1	1.29	1	(1.2)	1	1.15
>=10 years	0				0			
Cardiac failure congestive								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Cardiomegaly								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Cardiovascular disorder								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Conduction disorder								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Coronary artery disease								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Left ventricular hypertrophy								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Mitral valve incompetence								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Myocardial infarction								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Myocardial ischaemia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Palpitations								
<10 years	1	(1.3)	1	1.29	1	(1.2)	2	2.29
>=10 years	2	(0.9)	2	0.90	3	(1.4)	3	1.35
Tachycardia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Tricuspid valve incompetence								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Ventricular extrasystoles								
<10 years	0				0			
>=10 years	3	(1.4)	3	1.35	0			
Congenital, familial and genetic disorders								
All								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	1	(0.5)	1	0.45	0			
Arteriovenous malformation								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Colour blindness								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
<10 years	0				0			
>=10 years	2	(0.9)	2	0.90	4	(1.9)	4	1.80
Deafness neurosensory								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Ear pain								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Tinnitus								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Tympanic membrane perforation								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Vertigo								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Endocrine disorders								
All								
<10 years	1	(1.3)	1	1.29	2	(2.4)	2	2.29
>=10 years	1	(0.5)	1	0.45	0			
Autoimmune thyroiditis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Hypogonadism								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Hypothyroidism								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Thyroiditis chronic								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Eye disorders								
All								
<10 years	3	(4.0)	4	5.16	7	(8.5)	10	11.46
>=10 years	40	(18.6)	58	26.05	39	(18.6)	56	25.19

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Angle closure glaucoma								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Arteriosclerotic retinopathy								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Astigmatism								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				2	(1.0)	2	0.90
Cataract								
<10 years	1	(1.3)	1	1.29	1	(1.2)	1	1.15
>=10 years	5	(2.3)	5	2.25	3	(1.4)	4	1.80
Cataract nuclear								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Conjunctival haemorrhage								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Corneal erosion								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Diabetic retinal oedema								
<10 years	0				0			
>=10 years	2	(0.9)	2	0.90	1	(0.5)	1	0.45
Diabetic retinopathy								
<10 years	0				2	(2.4)	3	3.44
>=10 years	24	(11.2)	28	12.58	24	(11.4)	26	11.70
Dry eye								
<10 years	0				1	(1.2)	1	1.15
>=10 years	1	(0.5)	1	0.45	0			
Eczema eyelids								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Epiretinal membrane								
<10 years	0				1	(1.2)	1	1.15
>=10 years	2	(0.9)	2	0.90	0			
Eye pain								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Glaucoma								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				3	(1.4)	3	1.35

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Macular oedema								
<10 years	0				0			
>=10 years	4	(1.9)	5	2.25	1	(0.5)	1	0.45
Myopia								
<10 years	0				0			
>=10 years	0				2	(1.0)	2	0.90
Non-proliferative retinopathy								
<10 years	0				0			
>=10 years	3	(1.4)	3	1.35	2	(1.0)	2	0.90
Ocular hypertension								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				1	(0.5)	2	0.90
Photopsia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Posterior capsule opacification								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	2	0.90
Presbyopia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Pterygium								
<10 years	0				1	(1.2)	2	2.29
>=10 years	0				0			
Retinal drusen								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Retinal haemorrhage								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Retinal vascular disorder								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Retinopathy								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Retinopathy hypertensive								
<10 years	0				0			
>=10 years	2	(0.9)	2	0.90	1	(0.5)	1	0.45
Strabismus								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vision blurred								
<10 years	0				0			
>=10 years	2	(0.9)	2	0.90	0			
Visual acuity reduced								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Vitreous detachment								
<10 years	0				0			
>=10 years	0				2	(1.0)	2	0.90
Vitreous floaters								
<10 years	0				0			
>=10 years	0				2	(1.0)	2	0.90
Gastrointestinal disorders								
All								
<10 years	9	(12.0)	18	23.21	11	(13.4)	18	20.62
>=10 years	38	(17.7)	63	28.30	31	(14.8)	57	25.64
Abdominal discomfort								
<10 years	0				1	(1.2)	1	1.15
>=10 years	2	(0.9)	2	0.90	1	(0.5)	1	0.45
Abdominal distension								
<10 years	0				0			
>=10 years	2	(0.9)	3	1.35	1	(0.5)	1	0.45
Abdominal pain								
<10 years	3	(4.0)	3	3.87	0			
>=10 years	4	(1.9)	4	1.80	1	(0.5)	1	0.45
Abdominal pain upper								
<10 years	1	(1.3)	2	2.58	1	(1.2)	1	1.15
>=10 years	2	(0.9)	2	0.90	1	(0.5)	1	0.45
Anal fissure								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Change of bowel habit								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Chronic gastritis								
<10 years	0				1	(1.2)	1	1.15
>=10 years	1	(0.5)	1	0.45	2	(1.0)	2	0.90
Constipation								
<10 years	0				1	(1.2)	1	1.15
>=10 years	2	(0.9)	3	1.35	1	(0.5)	1	0.45
Dental caries								
<10 years	0				1	(1.2)	1	1.15
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Diarrhoea								
<10 years	3	(4.0)	5	6.45	2	(2.4)	2	2.29
>=10 years	7	(3.3)	8	3.59	4	(1.9)	5	2.25
Diverticulum intestinal								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Duodenitis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Dyspepsia								
<10 years	0				0			
>=10 years	3	(1.4)	3	1.35	2	(1.0)	2	0.90
Enteritis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Faeces soft								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Flatulence								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	2	(0.9)	2	0.90	0			
Food poisoning								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	2	(1.0)	2	0.90
Gastric polyps								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				1	(0.5)	1	0.45
Gastritis								
<10 years	1	(1.3)	1	1.29	1	(1.2)	1	1.15
>=10 years	1	(0.5)	1	0.45	0			
Gastritis erosive								
<10 years	0				0			
>=10 years	0				2	(1.0)	2	0.90
Gastrointestinal haemorrhage								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Gastrooesophageal reflux disease								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	2	(1.0)	2	0.90
Gastrooesophageal sphincter insufficiency								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Gingival recession								
<10 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	0				1	(0.5)	2	0.90
Gingival ulceration								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Haematochezia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Haemorrhoids								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Hiatus hernia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Impaired gastric emptying								
<10 years	0				0			
>=10 years	2	(0.9)	3	1.35	0			
Irritable bowel syndrome								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Lumbar hernia								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Mouth ulceration								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Nausea								
<10 years	1	(1.3)	1	1.29	3	(3.7)	3	3.44
>=10 years	8	(3.7)	8	3.59	7	(3.3)	7	3.15
Odynophagia								
<10 years	0				1	(1.2)	2	2.29
>=10 years	0				0			
Oesophagitis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Pancreatic failure								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Pancreatitis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Pneumatosis intestinalis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Proctitis ulcerative								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				0			
>=10 years	0				1	(0.5)	2	0.90
Toothache								
<10 years	2	(2.7)	3	3.87	1	(1.2)	1	1.15
>=10 years	2	(0.9)	3	1.35	2	(1.0)	5	2.25
Vomiting								
<10 years	1	(1.3)	1	1.29	2	(2.4)	2	2.29
>=10 years	10	(4.7)	11	4.94	8	(3.8)	8	3.60
General disorders and administration site conditions								
All								
<10 years	11	(14.7)	18	23.21	17	(20.7)	35	40.10
>=10 years	44	(20.5)	66	29.65	48	(22.9)	148	66.58
Asthenia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	3	(1.4)	3	1.35
Chest pain								
<10 years	0				1	(1.2)	1	1.15
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Chills								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Complication associated with device								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Cyst								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Facial discomfort								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Facial pain								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Fatigue								
<10 years	1	(1.3)	1	1.29	3	(3.7)	3	3.44
>=10 years	6	(2.8)	7	3.14	2	(1.0)	2	0.90
Hunger								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	2	0.90
Hyperthermia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Illness								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Inflammation								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Influenza like illness								
<10 years	2	(2.7)	2	2.58	1	(1.2)	1	1.15
>=10 years	2	(0.9)	2	0.90	3	(1.4)	3	1.35
Injection site mass								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Injection site pain								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Injection site urticaria								
<10 years	1	(1.3)	2	2.58	0			
>=10 years	0				0			
Malaise								
<10 years	1	(1.3)	1	1.29	1	(1.2)	4	4.58
>=10 years	3	(1.4)	3	1.35	4	(1.9)	80	35.99
Medical device site bruise								
<10 years	0				1	(1.2)	1	1.15
>=10 years	2	(0.9)	2	0.90	1	(0.5)	1	0.45
Medical device site dermatitis								
<10 years	2	(2.7)	3	3.87	1	(1.2)	1	1.15
>=10 years	3	(1.4)	3	1.35	5	(2.4)	8	3.60
Medical device site erythema								
<10 years	0				1	(1.2)	2	2.29
>=10 years	2	(0.9)	3	1.35	4	(1.9)	5	2.25
Medical device site haematoma								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Medical device site haemorrhage								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Medical device site inflammation								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Medical device site irritation								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Medical device site pain								
<10 years	0				1	(1.2)	1	1.15
>=10 years	1	(0.5)	1	0.45	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Medical device site pruritus								
<10 years	0				3	(3.7)	3	3.44
>=10 years	1	(0.5)	1	0.45	2	(1.0)	2	0.90
Medical device site rash								
<10 years	1	(1.3)	1	1.29	4	(4.9)	4	4.58
>=10 years	6	(2.8)	7	3.14	7	(3.3)	8	3.60
Medical device site reaction								
<10 years	1	(1.3)	1	1.29	1	(1.2)	1	1.15
>=10 years	2	(0.9)	2	0.90	1	(0.5)	1	0.45
Medical device site vesicles								
<10 years	0				0			
>=10 years	1	(0.5)	2	0.90	0			
Nodule								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Non-cardiac chest pain								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Oedema								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Oedema peripheral								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	2	(0.9)	2	0.90	1	(0.5)	1	0.45
Pain								
<10 years	1	(1.3)	1	1.29	1	(1.2)	1	1.15
>=10 years	2	(0.9)	2	0.90	1	(0.5)	1	0.45
Peripheral swelling								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				1	(0.5)	1	0.45
Pyrexia								
<10 years	3	(4.0)	4	5.16	6	(7.3)	6	6.87
>=10 years	13	(6.0)	18	8.09	14	(6.7)	19	8.55
Swelling face								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Vaccination site discomfort								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Vaccination site joint pain								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Vaccination site lymphadenopathy								
<10 years	1	(1.3)	1	1.29	0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	0				0			
Vaccination site pain								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Vaccination site swelling								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Hepatobiliary disorders								
All								
<10 years	0				1	(1.2)	1	1.15
>=10 years	5	(2.3)	6	2.70	5	(2.4)	5	2.25
Cholecystitis chronic								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Gallbladder disorder								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Gallbladder polyp								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	2	(1.0)	2	0.90
Hepatic calcification								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Hepatic function abnormal								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Hepatic steatosis								
<10 years	0				0			
>=10 years	3	(1.4)	3	1.35	1	(0.5)	1	0.45
Hypertransaminasaemia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
<10 years	2	(2.7)	2	2.58	0			
>=10 years	3	(1.4)	3	1.35	6	(2.9)	6	2.70
Allergy to arthropod bite								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Allergy to arthropod sting								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Hypersensitivity								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	1	(0.5)	1	0.45	0			
Seasonal allergy								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	1	(0.5)	1	0.45	5	(2.4)	5	2.25
Infections and infestations								
All								
<10 years	38	(50.7)	86	110.89	45	(54.9)	84	96.23
>=10 years	121	(56.3)	224	100.63	114	(54.3)	219	98.52
Abscess limb								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	2	0.90
Acute sinusitis								
<10 years	0				2	(2.4)	2	2.29
>=10 years	0				1	(0.5)	1	0.45
Asymptomatic COVID-19								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Beta haemolytic streptococcal infection								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Breast abscess								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Bronchitis								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	4	(1.9)	4	1.80	3	(1.4)	4	1.80
Conjunctivitis								
<10 years	0				0			
>=10 years	4	(1.9)	5	2.25	0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Coronavirus infection								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				2	(1.0)	2	0.90
COVID-19								
<10 years	15	(20.0)	16	20.63	23	(28.0)	24	27.49
>=10 years	60	(27.9)	65	29.20	61	(29.0)	65	29.24
COVID-19 pneumonia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Cystitis								
<10 years	1	(1.3)	1	1.29	2	(2.4)	2	2.29
>=10 years	2	(0.9)	2	0.90	1	(0.5)	1	0.45
Cystitis escherichia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Ear infection								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Erythema migrans								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Eye infection								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Febrile infection								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Fungal infection								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Fungal skin infection								
<10 years	2	(2.7)	2	2.58	1	(1.2)	1	1.15
>=10 years	0				0			
Furuncle								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Gastric infection								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Gastroenteritis								
<10 years	1	(1.3)	1	1.29	2	(2.4)	3	3.44
>=10 years	12	(5.6)	17	7.64	3	(1.4)	3	1.35
Gastroenteritis viral								
<10 years	2	(2.7)	2	2.58	0			
>=10 years	1	(0.5)	1	0.45	3	(1.4)	3	1.35

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Gastrointestinal infection								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	2	(1.0)	4	1.80
Genital infection fungal								
<10 years	0				0			
>=10 years	1	(0.5)	2	0.90	0			
Gingival abscess								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Gingivitis								
<10 years	0				1	(1.2)	1	1.15
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Herpes zoster								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	2	(1.0)	2	0.90
Hordeolum								
<10 years	1	(1.3)	1	1.29	1	(1.2)	1	1.15
>=10 years	0				2	(1.0)	2	0.90
Impetigo								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Infected cyst								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Influenza								
<10 years	3	(4.0)	4	5.16	5	(6.1)	6	6.87
>=10 years	5	(2.3)	5	2.25	3	(1.4)	3	1.35
Laryngitis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Laryngopharyngitis								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Localised infection								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Lower respiratory tract infection								
<10 years	0				1	(1.2)	1	1.15
>=10 years	1	(0.5)	1	0.45	0			
Nasopharyngitis								
<10 years	19	(25.3)	26	33.53	19	(23.2)	26	29.79
>=10 years	29	(13.5)	49	22.01	42	(20.0)	58	26.09

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Norovirus infection								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Oral herpes								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Otitis externa								
<10 years	0				0			
>=10 years	0				3	(1.4)	3	1.35
Otitis media								
<10 years	0				0			
>=10 years	0				3	(1.4)	3	1.35
Pericoronitis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Periodontitis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Pharyngitis								
<10 years	2	(2.7)	2	2.58	1	(1.2)	1	1.15
>=10 years	6	(2.8)	6	2.70	1	(0.5)	2	0.90
Pneumonia								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Pulpitis dental								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Pyelonephritis acute								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Respiratory tract infection								
<10 years	0				0			
>=10 years	2	(0.9)	2	0.90	0			
Respiratory tract infection viral								
<10 years	2	(2.7)	2	2.58	2	(2.4)	2	2.29
>=10 years	2	(0.9)	2	0.90	1	(0.5)	1	0.45
Rhinitis								
<10 years	0				1	(1.2)	1	1.15
>=10 years	4	(1.9)	4	1.80	4	(1.9)	5	2.25
Sepsis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severe acute respiratory syndrome								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	2	(0.9)	2	0.90	1	(0.5)	1	0.45
Sinobronchitis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Sinusitis								
<10 years	6	(8.0)	6	7.74	3	(3.7)	3	3.44
>=10 years	8	(3.7)	9	4.04	6	(2.9)	6	2.70
Skin infection								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				1	(0.5)	1	0.45
Tinea cruris								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Tinea pedis								
<10 years	1	(1.3)	2	2.58	0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Tonsillitis								
<10 years	2	(2.7)	2	2.58	0			
>=10 years	0				2	(1.0)	3	1.35
Tooth abscess								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	3	(1.4)	3	1.35	0			
Tooth infection								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	1	(0.5)	1	0.45	0			
Tracheobronchitis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Trichophytosis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Upper respiratory tract infection								
<10 years	5	(6.7)	7	9.03	1	(1.2)	2	2.29
>=10 years	10	(4.7)	11	4.94	10	(4.8)	11	4.95
Urinary tract infection								
<10 years	2	(2.7)	2	2.58	1	(1.2)	2	2.29
>=10 years	10	(4.7)	10	4.49	7	(3.3)	8	3.60
Vaginal infection								
<10 years	0				0			
>=10 years	1	(0.5)	3	1.35	1	(0.5)	1	0.45

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Varicella								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Viral infection								
<10 years	0				1	(1.2)	1	1.15
>=10 years	1	(0.5)	1	0.45	4	(1.9)	5	2.25
Viral rhinitis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Vulvitis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Vulvovaginal mycotic infection								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Vulvovaginitis								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Injury, poisoning and procedural complications								
All								
<10 years	14	(18.7)	24	30.95	19	(23.2)	23	26.35
>=10 years	29	(13.5)	37	16.62	31	(14.8)	41	18.44
Accidental overdose								
<10 years	1	(1.3)	1	1.29	1	(1.2)	1	1.15
>=10 years	6	(2.8)	7	3.14	1	(0.5)	1	0.45
Anaemia postoperative								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Animal bite								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Animal scratch								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Ankle fracture								
<10 years	0				0			
>=10 years	1	(0.5)	3	1.35	0			
Arthropod bite								
<10 years	1	(1.3)	1	1.29	1	(1.2)	1	1.15
>=10 years	0				2	(1.0)	2	0.90
Back injury								
<10 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	0				1	(0.5)	1	0.45
Burns first degree								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Chest injury								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Clavicle fracture								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Concussion								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Contusion								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	1	(0.5)	1	0.45	3	(1.4)	3	1.35
Corneal abrasion								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Epicondylitis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Face injury								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Fall								
<10 years	0				0			
>=10 years	2	(0.9)	2	0.90	2	(1.0)	5	2.25
Fibula fracture								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Hand fracture								
<10 years	1	(1.3)	1	1.29	1	(1.2)	1	1.15
>=10 years	0				1	(0.5)	1	0.45
Heat stroke								
<10 years	0				0			
>=10 years	0				2	(1.0)	2	0.90
Incorrect dose administered								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	2	(0.9)	2	0.90	0			
Intentional underdose								
<10 years	0				0			
>=10 years	0				1	(0.5)	2	0.90
Joint injury								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Ligament rupture								
<10 years	0				0			
>=10 years	1	(0.5)	2	0.90	0			
Ligament sprain								
<10 years	2	(2.7)	2	2.58	0			
>=10 years	3	(1.4)	3	1.35	2	(1.0)	2	0.90
Limb injury								
<10 years	1	(1.3)	1	1.29	1	(1.2)	1	1.15
>=10 years	0				0			
Medication error								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Meniscus injury								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Muscle rupture								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Muscle strain								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Nerve injury								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Overdose								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Post-traumatic neck syndrome								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Prescribed overdose								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	4	(1.9)	4	1.80	0			
Procedural pain								
<10 years	1	(1.3)	2	2.58	0			
>=10 years	0				0			
Product administration error								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Product dispensing error								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Radius fracture								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Road traffic accident								
<10 years	1	(1.3)	2	2.58	1	(1.2)	1	1.15
>=10 years	1	(0.5)	1	0.45	0			
Skin abrasion								
<10 years	2	(2.7)	3	3.87	0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Skin laceration								
<10 years	0				1	(1.2)	1	1.15
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Stress fracture								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Tendon rupture								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Thermal burn								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Tooth fracture								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Vaccination complication								
<10 years	1	(1.3)	1	1.29	5	(6.1)	8	9.16
>=10 years	5	(2.3)	5	2.25	3	(1.4)	4	1.80
Venous injury								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Wound								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Wound dehiscence								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Wrist fracture								
<10 years	0				0			
>=10 years	0				2	(1.0)	2	0.90
Wrong product administered								
<10 years	0				2	(2.4)	2	2.29
>=10 years	0				2	(1.0)	2	0.90

Investigations

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
<10 years	6	(8.0)	7	9.03	3	(3.7)	3	3.44
>=10 years	13	(6.0)	17	7.64	14	(6.7)	16	7.20
Angiogram								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Aspartate aminotransferase increased								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Blood cholesterol increased								
<10 years	0				1	(1.2)	1	1.15
>=10 years	1	(0.5)	1	0.45	0			
Blood glucose fluctuation								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Blood glucose increased								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Blood pressure increased								
<10 years	1	(1.3)	2	2.58	0			
>=10 years	1	(0.5)	1	0.45	0			
Blood testosterone decreased								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Blood triglycerides increased								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Blood uric acid increased								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Body temperature increased								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Cardiac murmur								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Electrocardiogram abnormal								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Electrocardiogram T wave abnormal								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Eosinophil count increased								
<10 years	0				0			
>=10 years	0				1	(0.5)	2	0.90

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Glomerular filtration rate decreased								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Haemoglobin decreased								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Heart rate increased								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Hepatic enzyme increased								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Hepatitis B virus test positive								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Lipids abnormal								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Low density lipoprotein increased								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Mycobacterium tuberculosis complex test positive								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	1	(0.5)	1	0.45	0			
Occult blood positive								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Platelet count decreased								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Pulse absent								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
SARS-CoV-2 test positive								
<10 years	0				2	(2.4)	2	2.29
>=10 years	0				3	(1.4)	3	1.35
Serum ferritin decreased								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Weight decreased								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Weight increased								
<10 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	2	(0.9)	2	0.90	0			
White blood cell count decreased								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Metabolism and nutrition disorders								
All								
<10 years	5	(6.7)	6	7.74	5	(6.1)	5	5.73
>=10 years	13	(6.0)	18	8.09	11	(5.2)	14	6.30
Decreased appetite								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				2	(1.0)	2	0.90
Dehydration								
<10 years	0				0			
>=10 years	0				1	(0.5)	2	0.90
Diabetic dyslipidaemia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Diabetic ketoacidosis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Dyslipidaemia								
<10 years	0				0			
>=10 years	0				2	(1.0)	2	0.90
Hypercholesterolaemia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Hyperlipidaemia								
<10 years	2	(2.7)	2	2.58	1	(1.2)	1	1.15
>=10 years	0				0			
Hyperuricaemia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Hypoglycaemia								
<10 years	2	(2.7)	2	2.58	2	(2.4)	2	2.29
>=10 years	8	(3.7)	13	5.84	2	(1.0)	3	1.35
Hypokalaemia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Hyponatraemia								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Insulin resistance								
<10 years	0				0			

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	0				1	(0.5)	1	0.45
Iron deficiency								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Obesity								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Vitamin D deficiency								
<10 years	0				1	(1.2)	1	1.15
>=10 years	1	(0.5)	1	0.45	2	(1.0)	2	0.90
Musculoskeletal and connective tissue disorders								
All								
<10 years	11	(14.7)	17	21.92	13	(15.9)	22	25.20
>=10 years	34	(15.8)	41	18.42	43	(20.5)	77	34.64
Acquired claw toe								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Arthralgia								
<10 years	3	(4.0)	4	5.16	4	(4.9)	5	5.73
>=10 years	9	(4.2)	9	4.04	11	(5.2)	11	4.95
Arthritis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Back pain								
<10 years	3	(4.0)	3	3.87	2	(2.4)	3	3.44
>=10 years	2	(0.9)	2	0.90	15	(7.1)	28	12.60
Bursitis								
<10 years	1	(1.3)	1	1.29	1	(1.2)	1	1.15
>=10 years	0				0			
Chondromalacia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Flank pain								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Foot deformity								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	2	0.90
Groin pain								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				1	(0.5)	1	0.45
Intervertebral disc protrusion								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				0			
>=10 years	0				2	(1.0)	3	1.35
Limb discomfort								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	1	(0.5)	1	0.45	0			
Limb mass								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Muscle spasms								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	3	(1.4)	4	1.80	1	(0.5)	1	0.45
Muscular weakness								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Musculoskeletal stiffness								
<10 years	1	(1.3)	1	1.29	1	(1.2)	1	1.15
>=10 years	0				0			
Myalgia								
<10 years	0				2	(2.4)	4	4.58
>=10 years	3	(1.4)	3	1.35	6	(2.9)	7	3.15
Myopathy								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Neck pain								
<10 years	1	(1.3)	1	1.29	1	(1.2)	1	1.15
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Nodal osteoarthritis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Osteoarthritis								
<10 years	3	(4.0)	3	3.87	1	(1.2)	1	1.15
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Pain in extremity								
<10 years	1	(1.3)	1	1.29	3	(3.7)	3	3.44
>=10 years	7	(3.3)	7	3.14	10	(4.8)	10	4.50
Periarthritis								
<10 years	0				1	(1.2)	1	1.15
>=10 years	2	(0.9)	2	0.90	3	(1.4)	3	1.35
Rheumatoid arthritis								
<10 years	0				1	(1.2)	1	1.15
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Rotator cuff syndrome								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Spinal stenosis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Synovial cyst								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Tendonitis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Tenosynovitis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Trigger finger								
<10 years	0				0			
>=10 years	2	(0.9)	2	0.90	1	(0.5)	1	0.45

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
<10 years	1	(1.3)	1	1.29	1	(1.2)	1	1.15
>=10 years	7	(3.3)	7	3.14	4	(1.9)	5	2.25
Benign neoplasm of thyroid gland								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Benign renal neoplasm								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Colon adenoma								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Eye naevus								
<10 years	1	(1.3)	1	1.29	1	(1.2)	1	1.15
>=10 years	0				1	(0.5)	1	0.45
Haemangioma of liver								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Lipoma								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Melanocytic naevus								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Myeloproliferative neoplasm								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Seborrhoeic keratosis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Skin papilloma								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Uterine leiomyoma								
<10 years	0				0			
>=10 years	0				2	(1.0)	2	0.90
Nervous system disorders								
All								
<10 years	15	(20.0)	41	52.87	11	(13.4)	16	18.33
>=10 years	25	(11.6)	31	13.93	28	(13.3)	103	46.34

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

adsl.xpt; variable(s): ONTRDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL02FL) == "Y" & (ANELFL) == "Y"

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ageusia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Autonomic nervous system imbalance								
<10 years	0				0			
>=10 years	1	(0.5)	2	0.90	0			
Burning sensation								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Carpal tunnel syndrome								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Cerebral haemorrhage								
<10 years	1	(1.3)	2	2.58	0			
>=10 years	0				0			
Cerebral infarction								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Cervicobrachial syndrome								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	1	(0.5)	1	0.45	0			
Diabetic neuropathy								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Disturbance in attention								
<10 years	1	(1.3)	11	14.18	0			
>=10 years	0				0			
Dizziness								
<10 years	1	(1.3)	2	2.58	0			
>=10 years	1	(0.5)	1	0.45	5	(2.4)	6	2.70
Dizziness postural								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Encephalopathy								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Haemorrhage intracranial								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Headache								
<10 years	6	(8.0)	13	16.76	7	(8.5)	9	10.31
>=10 years	11	(5.1)	14	6.29	9	(4.3)	13	5.85

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hemiparesis								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Hypoaesthesia								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	1	(0.5)	2	0.90	2	(1.0)	2	0.90
Hypoglycaemic seizure								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				1	(0.5)	1	0.45
Hypoglycaemic unconsciousness								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Hypotonia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
IIIrd nerve paralysis								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Ischaemic stroke								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Loss of consciousness								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	2	(1.0)	2	0.90
Loss of proprioception								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Migraine								
<10 years	3	(4.0)	4	5.16	1	(1.2)	2	2.29
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Neuropathy peripheral								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Optic neuritis								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Post herpetic neuralgia								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Presyncope								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Radiculopathy								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Restless legs syndrome								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Sinus headache								
<10 years	0				1	(1.2)	1	1.15
>=10 years	1	(0.5)	1	0.45	0			
Somnolence								
<10 years	0				0			
>=10 years	2	(0.9)	2	0.90	0			
Syncope								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	2	(0.9)	2	0.90	0			
Tension headache								
<10 years	0				1	(1.2)	2	2.29
>=10 years	0				0			
Tremor								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				4	(1.9)	68	30.59
Pregnancy, puerperium and perinatal conditions								
All								
<10 years	0				0			
>=10 years	2	(0.9)	2	0.90	0			
Abortion spontaneous								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Abortion threatened								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Psychiatric disorders								
All								
<10 years	3	(4.0)	3	3.87	8	(9.8)	10	11.46
>=10 years	5	(2.3)	5	2.25	3	(1.4)	4	1.80
Alcohol abuse								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Anxiety								
<10 years	0				3	(3.7)	3	3.44
>=10 years	1	(0.5)	1	0.45	2	(1.0)	2	0.90
Anxiety disorder								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Attention deficit hyperactivity disorder								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Depressed mood								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Depression								
<10 years	0				4	(4.9)	4	4.58
>=10 years	0				1	(0.5)	1	0.45
Insomnia								
<10 years	0				2	(2.4)	2	2.29
>=10 years	1	(0.5)	1	0.45	0			
Major depression								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Sleep disorder								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Stress								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Renal and urinary disorders								
All								
<10 years	3	(4.0)	3	3.87	1	(1.2)	1	1.15
>=10 years	4	(1.9)	4	1.80	4	(1.9)	7	3.15
Acute kidney injury								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Chronic kidney disease								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Diabetic nephropathy								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				1	(0.5)	1	0.45
Dysuria								
<10 years	0				0			
>=10 years	2	(0.9)	2	0.90	0			
Hydrocalyx								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Hypertensive nephropathy								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Microalbuminuria								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Pollakiuria								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Proteinuria								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Renal cyst								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Renal pain								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	1	(0.5)	1	0.45	0			
Reproductive system and breast disorders								
All								
<10 years	4	(5.3)	5	6.45	3	(3.7)	5	5.73
>=10 years	5	(2.3)	5	2.25	5	(2.4)	5	2.25

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Atrophic vulvovaginitis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Benign prostatic hyperplasia								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Dysmenorrhoea								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	2	(1.0)	2	0.90
Ectropion of cervix								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Erectile dysfunction								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Fibrocystic breast disease								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Heavy menstrual bleeding								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Menstruation irregular								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Ovarian cyst								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Ovarian disorder								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Penile pain								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Premenstrual syndrome								
<10 years	0				1	(1.2)	1	1.15
>=10 years	1	(0.5)	1	0.45	0			
Prostatic cyst								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Prostatitis								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Prostatomegaly								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Respiratory, thoracic and mediastinal disorders								
All								
<10 years	8	(10.7)	13	16.76	8	(9.8)	8	9.16
>=10 years	28	(13.0)	41	18.42	29	(13.8)	49	22.04
Acute respiratory failure								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Allergic cough								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Asthma								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Bronchial hyperreactivity								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Cough								
<10 years	2	(2.7)	3	3.87	0			
>=10 years	7	(3.3)	9	4.04	11	(5.2)	15	6.75
Cough variant asthma								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Dysphonia								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Dyspnoea								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Dyspnoea exertional								
<10 years	0				1	(1.2)	1	1.15
>=10 years	1	(0.5)	1	0.45	0			
Epiglottic oedema								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Epistaxis								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	2	(0.9)	2	0.90	0			
Hiccups								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Nasal congestion								
<10 years	1	(1.3)	1	1.29	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Oropharyngeal discomfort								
<10 years	0				0			
>=10 years	0				2	(1.0)	2	0.90
Oropharyngeal pain								
<10 years	1	(1.3)	1	1.29	2	(2.4)	2	2.29
>=10 years	7	(3.3)	8	3.59	8	(3.8)	9	4.05
Pleurisy								
<10 years	0				1	(1.2)	1	1.15
>=10 years	1	(0.5)	1	0.45	0			
Productive cough								
<10 years	0				0			
>=10 years	0				3	(1.4)	4	1.80
Pulmonary congestion								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Pulmonary mass								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Respiratory disorder								
<10 years	3	(4.0)	3	3.87	1	(1.2)	1	1.15
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Rhinitis allergic								
<10 years	0				1	(1.2)	1	1.15
>=10 years	3	(1.4)	4	1.80	1	(0.5)	1	0.45
Rhinorrhoea								
<10 years	0				1	(1.2)	1	1.15
>=10 years	3	(1.4)	4	1.80	6	(2.9)	7	3.15
Sinus congestion								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	1	(0.5)	1	0.45	2	(1.0)	2	0.90
Sleep apnoea syndrome								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Sneezing								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Throat irritation								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Upper-airway cough syndrome								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Skin and subcutaneous tissue disorders								
All								
<10 years	11	(14.7)	13	16.76	10	(12.2)	17	19.48
>=10 years	25	(11.6)	29	13.03	30	(14.3)	37	16.64
Alopecia								
<10 years	0				0			
>=10 years	3	(1.4)	3	1.35	0			
Alopecia areata								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Angioedema								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Chronic spontaneous urticaria								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Cold sweat								
<10 years	0				2	(2.4)	7	8.02
>=10 years	0				3	(1.4)	3	1.35
Dermal cyst								
<10 years	1	(1.3)	1	1.29	1	(1.2)	1	1.15
>=10 years	0				1	(0.5)	1	0.45
Dermatitis								
<10 years	2	(2.7)	3	3.87	0			
>=10 years	3	(1.4)	4	1.80	3	(1.4)	4	1.80
Dermatitis allergic								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Dermatitis atopic								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	2	(1.0)	2	0.90
Dermatitis contact								
<10 years	1	(1.3)	1	1.29	1	(1.2)	1	1.15
>=10 years	3	(1.4)	3	1.35	6	(2.9)	6	2.70
Dry skin								
<10 years	1	(1.3)	1	1.29	1	(1.2)	1	1.15
>=10 years	0				0			
Eczema								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				2	(1.0)	2	0.90
Eczema asteatotic								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Erythema								

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				1	(0.5)	1	0.45
Erythema multiforme								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Hidradenitis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Hyperkeratosis								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				1	(0.5)	1	0.45
Ingrowing nail								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				2	(1.0)	2	0.90
Ingrown hair								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Lichen sclerosus								
<10 years	0				0			
>=10 years	2	(0.9)	2	0.90	0			
Macule								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Miliaria								
<10 years	0				0			
>=10 years	0				2	(1.0)	2	0.90
Pruritus								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				2	(1.0)	2	0.90
Psoriasis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Rash								
<10 years	2	(2.7)	2	2.58	1	(1.2)	1	1.15
>=10 years	2	(0.9)	2	0.90	1	(0.5)	1	0.45
Rash erythematous								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Seborrhoeic dermatitis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Skin fissures								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Skin irritation								
<10 years	0				1	(1.2)	1	1.15
>=10 years	2	(0.9)	2	0.90	0			
Skin lesion								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	1	(0.5)	1	0.45
Skin reaction								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Skin ulcer								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Telangiectasia								
<10 years	0				1	(1.2)	1	1.15
>=10 years	1	(0.5)	1	0.45	0			
Urticaria								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				3	(1.4)	3	1.35
Urticaria papular								
<10 years	0				1	(1.2)	1	1.15
>=10 years	0				0			
Vitiligo								
<10 years	1	(1.3)	1	1.29	0			
>=10 years	0				0			
Xeroderma								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Surgical and medical procedures								
All								
<10 years	0				0			
>=10 years	4	(1.9)	4	1.80	0			
Cardiac ablation								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Skin neoplasm excision								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Tooth extraction								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Wisdom teeth removal								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			

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

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vascular disorders								
All								
<10 years	3	(4.0)	3	3.87	3	(3.7)	3	3.44
>=10 years	8	(3.7)	8	3.59	7	(3.3)	8	3.60
Aortic aneurysm								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Arteriosclerosis								
<10 years	0				0			
>=10 years	1	(0.5)	1	0.45	0			
Brachiocephalic artery stenosis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Hypertension								
<10 years	3	(4.0)	3	3.87	3	(3.7)	3	3.44
>=10 years	5	(2.3)	5	2.25	4	(1.9)	4	1.80
Hypertensive crisis								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45
Hypotension								
<10 years	0				0			
>=10 years	2	(0.9)	2	0.90	0			
Varicose vein								
<10 years	0				0			
>=10 years	0				1	(0.5)	1	0.45

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

adsl.xpt; variable(s): ONTRDURY DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL02FL) == "Y" & (ANELFL) == "Y"

7.24.17 Adverse events by baseline BMI group - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<25	87				80			
>=25 - <30	164				171			
>=30 - <35	162				146			
>=35	79				95			
PYE (years)								
<25	136.15				121.08			
>=25 - <30	255.18				269.64			
>=30 - <35	252.14				228.71			
>=35	122.03				147.32			
Events								
<25	75	(86.2)	308	226.22	60	(75.0)	243	200.70
>=25 - <30	131	(79.9)	644	252.37	142	(83.0)	621	230.30
>=30 - <35	125	(77.2)	645	255.81	113	(77.4)	582	254.47
>=35	66	(83.5)	285	233.56	74	(77.9)	377	255.90
Serious								
Yes								
<25	13	(14.9)	13	9.55	9	(11.3)	11	9.09
>=25 - <30	21	(12.8)	37	14.50	27	(15.8)	41	15.21
>=30 - <35	23	(14.2)	32	12.69	16	(11.0)	38	16.61
>=35	7	(8.9)	13	10.65	19	(20.0)	29	19.68
No								
<25	74	(85.1)	295	216.67	60	(75.0)	232	191.62
>=25 - <30	126	(76.8)	607	237.87	136	(79.5)	580	215.10
>=30 - <35	122	(75.3)	613	243.12	113	(77.4)	544	237.85
>=35	65	(82.3)	272	222.90	71	(74.7)	348	236.21
Missing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severity								
Severe								
<25	3	(3.4)	3	2.20	6	(7.5)	8	6.61
>=25 - <30	11	(6.7)	15	5.88	13	(7.6)	16	5.93
>=30 - <35	10	(6.2)	15	5.95	9	(6.2)	24	10.49
>=35	2	(2.5)	5	4.10	8	(8.4)	13	8.82
Moderate								
<25	33	(37.9)	60	44.07	26	(32.5)	42	34.69
>=25 - <30	64	(39.0)	134	52.51	63	(36.8)	123	45.62
>=30 - <35	58	(35.8)	125	49.58	60	(41.1)	150	65.58
>=35	37	(46.8)	82	67.20	34	(35.8)	82	55.66
Mild								
<25	69	(79.3)	245	179.95	50	(62.5)	193	159.40
>=25 - <30	118	(72.0)	495	193.98	124	(72.5)	482	178.76
>=30 - <35	108	(66.7)	505	200.28	100	(68.5)	408	178.39
>=35	56	(70.9)	198	162.26	66	(69.5)	282	191.42
Missing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Related to basal insulin								
Probable								
<25	4	(4.6)	11	8.08	4	(5.0)	4	3.30
>=25 - <30	15	(9.1)	18	7.05	18	(10.5)	32	11.87
>=30 - <35	6	(3.7)	8	3.17	6	(4.1)	8	3.50
>=35	5	(6.3)	6	4.92	5	(5.3)	7	4.75
Possible								
<25	8	(9.2)	10	7.34	9	(11.3)	18	14.87
>=25 - <30	20	(12.2)	32	12.54	11	(6.4)	13	4.82
>=30 - <35	12	(7.4)	18	7.14	12	(8.2)	18	7.87
>=35	6	(7.6)	7	5.74	7	(7.4)	11	7.47
Unlikely								
<25	74	(85.1)	287	210.80	57	(71.3)	220	181.70
>=25 - <30	129	(78.7)	593	232.39	135	(78.9)	573	212.50
>=30 - <35	124	(76.5)	618	245.10	113	(77.4)	554	242.22
>=35	65	(82.3)	272	222.90	73	(76.8)	359	243.68
Missing								
<25	0				1	(1.3)	1	0.83
>=25 - <30	1	(0.6)	1	0.39	2	(1.2)	3	1.11
>=30 - <35	1	(0.6)	1	0.40	2	(1.4)	2	0.87
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to technical complaint for basal insulin								
Yes								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
No								
<25	75	(86.2)	308	226.22	59	(73.8)	242	199.87
>=25 - <30	131	(79.9)	643	251.98	142	(83.0)	618	229.19
>=30 - <35	125	(77.2)	645	255.81	113	(77.4)	579	253.15
>=35	66	(83.5)	285	233.56	74	(77.9)	377	255.90
NA								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Missing								
<25	0				1	(1.3)	1	0.83
>=25 - <30	1	(0.6)	1	0.39	2	(1.2)	3	1.11
>=30 - <35	0				2	(1.4)	2	0.87
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
<25	1	(1.1)	1	0.73	1	(1.3)	2	1.65
>=25 - <30	2	(1.2)	3	1.18	0			
>=30 - <35	2	(1.2)	3	1.19	2	(1.4)	5	2.19
>=35	0				0			
Not recovered/not resolved								
<25	38	(43.7)	69	50.68	35	(43.8)	63	52.03
>=25 - <30	75	(45.7)	189	74.07	74	(43.3)	152	56.37
>=30 - <35	71	(43.8)	176	69.80	64	(43.8)	155	67.77
>=35	29	(36.7)	74	60.64	43	(45.3)	77	52.27
Recovered/resolved with sequelae								
<25	3	(3.4)	3	2.20	0			
>=25 - <30	2	(1.2)	2	0.78	2	(1.2)	2	0.74
>=30 - <35	2	(1.2)	2	0.79	5	(3.4)	5	2.19
>=35	2	(2.5)	2	1.64	1	(1.1)	1	0.68
Recovering/resolving								
<25	2	(2.3)	3	2.20	3	(3.8)	4	3.30
>=25 - <30	9	(5.5)	10	3.92	9	(5.3)	9	3.34
>=30 - <35	6	(3.7)	11	4.36	8	(5.5)	14	6.12
>=35	4	(5.1)	4	3.28	10	(10.5)	12	8.15
Recovered/resolved								
<25	65	(74.7)	232	170.40	54	(67.5)	174	143.71
>=25 - <30	115	(70.1)	440	172.43	120	(70.2)	458	169.85
>=30 - <35	113	(69.8)	453	179.66	108	(74.0)	403	176.20
>=35	61	(77.2)	205	168.00	69	(72.6)	287	194.81
Unknown								
<25	0				0			
					0			
>=25 - <30	0				0			
					0			
>=30 - <35	0				0			
					0			
>=35	0				0			
					0			
Missing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

7.24.18 Adverse events by baseline BMI group - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<25	105				135			
>=25 - <30	118				102			
>=30 - <35	46				41			
>=35	21				14			
PYE (years)								
<25	105.56				145.28			
>=25 - <30	122.72				106.74			
>=30 - <35	50.00				42.78			
>=35	21.89				14.79			
Events								
<25	84	(80.0)	284	269.04	103	(76.3)	595	409.56
>=25 - <30	97	(82.2)	383	312.10	86	(84.3)	336	314.78
>=30 - <35	43	(93.5)	236	472.04	36	(87.8)	160	374.04
>=35	16	(76.2)	62	283.28	11	(78.6)	55	371.95
Serious								
Yes								
<25	7	(6.7)	8	7.58	6	(4.4)	6	4.13
>=25 - <30	12	(10.2)	17	13.85	10	(9.8)	14	13.12
>=30 - <35	3	(6.5)	11	22.00	3	(7.3)	4	9.35
>=35	2	(9.5)	3	13.71	1	(7.1)	1	6.76
No								
<25	81	(77.1)	276	261.46	103	(76.3)	589	405.43
>=25 - <30	97	(82.2)	366	298.25	86	(84.3)	322	301.67
>=30 - <35	43	(93.5)	225	450.04	36	(87.8)	156	364.69
>=35	16	(76.2)	59	269.57	11	(78.6)	54	365.18
Missing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severity								
Severe								
<25	4	(3.8)	4	3.79	2	(1.5)	2	1.38
>=25 - <30	11	(9.3)	16	13.04	4	(3.9)	4	3.75
>=30 - <35	3	(6.5)	6	12.00	3	(7.3)	4	9.35
>=35	2	(9.5)	2	9.14	0			
Moderate								
<25	18	(17.1)	34	32.21	28	(20.7)	62	42.68
>=25 - <30	40	(33.9)	87	70.90	30	(29.4)	48	44.97
>=30 - <35	19	(41.3)	46	92.01	15	(36.6)	28	65.46
>=35	6	(28.6)	12	54.83	9	(64.3)	21	142.02
Mild								
<25	76	(72.4)	246	233.04	96	(71.1)	531	365.50
>=25 - <30	86	(72.9)	280	228.17	80	(78.4)	284	266.07
>=30 - <35	42	(91.3)	184	368.03	33	(80.5)	128	299.23
>=35	15	(71.4)	48	219.31	10	(71.4)	34	229.93
Missing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Related to basal insulin								
Probable								
<25	6	(5.7)	6	5.68	6	(4.4)	7	4.82
>=25 - <30	10	(8.5)	14	11.41	4	(3.9)	4	3.75
>=30 - <35	4	(8.7)	5	10.00	1	(2.4)	1	2.34
>=35	0				0			
Possible								
<25	9	(8.6)	13	12.32	12	(8.9)	59	40.61
>=25 - <30	17	(14.4)	19	15.48	5	(4.9)	5	4.68
>=30 - <35	2	(4.3)	2	4.00	5	(12.2)	8	18.70
>=35	2	(9.5)	2	9.14	0			
Unlikely								
<25	82	(78.1)	265	251.04	102	(75.6)	529	364.13
>=25 - <30	94	(79.7)	350	285.21	85	(83.3)	327	306.35
>=30 - <35	42	(91.3)	229	458.04	36	(87.8)	151	353.00
>=35	16	(76.2)	59	269.57	11	(78.6)	55	371.95
Missing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(4.8)	1	4.57	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to technical complaint for basal insulin								
Yes								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
No								
<25	84	(80.0)	284	269.04	103	(76.3)	595	409.56
>=25 - <30	97	(82.2)	383	312.10	86	(84.3)	336	314.78
>=30 - <35	43	(93.5)	236	472.04	36	(87.8)	160	374.04
>=35	16	(76.2)	61	278.71	11	(78.6)	55	371.95
NA								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Missing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(4.8)	1	4.57	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Not recovered/not resolved								
<25	28	(26.7)	61	57.79	44	(32.6)	97	66.77
>=25 - <30	47	(39.8)	86	70.08	35	(34.3)	79	74.01
>=30 - <35	21	(45.7)	34	68.01	19	(46.3)	31	72.47
>=35	9	(42.9)	14	63.97	6	(42.9)	10	67.63
Recovered/resolved with sequelae								
<25	0				1	(0.7)	1	0.69
>=25 - <30	2	(1.7)	3	2.44	1	(1.0)	1	0.94
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Recovering/resolving								
<25	5	(4.8)	8	7.58	8	(5.9)	10	6.88
>=25 - <30	9	(7.6)	9	7.33	2	(2.0)	3	2.81
>=30 - <35	4	(8.7)	4	8.00	7	(17.1)	8	18.70
>=35	2	(9.5)	3	13.71	3	(21.4)	4	27.05
Recovered/resolved								
<25	73	(69.5)	214	202.73	91	(67.4)	487	335.22
>=25 - <30	91	(77.1)	285	232.24	79	(77.5)	253	237.02
>=30 - <35	42	(91.3)	198	396.03	32	(78.0)	120	280.53
>=35	15	(71.4)	45	205.61	11	(78.6)	41	277.27
Unknown								
<25	0				0			
					0			
>=25 - <30	0				0			
					0			
>=30 - <35	0				0			
					0			
>=35	0				0			
					0			
Missing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

7.24.19 Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<25	87				80			
>=25 - <30	164				171			
>=30 - <35	162				146			
>=35	79				95			
PYE (years)								
<25	136.15				121.08			
>=25 - <30	255.18				269.64			
>=30 - <35	252.14				228.71			
>=35	122.03				147.32			
Events								
<25	75	(86.2)	308	226.22	60	(75.0)	243	200.70
>=25 - <30	131	(79.9)	644	252.37	142	(83.0)	621	230.30
>=30 - <35	125	(77.2)	645	255.81	113	(77.4)	582	254.47
>=35	66	(83.5)	285	233.56	74	(77.9)	377	255.90
Blood and lymphatic system disorders								
All								
<25	2	(2.3)	3	2.20	2	(2.5)	2	1.65
>=25 - <30	2	(1.2)	2	0.78	8	(4.7)	9	3.34
>=30 - <35	5	(3.1)	5	1.98	5	(3.4)	5	2.19
>=35	6	(7.6)	7	5.74	4	(4.2)	4	2.72
Anaemia								
<25	2	(2.3)	2	1.47	1	(1.3)	1	0.83
>=25 - <30	2	(1.2)	2	0.78	5	(2.9)	6	2.23
>=30 - <35	3	(1.9)	3	1.19	1	(0.7)	1	0.44
>=35	3	(3.8)	3	2.46	3	(3.2)	3	2.04
Blood loss anaemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Eosinophilia								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	0			
Hypochromic anaemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Iron deficiency anaemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	2	(2.5)	2	1.64	0			
Lymphadenopathy								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	0			
Normochromic normocytic anaemia								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Polycythaemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Thrombocytopenia								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Cardiac disorders								
All								
<25	8	(9.2)	8	5.88	7	(8.8)	10	8.26
>=25 - <30	14	(8.5)	28	10.97	15	(8.8)	17	6.30
>=30 - <35	15	(9.3)	31	12.29	13	(8.9)	25	10.93
>=35	7	(8.9)	12	9.83	7	(7.4)	9	6.11
Acute coronary syndrome								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Acute myocardial infarction								
<25	0				0			
>=25 - <30	2	(1.2)	2	0.78	2	(1.2)	2	0.74
>=30 - <35	0				3	(2.1)	3	1.31
>=35	2	(2.5)	2	1.64	0			
Angina pectoris								
<25	0				1	(1.3)	1	0.83
>=25 - <30	2	(1.2)	2	0.78	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Angina unstable								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	2	(1.2)	2	0.78	1	(0.6)	1	0.37
>=30 - <35	2	(1.2)	2	0.79	0			
>=35	0				0			
Aortic valve calcification								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Aortic valve incompetence								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	1	(1.3)	1	0.82	0			
Arrhythmia								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Arteriosclerosis coronary artery								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Atrial fibrillation								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	1	(0.6)	1	0.39	2	(1.2)	2	0.74
>=30 - <35	5	(3.1)	6	2.38	4	(2.7)	7	3.06
>=35	1	(1.3)	1	0.82	0			
Atrial flutter								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	2	1.64	1	(1.1)	1	0.68
Atrial thrombosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Atrioventricular block complete								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Atrioventricular block first degree								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Atrioventricular block second degree								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Bradycardia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	2	(2.1)	2	1.36
Bundle branch block left								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Bundle branch block right								
<25	0				0			
>=25 - <30	2	(1.2)	2	0.78	1	(0.6)	1	0.37
>=30 - <35	0				1	(0.7)	2	0.87
>=35	0				0			
Cardiac dysfunction								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Cardiac failure								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	3	(1.9)	3	1.19	0			
>=35	1	(1.3)	1	0.82	1	(1.1)	1	0.68
Cardiac failure chronic								
<25	0				1	(1.3)	1	0.83
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	2	(1.2)	2	0.79	0			
>=35	0				0			
Cardiac failure congestive								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	1	(1.1)	1	0.68
Cardiac ventricular thrombosis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Cardio-respiratory arrest								
<25	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Cardiomyopathy								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Chronic coronary syndrome								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Congestive cardiomyopathy								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Coronary artery disease								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	4	(2.5)	4	1.59	1	(0.7)	1	0.44
>=35	0				1	(1.1)	1	0.68
Coronary artery occlusion								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Coronary artery stenosis								
<25	0				0			
>=25 - <30	2	(1.2)	3	1.18	0			
>=30 - <35	0				0			
>=35	0				0			
Diastolic dysfunction								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Left atrial dilatation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				0			
Left ventricular dysfunction								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Left ventricular hypertrophy								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	0			
Mitral valve incompetence								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Myocardial infarction								
<25	1	(1.1)	1	0.73	1	(1.3)	1	0.83
>=25 - <30	2	(1.2)	2	0.78	1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Myocardial ischaemia								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Palpitations								
<25	0				1	(1.3)	2	1.65
>=25 - <30	2	(1.2)	2	0.78	2	(1.2)	2	0.74
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				1	(1.1)	1	0.68
Pericardial effusion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Pericarditis								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Sinus arrhythmia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Sinus bradycardia								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Sinus tachycardia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	2	(1.4)	2	0.87

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Supraventricular extrasystoles								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				2	(1.4)	2	0.87
>=35	0				0			
Supraventricular tachycardia								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Tachycardia								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Tricuspid valve incompetence								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Ventricular extrasystoles								
<25	1	(1.1)	1	0.73	1	(1.3)	1	0.83
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	3	(1.9)	3	1.19	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Congenital, familial and genetic disorders								
All								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				2	(2.1)	2	1.36
Congenital syphilitic osteochondritis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Corneal dystrophy								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Dolichocolon								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Hydrocele								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Type V hyperlipidaemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Ear and labyrinth disorders								
All								
<25	4	(4.6)	5	3.67	2	(2.5)	2	1.65
>=25 - <30	4	(2.4)	4	1.57	3	(1.8)	3	1.11
>=30 - <35	3	(1.9)	3	1.19	5	(3.4)	5	2.19
>=35	1	(1.3)	1	0.82	3	(3.2)	4	2.72
Cerumen impaction								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear discomfort								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Ear inflammation								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Ear pain								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Eustachian tube dysfunction								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Hypoacusis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Presbyacusis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Tinnitus								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Vertigo								
<25	3	(3.4)	4	2.94	2	(2.5)	2	1.65
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	2	(1.4)	2	0.87
>=35	1	(1.3)	1	0.82	2	(2.1)	3	2.04
Vertigo positional								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				3	(1.8)	3	1.11
>=30 - <35	1	(0.6)	1	0.40	4	(2.7)	4	1.75
>=35	3	(3.8)	3	2.46	0			
Goitre								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Hyperplasia adrenal								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Hyperprolactinaemia								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Hyperthyroidism								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Hypothyroidism								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	0			
Thyroid mass								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	2	(2.5)	2	1.64	0			
Eye disorders								
All								
<25	15	(17.2)	24	17.63	13	(16.3)	21	17.34
>=25 - <30	36	(22.0)	47	18.42	26	(15.2)	46	17.06
>=30 - <35	30	(18.5)	44	17.45	22	(15.1)	34	14.87
>=35	8	(10.1)	12	9.83	15	(15.8)	18	12.22

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Acquired epiblepharon								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Age-related macular degeneration								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Asthenopia								
<25	0				1	(1.3)	1	0.83
>=25 - <30	2	(1.2)	2	0.78	0			
>=30 - <35	0				0			
>=35	0				0			
Astigmatism								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	2	(1.2)	2	0.79	0			
>=35	1	(1.3)	1	0.82	0			
Blepharitis								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	1	(1.3)	1	0.82	0			
Blepharitis allergic								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Cataract								
<25	5	(5.7)	8	5.88	1	(1.3)	1	0.83
>=25 - <30	7	(4.3)	8	3.14	3	(1.8)	4	1.48
>=30 - <35	6	(3.7)	7	2.78	5	(3.4)	6	2.62
>=35	0				3	(3.2)	4	2.72
Cataract diabetic								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Cataract nuclear								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				2	(1.4)	2	0.87
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cataract subcapsular								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Chorioretinal disorder								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Conjunctival cyst								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Conjunctival erosion								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Conjunctival haemorrhage								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	2	(1.2)	2	0.74
>=30 - <35	0				0			
>=35	0				0			
Conjunctival hyperaemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Conjunctivitis allergic								
<25	4	(4.6)	5	3.67	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Corneal opacity								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Dacryoadenitis acquired								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dermatochalasis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Diabetic retinal oedema								
<25	0				3	(3.8)	3	2.48
>=25 - <30	0				2	(1.2)	2	0.74
>=30 - <35	0				1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	0			
Diabetic retinopathy								
<25	2	(2.3)	3	2.20	5	(6.3)	6	4.96
>=25 - <30	14	(8.5)	17	6.66	15	(8.8)	19	7.05
>=30 - <35	15	(9.3)	15	5.95	7	(4.8)	8	3.50
>=35	5	(6.3)	6	4.92	5	(5.3)	5	3.39
Dry age-related macular degeneration								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Dry eye								
<25	2	(2.3)	2	1.47	1	(1.3)	1	0.83
>=25 - <30	1	(0.6)	1	0.39	2	(1.2)	2	0.74
>=30 - <35	2	(1.2)	2	0.79	1	(0.7)	1	0.44
>=35	0				1	(1.1)	1	0.68
Eye discharge								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Eye disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Eye inflammation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Eye irritation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Eye pain								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	2	(1.2)	2	0.74
>=30 - <35	0				0			
>=35	0				0			
Eyelid ptosis								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Giant papillary conjunctivitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Glaucoma								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				0			
Iritis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Macular oedema								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				0			
Myopia								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				0			
Non-proliferative retinopathy								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				2	(1.4)	2	0.87
>=35	0				0			
Normal tension glaucoma								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ocular hypertension								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Open angle glaucoma								
<25	0				0			
>=25 - <30	0				1	(0.6)	2	0.74
>=30 - <35	0				0			
>=35	0				0			
Optic disc vascular disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Optic ischaemic neuropathy								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Photophobia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Post thrombotic retinopathy								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Posterior capsule opacification								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Presbyopia								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				0			
Pterygium								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Punctate keratitis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Retinal aneurysm								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Retinal artery occlusion								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Retinal degeneration								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	1	(1.1)	1	0.68
Retinal detachment								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Retinal drusen								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Retinal haemorrhage								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Retinal tear								
<25	0				1	(1.3)	1	0.83
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Retinal vascular disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Retinal vein occlusion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				0			
Retinal vein thrombosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Retinopathy								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Retinopathy hypertensive								
<25	0				0			
>=25 - <30	0				2	(1.2)	2	0.74
>=30 - <35	2	(1.2)	2	0.79	0			
>=35	0				0			
Retinopathy proliferative								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Scintillating scotoma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	2	0.87
>=35	0				0			
Uveitis								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Vision blurred								
<25	0				1	(1.3)	1	0.83
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	0				2	(1.4)	2	0.87
>=35	1	(1.3)	1	0.82	0			
Visual impairment								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	2	(1.2)	2	0.74
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vitreous detachment								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				1	(1.1)	1	0.68
Vitreous floaters								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Vitreous haemorrhage								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Vitreous opacities								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Gastrointestinal disorders								
All								
<25	21	(24.1)	33	24.24	15	(18.8)	20	16.52
>=25 - <30	37	(22.6)	64	25.08	37	(21.6)	59	21.88
>=30 - <35	39	(24.1)	79	31.33	29	(19.9)	56	24.48
>=35	15	(19.0)	26	21.31	23	(24.2)	43	29.19
Abdominal discomfort								
<25	0				1	(1.3)	2	1.65
>=25 - <30	2	(1.2)	2	0.78	0			
>=30 - <35	0				2	(1.4)	4	1.75
>=35	0				0			
Abdominal distension								
<25	0				0			
>=25 - <30	4	(2.4)	4	1.57	0			
>=30 - <35	3	(1.9)	4	1.59	0			
>=35	1	(1.3)	1	0.82	2	(2.1)	2	1.36
Abdominal hernia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Abdominal pain								
<25	1	(1.1)	1	0.73	2	(2.5)	2	1.65
>=25 - <30	2	(1.2)	2	0.78	0			
>=30 - <35	2	(1.2)	2	0.79	4	(2.7)	4	1.75
>=35	3	(3.8)	3	2.46	1	(1.1)	1	0.68

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Abdominal pain lower								
<25	0				0			
>=25 - <30	1	(0.6)	2	0.78	1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Abdominal pain upper								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				4	(2.3)	4	1.48
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	1	(1.3)	1	0.82	1	(1.1)	2	1.36
Abdominal wall haematoma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Acid peptic disease								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Anal eczema								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Anal fissure								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				1	(1.1)	1	0.68
Anal pruritus								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Angular cheilitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Aphthous ulcer								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Ascites								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Barrett's oesophagus								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Chronic gastritis								
<25	0				1	(1.3)	1	0.83
>=25 - <30	3	(1.8)	3	1.18	2	(1.2)	2	0.74
>=30 - <35	1	(0.6)	1	0.40	2	(1.4)	2	0.87
>=35	0				1	(1.1)	1	0.68
Colitis								
<25	1	(1.1)	1	0.73	1	(1.3)	1	0.83
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Colitis ischaemic								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Colitis microscopic								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Constipation								
<25	1	(1.1)	1	0.73	1	(1.3)	1	0.83
>=25 - <30	4	(2.4)	4	1.57	3	(1.8)	3	1.11
>=30 - <35	2	(1.2)	2	0.79	2	(1.4)	2	0.87
>=35	1	(1.3)	1	0.82	0			
Crohn's disease								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Dental caries								
<25	3	(3.4)	4	2.94	0			
>=25 - <30	4	(2.4)	4	1.57	0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	1	(1.3)	2	1.64	1	(1.1)	1	0.68
Diarrhoea								
<25	6	(6.9)	9	6.61	1	(1.3)	1	0.83
>=25 - <30	12	(7.3)	13	5.09	9	(5.3)	11	4.08
>=30 - <35	15	(9.3)	24	9.52	8	(5.5)	9	3.94
>=35	6	(7.6)	8	6.56	8	(8.4)	8	5.43
Diverticulum								
<25	0				1	(1.3)	1	0.83

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				2	(1.4)	2	0.87
>=35	0				0			
Diverticulum intestinal								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(1.2)	2	0.79	0			
>=35	0				0			
Dry mouth								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Duodenal ulcer								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Duodenitis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Duodenogastric reflux								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Dyspepsia								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	1	(0.6)	1	0.39	2	(1.2)	2	0.74
>=30 - <35	2	(1.2)	2	0.79	0			
>=35	1	(1.3)	1	0.82	2	(2.1)	2	1.36
Enteritis								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Enterocolitis								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	2	(1.2)	3	1.19	0			
>=35	0				0			
Epigastric discomfort								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Erosive duodenitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Flatulence								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	1	(1.3)	1	0.82	0			
Food poisoning								
<25	0				1	(1.3)	1	0.83
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Frequent bowel movements								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Gastric disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Gastric polyps								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Gastritis								
<25	0				0			
>=25 - <30	2	(1.2)	2	0.78	1	(0.6)	1	0.37
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Gastritis erosive								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				2	(1.4)	2	0.87
>=35	0				0			
Gastrointestinal disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				2	(2.1)	2	1.36
Gastrointestinal haemorrhage								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Gastrointestinal inflammation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Gastrooesophageal reflux disease								
<25	2	(2.3)	2	1.47	2	(2.5)	2	1.65
>=25 - <30	3	(1.8)	3	1.18	1	(0.6)	1	0.37
>=30 - <35	2	(1.2)	2	0.79	4	(2.7)	4	1.75
>=35	1	(1.3)	1	0.82	1	(1.1)	1	0.68
Haematemesis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Haematochezia								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Haemorrhoids								
<25	1	(1.1)	1	0.73	1	(1.3)	1	0.83
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	2	(1.2)	2	0.79	2	(1.4)	2	0.87
>=35	0				2	(2.1)	2	1.36
Hiatus hernia								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Hyperaesthesia teeth								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hyperchlorhydria								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Ileus								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Inguinal hernia								
<25	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				1	(0.6)	2	0.74
>=30 - <35	0				0			
>=35	0				0			
Intestinal obstruction								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Irritable bowel syndrome								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				0			
Large intestine polyp								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				2	(1.2)	3	1.11
>=30 - <35	2	(1.2)	2	0.79	0			
>=35	0				0			
Loose tooth								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Melaena								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Nausea								
<25	2	(2.3)	2	1.47	1	(1.3)	1	0.83
>=25 - <30	7	(4.3)	8	3.14	3	(1.8)	3	1.11
>=30 - <35	9	(5.6)	10	3.97	2	(1.4)	4	1.75
>=35	2	(2.5)	2	1.64	3	(3.2)	3	2.04
Odynophagia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Oral discomfort								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Pancreatitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(1.2)	2	0.79	0			
>=35	0				1	(1.1)	1	0.68

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pancreatitis acute								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Pancreatitis chronic								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Periodontal disease								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Periodontal inflammation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	2	0.87
>=35	0				0			
Portal hypertensive gastropathy								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Rectal polyp								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Rectal prolapse								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Salivary gland calculus								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Stomatitis								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Tooth disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Tooth impacted								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Tooth loss								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Toothache								
<25	2	(2.3)	2	1.47	0			
>=25 - <30	3	(1.8)	3	1.18	2	(1.2)	2	0.74
>=30 - <35	4	(2.5)	5	1.98	1	(0.7)	1	0.44
>=35	2	(2.5)	2	1.64	1	(1.1)	1	0.68
Ulcerative gastritis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Umbilical hernia								
<25	0				0			
>=25 - <30	0				2	(1.2)	2	0.74
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Varices oesophageal								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Vomiting								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	2	(1.2)	2	0.78	6	(3.5)	8	2.97
>=30 - <35	3	(1.9)	3	1.19	0			
>=35	1	(1.3)	1	0.82	5	(5.3)	7	4.75
General disorders and administration site conditions								
All								
<25	19	(21.8)	31	22.77	21	(26.3)	28	23.13
>=25 - <30	32	(19.5)	60	23.51	25	(14.6)	37	13.72
>=30 - <35	27	(16.7)	49	19.43	29	(19.9)	50	21.86
>=35	13	(16.5)	20	16.39	23	(24.2)	35	23.76
Asthenia								
<25	1	(1.1)	1	0.73	1	(1.3)	1	0.83
>=25 - <30	3	(1.8)	4	1.57	0			
>=30 - <35	1	(0.6)	1	0.40	4	(2.7)	4	1.75

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				1	(1.1)	1	0.68
Chest discomfort								
<25	1	(1.1)	1	0.73	1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	2	(1.2)	2	0.79	1	(0.7)	1	0.44
>=35	0				0			
Chest pain								
<25	1	(1.1)	1	0.73	1	(1.3)	1	0.83
>=25 - <30	2	(1.2)	2	0.78	3	(1.8)	3	1.11
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				2	(2.1)	2	1.36
Chills								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				1	(1.1)	1	0.68
Cyst								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Death								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Discomfort								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Drug intolerance								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	1	(1.3)	1	0.82	0			
Early satiety								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Effusion								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Fatigue								
<25	3	(3.4)	3	2.20	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	4	(2.4)	4	1.57	0			
>=30 - <35	6	(3.7)	8	3.17	1	(0.7)	1	0.44
>=35	3	(3.8)	3	2.46	6	(6.3)	7	4.75
Feeling abnormal								
<25	1	(1.1)	5	3.67	0			
>=25 - <30	1	(0.6)	2	0.78	0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Feeling hot								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Gait disturbance								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Hunger								
<25	0				1	(1.3)	1	0.83
>=25 - <30	5	(3.0)	6	2.35	0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Implant site pruritus								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Inflammation								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Influenza like illness								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Injection site bruising								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	2	(1.4)	2	0.87
>=35	0				0			
Injection site dermatitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Injection site erythema								
<25	0				0			
>=25 - <30	0				3	(1.8)	3	1.11
>=30 - <35	0				1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	0			
Injection site haemorrhage								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Injection site hypersensitivity								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Injection site hypertrophy								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Injection site mass								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Injection site pain								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Injection site reaction								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Injection site urticaria								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Malaise								
<25	3	(3.4)	3	2.20	3	(3.8)	3	2.48
>=25 - <30	4	(2.4)	6	2.35	4	(2.3)	5	1.85
>=30 - <35	0				3	(2.1)	4	1.75
>=35	0				0			
Mass								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	1	(1.3)	1	0.82	0			
Medical device site bruise								
<25	0				0			
>=25 - <30	2	(1.2)	2	0.78	0			
>=30 - <35	2	(1.2)	2	0.79	1	(0.7)	2	0.87
>=35	1	(1.3)	2	1.64	0			
Medical device site dermatitis								
<25	1	(1.1)	1	0.73	3	(3.8)	3	2.48
>=25 - <30	0				2	(1.2)	5	1.85
>=30 - <35	1	(0.6)	4	1.59	2	(1.4)	5	2.19
>=35	0				2	(2.1)	2	1.36
Medical device site discomfort								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Medical device site eczema								
<25	0				1	(1.3)	2	1.65
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	2	0.79	1	(0.7)	2	0.87
>=35	0				0			
Medical device site erythema								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Medical device site haematoma								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Medical device site haemorrhage								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	1	(1.3)	1	0.82	1	(1.1)	1	0.68
Medical device site hypersensitivity								
<25	1	(1.1)	2	1.47	0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Medical device site inflammation								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Medical device site pain								
<25	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				0			
Medical device site pruritus								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	3	(1.9)	3	1.19	1	(0.7)	1	0.44
>=35	0				0			
Medical device site reaction								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	3	2.46	1	(1.1)	1	0.68
Non-cardiac chest pain								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				0			
Oedema								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Oedema peripheral								
<25	1	(1.1)	1	0.73	2	(2.5)	2	1.65
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	4	(2.5)	5	1.98	6	(4.1)	8	3.50
>=35	2	(2.5)	2	1.64	2	(2.1)	2	1.36
Pain								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	1	(0.6)	1	0.39	2	(1.2)	2	0.74
>=30 - <35	1	(0.6)	1	0.40	2	(1.4)	2	0.87
>=35	1	(1.3)	1	0.82	3	(3.2)	4	2.72
Peripheral swelling								
<25	0				2	(2.5)	2	1.65
>=25 - <30	1	(0.6)	2	0.78	0			
>=30 - <35	2	(1.2)	2	0.79	1	(0.7)	1	0.44
>=35	0				3	(3.2)	3	2.04
Procedural failure								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Pyrexia								
<25	7	(8.0)	7	5.14	7	(8.8)	8	6.61
>=25 - <30	11	(6.7)	13	5.09	11	(6.4)	13	4.82
>=30 - <35	8	(4.9)	8	3.17	3	(2.1)	4	1.75
>=35	1	(1.3)	2	1.64	2	(2.1)	2	1.36

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Swelling								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				1	(1.1)	1	0.68
Thirst								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Vaccination site erythema								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Vaccination site pain								
<25	1	(1.1)	1	0.73	1	(1.3)	1	0.83
>=25 - <30	4	(2.4)	6	2.35	0			
>=30 - <35	0				2	(1.4)	2	0.87
>=35	0				1	(1.1)	1	0.68
Vaccination site reaction								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Hepatobiliary disorders								
All								
<25	1	(1.1)	2	1.47	3	(3.8)	3	2.48
>=25 - <30	7	(4.3)	8	3.14	2	(1.2)	2	0.74
>=30 - <35	5	(3.1)	6	2.38	3	(2.1)	4	1.75
>=35	0				2	(2.1)	2	1.36
Biliary colic								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Cholelithiasis								
<25	0				1	(1.3)	1	0.83
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Gallbladder cholesterolosis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Hepatic cirrhosis								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Hepatic cyst								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Hepatic function abnormal								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Hepatic steatosis								
<25	0				1	(1.3)	1	0.83
>=25 - <30	5	(3.0)	5	1.96	1	(0.6)	1	0.37
>=30 - <35	3	(1.9)	3	1.19	1	(0.7)	1	0.44
>=35	0				0			
Hepatitis								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hypertransaminasaemia								
<25	1	(1.1)	2	1.47	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Liver disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Non-alcoholic steatohepatitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Nonalcoholic fatty liver disease								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Steatohepatitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	3	(1.8)	4	1.57	1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	2	(1.4)	3	1.31
>=35	2	(2.5)	2	1.64	3	(3.2)	3	2.04
Allergy to arthropod bite								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Allergy to arthropod sting								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Immunisation reaction								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	2	0.87
>=35	0				0			
Seasonal allergy								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	3	(1.8)	3	1.18	1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	2	(2.5)	2	1.64	2	(2.1)	2	1.36
Infections and infestations								
All								
<25	37	(42.5)	65	47.74	39	(48.8)	63	52.03
>=25 - <30	74	(45.1)	133	52.12	81	(47.4)	146	54.15
>=30 - <35	70	(43.2)	136	53.94	84	(57.5)	142	62.09
>=35	44	(55.7)	81	66.38	48	(50.5)	98	66.52
Abscess								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Acarodermatitis								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Acute sinusitis								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	2	(2.5)	2	1.64	0			
Anal abscess								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				1	(1.1)	1	0.68
Asymptomatic COVID-19								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Bacterial infection								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Balanitis candida								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Body tinea								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Breast abscess								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Breast cellulitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Bronchitis								
<25	0				1	(1.3)	1	0.83
>=25 - <30	6	(3.7)	6	2.35	0			
>=30 - <35	2	(1.2)	2	0.79	4	(2.7)	5	2.19
>=35	4	(5.1)	4	3.28	2	(2.1)	2	1.36
Candida infection								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Cellulitis								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	1	(1.1)	1	0.68
Chlamydial infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				0			
Chronic hepatitis C								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Chronic sinusitis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Chronic tonsillitis								
<25	0				0			
>=25 - <30	0				2	(1.2)	4	1.48
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				1	(1.1)	1	0.68
Clostridium difficile infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Conjunctivitis								
<25	2	(2.3)	2	1.47	1	(1.3)	1	0.83
>=25 - <30	2	(1.2)	3	1.18	0			
>=30 - <35	2	(1.2)	2	0.79	2	(1.4)	2	0.87
>=35	0				0			
Conjunctivitis bacterial								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Coronavirus infection								
<25	2	(2.3)	2	1.47	1	(1.3)	1	0.83
>=25 - <30	3	(1.8)	3	1.18	0			
>=30 - <35	0				4	(2.7)	5	2.19
>=35	1	(1.3)	1	0.82	1	(1.1)	1	0.68
COVID-19								
<25	11	(12.6)	12	8.81	15	(18.8)	16	13.21
>=25 - <30	30	(18.3)	33	12.93	42	(24.6)	45	16.69
>=30 - <35	29	(17.9)	29	11.50	24	(16.4)	25	10.93
>=35	21	(26.6)	21	17.21	23	(24.2)	25	16.97

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
COVID-19 pneumonia								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	3	(1.9)	3	1.19	3	(2.1)	3	1.31
>=35	0				0			
Cystitis								
<25	4	(4.6)	5	3.67	3	(3.8)	5	4.13
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	0				2	(1.4)	3	1.31
>=35	0				2	(2.1)	2	1.36
Dermatophytosis of nail								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Diverticulitis								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				2	(1.4)	2	0.87
>=35	0				1	(1.1)	1	0.68
Ear infection								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	2	(2.5)	2	1.64	0			
Empyema								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Endophthalmitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Epididymitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Erysipelas								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Escherichia urinary tract infection								
<25	0				1	(1.3)	1	0.83
>=25 - <30	1	(0.6)	1	0.39	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	0				0			
>=35	0				0			
Eye infection bacterial								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Folliculitis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	2	(1.2)	2	0.79	0			
>=35	0				0			
Fungal balanitis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Fungal infection								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	0			
Furuncle								
<25	0				0			
>=25 - <30	1	(0.6)	2	0.78	1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Gastroenteritis								
<25	0				2	(2.5)	3	2.48
>=25 - <30	3	(1.8)	3	1.18	2	(1.2)	2	0.74
>=30 - <35	2	(1.2)	2	0.79	2	(1.4)	2	0.87
>=35	1	(1.3)	1	0.82	0			
Gastroenteritis norovirus								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Gastroenteritis viral								
<25	0				0			
>=25 - <30	2	(1.2)	2	0.78	0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	2	(2.5)	2	1.64	1	(1.1)	1	0.68
Gastrointestinal infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				0			
Genital infection fungal								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Giardiasis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Gingivitis								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	2	(1.2)	2	0.78	0			
>=30 - <35	0				0			
>=35	1	(1.3)	2	1.64	2	(2.1)	3	2.04
Helicobacter gastritis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Helicobacter infection								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Hepatitis B								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Herpes dermatitis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Herpes simplex								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Herpes virus infection								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Herpes zoster								
<25	0				4	(5.0)	4	3.30
>=25 - <30	1	(0.6)	1	0.39	3	(1.8)	3	1.11
>=30 - <35	3	(1.9)	3	1.19	0			
>=35	2	(2.5)	2	1.64	1	(1.1)	1	0.68

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hordeolum								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(1.2)	2	0.79	0			
>=35	0				0			
Infected bite								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Infected skin ulcer								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Influenza								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				3	(2.1)	3	1.31
>=35	0				0			
Intestinal sepsis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Labyrinthitis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Laryngitis								
<25	0				0			
>=25 - <30	0				2	(1.2)	2	0.74
>=30 - <35	2	(1.2)	2	0.79	1	(0.7)	1	0.44
>=35	0				1	(1.1)	1	0.68
Laryngopharyngitis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Localised infection								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Lower respiratory tract infection								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	3	(1.9)	5	1.98	1	(0.7)	3	1.31
>=35	3	(3.8)	3	2.46	1	(1.1)	1	0.68
Lyme disease								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Lymphangitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Mastitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Mycoplasma infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Nail infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Nasopharyngitis								
<25	13	(14.9)	15	11.02	10	(12.5)	10	8.26
>=25 - <30	12	(7.3)	17	6.66	15	(8.8)	21	7.79
>=30 - <35	8	(4.9)	10	3.97	15	(10.3)	15	6.56
>=35	5	(6.3)	8	6.56	7	(7.4)	10	6.79
Onychomycosis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Oophoritis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Oral candidiasis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Oral herpes								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	2	(2.3)	2	1.47	0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	1	(1.1)	1	0.68
Oral infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Orchitis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Oropharyngeal candidiasis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Osteomyelitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Osteomyelitis chronic								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Otitis externa								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Otitis media								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				1	(0.7)	2	0.87
>=35	0				0			
Otitis media acute								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Otitis media chronic								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Parotitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	3	2.04
Peri-implantitis								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Pericoronitis								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Periodontitis								
<25	2	(2.3)	2	1.47	1	(1.3)	1	0.83
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				2	(1.4)	3	1.31
>=35	0				1	(1.1)	1	0.68
Pharyngitis								
<25	1	(1.1)	1	0.73	1	(1.3)	1	0.83
>=25 - <30	4	(2.4)	4	1.57	5	(2.9)	6	2.23
>=30 - <35	8	(4.9)	13	5.16	3	(2.1)	4	1.75
>=35	2	(2.5)	3	2.46	3	(3.2)	6	4.07
Pharyngitis bacterial								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				0			
Pharyngotonsillitis								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				1	(0.6)	2	0.74
>=30 - <35	0				0			
>=35	0				2	(2.1)	2	1.36
Pneumonia								
<25	0				0			
>=25 - <30	2	(1.2)	2	0.78	0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	2	(2.1)	2	1.36
Post procedural infection								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Pulpitis dental								
<25	0				0			
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Purulence								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Pyelonephritis chronic								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Respiratory syncytial virus infection								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Respiratory tract infection								
<25	1	(1.1)	1	0.73	1	(1.3)	1	0.83
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	2	(2.5)	2	1.64	3	(3.2)	4	2.72
Respiratory tract infection viral								
<25	1	(1.1)	4	2.94	0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	4	(2.5)	4	1.59	2	(1.4)	2	0.87
>=35	0				0			
Rhinitis								
<25	2	(2.3)	2	1.47	0			
>=25 - <30	2	(1.2)	2	0.78	5	(2.9)	6	2.23
>=30 - <35	2	(1.2)	3	1.19	2	(1.4)	3	1.31
>=35	1	(1.3)	1	0.82	2	(2.1)	2	1.36
Rotavirus infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Salpingitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Sepsis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Sinusitis								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	1	(1.1)	1	0.73	1	(1.3)	1	0.83
>=25 - <30	1	(0.6)	2	0.78	1	(0.6)	2	0.74
>=30 - <35	2	(1.2)	2	0.79	3	(2.1)	5	2.19
>=35	1	(1.3)	1	0.82	2	(2.1)	3	2.04
Skin bacterial infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Skin infection								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Staphylococcal infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Subcutaneous abscess								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	4	1.48
>=30 - <35	0				0			
>=35	0				0			
Tinea infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Tonsillitis								
<25	0				1	(1.3)	1	0.83
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	1	(1.3)	2	1.64	0			
Tooth abscess								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	1	0.40	4	(2.7)	4	1.75
>=35	2	(2.5)	2	1.64	0			
Tooth infection								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	1	0.40	3	(2.1)	4	1.75
>=35	0				0			
Tracheitis								
<25	0				0			
>=25 - <30	1	(0.6)	3	1.18	0			
>=30 - <35	0				2	(1.4)	2	0.87
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Upper respiratory tract infection								
<25	3	(3.4)	4	2.94	3	(3.8)	3	2.48
>=25 - <30	8	(4.9)	12	4.70	5	(2.9)	5	1.85
>=30 - <35	9	(5.6)	15	5.95	9	(6.2)	10	4.37
>=35	8	(10.1)	9	7.38	5	(5.3)	6	4.07
Urethritis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Urinary tract infection								
<25	1	(1.1)	1	0.73	4	(5.0)	5	4.13
>=25 - <30	2	(1.2)	3	1.18	8	(4.7)	11	4.08
>=30 - <35	5	(3.1)	7	2.78	5	(3.4)	5	2.19
>=35	1	(1.3)	1	0.82	4	(4.2)	4	2.72
Vaginal infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				1	(1.1)	1	0.68
Varicella								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Viral infection								
<25	0				0			
>=25 - <30	2	(1.2)	2	0.78	3	(1.8)	3	1.11
>=30 - <35	2	(1.2)	2	0.79	1	(0.7)	1	0.44
>=35	0				1	(1.1)	1	0.68
Viral pharyngitis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	2	(1.2)	2	0.74
>=30 - <35	0				0			
>=35	0				0			
Viral upper respiratory tract infection								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				1	(1.1)	1	0.68
Vulvovaginal candidiasis								
<25	1	(1.1)	1	0.73	1	(1.3)	1	0.83
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	1	(1.3)	3	2.46	1	(1.1)	1	0.68
Vulvovaginal mycotic infection								
<25	0				0			
>=25 - <30	1	(0.6)	2	0.78	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	0				0			
>=35	0				0			
Wound infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Injury, poisoning and procedural complications								
All								
<25	18	(20.7)	21	15.42	10	(12.5)	17	14.04
>=25 - <30	33	(20.1)	40	15.68	27	(15.8)	45	16.69
>=30 - <35	26	(16.0)	28	11.10	16	(11.0)	18	7.87
>=35	12	(15.2)	13	10.65	14	(14.7)	23	15.61
Accidental overdose								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Alcohol poisoning								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Animal bite								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Ankle fracture								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Arthropod bite								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Arthropod sting								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Avulsion fracture								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	0				0			
>=35	0				0			
Bone contusion								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Burn oral cavity								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Burns first degree								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Cervical vertebral fracture								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Chillblains								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Concussion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Contusion								
<25	2	(2.3)	2	1.47	2	(2.5)	2	1.65
>=25 - <30	1	(0.6)	1	0.39	8	(4.7)	10	3.71
>=30 - <35	2	(1.2)	3	1.19	3	(2.1)	4	1.75
>=35	0				0			
Deafness traumatic								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Endotracheal intubation complication								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Eye injury								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Fall								
<25	2	(2.3)	3	2.20	2	(2.5)	3	2.48
>=25 - <30	4	(2.4)	5	1.96	0			
>=30 - <35	1	(0.6)	1	0.40	3	(2.1)	3	1.31
>=35	1	(1.3)	1	0.82	2	(2.1)	2	1.36
Fibula fracture								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	0			
Foot fracture								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				1	(1.1)	1	0.68
Hand fracture								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Head injury								
<25	0				1	(1.3)	1	0.83
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Heat illness								
<25	1	(1.1)	1	0.73	1	(1.3)	2	1.65
>=25 - <30	0				2	(1.2)	2	0.74
>=30 - <35	0				0			
>=35	0				0			
Hip fracture								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Injury								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	2	(1.2)	2	0.78	0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Joint injury								
<25	0				0			
>=25 - <30	2	(1.2)	2	0.78	0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				1	(1.1)	1	0.68

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ligament sprain								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				3	(1.8)	3	1.11
>=30 - <35	0				0			
>=35	3	(3.8)	3	2.46	0			
Limb fracture								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Limb injury								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	1	(1.3)	1	0.82	0			
Lower limb fracture								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				2	(2.1)	2	1.36
Meniscus injury								
<25	0				0			
>=25 - <30	2	(1.2)	2	0.78	0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Muscle strain								
<25	1	(1.1)	1	0.73	1	(1.3)	1	0.83
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				1	(1.1)	1	0.68
Overdose								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Patella fracture								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Periprocedural myocardial infarction								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Post procedural fistula								
<25	0				0			
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Post procedural haemorrhage								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Post procedural hypothyroidism								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Post procedural stroke								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Post procedural swelling								
<25	0				0			
>=25 - <30	0				1	(0.6)	2	0.74
>=30 - <35	0				0			
>=35	0				0			
Post-traumatic neck syndrome								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Procedural pain								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Product administration error								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Radius fracture								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	1	(1.3)	1	0.82	0			
Rib fracture								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Road traffic accident								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Scar								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Skin abrasion								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	2	(2.5)	2	1.64	0			
Skin laceration								
<25	0				0			
>=25 - <30	2	(1.2)	2	0.78	0			
>=30 - <35	2	(1.2)	2	0.79	0			
>=35	0				0			
Soft tissue injury								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Spinal column injury								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Spinal cord injury cervical								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Stress fracture								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Subcutaneous haematoma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Tendon rupture								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Thermal burn								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				2	(2.1)	2	1.36
Tooth fracture								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	2	(1.2)	2	0.78	1	(0.6)	1	0.37
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Traumatic arthritis								
<25	1	(1.1)	2	1.47	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Traumatic haematoma								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Ulna fracture								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Underdose								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Upper limb fracture								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Vaccination complication								
<25	2	(2.3)	2	1.47	2	(2.5)	3	2.48
>=25 - <30	7	(4.3)	8	3.14	7	(4.1)	12	4.45
>=30 - <35	3	(1.9)	3	1.19	4	(2.7)	5	2.19
>=35	0				3	(3.2)	4	2.72
Wound								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	2	(1.2)	2	0.78	1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				1	(1.1)	1	0.68
Wrist fracture								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Investigations								
All								
<25	9	(10.3)	9	6.61	4	(5.0)	4	3.30
>=25 - <30	13	(7.9)	16	6.27	11	(6.4)	11	4.08
>=30 - <35	9	(5.6)	11	4.36	14	(9.6)	16	7.00
>=35	4	(5.1)	4	3.28	5	(5.3)	5	3.39
Alanine aminotransferase increased								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Aspartate aminotransferase increased								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Blood cholesterol increased								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	2	(1.2)	2	0.78	0			
>=30 - <35	0				0			
>=35	0				0			
Blood creatine increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Blood creatine phosphokinase increased								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Blood glucose increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Blood potassium increased								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Blood pressure decreased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Blood pressure increased								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	0			
Blood triglycerides increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				0			
Body temperature increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Cardiac stress test abnormal								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Electrocardiogram change								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Electrocardiogram repolarisation abnormality								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Electrocardiogram T wave inversion								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Glycosylated haemoglobin increased								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Haemoglobin decreased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	2	0.87
>=35	0				0			
Hepatic enzyme abnormal								
<25	0				1	(1.3)	1	0.83

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hepatic enzyme increased								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				1	(1.1)	1	0.68
International normalised ratio abnormal								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
International normalised ratio decreased								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
International normalised ratio increased								
<25	0				0			
>=25 - <30	1	(0.6)	2	0.78	0			
>=30 - <35	0				0			
>=35	0				0			
Intraocular pressure increased								
<25	0				0			
>=25 - <30	1	(0.6)	2	0.78	0			
>=30 - <35	0				0			
>=35	0				0			
Lipids increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Low density lipoprotein increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Prostatic specific antigen increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				0			
Protein urine present								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pulse absent								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Red blood cell count decreased								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
SARS-CoV-2 test positive								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	2	(2.1)	2	1.36
Serum ferritin decreased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Transferrin saturation decreased								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Troponin increased								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Weight decreased								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				0			
Weight increased								
<25	2	(2.3)	2	1.47	1	(1.3)	1	0.83
>=25 - <30	3	(1.8)	3	1.18	3	(1.8)	3	1.11
>=30 - <35	3	(1.9)	3	1.19	4	(2.7)	4	1.75
>=35	1	(1.3)	1	0.82	2	(2.1)	2	1.36
White blood cell count decreased								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Metabolism and nutrition disorders								
All								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	11	(12.6)	11	8.08	11	(13.8)	13	10.74
>=25 - <30	26	(15.9)	31	12.15	27	(15.8)	45	16.69
>=30 - <35	12	(7.4)	13	5.16	14	(9.6)	16	7.00
>=35	10	(12.7)	11	9.01	11	(11.6)	15	10.18
Adult failure to thrive								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Appetite disorder								
<25	0				0			
>=25 - <30	0				1	(0.6)	2	0.74
>=30 - <35	0				0			
>=35	0				0			
Decreased appetite								
<25	0				0			
>=25 - <30	3	(1.8)	3	1.18	0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				1	(1.1)	1	0.68
Dehydration								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Diabetes mellitus								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				2	(2.1)	2	1.36
Diabetes mellitus inadequate control								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Dyslipidaemia								
<25	3	(3.4)	3	2.20	2	(2.5)	2	1.65
>=25 - <30	7	(4.3)	7	2.74	5	(2.9)	6	2.23
>=30 - <35	1	(0.6)	1	0.40	2	(1.4)	3	1.31
>=35	3	(3.8)	4	3.28	0			
Electrolyte depletion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Electrolyte imbalance								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Fluid retention								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Gout								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	2	0.79	1	(0.7)	1	0.44
>=35	0				1	(1.1)	1	0.68
Hypercalcaemia								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hypercholesterolaemia								
<25	0				0			
>=25 - <30	0				2	(1.2)	2	0.74
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	0			
Hyperglycaemia								
<25	1	(1.1)	1	0.73	2	(2.5)	2	1.65
>=25 - <30	0				3	(1.8)	3	1.11
>=30 - <35	0				2	(1.4)	2	0.87
>=35	0				0			
Hyperkalaemia								
<25	1	(1.1)	1	0.73	2	(2.5)	2	1.65
>=25 - <30	3	(1.8)	3	1.18	1	(0.6)	1	0.37
>=30 - <35	2	(1.2)	2	0.79	1	(0.7)	1	0.44
>=35	0				0			
Hyperlipidaemia								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	2	(1.2)	2	0.79	1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	2	(2.1)	2	1.36
Hypertriglyceridaemia								
<25	1	(1.1)	1	0.73	1	(1.3)	1	0.83
>=25 - <30	3	(1.8)	3	1.18	4	(2.3)	4	1.48
>=30 - <35	2	(1.2)	2	0.79	4	(2.7)	4	1.75
>=35	0				0			
Hyperuricaemia								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Hypoglycaemia								
<25	3	(3.4)	3	2.20	2	(2.5)	2	1.65
>=25 - <30	3	(1.8)	4	1.57	8	(4.7)	20	7.42

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	3	(3.2)	4	2.72
Hypokalaemia								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Hypophosphataemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Increased appetite								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	1	(1.1)	1	0.68
Iron deficiency								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Lactic acidosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Malnutrition								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Metabolic disorder								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Obesity								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Type 2 diabetes mellitus								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Vitamin B12 deficiency								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	2	(2.3)	2	1.47	0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Vitamin D deficiency								
<25	0				0			
>=25 - <30	1	(0.6)	2	0.78	2	(1.2)	2	0.74
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	2	(2.5)	2	1.64	0			
Zinc deficiency								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Musculoskeletal and connective tissue disorders								
All								
<25	18	(20.7)	21	15.42	12	(15.0)	21	17.34
>=25 - <30	43	(26.2)	75	29.39	39	(22.8)	57	21.14
>=30 - <35	50	(30.9)	88	34.90	38	(26.0)	62	27.11
>=35	19	(24.1)	34	27.86	28	(29.5)	44	29.87
Arthralgia								
<25	4	(4.6)	4	2.94	3	(3.8)	4	3.30
>=25 - <30	8	(4.9)	10	3.92	4	(2.3)	7	2.60
>=30 - <35	12	(7.4)	15	5.95	9	(6.2)	10	4.37
>=35	6	(7.6)	7	5.74	6	(6.3)	7	4.75
Arthritis								
<25	0				1	(1.3)	2	1.65
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	2	(1.4)	2	0.87
>=35	0				0			
Axillary mass								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Back disorder								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Back pain								
<25	6	(6.9)	6	4.41	4	(5.0)	5	4.13
>=25 - <30	15	(9.1)	18	7.05	9	(5.3)	10	3.71
>=30 - <35	16	(9.9)	16	6.35	9	(6.2)	9	3.94
>=35	3	(3.8)	3	2.46	10	(10.5)	10	6.79
Bone cyst								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Bursitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	2	(1.4)	2	0.87
>=35	1	(1.3)	1	0.82	1	(1.1)	1	0.68
Cervical spinal stenosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Chondrodynia								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Chondropathy								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				1	(1.1)	1	0.68
Coccydynia								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Costochondritis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(1.2)	2	0.79	1	(0.7)	1	0.44
>=35	0				0			
Dupuytren's contracture								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Exostosis								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Fibromyalgia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(1.2)	2	0.79	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Fistula								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Flank pain								
<25	0				2	(2.5)	2	1.65
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Fracture nonunion								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Gouty arthritis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Groin pain								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	1	(1.3)	1	0.82	0			
Intervertebral disc disorder								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	2	(1.2)	2	0.79	1	(0.7)	1	0.44
>=35	0				0			
Intervertebral disc protrusion								
<25	0				0			
>=25 - <30	5	(3.0)	6	2.35	1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	3	(2.1)	4	1.75
>=35	1	(1.3)	1	0.82	1	(1.1)	1	0.68
Intervertebral disc space narrowing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Joint effusion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Joint swelling								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Ligamentitis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Limb deformity								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Lordosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Lumbar spinal stenosis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Mastication disorder								
<25	0				0			
>=25 - <30	0				1	(0.6)	2	0.74
>=30 - <35	0				0			
>=35	0				0			
Muscle contracture								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Muscle spasms								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	3	(1.8)	3	1.18	1	(0.6)	1	0.37
>=30 - <35	4	(2.5)	4	1.59	2	(1.4)	2	0.87
>=35	4	(5.1)	4	3.28	1	(1.1)	1	0.68
Muscular weakness								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Musculoskeletal chest pain								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	3	(1.9)	3	1.19	0			
>=35	0				1	(1.1)	1	0.68
Musculoskeletal pain								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Musculoskeletal stiffness								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	2	(1.2)	2	0.79	0			
>=35	0				0			
Myalgia								
<25	0				0			
>=25 - <30	2	(1.2)	2	0.78	0			
>=30 - <35	1	(0.6)	1	0.40	2	(1.4)	2	0.87
>=35	0				1	(1.1)	1	0.68
Myositis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Neck pain								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	3	(1.8)	3	1.18	1	(0.6)	1	0.37
>=30 - <35	3	(1.9)	3	1.19	2	(1.4)	2	0.87
>=35	0				5	(5.3)	5	3.39
Osteoarthritis								
<25	3	(3.4)	3	2.20	1	(1.3)	1	0.83
>=25 - <30	5	(3.0)	6	2.35	5	(2.9)	6	2.23
>=30 - <35	8	(4.9)	9	3.57	6	(4.1)	7	3.06
>=35	3	(3.8)	3	2.46	2	(2.1)	3	2.04
Osteochondrosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Osteopenia								
<25	0				0			
>=25 - <30	2	(1.2)	2	0.78	1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Pain in extremity								
<25	2	(2.3)	2	1.47	0			
>=25 - <30	5	(3.0)	7	2.74	5	(2.9)	7	2.60
>=30 - <35	7	(4.3)	9	3.57	5	(3.4)	5	2.19
>=35	4	(5.1)	5	4.10	4	(4.2)	5	3.39
Periarthritis								
<25	1	(1.1)	1	0.73	3	(3.8)	3	2.48
>=25 - <30	2	(1.2)	2	0.78	0			
>=30 - <35	2	(1.2)	2	0.79	2	(1.4)	2	0.87
>=35	1	(1.3)	1	0.82	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Plantar fasciitis								
<25	0				0			
>=25 - <30	3	(1.8)	3	1.18	1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	2	0.79	0			
>=35	1	(1.3)	1	0.82	0			
Polyarthritis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Rotator cuff syndrome								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	2	(1.2)	2	0.79	0			
>=35	0				0			
Scoliosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Spinal osteoarthritis								
<25	0				0			
>=25 - <30	3	(1.8)	3	1.18	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Spinal pain								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				3	(3.2)	3	2.04
Spinal stenosis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	0			
Spondylolisthesis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Synovial cyst								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Tendon calcification								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	0				0			
>=35	0				0			
Tendonitis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	0				1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	0			
Tenosynovitis								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				3	(1.8)	3	1.11
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	2	0.87
>=35	0				1	(1.1)	1	0.68
Tenosynovitis stenosans								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Torticollis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Trigger finger								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				2	(1.2)	5	1.85
>=30 - <35	0				0			
>=35	2	(2.5)	2	1.64	1	(1.1)	1	0.68
Vertebral osteophyte								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	8	(4.9)	9	3.53	4	(2.3)	6	2.23
>=30 - <35	9	(5.6)	10	3.97	5	(3.4)	7	3.06
>=35	1	(1.3)	1	0.82	0			
Acrochordon								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Basal cell carcinoma								
<25	0				0			
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	2	(1.2)	2	0.79	2	(1.4)	2	0.87
>=35	0				0			
Colon adenoma								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Colon cancer								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Dysplastic naevus								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Glioblastoma multiforme								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Haemangioma of liver								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Hepatocellular carcinoma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Hypergammaglobulinaemia benign monoclonal								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Lipoma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Lung adenocarcinoma								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Malignant melanoma in situ								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Metastases to liver								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Metastatic renal cell carcinoma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Neoplasm skin								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Oral fibroma								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Ovarian cancer metastatic								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Pancreatic carcinoma metastatic								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Pancreatic neoplasm								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Prostate cancer								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Seborrhoeic keratosis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	2	0.79	0			
>=35	1	(1.3)	1	0.82	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Skin papilloma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Small cell lung cancer								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Squamous cell carcinoma								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Uterine leiomyoma								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Nervous system disorders								
All								
<25	15	(17.2)	24	17.63	8	(10.0)	10	8.26
>=25 - <30	25	(15.2)	36	14.11	27	(15.8)	36	13.35
>=30 - <35	32	(19.8)	47	18.64	21	(14.4)	36	15.74
>=35	12	(15.2)	18	14.75	24	(25.3)	33	22.40
Ageusia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Anosmia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Balance disorder								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Brain injury								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Burning sensation								
<25	1	(1.1)	1	0.73	2	(2.5)	2	1.65
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Carotid arteriosclerosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Carotid artery stenosis								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Carpal tunnel syndrome								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	3	(1.9)	3	1.19	1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	1	(1.1)	1	0.68
Cerebral arteriosclerosis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Cerebral atrophy								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Cerebral haemorrhage								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Cerebral infarction								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Cerebrovascular accident								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Cerebrovascular disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Cervical radiculopathy								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Cognitive disorder								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Diabetic neuropathy								
<25	0				0			
>=25 - <30	2	(1.2)	2	0.78	1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				3	(3.2)	3	2.04
Dizziness								
<25	3	(3.4)	7	5.14	1	(1.3)	1	0.83
>=25 - <30	5	(3.0)	5	1.96	4	(2.3)	5	1.85
>=30 - <35	5	(3.1)	7	2.78	4	(2.7)	4	1.75
>=35	2	(2.5)	2	1.64	6	(6.3)	6	4.07
Dizziness postural								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Dysgeusia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Essential tremor								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Headache								
<25	5	(5.7)	6	4.41	2	(2.5)	2	1.65
>=25 - <30	6	(3.7)	11	4.31	6	(3.5)	8	2.97
>=30 - <35	7	(4.3)	7	2.78	7	(4.8)	15	6.56
>=35	4	(5.1)	4	3.28	6	(6.3)	7	4.75
Hypoaesthesia								
<25	2	(2.3)	2	1.47	0			
>=25 - <30	1	(0.6)	3	1.18	2	(1.2)	3	1.11
>=30 - <35	2	(1.2)	2	0.79	0			
>=35	1	(1.3)	1	0.82	2	(2.1)	2	1.36
Hypoglycaemic unconsciousness								
<25	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Ischaemic stroke								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Lethargy								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				2	(1.4)	2	0.87
>=35	0				0			
Lumbar radiculopathy								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				2	(1.4)	2	0.87
>=35	1	(1.3)	1	0.82	1	(1.1)	1	0.68
Memory impairment								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Mental impairment								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Metabolic encephalopathy								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Migraine								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(1.2)	2	0.79	0			
>=35	1	(1.3)	1	0.82	1	(1.1)	1	0.68
Movement disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Muscle tone disorder								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neuralgia								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Neuroglycopenia								
<25	0				1	(1.3)	3	2.48
>=25 - <30	0				0			
>=30 - <35	2	(1.2)	4	1.59	0			
>=35	0				0			
Neuropathy peripheral								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	1	(1.1)	1	0.68
Paraesthesia								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	2	(1.2)	2	0.74
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	2	(2.5)	2	1.64	2	(2.1)	2	1.36
Parkinsonian gait								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Pineal gland cyst								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Post herpetic neuralgia								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Presyncope								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	2	(1.2)	2	0.79	0			
>=35	0				1	(1.1)	1	0.68
Sciatica								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	1	(0.6)	1	0.39	4	(2.3)	4	1.48
>=30 - <35	1	(0.6)	1	0.40	2	(1.4)	3	1.31
>=35	0				2	(2.1)	4	2.72
Somnolence								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Stiff leg syndrome								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Syncope								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	3	1.19	1	(0.7)	1	0.44
>=35	3	(3.8)	3	2.46	0			
Tension headache								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	1	(0.6)	2	0.78	0			
>=30 - <35	0				0			
>=35	0				0			
Thrombotic stroke								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Transient ischaemic attack								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				1	(1.1)	1	0.68
Tremor								
<25	0				0			
>=25 - <30	2	(1.2)	3	1.18	0			
>=30 - <35	2	(1.2)	2	0.79	0			
>=35	2	(2.5)	2	1.64	1	(1.1)	1	0.68
Trigeminal neuralgia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Vertebral artery occlusion								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
VIth nerve paralysis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
VIth nerve paresis								
<25	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Psychiatric disorders								
All								
<25	4	(4.6)	4	2.94	1	(1.3)	1	0.83
>=25 - <30	11	(6.7)	13	5.09	3	(1.8)	3	1.11
>=30 - <35	4	(2.5)	4	1.59	6	(4.1)	6	2.62
>=35	4	(5.1)	4	3.28	3	(3.2)	3	2.04
Anxiety								
<25	0				1	(1.3)	1	0.83
>=25 - <30	3	(1.8)	3	1.18	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	0			
Depressed mood								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Depression								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	4	(2.4)	4	1.57	1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	2	(1.4)	2	0.87
>=35	1	(1.3)	1	0.82	1	(1.1)	1	0.68
Insomnia								
<25	3	(3.4)	3	2.20	0			
>=25 - <30	5	(3.0)	5	1.96	1	(0.6)	1	0.37
>=30 - <35	0				1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	2	(2.1)	2	1.36
Mood swings								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Nightmare								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Persistent depressive disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Psychotic disorder								
<25	0				0			
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Schizophrenia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Sleep disorder								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Renal and urinary disorders								
All								
<25	2	(2.3)	4	2.94	2	(2.5)	2	1.65
>=25 - <30	4	(2.4)	4	1.57	9	(5.3)	13	4.82
>=30 - <35	10	(6.2)	12	4.76	15	(10.3)	18	7.87
>=35	4	(5.1)	4	3.28	2	(2.1)	2	1.36
Acute kidney injury								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				0			
Calculus urinary								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Chronic kidney disease								
<25	1	(1.1)	1	0.73	1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				3	(2.1)	3	1.31
>=35	0				0			
Diabetic nephropathy								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				0			
Dysuria								
<25	0				1	(1.3)	1	0.83
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	2	(1.2)	2	0.79	1	(0.7)	1	0.44
>=35	0				1	(1.1)	1	0.68
Haematuria								
<25	0				0			
>=25 - <30	0				2	(1.2)	2	0.74
>=30 - <35	0				2	(1.4)	2	0.87

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	1	(1.3)	1	0.82	0			
Hypercalciuria								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Hypertonic bladder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Ketonuria								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Microalbuminuria								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Nephrolithiasis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	1	(1.1)	1	0.68
Nocturia								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Pollakiuria								
<25	0				0			
>=25 - <30	2	(1.2)	2	0.78	1	(0.6)	1	0.37
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Pyelocaliectasis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Renal colic								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Renal cyst								
<25	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				0			
>=30 - <35	2	(1.2)	2	0.79	2	(1.4)	2	0.87
>=35	0				0			
Renal impairment								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	3	(1.8)	3	1.11
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Ureterolithiasis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				0			
Urinary incontinence								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Urinary retention								
<25	0				0			
>=25 - <30	0				1	(0.6)	2	0.74
>=30 - <35	0				0			
>=35	0				0			
Urinary tract obstruction								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Urine odour abnormal								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Reproductive system and breast disorders								
All								
<25	2	(2.3)	2	1.47	1	(1.3)	1	0.83
>=25 - <30	5	(3.0)	5	1.96	8	(4.7)	11	4.08
>=30 - <35	3	(1.9)	3	1.19	4	(2.7)	6	2.62
>=35	5	(6.3)	5	4.10	3	(3.2)	4	2.72
Adenomyosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Atrophic vulvovaginitis								
<25	0				0			
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				1	(1.1)	1	0.68
Balanoposthitis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Benign prostatic hyperplasia								
<25	0				0			
>=25 - <30	2	(1.2)	2	0.78	2	(1.2)	2	0.74
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Breast mass								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Breast pain								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Erectile dysfunction								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	2	(2.5)	2	1.64	0			
Galactorrhoea								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Hydrometra								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Menopausal symptoms								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Ovarian cyst								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Penile rash								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	3	1.31
>=35	0				0			
Prostatism								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Prostatitis								
<25	0				0			
>=25 - <30	0				1	(0.6)	2	0.74
>=30 - <35	0				0			
>=35	0				0			
Pruritus genital								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Uterine haemorrhage								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Uterine polyp								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Uterine prolapse								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Vaginal prolapse								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Vulval eczema								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Vulval leukoplakia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vulvovaginal dryness								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Vulvovaginal pruritus								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	1	(1.1)	1	0.68
Respiratory, thoracic and mediastinal disorders								
All								
<25	10	(11.5)	16	11.75	7	(8.8)	9	7.43
>=25 - <30	11	(6.7)	12	4.70	15	(8.8)	27	10.01
>=30 - <35	28	(17.3)	39	15.47	16	(11.0)	23	10.06
>=35	6	(7.6)	9	7.38	10	(10.5)	10	6.79
Acquired diaphragmatic eventration								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Acute pulmonary oedema								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Acute respiratory failure								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Allergic bronchitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	2	0.87
>=35	0				0			
Asthma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	2	1.64	1	(1.1)	1	0.68
Bronchiectasis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Bronchitis chronic								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Chronic eosinophilic rhinosinusitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Chronic obstructive pulmonary disease								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	0			
Cough								
<25	3	(3.4)	3	2.20	1	(1.3)	1	0.83
>=25 - <30	1	(0.6)	1	0.39	4	(2.3)	4	1.48
>=30 - <35	9	(5.6)	10	3.97	1	(0.7)	2	0.87
>=35	1	(1.3)	1	0.82	2	(2.1)	2	1.36
Dry throat								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Dyspnoea								
<25	0				3	(3.8)	3	2.48
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	2	(1.4)	2	0.87
>=35	0				0			
Dyspnoea exertional								
<25	0				0			
>=25 - <30	2	(1.2)	2	0.78	1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Emphysema								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Epistaxis								
<25	0				0			
>=25 - <30	0				1	(0.6)	3	1.11
>=30 - <35	0				0			
>=35	0				0			
Haemoptysis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	0				0			
>=35	0				0			
Interstitial lung disease								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Laryngeal cyst								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Nasal congestion								
<25	2	(2.3)	2	1.47	0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	2	(1.2)	3	1.19	1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	0			
Nasal dryness								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Nasal turbinate hypertrophy								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Oropharyngeal pain								
<25	5	(5.7)	5	3.67	3	(3.8)	4	3.30
>=25 - <30	2	(1.2)	2	0.78	2	(1.2)	5	1.85
>=30 - <35	5	(3.1)	6	2.38	3	(2.1)	3	1.31
>=35	1	(1.3)	1	0.82	1	(1.1)	1	0.68
Paranasal sinus discomfort								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Pleural calcification								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Pleural effusion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Pleuritic pain								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Pneumothorax								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Productive cough								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				2	(1.4)	2	0.87
>=35	0				0			
Pulmonary embolism								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Pulmonary fibrosis								
<25	0				0			
>=25 - <30	1	(0.6)	2	0.78	0			
>=30 - <35	0				0			
>=35	0				0			
Pulmonary mass								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Respiratory disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	3	(2.1)	3	1.31
>=35	0				0			
Respiratory failure								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Rhinitis allergic								
<25	0				0			
>=25 - <30	0				1	(0.6)	5	1.85
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Rhinorrhoea								
<25	0				0			
>=25 - <30	0				2	(1.2)	2	0.74
>=30 - <35	5	(3.1)	5	1.98	1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Sinus congestion								
<25	1	(1.1)	2	1.47	0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Sinus pain								
<25	1	(1.1)	2	1.47	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Sleep apnoea syndrome								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	3	(1.9)	3	1.19	0			
>=35	0				1	(1.1)	1	0.68
Sneezing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Throat irritation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Upper respiratory tract inflammation								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Upper-airway cough syndrome								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Skin and subcutaneous tissue disorders								
All								
<25	13	(14.9)	16	11.75	7	(8.8)	10	8.26
>=25 - <30	22	(13.4)	32	12.54	17	(9.9)	24	8.90
>=30 - <35	16	(9.9)	20	7.93	21	(14.4)	28	12.24
>=35	8	(10.1)	9	7.38	8	(8.4)	13	8.82
Actinic keratosis								
<25	0				0			
>=25 - <30	1	(0.6)	2	0.78	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Alopecia								
<25	0				0			
>=25 - <30	3	(1.8)	3	1.18	0			
>=30 - <35	0				2	(1.4)	2	0.87
>=35	3	(3.8)	3	2.46	0			
Alopecia areata								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Angioedema								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Asteatosis								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Blister								
<25	0				0			
>=25 - <30	0				2	(1.2)	2	0.74
>=30 - <35	0				0			
>=35	0				0			
Cellulite								
<25	0				0			
>=25 - <30	0				1	(0.6)	2	0.74
>=30 - <35	0				0			
>=35	0				0			
Chloasma								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Cold sweat								
<25	1	(1.1)	2	1.47	1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	1	(1.1)	1	0.68
Cold urticaria								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Dermal cyst								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				1	(1.1)	1	0.68
Dermatitis								
<25	0				0			
>=25 - <30	0				2	(1.2)	2	0.74
>=30 - <35	1	(0.6)	1	0.40	2	(1.4)	2	0.87
>=35	0				0			
Dermatitis allergic								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Dermatitis contact								
<25	0				0			
>=25 - <30	4	(2.4)	5	1.96	3	(1.8)	3	1.11
>=30 - <35	2	(1.2)	3	1.19	3	(2.1)	3	1.31
>=35	0				1	(1.1)	2	1.36
Diabetic foot								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				0			
Drug eruption								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Dry skin								
<25	2	(2.3)	2	1.47	0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Ecchymosis								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	0			
Eczema								
<25	1	(1.1)	1	0.73	1	(1.3)	1	0.83
>=25 - <30	4	(2.4)	4	1.57	2	(1.2)	2	0.74
>=30 - <35	2	(1.2)	2	0.79	0			
>=35	1	(1.3)	1	0.82	1	(1.1)	1	0.68
Eczema nummular								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Erythema								
<25	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Granuloma annulare								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Haemorrhage subcutaneous								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Hyperhidrosis								
<25	2	(2.3)	2	1.47	0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	1	(1.3)	1	0.82	0			
Hyperkeratosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Ingrowing nail								
<25	1	(1.1)	1	0.73	1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Lentigo								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Lipodystrophy acquired								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Lipohypertrophy								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Macule								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Miliaria								
<25	0				2	(2.5)	2	1.65
>=25 - <30	1	(0.6)	2	0.78	0			
>=30 - <35	2	(1.2)	2	0.79	1	(0.7)	1	0.44
>=35	0				2	(2.1)	2	1.36
Myxoid cyst								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Night sweats								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Onychalgia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Pruritus								
<25	0				0			
>=25 - <30	1	(0.6)	3	1.18	1	(0.6)	1	0.37
>=30 - <35	2	(1.2)	2	0.79	2	(1.4)	2	0.87
>=35	1	(1.3)	1	0.82	1	(1.1)	1	0.68
Psoriasis								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Purpura								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Rash								
<25	0				0			
>=25 - <30	2	(1.2)	2	0.78	3	(1.8)	3	1.11
>=30 - <35	0				3	(2.1)	3	1.31
>=35	0				2	(2.1)	2	1.36
Rosacea								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Skin exfoliation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Skin fissures								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Skin irritation								
<25	0				0			
>=25 - <30	1	(0.6)	2	0.78	1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Skin lesion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	2	(1.4)	2	0.87
>=35	1	(1.3)	1	0.82	0			
Skin ulcer								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Urticaria								
<25	1	(1.1)	2	1.47	0			
>=25 - <30	0				2	(1.2)	2	0.74
>=30 - <35	0				2	(1.4)	2	0.87
>=35	0				1	(1.1)	1	0.68
Urticaria contact								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Urticaria thermal								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Surgical and medical procedures								
All								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Removal of foreign body								
<25	0				1	(1.3)	1	0.83
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vascular disorders								
All								
<25	5	(5.7)	6	4.41	4	(5.0)	4	3.30
>=25 - <30	15	(9.1)	20	7.84	17	(9.9)	20	7.42
>=30 - <35	13	(8.0)	14	5.55	16	(11.0)	18	7.87
>=35	7	(8.9)	9	7.38	6	(6.3)	7	4.75
Aneurysm								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Aortic arteriosclerosis								
<25	0				0			
>=25 - <30	2	(1.2)	2	0.78	0			
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				0			
Aortic stenosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Arteriosclerosis								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				0			
Blood pressure inadequately controlled								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Brachiocephalic arteriosclerosis								
<25	0				0			
>=25 - <30	0				2	(1.2)	2	0.74
>=30 - <35	1	(0.6)	1	0.40	1	(0.7)	1	0.44
>=35	0				0			
Diabetic vascular disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Flushing								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Haematoma								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	3	(1.9)	3	1.19	1	(0.7)	1	0.44
>=35	0				0			
Hypertension								
<25	2	(2.3)	2	1.47	3	(3.8)	3	2.48
>=25 - <30	7	(4.3)	7	2.74	7	(4.1)	8	2.97
>=30 - <35	3	(1.9)	3	1.19	4	(2.7)	4	1.75
>=35	3	(3.8)	3	2.46	2	(2.1)	2	1.36
Hypertensive angiopathy								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	0				1	(0.7)	1	0.44
>=35	1	(1.3)	1	0.82	0			
Hypertensive crisis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Hypertensive urgency								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Hypotension								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	0				0			
>=30 - <35	2	(1.2)	2	0.79	1	(0.7)	1	0.44
>=35	0				1	(1.1)	1	0.68
Iliac artery stenosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Intermittent claudication								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				1	(1.1)	1	0.68
Macroangiopathy								
<25	0				0			
>=25 - <30	0				1	(0.6)	1	0.37
>=30 - <35	0				0			
>=35	0				0			
Peripheral arterial occlusive disease								
<25	0				0			
>=25 - <30	1	(0.6)	2	0.78	2	(1.2)	2	0.74
>=30 - <35	0				3	(2.1)	3	1.31

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Peripheral artery occlusion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Peripheral artery stenosis								
<25	0				0			
>=25 - <30	1	(0.6)	2	0.78	0			
>=30 - <35	0				0			
>=35	0				0			
Peripheral coldness								
<25	2	(2.3)	2	1.47	1	(1.3)	1	0.83
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Peripheral vascular disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Peripheral venous disease								
<25	0				0			
>=25 - <30	0				2	(1.2)	2	0.74
>=30 - <35	0				0			
>=35	1	(1.3)	1	0.82	0			
Post thrombotic syndrome								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(1.1)	1	0.68
Secondary hypertension								
<25	0				0			
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Superficial vein thrombosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(0.6)	1	0.40	0			
>=35	0				0			
Thrombophlebitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			
Thrombosis								
<25	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	1	(0.6)	1	0.39	0			
>=30 - <35	0				0			
>=35	0				0			
Varicose vein								
<25	1	(1.1)	1	0.73	0			
>=25 - <30	1	(0.6)	1	0.39	1	(0.6)	1	0.37
>=30 - <35	0				1	(0.7)	1	0.44
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"
nn1436/nn1436-japan/submission_ext_20230612_er
21JUN2023:08:58:47 - taesocptgrptrl.R/taesocptgrpbmisumontow1sas.txt

7.24.20 Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
<25	105				135			
>=25 - <30	118				102			
>=30 - <35	46				41			
>=35	21				14			
PYE (years)								
<25	105.56				145.28			
>=25 - <30	122.72				106.74			
>=30 - <35	50.00				42.78			
>=35	21.89				14.79			
Events								
<25	84	(80.0)	284	269.04	103	(76.3)	595	409.56
>=25 - <30	97	(82.2)	383	312.10	86	(84.3)	336	314.78
>=30 - <35	43	(93.5)	236	472.04	36	(87.8)	160	374.04
>=35	16	(76.2)	62	283.28	11	(78.6)	55	371.95

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blood and lymphatic system disorders								
All								
<25	3	(2.9)	3	2.84	0			
>=25 - <30	3	(2.5)	3	2.44	3	(2.9)	4	3.75
>=30 - <35	1	(2.2)	2	4.00	2	(4.9)	2	4.68
>=35	0				0			
Anaemia								
<25	3	(2.9)	3	2.84	0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Blood loss anaemia								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Iron deficiency anaemia								
<25	0				0			
>=25 - <30	0				2	(2.0)	3	2.81
>=30 - <35	0				0			
>=35	0				0			
Lymphadenitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Lymphadenopathy								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	1	(2.2)	1	2.00	1	(2.4)	1	2.34
>=35	0				0			
Splenomegaly								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Thrombocytopenia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Cardiac disorders								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
<25	6	(5.7)	6	5.68	5	(3.7)	8	5.51
>=25 - <30	6	(5.1)	7	5.70	2	(2.0)	2	1.87
>=30 - <35	4	(8.7)	5	10.00	3	(7.3)	4	9.35
>=35	0				1	(7.1)	1	6.76
Acute myocardial infarction								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Angina pectoris								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Angina unstable								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Aortic valve incompetence								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Atrial fibrillation								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Bundle branch block right								
<25	0				1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Cardiac failure congestive								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Cardiomegaly								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cardiovascular disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Conduction disorder								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Coronary artery disease								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	6.76
Left ventricular hypertrophy								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Mitral valve incompetence								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Myocardial infarction								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Myocardial ischaemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Palpitations								
<25	2	(1.9)	2	1.89	2	(1.5)	3	2.06
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	2	(4.9)	2	4.68
>=35	0				0			
Tachycardia								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tricuspid valve incompetence								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Ventricular extrasystoles								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	2	(1.7)	2	1.63	0			
>=30 - <35	0				0			
>=35	0				0			
Congenital, familial and genetic disorders								
All								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Arteriovenous malformation								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Colour blindness								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
<25	2	(1.9)	2	1.89	3	(2.2)	3	2.06
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Deafness neurosensory								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Ear pain								
<25	1	(1.0)	1	0.95	1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Tinnitus								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Tympanic membrane perforation								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Vertigo								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
<25	0				1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	1	(4.8)	1	4.57	0			
Autoimmune thyroiditis								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Hypogonadism								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(4.8)	1	4.57	0			
Hypothyroidism								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Thyroiditis chronic								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Eye disorders								
All								
<25	19	(18.1)	27	25.58	18	(13.3)	28	19.27
>=25 - <30	18	(15.3)	27	22.00	13	(12.7)	19	17.80
>=30 - <35	4	(8.7)	5	10.00	11	(26.8)	15	35.07
>=35	2	(9.5)	3	13.71	4	(28.6)	4	27.05
Angle closure glaucoma								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Arteriosclerotic retinopathy								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Astigmatism								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Cataract								
<25	3	(2.9)	3	2.84	1	(0.7)	1	0.69
>=25 - <30	2	(1.7)	2	1.63	1	(1.0)	1	0.94
>=30 - <35	1	(2.2)	1	2.00	2	(4.9)	3	7.01
>=35	0				0			
Cataract nuclear								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Conjunctival haemorrhage								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Corneal erosion								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Diabetic retinal oedema								
<25	0				0			
>=25 - <30	2	(1.7)	2	1.63	1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Diabetic retinopathy								
<25	13	(12.4)	16	15.16	11	(8.1)	12	8.26
>=25 - <30	10	(8.5)	11	8.96	7	(6.9)	8	7.49
>=30 - <35	0				7	(17.1)	8	18.70
>=35	1	(4.8)	1	4.57	1	(7.1)	1	6.76
Dry eye								
<25	0				1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Eczema eyelids								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Epiretinal membrane								
<25	0				0			
>=25 - <30	2	(1.7)	2	1.63	0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Eye pain								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	6.76
Glaucoma								
<25	0				2	(1.5)	2	1.38
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				1	(7.1)	1	6.76
Macular oedema								
<25	2	(1.9)	2	1.89	0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	2	(4.3)	3	6.00	0			
>=35	0				0			
Myopia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Non-proliferative retinopathy								
<25	0				2	(1.5)	2	1.38
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	2	(9.5)	2	9.14	0			
Ocular hypertension								
<25	0				1	(0.7)	2	1.38
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Photopsia								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Posterior capsule opacification								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	2	1.87
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Presbyopia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Pterygium								
<25	0				1	(0.7)	2	1.38
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Retinal drusen								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	6.76
Retinal haemorrhage								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Retinal vascular disorder								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Retinopathy								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Retinopathy hypertensive								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Strabismus								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Vision blurred								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Visual acuity reduced								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Vitreous detachment								
<25	0				2	(1.5)	2	1.38
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Vitreous floaters								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Gastrointestinal disorders								
All								
<25	11	(10.5)	13	12.32	21	(15.6)	40	27.53
>=25 - <30	17	(14.4)	24	19.56	12	(11.8)	18	16.86
>=30 - <35	15	(32.6)	39	78.01	5	(12.2)	9	21.04
>=35	4	(19.0)	5	22.85	4	(28.6)	8	54.10
Abdominal discomfort								
<25	0				1	(0.7)	1	0.69
>=25 - <30	2	(1.7)	2	1.63	0			
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	6.76
Abdominal distension								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	2	(4.3)	3	6.00	0			
>=35	0				0			
Abdominal pain								
<25	2	(1.9)	2	1.89	0			
>=25 - <30	4	(3.4)	4	3.26	0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				1	(7.1)	1	6.76
Abdominal pain upper								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				2	(2.0)	2	1.87
>=30 - <35	2	(4.3)	3	6.00	0			
>=35	0				0			
Anal fissure								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Change of bowel habit								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Chronic gastritis								
<25	0				1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Constipation								
<25	1	(1.0)	1	0.95	1	(0.7)	1	0.69
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	1	(2.2)	2	4.00	0			
>=35	0				0			
Dental caries								
<25	1	(1.0)	1	0.95	1	(0.7)	1	0.69
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Diarrhoea								
<25	1	(1.0)	1	0.95	2	(1.5)	2	1.38
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	6	(13.0)	9	18.00	1	(2.4)	1	2.34
>=35	2	(9.5)	2	9.14	2	(14.3)	3	20.29
Diverticulum intestinal								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Duodenitis								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Dyspepsia								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	1	(0.8)	1	0.81	2	(2.0)	2	1.87
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Enteritis								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Faeces soft								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Flatulence								
<25	0				0			
>=25 - <30	2	(1.7)	2	1.63	0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Food poisoning								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	1	(4.8)	1	4.57	0			
Gastric polyps								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Gastritis								
<25	1	(1.0)	1	0.95	1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Gastritis erosive								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Gastrointestinal haemorrhage								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Gastrooesophageal reflux disease								
<25	1	(1.0)	1	0.95	2	(1.5)	2	1.38
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Gastrooesophageal sphincter insufficiency								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Gingival recession								
<25	0				1	(0.7)	2	1.38
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Gingival ulceration								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Haematochezia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Haemorrhoids								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hiatus hernia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Impaired gastric emptying								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(4.3)	3	6.00	0			
>=35	0				0			
Irritable bowel syndrome								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Lumbar hernia								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Mouth ulceration								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Nausea								
<25	1	(1.0)	1	0.95	5	(3.7)	5	3.44
>=25 - <30	1	(0.8)	1	0.81	3	(2.9)	3	2.81
>=30 - <35	6	(13.0)	6	12.00	0			
>=35	1	(4.8)	1	4.57	2	(14.3)	2	13.53
Odynophagia								
<25	0				1	(0.7)	2	1.38
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Oesophagitis								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Pancreatic failure								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Pancreatitis								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Pneumatosis intestinalis								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Proctitis ulcerative								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	2	4.68
>=35	0				0			
Toothache								
<25	1	(1.0)	1	0.95	2	(1.5)	4	2.75
>=25 - <30	2	(1.7)	3	2.44	0			
>=30 - <35	1	(2.2)	2	4.00	1	(2.4)	2	4.68
>=35	0				0			
Vomiting								
<25	1	(1.0)	1	0.95	5	(3.7)	5	3.44
>=25 - <30	6	(5.1)	6	4.89	3	(2.9)	3	2.81
>=30 - <35	3	(6.5)	4	8.00	1	(2.4)	1	2.34
>=35	1	(4.8)	1	4.57	1	(7.1)	1	6.76
General disorders and administration site conditions								
All								
<25	18	(17.1)	24	22.74	30	(22.2)	123	84.66
>=25 - <30	19	(16.1)	35	28.52	24	(23.5)	42	39.35
>=30 - <35	14	(30.4)	20	40.00	7	(17.1)	14	32.73
>=35	4	(19.0)	5	22.85	4	(28.6)	4	27.05
Asthenia								
<25	1	(1.0)	1	0.95	1	(0.7)	1	0.69
>=25 - <30	0				2	(2.0)	2	1.87
>=30 - <35	0				0			
>=35	0				0			
Chest pain								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	6.76

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Chills								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Complication associated with device								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Cyst								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Facial discomfort								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Facial pain								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Fatigue								
<25	1	(1.0)	1	0.95	2	(1.5)	2	1.38
>=25 - <30	2	(1.7)	3	2.44	3	(2.9)	3	2.81
>=30 - <35	3	(6.5)	3	6.00	0			
>=35	1	(4.8)	1	4.57	0			
Hunger								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				1	(2.4)	2	4.68
>=35	0				0			
Hyperthermia								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Illness								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Inflammation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	1	(4.8)	1	4.57	0			
Influenza like illness								
<25	1	(1.0)	1	0.95	1	(0.7)	1	0.69
>=25 - <30	2	(1.7)	2	1.63	3	(2.9)	3	2.81
>=30 - <35	0				0			
>=35	1	(4.8)	1	4.57	0			
Injection site mass								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Injection site pain								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Injection site urticaria								
<25	0				0			
>=25 - <30	1	(0.8)	2	1.63	0			
>=30 - <35	0				0			
>=35	0				0			
Malaise								
<25	3	(2.9)	3	2.84	2	(1.5)	76	52.31
>=25 - <30	0				2	(2.0)	5	4.68
>=30 - <35	1	(2.2)	1	2.00	1	(2.4)	3	7.01
>=35	0				0			
Medical device site bruise								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Medical device site dermatitis								
<25	3	(2.9)	3	2.84	4	(3.0)	6	4.13
>=25 - <30	1	(0.8)	2	1.63	2	(2.0)	3	2.81
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Medical device site erythema								
<25	0				2	(1.5)	2	1.38
>=25 - <30	1	(0.8)	2	1.63	3	(2.9)	5	4.68
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Medical device site haematoma								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Medical device site haemorrhage								
<25	0				0			
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	6.76
Medical device site inflammation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Medical device site irritation								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Medical device site pain								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Medical device site pruritus								
<25	0				4	(3.0)	4	2.75
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Medical device site rash								
<25	3	(2.9)	3	2.84	6	(4.4)	6	4.13
>=25 - <30	2	(1.7)	2	1.63	4	(3.9)	4	3.75
>=30 - <35	1	(2.2)	2	4.00	1	(2.4)	2	4.68
>=35	1	(4.8)	1	4.57	0			
Medical device site reaction								
<25	0				1	(0.7)	1	0.69
>=25 - <30	2	(1.7)	2	1.63	0			
>=30 - <35	1	(2.2)	1	2.00	1	(2.4)	1	2.34
>=35	0				0			
Medical device site vesicles								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	2	4.00	0			
>=35	0				0			
Nodule								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	6.76
Non-cardiac chest pain								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Oedema								
<25	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	1	(2.4)	1	2.34
>=35	0				0			
Oedema peripheral								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	1	(4.8)	1	4.57	0			
Pain								
<25	0				1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	2	(4.3)	2	4.00	0			
>=35	0				0			
Peripheral swelling								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Pyrexia								
<25	6	(5.7)	7	6.63	9	(6.7)	12	8.26
>=25 - <30	6	(5.1)	11	8.96	8	(7.8)	10	9.37
>=30 - <35	4	(8.7)	4	8.00	2	(4.9)	2	4.68
>=35	0				1	(7.1)	1	6.76
Swelling face								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Vaccination site discomfort								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Vaccination site joint pain								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Vaccination site lymphadenopathy								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Vaccination site pain								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Vaccination site swelling								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hepatobiliary disorders								
All								
<25	3	(2.9)	3	2.84	3	(2.2)	3	2.06
>=25 - <30	2	(1.7)	3	2.44	2	(2.0)	2	1.87
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Cholecystitis chronic								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Gallbladder disorder								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Gallbladder polyp								
<25	0				1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Hepatic calcification								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Hepatic function abnormal								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hepatic steatosis								
<25	2	(1.9)	2	1.89	0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Hypertransaminasaemia								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
<25	1	(1.0)	1	0.95	1	(0.7)	1	0.69
>=25 - <30	3	(2.5)	3	2.44	3	(2.9)	3	2.81
>=30 - <35	1	(2.2)	1	2.00	2	(4.9)	2	4.68
>=35	0				0			
Allergy to arthropod bite								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Allergy to arthropod sting								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Hypersensitivity								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Seasonal allergy								
<25	0				1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	2	(2.0)	2	1.87
>=30 - <35	1	(2.2)	1	2.00	2	(4.9)	2	4.68
>=35	0				0			
Infections and infestations								
All								
<25	49	(46.7)	83	78.63	69	(51.1)	132	90.86
>=25 - <30	70	(59.3)	125	101.86	55	(53.9)	105	98.37
>=30 - <35	30	(65.2)	76	152.01	26	(63.4)	53	123.90
>=35	10	(47.6)	26	118.80	9	(64.3)	13	87.91
Abscess limb								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				1	(2.4)	2	4.68
>=35	0				0			
Acute sinusitis								
<25	0				2	(1.5)	2	1.38
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Asymptomatic COVID-19								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Beta haemolytic streptococcal infection								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Breast abscess								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Bronchitis								
<25	1	(1.0)	1	0.95	2	(1.5)	3	2.06
>=25 - <30	2	(1.7)	2	1.63	0			
>=30 - <35	2	(4.3)	2	4.00	1	(2.4)	1	2.34
>=35	0				0			
Conjunctivitis								
<25	3	(2.9)	3	2.84	0			
>=25 - <30	1	(0.8)	2	1.63	0			
>=30 - <35	0				0			
>=35	0				0			
Coronavirus infection								
<25	0				0			
>=25 - <30	0				3	(2.9)	3	2.81
>=30 - <35	0				0			
>=35	0				0			
COVID-19								
<25	20	(19.0)	22	20.84	36	(26.7)	40	27.53
>=25 - <30	28	(23.7)	31	25.26	29	(28.4)	30	28.11
>=30 - <35	21	(45.7)	22	44.00	14	(34.1)	14	32.73
>=35	6	(28.6)	6	27.41	5	(35.7)	5	33.81
COVID-19 pneumonia								
<25	0				1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Cystitis								
<25	0				3	(2.2)	3	2.06
>=25 - <30	2	(1.7)	2	1.63	0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cystitis escherichia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Ear infection								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Erythema migrans								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Eye infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Febrile infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(4.8)	1	4.57	0			
Fungal infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Fungal skin infection								
<25	0				1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Furuncle								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Gastric infection								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Gastroenteritis								
<25	6	(5.7)	10	9.47	5	(3.7)	6	4.13
>=25 - <30	3	(2.5)	4	3.26	0			
>=30 - <35	3	(6.5)	3	6.00	0			
>=35	1	(4.8)	1	4.57	0			
Gastroenteritis viral								
<25	0				2	(1.5)	2	1.38
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	1	(4.8)	1	4.57	0			
Gastrointestinal infection								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				2	(4.9)	4	9.35
>=35	0				0			
Genital infection fungal								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(4.8)	2	9.14	0			
Gingival abscess								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Gingivitis								
<25	0				1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Herpes zoster								
<25	0				2	(1.5)	2	1.38
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Hordeolum								
<25	0				2	(1.5)	2	1.38
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	1	(4.8)	1	4.57	0			
Impetigo								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Infected cyst								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Influenza								
<25	3	(2.9)	3	2.84	3	(2.2)	3	2.06
>=25 - <30	3	(2.5)	3	2.44	2	(2.0)	2	1.87
>=30 - <35	1	(2.2)	2	4.00	2	(4.9)	3	7.01
>=35	1	(4.8)	1	4.57	1	(7.1)	1	6.76
Laryngitis								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Laryngopharyngitis								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Localised infection								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Lower respiratory tract infection								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Nasopharyngitis								
<25	16	(15.2)	20	18.95	24	(17.8)	32	22.03
>=25 - <30	18	(15.3)	30	24.45	24	(23.5)	36	33.73
>=30 - <35	12	(26.1)	20	40.00	10	(24.4)	13	30.39
>=35	2	(9.5)	5	22.85	3	(21.4)	3	20.29
Norovirus infection								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Oral herpes								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Otitis externa								
<25	0				2	(1.5)	2	1.38
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Otitis media								
<25	0				0			
>=25 - <30	0				2	(2.0)	2	1.87
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Pericoronitis								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Periodontitis								
<25	0				1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Pharyngitis								
<25	3	(2.9)	3	2.84	0			
>=25 - <30	4	(3.4)	4	3.26	2	(2.0)	3	2.81
>=30 - <35	0				0			
>=35	1	(4.8)	1	4.57	0			
Pneumonia								
<25	0				1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	1	(4.8)	1	4.57	0			
Pulpitis dental								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Pyelonephritis acute								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Respiratory tract infection								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Respiratory tract infection viral								
<25	1	(1.0)	1	0.95	2	(1.5)	2	1.38
>=25 - <30	3	(2.5)	3	2.44	1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Rhinitis								
<25	0				3	(2.2)	3	2.06
>=25 - <30	2	(1.7)	2	1.63	2	(2.0)	3	2.81
>=30 - <35	2	(4.3)	2	4.00	0			
>=35	0				0			
Sepsis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Severe acute respiratory syndrome								
<25	0				1	(0.7)	1	0.69
>=25 - <30	3	(2.5)	3	2.44	0			
>=30 - <35	0				0			
>=35	0				0			
Sinobronchitis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Sinusitis								
<25	2	(1.9)	2	1.89	5	(3.7)	5	3.44
>=25 - <30	5	(4.2)	5	4.07	2	(2.0)	2	1.87
>=30 - <35	7	(15.2)	8	16.00	2	(4.9)	2	4.68
>=35	0				0			
Skin infection								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Tinea cruris								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Tinea pedis								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	1	(4.8)	2	9.14	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tonsillitis								
<25	1	(1.0)	1	0.95	1	(0.7)	1	0.69
>=25 - <30	0				1	(1.0)	2	1.87
>=30 - <35	0				0			
>=35	1	(4.8)	1	4.57	0			
Tooth abscess								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	3	(6.5)	3	6.00	0			
>=35	0				0			
Tooth infection								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Tracheobronchitis								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Trichophytosis								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Upper respiratory tract infection								
<25	4	(3.8)	5	4.74	2	(1.5)	2	1.38
>=25 - <30	6	(5.1)	8	6.52	4	(3.9)	6	5.62
>=30 - <35	2	(4.3)	2	4.00	4	(9.8)	4	9.35
>=35	3	(14.3)	3	13.71	1	(7.1)	1	6.76
Urinary tract infection								
<25	4	(3.8)	4	3.79	2	(1.5)	2	1.38
>=25 - <30	6	(5.1)	6	4.89	2	(2.0)	4	3.75
>=30 - <35	2	(4.3)	2	4.00	2	(4.9)	2	4.68
>=35	0				2	(14.3)	2	13.53
Vaginal infection								
<25	0				0			
>=25 - <30	1	(0.8)	3	2.44	0			
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	6.76
Varicella								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Viral infection								
<25	0				4	(3.0)	5	3.44
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Viral rhinitis								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Vulvitis								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Vulvovaginal mycotic infection								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Vulvovaginitis								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Injury, poisoning and procedural complications								
All								
<25	14	(13.3)	17	16.10	26	(19.3)	35	24.09
>=25 - <30	20	(16.9)	31	25.26	13	(12.7)	13	12.18
>=30 - <35	9	(19.6)	13	26.00	9	(22.0)	14	32.73
>=35	0				2	(14.3)	2	13.53
Accidental overdose								
<25	0				0			
>=25 - <30	5	(4.2)	6	4.89	1	(1.0)	1	0.94
>=30 - <35	2	(4.3)	2	4.00	1	(2.4)	1	2.34
>=35	0				0			
Anaemia postoperative								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Animal bite								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Animal scratch								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Ankle fracture								
<25	0				0			
>=25 - <30	1	(0.8)	3	2.44	0			
>=30 - <35	0				0			
>=35	0				0			
Arthropod bite								
<25	0				3	(2.2)	3	2.06
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Back injury								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Burns first degree								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	6.76
Chest injury								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Clavicle fracture								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Concussion								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Contusion								
<25	1	(1.0)	1	0.95	1	(0.7)	1	0.69
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	1	(2.2)	1	2.00	1	(2.4)	1	2.34
>=35	0				0			
Corneal abrasion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	6.76

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Epicondylitis								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Face injury								
<25	1	(1.0)	1	0.95	1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Fall								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	1	(2.2)	1	2.00	1	(2.4)	4	9.35
>=35	0				0			
Fibula fracture								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Hand fracture								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	1	(2.4)	1	2.34
>=35	0				0			
Heat stroke								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Incorrect dose administered								
<25	0				0			
>=25 - <30	3	(2.5)	3	2.44	0			
>=30 - <35	0				0			
>=35	0				0			
Intentional underdose								
<25	0				1	(0.7)	2	1.38
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Joint injury								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Ligament rupture								
<25	0				0			
>=25 - <30	1	(0.8)	2	1.63	0			
>=30 - <35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Ligament sprain								
<25	3	(2.9)	3	2.84	1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	1	(2.2)	1	2.00	1	(2.4)	1	2.34
>=35	0				0			
Limb injury								
<25	0				1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Medication error								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Meniscus injury								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Muscle rupture								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Muscle strain								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Nerve injury								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Overdose								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Post-traumatic neck syndrome								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Prescribed overdose								
<25	2	(1.9)	2	1.89	0			
>=25 - <30	2	(1.7)	2	1.63	0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Procedural pain								
<25	0				0			
>=25 - <30	1	(0.8)	2	1.63	0			
>=30 - <35	0				0			
>=35	0				0			
Product administration error								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Product dispensing error								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Radius fracture								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Road traffic accident								
<25	1	(1.0)	2	1.89	1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Skin abrasion								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	1	(0.8)	2	1.63	0			
>=30 - <35	1	(2.2)	1	2.00	1	(2.4)	1	2.34
>=35	0				0			
Skin laceration								
<25	0				1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Stress fracture								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Tendon rupture								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Thermal burn								
<25	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Tooth fracture								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Vaccination complication								
<25	3	(2.9)	3	2.84	5	(3.7)	9	6.19
>=25 - <30	2	(1.7)	2	1.63	2	(2.0)	2	1.87
>=30 - <35	1	(2.2)	1	2.00	1	(2.4)	1	2.34
>=35	0				0			
Venous injury								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Wound								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Wound dehiscence								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Wrist fracture								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Wrong product administered								
<25	0				2	(1.5)	2	1.38
>=25 - <30	0				2	(2.0)	2	1.87
>=30 - <35	0				0			
>=35	0				0			
Investigations								
All								
<25	4	(3.8)	5	4.74	5	(3.7)	6	4.13
>=25 - <30	10	(8.5)	13	10.59	9	(8.8)	9	8.43
>=30 - <35	5	(10.9)	6	12.00	1	(2.4)	2	4.68
>=35	0				2	(14.3)	2	13.53
Angiogram								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Aspartate aminotransferase increased								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Blood cholesterol increased								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Blood glucose fluctuation								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	6.76
Blood glucose increased								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Blood pressure increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(4.3)	3	6.00	0			
>=35	0				0			
Blood testosterone decreased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	6.76
Blood triglycerides increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Blood uric acid increased								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Body temperature increased								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Cardiac murmur								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	0				0			
>=35	0				0			
Electrocardiogram abnormal								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Electrocardiogram T wave abnormal								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Eosinophil count increased								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	2	4.68
>=35	0				0			
Glomerular filtration rate decreased								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Haemoglobin decreased								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Heart rate increased								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Hepatic enzyme increased								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Hepatitis B virus test positive								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Lipids abnormal								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Low density lipoprotein increased								
<25	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Mycobacterium tuberculosis complex test positive								
<25	0				0			
>=25 - <30	2	(1.7)	2	1.63	0			
>=30 - <35	0				0			
>=35	0				0			
Occult blood positive								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Platelet count decreased								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Pulse absent								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
SARS-CoV-2 test positive								
<25	0				2	(1.5)	2	1.38
>=25 - <30	0				3	(2.9)	3	2.81
>=30 - <35	0				0			
>=35	0				0			
Serum ferritin decreased								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Weight decreased								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Weight increased								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
White blood cell count decreased								
<25	0				1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Metabolism and nutrition disorders								
All								
<25	5	(4.8)	5	4.74	9	(6.7)	11	7.57
>=25 - <30	7	(5.9)	10	8.15	6	(5.9)	7	6.56
>=30 - <35	3	(6.5)	5	10.00	1	(2.4)	1	2.34
>=35	3	(14.3)	4	18.28	0			
Decreased appetite								
<25	0				1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Dehydration								
<25	0				1	(0.7)	2	1.38
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Diabetic dyslipidaemia								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Diabetic ketoacidosis								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Dyslipidaemia								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Hypercholesterolaemia								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hyperlipidaemia								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	1	(4.8)	1	4.57	0			
Hyperuricaemia								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hypoglycaemia								
<25	2	(1.9)	2	1.89	3	(2.2)	4	2.75
>=25 - <30	5	(4.2)	8	6.52	1	(1.0)	1	0.94

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	1	(2.2)	3	6.00	0			
>=35	2	(9.5)	2	9.14	0			
Hypokalaemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Hyponatraemia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(4.8)	1	4.57	0			
Insulin resistance								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Iron deficiency								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Obesity								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Vitamin D deficiency								
<25	0				1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	2	(2.0)	2	1.87
>=30 - <35	0				0			
>=35	0				0			
Musculoskeletal and connective tissue disorders								
All								
<25	13	(12.4)	16	15.16	20	(14.8)	46	31.66
>=25 - <30	20	(16.9)	25	20.37	19	(18.6)	30	28.11
>=30 - <35	9	(19.6)	14	28.00	12	(29.3)	15	35.07
>=35	3	(14.3)	3	13.71	5	(35.7)	8	54.10
Acquired claw toe								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Arthralgia								
<25	1	(1.0)	1	0.95	6	(4.4)	7	4.82
>=25 - <30	6	(5.1)	6	4.89	6	(5.9)	6	5.62
>=30 - <35	4	(8.7)	5	10.00	2	(4.9)	2	4.68

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	1	(4.8)	1	4.57	1	(7.1)	1	6.76
Arthritis								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Back pain								
<25	2	(1.9)	2	1.89	6	(4.4)	20	13.77
>=25 - <30	3	(2.5)	3	2.44	5	(4.9)	5	4.68
>=30 - <35	0				3	(7.3)	3	7.01
>=35	0				3	(21.4)	3	20.29
Bursitis								
<25	0				1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Chondromalacia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Flank pain								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Foot deformity								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	2	1.87
>=30 - <35	0				0			
>=35	0				0			
Groin pain								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Intervertebral disc protrusion								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(7.1)	2	13.53
Limb discomfort								
<25	0				0			
>=25 - <30	2	(1.7)	2	1.63	0			
>=30 - <35	0				0			
>=35	0				0			
Limb mass								
<25	0				0			
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Muscle spasms								
<25	1	(1.0)	1	0.95	1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	2	(4.3)	3	6.00	0			
>=35	0				0			
Muscular weakness								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Musculoskeletal stiffness								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Myalgia								
<25	2	(1.9)	2	1.89	4	(3.0)	5	3.44
>=25 - <30	0				3	(2.9)	5	4.68
>=30 - <35	0				1	(2.4)	1	2.34
>=35	1	(4.8)	1	4.57	0			
Myopathy								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Neck pain								
<25	1	(1.0)	1	0.95	2	(1.5)	2	1.38
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Nodal osteoarthritis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Osteoarthritis								
<25	1	(1.0)	1	0.95	2	(1.5)	2	1.38
>=25 - <30	2	(1.7)	2	1.63	0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Pain in extremity								
<25	3	(2.9)	3	2.84	2	(1.5)	2	1.38
>=25 - <30	1	(0.8)	1	0.81	7	(6.9)	7	6.56
>=30 - <35	3	(6.5)	3	6.00	3	(7.3)	3	7.01
>=35	1	(4.8)	1	4.57	1	(7.1)	1	6.76
Periarthritis								
<25	1	(1.0)	1	0.95	2	(1.5)	2	1.38

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	1	(0.8)	1	0.81	2	(2.0)	2	1.87
>=30 - <35	0				0			
>=35	0				0			
Rheumatoid arthritis								
<25	1	(1.0)	1	0.95	1	(0.7)	1	0.69
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Rotator cuff syndrome								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Spinal stenosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	6.76
Synovial cyst								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Tendonitis								
<25	1	(1.0)	1	0.95	1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Tenosynovitis								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Trigger finger								
<25	0				0			
>=25 - <30	2	(1.7)	2	1.63	0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
<25	2	(1.9)	2	1.89	2	(1.5)	3	2.06
>=25 - <30	3	(2.5)	3	2.44	0			
>=30 - <35	3	(6.5)	3	6.00	2	(4.9)	2	4.68
>=35	0				1	(7.1)	1	6.76
Benign neoplasm of thyroid gland								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	0				0			
>=35	0				0			
Benign renal neoplasm								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Colon adenoma								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Eye naevus								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	1	(2.4)	1	2.34
>=35	0				0			
Haemangioma of liver								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Lipoma								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Melanocytic naevus								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Myeloproliferative neoplasm								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	6.76
Seborrhoeic keratosis								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Skin papilloma								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Uterine leiomyoma								
<25	0				1	(0.7)	1	0.69

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Nervous system disorders								
All								
<25	16	(15.2)	35	33.16	18	(13.3)	89	61.26
>=25 - <30	11	(9.3)	17	13.85	13	(12.7)	18	16.86
>=30 - <35	10	(21.7)	17	34.00	6	(14.6)	10	23.38
>=35	3	(14.3)	3	13.71	2	(14.3)	2	13.53
Ageusia								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Autonomic nervous system imbalance								
<25	1	(1.0)	2	1.89	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Burning sensation								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Carpal tunnel syndrome								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Cerebral haemorrhage								
<25	0				0			
>=25 - <30	1	(0.8)	2	1.63	0			
>=30 - <35	0				0			
>=35	0				0			
Cerebral infarction								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Cervicobrachial syndrome								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Diabetic neuropathy								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=35	0				0			
Disturbance in attention								
<25	1	(1.0)	11	10.42	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Dizziness								
<25	2	(1.9)	3	2.84	3	(2.2)	4	2.75
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Dizziness postural								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Encephalopathy								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Haemorrhage intracranial								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Headache								
<25	6	(5.7)	9	8.53	8	(5.9)	10	6.88
>=25 - <30	5	(4.2)	6	4.89	6	(5.9)	10	9.37
>=30 - <35	6	(13.0)	12	24.00	1	(2.4)	1	2.34
>=35	0				1	(7.1)	1	6.76
Hemiparesis								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Hypoaesthesia								
<25	1	(1.0)	2	1.89	1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	1	(2.4)	1	2.34
>=35	0				0			
Hypoglycaemic seizure								
<25	1	(1.0)	1	0.95	1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hypoglycaemic unconsciousness								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	0				0			
>=35	0				0			
Hypotonia								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
IIIrd nerve paralysis								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Ischaemic stroke								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Loss of consciousness								
<25	1	(1.0)	1	0.95	1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Loss of proprioception								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Migraine								
<25	1	(1.0)	1	0.95	1	(0.7)	2	1.38
>=25 - <30	1	(0.8)	2	1.63	1	(1.0)	1	0.94
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	1	(4.8)	1	4.57	0			
Neuropathy peripheral								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Optic neuritis								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Post herpetic neuralgia								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Presyncope								
<25	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Radiculopathy								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Restless legs syndrome								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Sinus headache								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	6.76
Somnolence								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	1	(4.8)	1	4.57	0			
Syncope								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	1	(4.8)	1	4.57	0			
Tension headache								
<25	0				1	(0.7)	2	1.38
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Tremor								
<25	1	(1.0)	1	0.95	1	(0.7)	62	42.68
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				2	(4.9)	5	11.69
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pregnancy, puerperium and perinatal conditions								
All								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Abortion spontaneous								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Abortion threatened								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Psychiatric disorders								
All								
<25	1	(1.0)	1	0.95	5	(3.7)	7	4.82
>=25 - <30	5	(4.2)	5	4.07	5	(4.9)	6	5.62
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	1	(4.8)	1	4.57	1	(7.1)	1	6.76
Alcohol abuse								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Anxiety								
<25	0				2	(1.5)	2	1.38
>=25 - <30	1	(0.8)	1	0.81	2	(2.0)	2	1.87
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	6.76
Anxiety disorder								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Attention deficit hyperactivity disorder								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Depressed mood								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Depression								
<25	0				3	(2.2)	3	2.06
>=25 - <30	0				2	(2.0)	2	1.87
>=30 - <35	0				0			
>=35	0				0			
Insomnia								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	1	(4.8)	1	4.57	0			
Major depression								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Sleep disorder								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Stress								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Renal and urinary disorders								
All								
<25	2	(1.9)	2	1.89	0			
>=25 - <30	2	(1.7)	2	1.63	3	(2.9)	6	5.62
>=30 - <35	2	(4.3)	2	4.00	1	(2.4)	1	2.34
>=35	1	(4.8)	1	4.57	1	(7.1)	1	6.76
Acute kidney injury								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Chronic kidney disease								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Diabetic nephropathy								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				0			
>=25 - <30	0				2	(2.0)	2	1.87
>=30 - <35	0				0			
>=35	0				0			
Dysuria								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	1	(4.8)	1	4.57	0			
Hydrocalyx								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Hypertensive nephropathy								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Microalbuminuria								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Pollakiuria								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	6.76
Proteinuria								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Renal cyst								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Renal pain								
<25	2	(1.9)	2	1.89	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Reproductive system and breast disorders								
All								
<25	4	(3.8)	5	4.74	1	(0.7)	3	2.06
>=25 - <30	3	(2.5)	3	2.44	5	(4.9)	5	4.68

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	1	(2.2)	1	2.00	1	(2.4)	1	2.34
>=35	1	(4.8)	1	4.57	1	(7.1)	1	6.76
Atrophic vulvovaginitis								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Benign prostatic hyperplasia								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Dysmenorrhoea								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				2	(2.0)	2	1.87
>=30 - <35	0				0			
>=35	0				0			
Ectropion of cervix								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Erectile dysfunction								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	1	(4.8)	1	4.57	0			
Fibrocystic breast disease								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Heavy menstrual bleeding								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	6.76
Menstruation irregular								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Ovarian cyst								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Ovarian disorder								
<25	0				1	(0.7)	1	0.69

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Penile pain								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Premenstrual syndrome								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Prostatic cyst								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Prostatitis								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Prostatomegaly								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Respiratory, thoracic and mediastinal disorders								
All								
<25	11	(10.5)	16	15.16	16	(11.9)	25	17.21
>=25 - <30	10	(8.5)	19	15.48	12	(11.8)	18	16.86
>=30 - <35	13	(28.3)	17	34.00	6	(14.6)	11	25.72
>=35	2	(9.5)	2	9.14	3	(21.4)	3	20.29
Acute respiratory failure								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Allergic cough								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Asthma								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Bronchial hyperreactivity								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Cough								
<25	3	(2.9)	4	3.79	4	(3.0)	5	3.44
>=25 - <30	2	(1.7)	4	3.26	2	(2.0)	4	3.75
>=30 - <35	4	(8.7)	4	8.00	4	(9.8)	5	11.69
>=35	0				1	(7.1)	1	6.76
Cough variant asthma								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Dysphonia								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Dyspnoea								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Dyspnoea exertional								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Epiglottic oedema								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Epistaxis								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Hiccups								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Nasal congestion								
<25	0				1	(0.7)	1	0.69

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	2	(9.5)	2	9.14	0			
Oropharyngeal discomfort								
<25	0				2	(1.5)	2	1.38
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Oropharyngeal pain								
<25	4	(3.8)	4	3.79	2	(1.5)	2	1.38
>=25 - <30	1	(0.8)	1	0.81	5	(4.9)	6	5.62
>=30 - <35	3	(6.5)	4	8.00	2	(4.9)	2	4.68
>=35	0				1	(7.1)	1	6.76
Pleurisy								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Productive cough								
<25	0				3	(2.2)	4	2.75
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Pulmonary congestion								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Pulmonary mass								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				1	(7.1)	1	6.76
Respiratory disorder								
<25	2	(1.9)	2	1.89	2	(1.5)	2	1.38
>=25 - <30	2	(1.7)	2	1.63	0			
>=30 - <35	0				0			
>=35	0				0			
Rhinitis allergic								
<25	0				0			
>=25 - <30	2	(1.7)	3	2.44	2	(2.0)	2	1.87
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Rhinorrhoea								
<25	1	(1.0)	1	0.95	4	(3.0)	5	3.44
>=25 - <30	2	(1.7)	3	2.44	2	(2.0)	2	1.87
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Sinus congestion								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	1	(2.2)	1	2.00	1	(2.4)	1	2.34
>=35	0				0			
Sleep apnoea syndrome								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Sneezing								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Throat irritation								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Upper-airway cough syndrome								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Skin and subcutaneous tissue disorders								
All								
<25	9	(8.6)	11	10.42	19	(14.1)	26	17.90
>=25 - <30	16	(13.6)	20	16.30	15	(14.7)	22	20.61
>=30 - <35	6	(13.0)	6	12.00	2	(4.9)	2	4.68
>=35	5	(23.8)	5	22.85	4	(28.6)	4	27.05
Alopecia								
<25	0				0			
>=25 - <30	2	(1.7)	2	1.63	0			
>=30 - <35	0				0			
>=35	1	(4.8)	1	4.57	0			
Alopecia areata								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Angioedema								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Chronic spontaneous urticaria								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=30 - <35	0				0			
>=35	0				0			
Cold sweat								
<25	0				3	(2.2)	5	3.44
>=25 - <30	0				2	(2.0)	5	4.68
>=30 - <35	0				0			
>=35	0				0			
Dermal cyst								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				1	(7.1)	1	6.76
Dermatitis								
<25	2	(1.9)	2	1.89	0			
>=25 - <30	3	(2.5)	5	4.07	2	(2.0)	3	2.81
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	6.76
Dermatitis allergic								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Dermatitis atopic								
<25	1	(1.0)	1	0.95	1	(0.7)	1	0.69
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Dermatitis contact								
<25	0				4	(3.0)	4	2.75
>=25 - <30	3	(2.5)	3	2.44	2	(2.0)	2	1.87
>=30 - <35	0				1	(2.4)	1	2.34
>=35	1	(4.8)	1	4.57	0			
Dry skin								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Eczema								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				2	(2.0)	2	1.87
>=30 - <35	0				0			
>=35	0				0			
Eczema asteatotic								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Erythema								
<25	0				2	(1.5)	2	1.38

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Erythema multiforme								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Hidradenitis								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Hyperkeratosis								
<25	1	(1.0)	1	0.95	1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Ingrowing nail								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				2	(2.0)	2	1.87
>=30 - <35	0				0			
>=35	0				0			
Ingrown hair								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Lichen sclerosus								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	1	(4.8)	1	4.57	0			
Macule								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Miliaria								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				1	(2.4)	1	2.34
>=35	0				0			
Pruritus								
<25	0				2	(1.5)	2	1.38
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Psoriasis								

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): ONTRDURY BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Rash								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	1	(1.0)	1	0.94
>=30 - <35	2	(4.3)	2	4.00	0			
>=35	1	(4.8)	1	4.57	1	(7.1)	1	6.76
Rash erythematous								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Seborrhoeic dermatitis								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Skin fissures								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	1	(2.2)	1	2.00	0			
>=35	0				0			
Skin irritation								
<25	0				1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	1	(4.8)	1	4.57	0			
Skin lesion								
<25	0				1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Skin reaction								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Skin ulcer								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Telangiectasia								
<25	0				1	(0.7)	1	0.69
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Urticaria								
<25	0				2	(1.5)	2	1.38
>=25 - <30	0				2	(2.0)	2	1.87
>=30 - <35	0				0			
>=35	0				0			
Urticaria papular								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				1	(7.1)	1	6.76
Vitiligo								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Xeroderma								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Surgical and medical procedures								
All								
<25	2	(1.9)	2	1.89	0			
>=25 - <30	2	(1.7)	2	1.63	0			
>=30 - <35	0				0			
>=35	0				0			
Cardiac ablation								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Skin neoplasm excision								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Tooth extraction								
<25	0				0			
>=25 - <30	1	(0.8)	1	0.81	0			
>=30 - <35	0				0			
>=35	0				0			
Wisdom teeth removal								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline BMI group, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vascular disorders								
All								
<25	3	(2.9)	3	2.84	5	(3.7)	5	3.44
>=25 - <30	3	(2.5)	3	2.44	4	(3.9)	5	4.68
>=30 - <35	3	(6.5)	3	6.00	1	(2.4)	1	2.34
>=35	2	(9.5)	2	9.14	0			
Aortic aneurysm								
<25	0				1	(0.7)	1	0.69
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Arteriosclerosis								
<25	1	(1.0)	1	0.95	0			
>=25 - <30	0				0			
>=30 - <35	0				0			
>=35	0				0			
Brachiocephalic artery stenosis								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Hypertension								
<25	2	(1.9)	2	1.89	4	(3.0)	4	2.75
>=25 - <30	3	(2.5)	3	2.44	2	(2.0)	2	1.87
>=30 - <35	1	(2.2)	1	2.00	1	(2.4)	1	2.34
>=35	2	(9.5)	2	9.14	0			
Hypertensive crisis								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			
Hypotension								
<25	0				0			
>=25 - <30	0				0			
>=30 - <35	2	(4.3)	2	4.00	0			
>=35	0				0			
Varicose vein								
<25	0				0			
>=25 - <30	0				1	(1.0)	1	0.94
>=30 - <35	0				0			
>=35	0				0			

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

7.24.21 Adverse events by baseline renal function - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	224				222			
Mild impairment	223				213			
Moderate or severe impairment	45				57			
PYE (years)								
Normal	348.90				349.01			
Mild impairment	349.01				332.31			
Moderate or severe impairment	67.58				85.44			
Events								
Normal	175	(78.1)	801	229.58	173	(77.9)	704	201.71
Mild impairment	185	(83.0)	902	258.44	172	(80.8)	845	254.28
Moderate or severe impairment	37	(82.2)	179	264.87	44	(77.2)	274	320.70
Serious								
Yes								
Normal	22	(9.8)	33	9.46	26	(11.7)	35	10.03
Mild impairment	31	(13.9)	44	12.61	35	(16.4)	64	19.26
Moderate or severe impairment	11	(24.4)	18	26.63	10	(17.5)	20	23.41
No								
Normal	172	(76.8)	768	220.12	171	(77.0)	669	191.68
Mild impairment	180	(80.7)	858	245.84	166	(77.9)	781	235.02
Moderate or severe impairment	35	(77.8)	161	238.23	43	(75.4)	254	297.29
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severity								
Severe								
Normal	9	(4.0)	13	3.73	10	(4.5)	13	3.72
Mild impairment	9	(4.0)	14	4.01	19	(8.9)	32	9.63
Moderate or severe impairment	8	(17.8)	11	16.28	7	(12.3)	16	18.73
Moderate								
Normal	88	(39.3)	181	51.88	93	(41.9)	181	51.86
Mild impairment	82	(36.8)	169	48.42	71	(33.3)	176	52.96
Moderate or severe impairment	22	(48.9)	51	75.46	19	(33.3)	40	46.82
Mild								
Normal	150	(67.0)	607	173.97	141	(63.5)	510	146.13
Mild impairment	171	(76.7)	719	206.01	158	(74.2)	637	191.69
Moderate or severe impairment	30	(66.7)	117	173.13	41	(71.9)	218	255.16
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Related to basal insulin								
Probable								
Normal	11	(4.9)	12	3.44	14	(6.3)	19	5.44
Mild impairment	16	(7.2)	27	7.74	17	(8.0)	26	7.82
Moderate or severe impairment	3	(6.7)	4	5.92	2	(3.5)	6	7.02
Possible								
Normal	16	(7.1)	21	6.02	11	(5.0)	14	4.01
Mild impairment	27	(12.1)	41	11.75	20	(9.4)	33	9.93
Moderate or severe impairment	3	(6.7)	5	7.40	8	(14.0)	13	15.22
Unlikely								
Normal	172	(76.8)	767	219.83	166	(74.8)	667	191.11
Mild impairment	183	(82.1)	833	238.67	170	(79.8)	784	235.92
Moderate or severe impairment	37	(82.2)	170	251.55	42	(73.7)	255	298.46
Missing								
Normal	1	(0.4)	1	0.29	3	(1.4)	4	1.15
Mild impairment	1	(0.4)	1	0.29	2	(0.9)	2	0.60
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to technical complaint for basal insulin								
Yes								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
No								
Normal	175	(78.1)	800	229.29	172	(77.5)	699	200.28
Mild impairment	185	(83.0)	902	258.44	172	(80.8)	843	253.68
Moderate or severe impairment	37	(82.2)	179	264.87	44	(77.2)	274	320.70
NA								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Missing								
Normal	1	(0.4)	1	0.29	3	(1.4)	4	1.15
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
Normal	2	(0.9)	3	0.86	0			
Mild impairment	1	(0.4)	2	0.57	2	(0.9)	6	1.81
Moderate or severe impairment	2	(4.4)	2	2.96	1	(1.8)	1	1.17
Not recovered/not resolved								
Normal	89	(39.7)	200	57.32	81	(36.5)	157	44.98
Mild impairment	104	(46.6)	265	75.93	104	(48.8)	209	62.89
Moderate or severe impairment	20	(44.4)	43	63.63	31	(54.4)	81	94.81
Recovered/resolved with sequelae								
Normal	2	(0.9)	2	0.57	4	(1.8)	4	1.15
Mild impairment	5	(2.2)	5	1.43	4	(1.9)	4	1.20
Moderate or severe impairment	2	(4.4)	2	2.96	0			
Recovering/resolving								
Normal	5	(2.2)	9	2.58	13	(5.9)	17	4.87
Mild impairment	13	(5.8)	16	4.58	12	(5.6)	17	5.12
Moderate or severe impairment	3	(6.7)	3	4.44	5	(8.8)	5	5.85
Recovered/resolved								
Normal	154	(68.8)	587	168.24	154	(69.4)	526	150.71
Mild impairment	165	(74.0)	614	175.92	160	(75.1)	609	183.26
Moderate or severe impairment	35	(77.8)	129	190.88	37	(64.9)	187	218.87
Unknown								
Normal	0				0			
					0			
Mild impairment	0				0			
					0			
Moderate or severe impairment	0				0			
					0			
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

7.24.22 Adverse events by baseline renal function - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	197				190			
Mild impairment	88				93			
Moderate impairment	5				9			
PYE (years)								
Normal	205.47				199.83			
Mild impairment	89.22				99.88			
Moderate impairment	5.46				9.87			
Events								
Normal	161	(81.7)	623	303.20	148	(77.9)	598	299.25
Mild impairment	75	(85.2)	329	368.75	80	(86.0)	518	518.62
Moderate impairment	4	(80.0)	13	237.89	8	(88.9)	30	303.95
Serious								
Yes								
Normal	14	(7.1)	25	12.17	13	(6.8)	16	8.01
Mild impairment	10	(11.4)	14	15.69	4	(4.3)	5	5.01
Moderate impairment	0				3	(33.3)	4	40.53
No								
Normal	159	(80.7)	598	291.04	148	(77.9)	582	291.24
Mild impairment	74	(84.1)	315	353.06	80	(86.0)	513	513.62
Moderate impairment	4	(80.0)	13	237.89	8	(88.9)	26	263.43
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severity								
Severe								
Normal	14	(7.1)	17	8.27	8	(4.2)	9	4.50
Mild impairment	6	(6.8)	11	12.33	1	(1.1)	1	1.00
Moderate impairment	0				0			
Moderate								
Normal	58	(29.4)	118	57.43	52	(27.4)	96	48.04
Mild impairment	25	(28.4)	61	68.37	24	(25.8)	51	51.06
Moderate impairment	0				6	(66.7)	12	121.58
Mild								
Normal	146	(74.1)	488	237.50	138	(72.6)	493	246.71
Mild impairment	69	(78.4)	257	288.05	74	(79.6)	466	466.56
Moderate impairment	4	(80.0)	13	237.89	7	(77.8)	18	182.37
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				0			
Related to basal insulin								
Probable								
Normal	13	(6.6)	14	6.81	9	(4.7)	9	4.50
Mild impairment	7	(8.0)	11	12.33	2	(2.2)	3	3.00
Moderate impairment	0				0			
Possible								
Normal	16	(8.1)	20	9.73	11	(5.8)	13	6.51
Mild impairment	14	(15.9)	16	17.93	9	(9.7)	57	57.07
Moderate impairment	0				2	(22.2)	2	20.26
Unlikely								
Normal	156	(79.2)	588	286.17	147	(77.4)	576	288.24
Mild impairment	74	(84.1)	302	338.49	80	(86.0)	458	458.55
Moderate impairment	4	(80.0)	13	237.89	7	(77.8)	28	283.69
Missing								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to technical complaint for basal insulin								
Yes								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				0			
No								
Normal	161	(81.7)	622	302.72	148	(77.9)	598	299.25
Mild impairment	75	(85.2)	329	368.75	80	(86.0)	518	518.62
Moderate impairment	4	(80.0)	13	237.89	8	(88.9)	30	303.95
NA								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				0			
Missing								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Not recovered/not resolved								
Normal	65	(33.0)	104	50.61	60	(31.6)	117	58.55
Mild impairment	38	(43.2)	89	99.75	40	(43.0)	94	94.11
Moderate impairment	2	(40.0)	2	36.60	4	(44.4)	6	60.79
Recovered/resolved with sequelae								
Normal	0				1	(0.5)	1	0.50
Mild impairment	2	(2.3)	3	3.36	2	(2.2)	2	2.00
Moderate impairment	0				0			
Recovering/resolving								
Normal	13	(6.6)	16	7.79	7	(3.7)	8	4.00
Mild impairment	7	(8.0)	8	8.97	12	(12.9)	16	16.02
Moderate impairment	0				1	(11.1)	1	10.13
Recovered/resolved								
Normal	149	(75.6)	503	244.80	135	(71.1)	472	236.20
Mild impairment	68	(77.3)	228	255.54	70	(75.3)	406	406.49
Moderate impairment	4	(80.0)	11	201.29	8	(88.9)	23	233.03
Unknown								
Normal	0				0			
					0			
Mild impairment	0				0			
					0			
Moderate impairment	0				0			
					0			
Missing								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

7.24.23 Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	224				222			
Mild impairment	223				213			
Moderate or severe impairment	45				57			
PYE (years)								
Normal	348.90				349.01			
Mild impairment	349.01				332.31			
Moderate or severe impairment	67.58				85.44			
Events								
Normal	175	(78.1)	801	229.58	173	(77.9)	704	201.71
Mild impairment	185	(83.0)	902	258.44	172	(80.8)	845	254.28
Moderate or severe impairment	37	(82.2)	179	264.87	44	(77.2)	274	320.70

%: 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. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blood and lymphatic system disorders								
All								
Normal	6	(2.7)	6	1.72	9	(4.1)	10	2.87
Mild impairment	7	(3.1)	9	2.58	6	(2.8)	6	1.81
Moderate or severe impairment	2	(4.4)	2	2.96	4	(7.0)	4	4.68
Anaemia								
Normal	2	(0.9)	2	0.57	5	(2.3)	6	1.72
Mild impairment	6	(2.7)	6	1.72	4	(1.9)	4	1.20
Moderate or severe impairment	2	(4.4)	2	2.96	1	(1.8)	1	1.17
Blood loss anaemia								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Eosinophilia								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Hypochromic anaemia								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Iron deficiency anaemia								
Normal	3	(1.3)	3	0.86	1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Lymphadenopathy								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				1	(1.8)	1	1.17
Normochromic normocytic anaemia								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Polycythaemia								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Thrombocytopenia								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				1	(1.8)	1	1.17

%: 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. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cardiac disorders								
All								
Normal	13	(5.8)	23	6.59	13	(5.9)	19	5.44
Mild impairment	22	(9.9)	41	11.75	21	(9.9)	31	9.33
Moderate or severe impairment	9	(20.0)	15	22.20	8	(14.0)	11	12.87
Acute coronary syndrome								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Acute myocardial infarction								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	2	(0.9)	2	0.57	3	(1.4)	3	0.90
Moderate or severe impairment	1	(2.2)	1	1.48	1	(1.8)	1	1.17
Angina pectoris								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	1	(0.4)	1	0.29	2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Angina unstable								
Normal	3	(1.3)	3	0.86	1	(0.5)	1	0.29
Mild impairment	2	(0.9)	2	0.57	0			
Moderate or severe impairment	0				0			
Aortic valve calcification								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Aortic valve incompetence								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Arrhythmia								
Normal	0				0			
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Arteriosclerosis coronary artery								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Atrial fibrillation								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	5	(2.2)	5	1.43	3	(1.4)	6	1.81
Moderate or severe impairment	2	(4.4)	3	4.44	2	(3.5)	2	2.34

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Atrial flutter								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	2	2.96	0			
Atrial thrombosis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Atrioventricular block complete								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				1	(1.8)	1	1.17
Atrioventricular block first degree								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Atrioventricular block second degree								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Bradycardia								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	1	(1.8)	1	1.17
Bundle branch block left								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Bundle branch block right								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	1	(0.4)	1	0.29	2	(0.9)	3	0.90
Moderate or severe impairment	0				0			
Cardiac dysfunction								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Cardiac failure								
Normal	0				1	(0.5)	1	0.29
Mild impairment	3	(1.3)	3	0.86	0			
Moderate or severe impairment	1	(2.2)	1	1.48	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. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cardiac failure chronic								
Normal	2	(0.9)	2	0.57	1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Cardiac failure congestive								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Cardiac ventricular thrombosis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Cardio-respiratory arrest								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Cardiomyopathy								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Chronic coronary syndrome								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Congestive cardiomyopathy								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Coronary artery disease								
Normal	2	(0.9)	2	0.57	1	(0.5)	1	0.29
Mild impairment	3	(1.3)	3	0.86	1	(0.5)	1	0.30
Moderate or severe impairment	1	(2.2)	1	1.48	1	(1.8)	1	1.17
Coronary artery occlusion								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Coronary artery stenosis								
Normal	1	(0.4)	2	0.57	0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Diastolic dysfunction								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Left atrial dilatation								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Left ventricular dysfunction								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Left ventricular hypertrophy								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.57	0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Mitral valve incompetence								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Myocardial infarction								
Normal	3	(1.3)	3	0.86	2	(0.9)	2	0.57
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Myocardial ischaemia								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Palpitations								
Normal	1	(0.4)	1	0.29	2	(0.9)	2	0.57
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	2	0.60
Moderate or severe impairment	1	(2.2)	1	1.48	1	(1.8)	1	1.17
Pericardial effusion								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Pericarditis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Sinus arrhythmia								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Sinus bradycardia								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Sinus tachycardia								
Normal	0				2	(0.9)	2	0.57
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Supraventricular extrasystoles								
Normal	0				0			
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Supraventricular tachycardia								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Tachycardia								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Tricuspid valve incompetence								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Ventricular extrasystoles								
Normal	2	(0.9)	2	0.57	0			
Mild impairment	3	(1.3)	3	0.86	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Congenital, familial and genetic disorders								
All								
Normal	1	(0.4)	1	0.29	2	(0.9)	2	0.57
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Congenital syphilitic osteochondritis								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Corneal dystrophy								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Dolichocolon								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hydrocele								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Type V hyperlipidaemia								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Ear and labyrinth disorders								
All								
Normal	6	(2.7)	6	1.72	1	(0.5)	1	0.29
Mild impairment	6	(2.7)	7	2.01	8	(3.8)	8	2.41
Moderate or severe impairment	0				4	(7.0)	5	5.85
Cerumen impaction								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Ear discomfort								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17

%: 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. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear inflammation								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Ear pain								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Eustachian tube dysfunction								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hypoacusis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Presbyacusis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Tinnitus								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Vertigo								
Normal	2	(0.9)	2	0.57	0			
Mild impairment	4	(1.8)	5	1.43	5	(2.3)	5	1.50
Moderate or severe impairment	0				2	(3.5)	3	3.51
Vertigo positional								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
Normal	2	(0.9)	2	0.57	3	(1.4)	3	0.86
Mild impairment	2	(0.9)	2	0.57	5	(2.3)	5	1.50
Moderate or severe impairment	0				0			
Goitre								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Hyperplasia adrenal								
Normal	0				0			
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Hyperprolactinaemia								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hyperthyroidism								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hypothyroidism								
Normal	2	(0.9)	2	0.57	0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Thyroid mass								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Eye disorders								
All								
Normal	36	(16.1)	49	14.04	30	(13.5)	42	12.03
Mild impairment	48	(21.5)	72	20.63	36	(16.9)	51	15.35
Moderate or severe impairment	5	(11.1)	6	8.88	10	(17.5)	26	30.43
Acquired epiblepharon								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Age-related macular degeneration								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Asthenopia								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Astigmatism								
Normal	2	(0.9)	2	0.57	1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Blepharitis								
Normal	0				0			
Mild impairment	3	(1.3)	3	0.86	0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Blepharitis allergic								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cataract								
Normal	6	(2.7)	7	2.01	4	(1.8)	5	1.43
Mild impairment	11	(4.9)	15	4.30	4	(1.9)	5	1.50
Moderate or severe impairment	1	(2.2)	1	1.48	4	(7.0)	5	5.85
Cataract diabetic								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cataract nuclear								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Cataract subcapsular								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Chorioretinal disorder								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Conjunctival cyst								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Conjunctival erosion								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Conjunctival haemorrhage								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Conjunctival hyperaemia								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Conjunctivitis allergic								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	3	(1.3)	4	1.15	0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Corneal opacity								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Dacryoadenitis acquired								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Dermatochalasis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Diabetic retinal oedema								
Normal	1	(0.4)	1	0.29	2	(0.9)	2	0.57
Mild impairment	0				3	(1.4)	3	0.90
Moderate or severe impairment	0				1	(1.8)	1	1.17
Diabetic retinopathy								
Normal	16	(7.1)	17	4.87	16	(7.2)	17	4.87
Mild impairment	20	(9.0)	24	6.88	11	(5.2)	14	4.21
Moderate or severe impairment	0				5	(8.8)	7	8.19

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dry age-related macular degeneration								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Dry eye								
Normal	2	(0.9)	2	0.57	0			
Mild impairment	3	(1.3)	3	0.86	5	(2.3)	5	1.50
Moderate or severe impairment	0				0			
Eye discharge								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Eye disorder								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Eye inflammation								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Eye irritation								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Eye pain								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Eyelid ptosis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Giant papillary conjunctivitis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Glaucoma								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	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. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Iritis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Macular oedema								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	2	(0.9)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Myopia								
Normal	2	(0.9)	2	0.57	1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Non-proliferative retinopathy								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				1	(1.8)	1	1.17
Normal tension glaucoma								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Ocular hypertension								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Open angle glaucoma								
Normal	0				0			
Mild impairment	0				1	(0.5)	2	0.60
Moderate or severe impairment	0				0			
Optic disc vascular disorder								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Optic ischaemic neuropathy								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Photophobia								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17

%: 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. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Post thrombotic retinopathy								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Posterior capsule opacification								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Presbyopia								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Pterygium								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Punctate keratitis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Retinal aneurysm								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Retinal artery occlusion								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Retinal degeneration								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Retinal detachment								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Retinal drusen								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Retinal haemorrhage								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Retinal tear								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Retinal vascular disorder								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Retinal vein occlusion								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Retinal vein thrombosis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Retinopathy								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Retinopathy hypertensive								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Retinopathy proliferative								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Scintillating scotoma								
Normal	0				0			
Mild impairment	0				1	(0.5)	2	0.60
Moderate or severe impairment	0				0			
Uveitis								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vision blurred								
Normal	0				1	(0.5)	1	0.29
Mild impairment	2	(0.9)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	0				2	(3.5)	2	2.34
Visual impairment								
Normal	1	(0.4)	1	0.29	2	(0.9)	2	0.57
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Vitreous detachment								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Vitreous floaters								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Vitreous haemorrhage								
Normal	0				0			
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Vitreous opacities								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Gastrointestinal disorders								
All								
Normal	49	(21.9)	83	23.79	41	(18.5)	58	16.62
Mild impairment	50	(22.4)	91	26.07	45	(21.1)	86	25.88
Moderate or severe impairment	13	(28.9)	28	41.43	18	(31.6)	34	39.80
Abdominal discomfort								
Normal	0				1	(0.5)	1	0.29
Mild impairment	2	(0.9)	2	0.57	2	(0.9)	5	1.50
Moderate or severe impairment	0				0			
Abdominal distension								
Normal	3	(1.3)	4	1.15	1	(0.5)	1	0.29
Mild impairment	4	(1.8)	4	1.15	1	(0.5)	1	0.30
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Abdominal hernia								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17

%: 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. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Abdominal pain								
Normal	5	(2.2)	5	1.43	1	(0.5)	1	0.29
Mild impairment	3	(1.3)	3	0.86	5	(2.3)	5	1.50
Moderate or severe impairment	0				1	(1.8)	1	1.17
Abdominal pain lower								
Normal	0				0			
Mild impairment	1	(0.4)	2	0.57	2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Abdominal pain upper								
Normal	0				1	(0.5)	1	0.29
Mild impairment	3	(1.3)	3	0.86	3	(1.4)	4	1.20
Moderate or severe impairment	0				1	(1.8)	1	1.17
Abdominal wall haematoma								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Acid peptic disease								
Normal	0				2	(0.9)	2	0.57
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Anal eczema								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Anal fissure								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Anal pruritus								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Angular cheilitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Aphthous ulcer								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Ascites								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Barrett's oesophagus								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Chronic gastritis								
Normal	2	(0.9)	2	0.57	2	(0.9)	2	0.57
Mild impairment	2	(0.9)	2	0.57	2	(0.9)	2	0.60
Moderate or severe impairment	0				2	(3.5)	2	2.34
Colitis								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				2	(3.5)	2	2.34
Colitis ischaemic								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Colitis microscopic								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Constipation								
Normal	2	(0.9)	2	0.57	3	(1.4)	3	0.86
Mild impairment	4	(1.8)	4	1.15	2	(0.9)	2	0.60
Moderate or severe impairment	2	(4.4)	2	2.96	1	(1.8)	1	1.17
Crohn's disease								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Dental caries								
Normal	2	(0.9)	3	0.86	0			
Mild impairment	4	(1.8)	5	1.43	1	(0.5)	1	0.30
Moderate or severe impairment	3	(6.7)	3	4.44	0			
Diarrhoea								
Normal	14	(6.3)	20	5.73	10	(4.5)	11	3.15
Mild impairment	16	(7.2)	21	6.02	9	(4.2)	10	3.01
Moderate or severe impairment	9	(20.0)	13	19.24	7	(12.3)	8	9.36
Diverticulum								
Normal	0				3	(1.4)	3	0.86
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Diverticulum intestinal								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	1	(0.4)	1	0.29	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	0				0			
Dry mouth								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Duodenal ulcer								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Duodenitis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Duodenogastric reflux								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Dyspepsia								
Normal	3	(1.3)	3	0.86	3	(1.4)	3	0.86
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Enteritis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Enterocolitis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	2	(0.9)	3	0.86	0			
Moderate or severe impairment	0				0			
Epigastric discomfort								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Erosive duodenitis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Flatulence								
Normal	2	(0.9)	2	0.57	0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Food poisoning								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	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. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Frequent bowel movements								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Gastric disorder								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gastric polyps								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Gastritis								
Normal	0				2	(0.9)	2	0.57
Mild impairment	2	(0.9)	2	0.57	0			
Moderate or severe impairment	0				0			
Gastritis erosive								
Normal	0				0			
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Gastrointestinal disorder								
Normal	0				2	(0.9)	2	0.57
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gastrointestinal haemorrhage								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Gastrointestinal inflammation								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Gastrooesophageal reflux disease								
Normal	4	(1.8)	4	1.15	2	(0.9)	2	0.57
Mild impairment	4	(1.8)	4	1.15	2	(0.9)	2	0.60
Moderate or severe impairment	0				4	(7.0)	4	4.68
Haematemesis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Haematochezia								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				0			
Mild impairment	2	(0.9)	2	0.57	0			
Moderate or severe impairment	0				0			
Haemorrhoids								
Normal	2	(0.9)	2	0.57	2	(0.9)	2	0.57
Mild impairment	2	(0.9)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	0				2	(3.5)	2	2.34
Hiatus hernia								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Hyperaesthesia teeth								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hyperchlorhydria								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Ileus								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Inguinal hernia								
Normal	0				0			
Mild impairment	0				1	(0.5)	2	0.60
Moderate or severe impairment	0				0			
Intestinal obstruction								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Irritable bowel syndrome								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Large intestine polyp								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				3	(1.4)	4	1.20
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Loose tooth								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Melaena								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nausea								
Normal	9	(4.0)	10	2.87	2	(0.9)	2	0.57
Mild impairment	7	(3.1)	8	2.29	5	(2.3)	6	1.81
Moderate or severe impairment	4	(8.9)	4	5.92	2	(3.5)	3	3.51
Odynophagia								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Oral discomfort								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pancreatitis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	1	(1.8)	1	1.17
Pancreatitis acute								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Pancreatitis chronic								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Periodontal disease								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Periodontal inflammation								
Normal	0				1	(0.5)	2	0.57
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Portal hypertensive gastropathy								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Rectal polyp								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): ONTRDURY GFRGR3; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR3; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"
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Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Rectal prolapse								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Salivary gland calculus								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Stomatitis								
Normal	0				0			
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Tooth disorder								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Tooth impacted								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Tooth loss								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Toothache								
Normal	7	(3.1)	8	2.29	0			
Mild impairment	3	(1.3)	3	0.86	4	(1.9)	4	1.20
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Ulcerative gastritis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Umbilical hernia								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Varices oesophageal								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Vomiting								
Normal	4	(1.8)	4	1.15	3	(1.4)	3	0.86
Mild impairment	3	(1.3)	3	0.86	5	(2.3)	7	2.11

%: 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. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	0				3	(5.3)	5	5.85
General disorders and administration site conditions								
All								
Normal	36	(16.1)	54	15.48	37	(16.7)	58	16.62
Mild impairment	45	(20.2)	91	26.07	47	(22.1)	72	21.67
Moderate or severe impairment	10	(22.2)	15	22.20	14	(24.6)	20	23.41
Asthenia								
Normal	2	(0.9)	2	0.57	2	(0.9)	2	0.57
Mild impairment	3	(1.3)	4	1.15	3	(1.4)	3	0.90
Moderate or severe impairment	0				1	(1.8)	1	1.17
Chest discomfort								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	2	(0.9)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Chest pain								
Normal	2	(0.9)	2	0.57	5	(2.3)	5	1.43
Mild impairment	2	(0.9)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	0				1	(1.8)	1	1.17
Chills								
Normal	0				1	(0.5)	1	0.29
Mild impairment	2	(0.9)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Cyst								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Death								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Discomfort								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Drug intolerance								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Early satiety								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	0				0			
Effusion								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Fatigue								
Normal	6	(2.7)	6	1.72	3	(1.4)	3	0.86
Mild impairment	9	(4.0)	11	3.15	3	(1.4)	4	1.20
Moderate or severe impairment	1	(2.2)	1	1.48	1	(1.8)	1	1.17
Feeling abnormal								
Normal	0				0			
Mild impairment	2	(0.9)	7	2.01	0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Feeling hot								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gait disturbance								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Hunger								
Normal	1	(0.4)	2	0.57	0			
Mild impairment	3	(1.3)	3	0.86	2	(0.9)	2	0.60
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Implant site pruritus								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Inflammation								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Influenza like illness								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Injection site bruising								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Injection site dermatitis								
Normal	1	(0.4)	1	0.29	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Injection site erythema								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	0				1	(1.8)	1	1.17
Injection site haemorrhage								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Injection site hypersensitivity								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Injection site hypertrophy								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Injection site mass								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Injection site pain								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Injection site reaction								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Injection site urticaria								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Malaise								
Normal	1	(0.4)	1	0.29	1	(0.5)	2	0.57
Mild impairment	6	(2.7)	8	2.29	8	(3.8)	9	2.71
Moderate or severe impairment	0				1	(1.8)	1	1.17
Mass								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Medical device site bruise								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	2	(0.9)	3	0.86	1	(0.5)	2	0.57
Mild impairment	3	(1.3)	3	0.86	0			
Moderate or severe impairment	0				0			
Medical device site dermatitis								
Normal	0				1	(0.5)	1	0.29
Mild impairment	2	(0.9)	5	1.43	6	(2.8)	12	3.61
Moderate or severe impairment	0				2	(3.5)	2	2.34
Medical device site discomfort								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Medical device site eczema								
Normal	1	(0.4)	2	0.57	1	(0.5)	2	0.57
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	2	2.34
Medical device site erythema								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Medical device site haematoma								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Medical device site haemorrhage								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	2	(4.4)	2	2.96	1	(1.8)	1	1.17
Medical device site hypersensitivity								
Normal	2	(0.9)	3	0.86	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Medical device site inflammation								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Medical device site pain								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Medical device site pruritus								
Normal	3	(1.3)	3	0.86	0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Medical device site reaction								
Normal	0				0			
Mild impairment	1	(0.4)	3	0.86	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Non-cardiac chest pain								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Oedema								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Oedema peripheral								
Normal	4	(1.8)	4	1.15	8	(3.6)	10	2.87
Mild impairment	1	(0.4)	1	0.29	2	(0.9)	2	0.60
Moderate or severe impairment	3	(6.7)	4	5.92	1	(1.8)	1	1.17
Pain								
Normal	2	(0.9)	2	0.57	3	(1.4)	3	0.86
Mild impairment	2	(0.9)	2	0.57	3	(1.4)	4	1.20
Moderate or severe impairment	0				1	(1.8)	1	1.17
Peripheral swelling								
Normal	0				2	(0.9)	2	0.57
Mild impairment	3	(1.3)	4	1.15	3	(1.4)	3	0.90
Moderate or severe impairment	0				1	(1.8)	1	1.17
Procedural failure								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Pyrexia								
Normal	7	(3.1)	7	2.01	6	(2.7)	7	2.01
Mild impairment	16	(7.2)	18	5.16	15	(7.0)	17	5.12
Moderate or severe impairment	4	(8.9)	5	7.40	2	(3.5)	3	3.51
Swelling								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Thirst								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Vaccination site erythema								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vaccination site pain								
Normal	1	(0.4)	1	0.29	3	(1.4)	3	0.86
Mild impairment	4	(1.8)	6	1.72	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Vaccination site reaction								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Hepatobiliary disorders								
All								
Normal	4	(1.8)	7	2.01	4	(1.8)	4	1.15
Mild impairment	9	(4.0)	9	2.58	5	(2.3)	6	1.81
Moderate or severe impairment	0				1	(1.8)	1	1.17
Biliary colic								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Cholelithiasis								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Gallbladder cholesterolosis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hepatic cirrhosis								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Hepatic cyst								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Hepatic function abnormal								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Hepatic steatosis								
Normal	3	(1.3)	3	0.86	1	(0.5)	1	0.29
Mild impairment	5	(2.2)	5	1.43	2	(0.9)	2	0.60
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hepatitis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Hypertransaminasaemia								
Normal	1	(0.4)	2	0.57	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Liver disorder								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Non-alcoholic steatohepatitis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nonalcoholic fatty liver disease								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Steatohepatitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17

%: 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. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
Normal	3	(1.3)	4	1.15	4	(1.8)	5	1.43
Mild impairment	3	(1.3)	3	0.86	2	(0.9)	2	0.60
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Allergy to arthropod bite								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Allergy to arthropod sting								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Immunisation reaction								
Normal	0				1	(0.5)	2	0.57
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Seasonal allergy								
Normal	3	(1.3)	3	0.86	2	(0.9)	2	0.57
Mild impairment	3	(1.3)	3	0.86	2	(0.9)	2	0.60
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Infections and infestations								
All								
Normal	99	(44.2)	215	61.62	120	(54.1)	211	60.46
Mild impairment	103	(46.2)	167	47.85	109	(51.2)	194	58.38
Moderate or severe impairment	23	(51.1)	33	48.83	23	(40.4)	44	51.50
Abscess								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Acarodermatitis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Acute sinusitis								
Normal	3	(1.3)	3	0.86	0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Anal abscess								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Asymptomatic COVID-19								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Bacterial infection								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Balanitis candida								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Body tinea								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Breast abscess								
Normal	0				2	(0.9)	2	0.57
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Breast cellulitis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Bronchitis								
Normal	8	(3.6)	8	2.29	4	(1.8)	5	1.43
Mild impairment	3	(1.3)	3	0.86	1	(0.5)	1	0.30
Moderate or severe impairment	1	(2.2)	1	1.48	2	(3.5)	2	2.34
Candida infection								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	2	(0.9)	2	0.57	0			
Moderate or severe impairment	0				0			
Cellulitis								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	2	(0.9)	2	0.60
Moderate or severe impairment	1	(2.2)	1	1.48	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. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Chlamydial infection								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Chronic hepatitis C								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Chronic sinusitis								
Normal	0				2	(0.9)	2	0.57
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Chronic tonsillitis								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				2	(0.9)	4	1.20
Moderate or severe impairment	0				0			
Clostridium difficile infection								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Conjunctivitis								
Normal	2	(0.9)	2	0.57	1	(0.5)	1	0.29
Mild impairment	3	(1.3)	3	0.86	1	(0.5)	1	0.30
Moderate or severe impairment	1	(2.2)	2	2.96	1	(1.8)	1	1.17
Conjunctivitis bacterial								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Coronavirus infection								
Normal	1	(0.4)	1	0.29	2	(0.9)	2	0.57
Mild impairment	4	(1.8)	4	1.15	4	(1.9)	5	1.50
Moderate or severe impairment	1	(2.2)	1	1.48	0			
COVID-19								
Normal	43	(19.2)	45	12.90	56	(25.2)	57	16.33
Mild impairment	39	(17.5)	41	11.75	44	(20.7)	49	14.75
Moderate or severe impairment	9	(20.0)	9	13.32	4	(7.0)	5	5.85
COVID-19 pneumonia								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	3	(1.3)	3	0.86	2	(0.9)	2	0.60
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cystitis								
Normal	0				3	(1.4)	4	1.15
Mild impairment	5	(2.2)	6	1.72	4	(1.9)	5	1.50
Moderate or severe impairment	0				1	(1.8)	2	2.34
Dermatophytosis of nail								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Diverticulitis								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	0				2	(3.5)	2	2.34
Ear infection								
Normal	3	(1.3)	3	0.86	1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Empyema								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Endophthalmitis								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Epididymitis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Erysipelas								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Escherichia urinary tract infection								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Eye infection bacterial								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Folliculitis								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Fungal balanitis								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Fungal infection								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Furuncle								
Normal	1	(0.4)	2	0.57	1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gastroenteritis								
Normal	5	(2.2)	5	1.43	2	(0.9)	2	0.57
Mild impairment	1	(0.4)	1	0.29	3	(1.4)	4	1.20
Moderate or severe impairment	0				1	(1.8)	1	1.17
Gastroenteritis norovirus								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gastroenteritis viral								
Normal	3	(1.3)	3	0.86	0			
Mild impairment	2	(0.9)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Gastrointestinal infection								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Genital infection fungal								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Giardiasis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Gingivitis								
Normal	1	(0.4)	1	0.29	1	(0.5)	2	0.57
Mild impairment	3	(1.3)	4	1.15	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Helicobacter gastritis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Helicobacter infection								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Hepatitis B								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Herpes dermatitis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Herpes simplex								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Herpes virus infection								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.57	0			
Moderate or severe impairment	0				0			
Herpes zoster								
Normal	4	(1.8)	4	1.15	1	(0.5)	1	0.29
Mild impairment	2	(0.9)	2	0.57	6	(2.8)	6	1.81
Moderate or severe impairment	0				1	(1.8)	1	1.17
Hordeolum								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.57	0			
Moderate or severe impairment	0				0			
Infected bite								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Infected skin ulcer								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Influenza								
Normal	0				2	(0.9)	2	0.57
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Intestinal sepsis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Labyrinthitis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Laryngitis								
Normal	2	(0.9)	2	0.57	3	(1.4)	3	0.86
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Laryngopharyngitis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Localised infection								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Lower respiratory tract infection								
Normal	3	(1.3)	3	0.86	1	(0.5)	3	0.86
Mild impairment	4	(1.8)	6	1.72	0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Lyme disease								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Lymphangitis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mastitis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Mycoplasma infection								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Nail infection								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nasopharyngitis								
Normal	17	(7.6)	22	6.31	17	(7.7)	20	5.73
Mild impairment	18	(8.1)	25	7.16	24	(11.3)	27	8.12
Moderate or severe impairment	3	(6.7)	3	4.44	6	(10.5)	9	10.53
Onychomycosis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Oophoritis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Oral candidiasis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Oral herpes								
Normal	2	(0.9)	2	0.57	1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Oral infection								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Orchitis								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Oropharyngeal candidiasis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Osteomyelitis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Osteomyelitis chronic								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Otitis externa								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Otitis media								
Normal	1	(0.4)	1	0.29	1	(0.5)	2	0.57
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Otitis media acute								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Otitis media chronic								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Parotitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	3	3.51
Peri-implantitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Pericoronitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	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. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Periodontitis								
Normal	0				1	(0.5)	2	0.57
Mild impairment	0				4	(1.9)	4	1.20
Moderate or severe impairment	2	(4.4)	2	2.96	0			
Pharyngitis								
Normal	10	(4.5)	15	4.30	8	(3.6)	12	3.44
Mild impairment	4	(1.8)	5	1.43	3	(1.4)	4	1.20
Moderate or severe impairment	1	(2.2)	1	1.48	1	(1.8)	1	1.17
Pharyngitis bacterial								
Normal	0				2	(0.9)	2	0.57
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Pharyngotonsillitis								
Normal	0				2	(0.9)	2	0.57
Mild impairment	0				2	(0.9)	3	0.90
Moderate or severe impairment	0				0			
Pneumonia								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	2	(0.9)	2	0.57	0			
Moderate or severe impairment	1	(2.2)	1	1.48	2	(3.5)	2	2.34
Post procedural infection								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Pulpitis dental								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Purulence								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Pyelonephritis chronic								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Respiratory syncytial virus infection								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Respiratory tract infection								
Normal	1	(0.4)	1	0.29	2	(0.9)	2	0.57
Mild impairment	1	(0.4)	1	0.29	4	(1.9)	5	1.50
Moderate or severe impairment	2	(4.4)	2	2.96	0			
Respiratory tract infection viral								
Normal	3	(1.3)	6	1.72	0			
Mild impairment	2	(0.9)	2	0.57	3	(1.4)	3	0.90
Moderate or severe impairment	0				0			
Rhinitis								
Normal	5	(2.2)	6	1.72	4	(1.8)	4	1.15
Mild impairment	2	(0.9)	2	0.57	4	(1.9)	6	1.81
Moderate or severe impairment	0				1	(1.8)	1	1.17
Rotavirus infection								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Salpingitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Sepsis								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Sinusitis								
Normal	3	(1.3)	4	1.15	5	(2.3)	9	2.58
Mild impairment	2	(0.9)	2	0.57	2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Skin bacterial infection								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Skin infection								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Staphylococcal infection								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Subcutaneous abscess								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				1	(0.5)	4	1.20
Moderate or severe impairment	0				0			
Tinea infection								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Tonsillitis								
Normal	0				1	(0.5)	1	0.29
Mild impairment	2	(0.9)	3	0.86	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Tooth abscess								
Normal	3	(1.3)	3	0.86	1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	2	(0.9)	2	0.60
Moderate or severe impairment	1	(2.2)	1	1.48	1	(1.8)	1	1.17
Tooth infection								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	2	(0.9)	3	0.90
Moderate or severe impairment	0				0			
Tracheitis								
Normal	1	(0.4)	3	0.86	1	(0.5)	1	0.29
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Upper respiratory tract infection								
Normal	17	(7.6)	26	7.45	8	(3.6)	8	2.29
Mild impairment	9	(4.0)	10	2.87	10	(4.7)	12	3.61
Moderate or severe impairment	2	(4.4)	4	5.92	4	(7.0)	4	4.68
Urethritis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Urinary tract infection								
Normal	4	(1.8)	7	2.01	13	(5.9)	14	4.01
Mild impairment	3	(1.3)	3	0.86	6	(2.8)	9	2.71
Moderate or severe impairment	2	(4.4)	2	2.96	2	(3.5)	2	2.34
Vaginal infection								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17

%: 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. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Varicella								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Viral infection								
Normal	3	(1.3)	3	0.86	4	(1.8)	4	1.15
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Viral pharyngitis								
Normal	1	(0.4)	1	0.29	2	(0.9)	2	0.57
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Viral upper respiratory tract infection								
Normal	1	(0.4)	1	0.29	3	(1.4)	3	0.86
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Vulvovaginal candidiasis								
Normal	2	(0.9)	4	1.15	4	(1.8)	4	1.15
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Vulvovaginal mycotic infection								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	2	2.96	0			
Wound infection								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Injury, poisoning and procedural complications								
All								
Normal	39	(17.4)	46	13.18	24	(10.8)	33	9.46
Mild impairment	43	(19.3)	49	14.04	30	(14.1)	48	14.44
Moderate or severe impairment	7	(15.6)	7	10.36	13	(22.8)	22	25.75
Accidental overdose								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Alcohol poisoning								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Animal bite								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Ankle fracture								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Arthropod bite								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Arthropod sting								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Avulsion fracture								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Bone contusion								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Burn oral cavity								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Burns first degree								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Cervical vertebral fracture								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Chillblains								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Concussion								
Normal	0				0			
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Contusion								
Normal	2	(0.9)	3	0.86	2	(0.9)	2	0.57
Mild impairment	3	(1.3)	3	0.86	9	(4.2)	11	3.31
Moderate or severe impairment	0				2	(3.5)	3	3.51
Deafness traumatic								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Endotracheal intubation complication								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Eye injury								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Fall								
Normal	6	(2.7)	7	2.01	6	(2.7)	7	2.01
Mild impairment	2	(0.9)	3	0.86	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Fibula fracture								
Normal	2	(0.9)	2	0.57	0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Foot fracture								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Hand fracture								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Head injury								
Normal	1	(0.4)	1	0.29	2	(0.9)	2	0.57
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Heat illness								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				2	(3.5)	3	3.51
Hip 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. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Injury								
Normal	3	(1.3)	3	0.86	0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Joint injury								
Normal	2	(0.9)	2	0.57	1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Ligament sprain								
Normal	2	(0.9)	2	0.57	1	(0.5)	1	0.29
Mild impairment	2	(0.9)	2	0.57	2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Limb fracture								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Limb injury								
Normal	4	(1.8)	4	1.15	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Lower limb fracture								
Normal	0				0			
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Meniscus injury								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	2	(0.9)	2	0.57	0			
Moderate or severe impairment	0				0			
Muscle strain								
Normal	1	(0.4)	1	0.29	2	(0.9)	2	0.57
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	1	(2.2)	1	1.48	1	(1.8)	1	1.17
Overdose								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Patella fracture								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Periprocedural myocardial infarction								

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Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Post procedural fistula								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Post procedural haemorrhage								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Post procedural hypothyroidism								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Post procedural stroke								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Post procedural swelling								
Normal	0				1	(0.5)	2	0.57
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Post-traumatic neck syndrome								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Procedural pain								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Product administration error								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Radius fracture								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	2	(0.9)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Rib fracture								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Road traffic accident								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Scar								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Skin abrasion								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	2	(0.9)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Skin laceration								
Normal	3	(1.3)	3	0.86	0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Soft tissue injury								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Spinal column injury								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Spinal cord injury cervical								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Stress fracture								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Subcutaneous haematoma								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Tendon rupture								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Thermal burn								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				1	(1.8)	1	1.17

%: 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. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tooth fracture								
Normal	1	(0.4)	1	0.29	2	(0.9)	2	0.57
Mild impairment	2	(0.9)	2	0.57	0			
Moderate or severe impairment	0				0			
Traumatic arthritis								
Normal	1	(0.4)	2	0.57	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Traumatic haematoma								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Ulna fracture								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Underdose								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Upper limb fracture								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Vaccination complication								
Normal	3	(1.3)	3	0.86	4	(1.8)	6	1.72
Mild impairment	9	(4.0)	10	2.87	8	(3.8)	11	3.31
Moderate or severe impairment	0				4	(7.0)	7	8.19
Wound								
Normal	2	(0.9)	2	0.57	1	(0.5)	1	0.29
Mild impairment	2	(0.9)	2	0.57	0			
Moderate or severe impairment	0				2	(3.5)	2	2.34
Wrist fracture								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Investigations								
All								
Normal	14	(6.3)	15	4.30	16	(7.2)	18	5.16
Mild impairment	19	(8.5)	23	6.59	13	(6.1)	13	3.91
Moderate or severe impairment	2	(4.4)	2	2.96	5	(8.8)	5	5.85

%: 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. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Alanine aminotransferase increased								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Aspartate aminotransferase increased								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Blood cholesterol increased								
Normal	2	(0.9)	2	0.57	0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Blood creatine increased								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Blood creatine phosphokinase increased								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Blood glucose increased								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Blood potassium increased								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Blood pressure decreased								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Blood pressure increased								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				1	(1.8)	1	1.17
Blood triglycerides increased								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Body temperature increased								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cardiac stress test abnormal								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Electrocardiogram change								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Electrocardiogram repolarisation abnormality								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Electrocardiogram T wave inversion								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Glycosylated haemoglobin increased								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Haemoglobin decreased								
Normal	0				1	(0.5)	2	0.57
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hepatic enzyme abnormal								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Hepatic enzyme increased								
Normal	0				2	(0.9)	2	0.57
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
International normalised ratio abnormal								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
International normalised ratio decreased								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
International normalised ratio increased								
Normal	0				0			
Mild impairment	1	(0.4)	2	0.57	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	0				0			
Intraocular pressure increased								
Normal	1	(0.4)	2	0.57	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Lipids increased								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Low density lipoprotein increased								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Prostatic specific antigen increased								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Protein urine present								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Pulse absent								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Red blood cell count decreased								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
SARS-CoV-2 test positive								
Normal	2	(0.9)	2	0.57	3	(1.4)	3	0.86
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Serum ferritin decreased								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Transferrin saturation decreased								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Troponin increased								
Normal	0				1	(0.5)	1	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. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): ONTRDURY GFRGR3; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR3; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"
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Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Weight decreased								
Normal	0				1	(0.5)	1	0.29
Mild impairment	3	(1.3)	3	0.86	0			
Moderate or severe impairment	0				0			
Weight increased								
Normal	4	(1.8)	4	1.15	6	(2.7)	6	1.72
Mild impairment	4	(1.8)	4	1.15	4	(1.9)	4	1.20
Moderate or severe impairment	1	(2.2)	1	1.48	0			
White blood cell count decreased								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Metabolism and nutrition disorders								
All								
Normal	27	(12.1)	30	8.60	27	(12.2)	39	11.17
Mild impairment	26	(11.7)	30	8.60	31	(14.6)	40	12.04
Moderate or severe impairment	6	(13.3)	6	8.88	5	(8.8)	10	11.70
Adult failure to thrive								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Appetite disorder								
Normal	0				0			
Mild impairment	0				1	(0.5)	2	0.60
Moderate or severe impairment	0				0			
Decreased appetite								
Normal	2	(0.9)	2	0.57	1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Dehydration								
Normal	0				0			
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Diabetes mellitus								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Diabetes mellitus inadequate control								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	0				0			
Dyslipidaemia								
Normal	10	(4.5)	10	2.87	6	(2.7)	8	2.29
Mild impairment	3	(1.3)	4	1.15	3	(1.4)	3	0.90
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Electrolyte depletion								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Electrolyte imbalance								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Fluid retention								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gout								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	1	(0.4)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	0				1	(1.8)	1	1.17
Hypercalcaemia								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hypercholesterolaemia								
Normal	2	(0.9)	2	0.57	1	(0.5)	1	0.29
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Hyperglycaemia								
Normal	0				6	(2.7)	6	1.72
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Hyperkalaemia								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	3	(1.3)	3	0.86	2	(0.9)	2	0.60
Moderate or severe impairment	2	(4.4)	2	2.96	1	(1.8)	1	1.17
Hyperlipidaemia								
Normal	2	(0.9)	2	0.57	2	(0.9)	2	0.57
Mild impairment	2	(0.9)	2	0.57	0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Hypertriglyceridaemia								
Normal	3	(1.3)	3	0.86	6	(2.7)	6	1.72

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	3	(1.3)	3	0.86	3	(1.4)	3	0.90
Moderate or severe impairment	0				0			
Hyperuricaemia								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Hypoglycaemia								
Normal	5	(2.2)	6	1.72	2	(0.9)	7	2.01
Mild impairment	2	(0.9)	2	0.57	8	(3.8)	12	3.61
Moderate or severe impairment	0				3	(5.3)	7	8.19
Hypokalaemia								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Hypophosphataemia								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Increased appetite								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Iron deficiency								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Lactic acidosis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Malnutrition								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Metabolic disorder								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Obesity								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Type 2 diabetes mellitus								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Vitamin B12 deficiency								
Normal	0				0			
Mild impairment	3	(1.3)	3	0.86	0			
Moderate or severe impairment	0				0			
Vitamin D deficiency								
Normal	0				1	(0.5)	1	0.29
Mild impairment	4	(1.8)	5	1.43	2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Zinc deficiency								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Musculoskeletal and connective tissue disorders								
All								
Normal	57	(25.4)	95	27.23	48	(21.6)	75	21.49
Mild impairment	60	(26.9)	105	30.08	54	(25.4)	82	24.68
Moderate or severe impairment	13	(28.9)	18	26.63	15	(26.3)	27	31.60
Arthralgia								
Normal	12	(5.4)	16	4.59	7	(3.2)	8	2.29
Mild impairment	14	(6.3)	16	4.58	7	(3.3)	9	2.71
Moderate or severe impairment	4	(8.9)	4	5.92	8	(14.0)	11	12.87
Arthritis								
Normal	2	(0.9)	2	0.57	2	(0.9)	2	0.57
Mild impairment	0				2	(0.9)	3	0.90
Moderate or severe impairment	0				0			
Axillary mass								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Back disorder								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Back pain								
Normal	12	(5.4)	13	3.73	12	(5.4)	13	3.72
Mild impairment	23	(10.3)	25	7.16	16	(7.5)	17	5.12
Moderate or severe impairment	5	(11.1)	5	7.40	4	(7.0)	4	4.68
Bone cyst								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Bursitis								
Normal	1	(0.4)	1	0.29	2	(0.9)	2	0.57
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Cervical spinal stenosis								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Chondrodynia								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Chondropathy								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Coccydynia								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Costochondritis								
Normal	2	(0.9)	2	0.57	1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Dupuytren's contracture								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Exostosis								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Fibromyalgia								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Fistula								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Flank pain								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Fracture nonunion								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Gouty arthritis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Groin pain								
Normal	2	(0.9)	2	0.57	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Intervertebral disc disorder								
Normal	2	(0.9)	2	0.57	1	(0.5)	1	0.29
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Intervertebral disc protrusion								
Normal	0				2	(0.9)	3	0.86
Mild impairment	7	(3.1)	8	2.29	3	(1.4)	3	0.90
Moderate or severe impairment	0				0			
Intervertebral disc space narrowing								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Joint effusion								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Joint swelling								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				1	(1.8)	1	1.17
Ligamentitis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Limb deformity								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Lordosis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Lumbar spinal stenosis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Mastication disorder								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	2	2.34
Muscle contracture								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Muscle spasms								
Normal	4	(1.8)	4	1.15	1	(0.5)	1	0.29
Mild impairment	7	(3.1)	7	2.01	3	(1.4)	3	0.90
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Muscular weakness								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Musculoskeletal chest pain								
Normal	4	(1.8)	4	1.15	0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Musculoskeletal pain								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Musculoskeletal stiffness								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Myalgia								
Normal	2	(0.9)	2	0.57	1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				1	(1.8)	1	1.17
Myositis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	0				0			
Neck pain								
Normal	4	(1.8)	4	1.15	6	(2.7)	6	1.72
Mild impairment	2	(0.9)	2	0.57	2	(0.9)	2	0.60
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Osteoarthritis								
Normal	9	(4.0)	11	3.15	9	(4.1)	11	3.15
Mild impairment	9	(4.0)	9	2.58	5	(2.3)	6	1.81
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Osteochondrosis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Osteopenia								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Pain in extremity								
Normal	8	(3.6)	11	3.15	6	(2.7)	6	1.72
Mild impairment	8	(3.6)	10	2.87	8	(3.8)	11	3.31
Moderate or severe impairment	2	(4.4)	2	2.96	0			
Periarthritis								
Normal	3	(1.3)	3	0.86	1	(0.5)	1	0.29
Mild impairment	2	(0.9)	2	0.57	2	(0.9)	2	0.60
Moderate or severe impairment	1	(2.2)	1	1.48	2	(3.5)	2	2.34
Plantar fasciitis								
Normal	1	(0.4)	2	0.57	1	(0.5)	1	0.29
Mild impairment	3	(1.3)	3	0.86	0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Polyarthritis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Rotator cuff syndrome								
Normal	2	(0.9)	2	0.57	1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Scoliosis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Spinal osteoarthritis								
Normal	2	(0.9)	2	0.57	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Spinal pain								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	0				1	(1.8)	1	1.17
Spinal stenosis								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.57	0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Spondylolisthesis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Synovial cyst								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.57	0			
Moderate or severe impairment	0				0			
Tendon calcification								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Tendonitis								
Normal	1	(0.4)	1	0.29	2	(0.9)	2	0.57
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Tenosynovitis								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				4	(1.9)	5	1.50
Moderate or severe impairment	0				1	(1.8)	1	1.17
Tenosynovitis stenosans								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Torticollis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Trigger finger								
Normal	0				1	(0.5)	1	0.29
Mild impairment	3	(1.3)	3	0.86	2	(0.9)	5	1.50
Moderate or severe impairment	0				0			
Vertebral osteophyte								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
Normal	3	(1.3)	3	0.86	1	(0.5)	1	0.29
Mild impairment	10	(4.5)	12	3.44	5	(2.3)	9	2.71
Moderate or severe impairment	6	(13.3)	6	8.88	3	(5.3)	3	3.51
Acrochordon								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Basal cell carcinoma								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	1	(2.2)	1	1.48	1	(1.8)	1	1.17
Colon adenoma								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Colon cancer								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Dysplastic naevus								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Glioblastoma multiforme								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Haemangioma of liver								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Hepatocellular carcinoma								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Hypergammaglobulinaemia benign monoclonal								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Lipoma								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Lung adenocarcinoma								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Malignant melanoma in situ								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Metastases to liver								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Metastatic renal cell carcinoma								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Neoplasm skin								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Oral fibroma								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Ovarian cancer metastatic								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Pancreatic carcinoma metastatic								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Pancreatic neoplasm								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Prostate cancer								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Seborrhoeic keratosis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	1	(0.4)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Skin papilloma								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Small cell lung cancer								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Squamous cell carcinoma								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Uterine leiomyoma								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Nervous system disorders								
All								
Normal	35	(15.6)	51	14.62	29	(13.1)	34	9.74
Mild impairment	44	(19.7)	67	19.20	39	(18.3)	65	19.56
Moderate or severe impairment	5	(11.1)	7	10.36	12	(21.1)	16	18.73
Ageusia								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Anosmia								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Balance disorder								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Brain injury								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Burning sensation								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	2	(0.9)	2	0.57	0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Carotid arteriosclerosis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Carotid artery stenosis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Carpal tunnel syndrome								
Normal	2	(0.9)	2	0.57	1	(0.5)	1	0.29
Mild impairment	2	(0.9)	2	0.57	2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Cerebral arteriosclerosis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cerebral atrophy								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cerebral haemorrhage								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Cerebral infarction								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Cerebrovascular accident								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Cerebrovascular disorder								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cervical radiculopathy								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Cognitive disorder								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Diabetic neuropathy								
Normal	1	(0.4)	1	0.29	2	(0.9)	2	0.57
Mild impairment	2	(0.9)	2	0.57	2	(0.9)	2	0.60
Moderate or severe impairment	0				1	(1.8)	1	1.17
Dizziness								
Normal	6	(2.7)	8	2.29	4	(1.8)	4	1.15
Mild impairment	8	(3.6)	12	3.44	8	(3.8)	9	2.71
Moderate or severe impairment	1	(2.2)	1	1.48	3	(5.3)	3	3.51
Dizziness postural								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Dysgeusia								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Essential tremor								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Headache								
Normal	10	(4.5)	10	2.87	7	(3.2)	7	2.01
Mild impairment	10	(4.5)	15	4.30	12	(5.6)	23	6.92
Moderate or severe impairment	2	(4.4)	3	4.44	2	(3.5)	2	2.34
Hypoaesthesia								
Normal	2	(0.9)	4	1.15	0			
Mild impairment	3	(1.3)	3	0.86	2	(0.9)	2	0.60
Moderate or severe impairment	1	(2.2)	1	1.48	2	(3.5)	3	3.51
Hypoglycaemic unconsciousness								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Ischaemic stroke								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Lethargy								
Normal	0				0			
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Lumbar radiculopathy								
Normal	0				2	(0.9)	2	0.57
Mild impairment	2	(0.9)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Memory impairment								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Mental impairment								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Metabolic encephalopathy								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Migraine								
Normal	3	(1.3)	3	0.86	0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Movement disorder								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Muscle tone disorder								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Neuralgia								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Neuroglycopenia								
Normal	1	(0.4)	1	0.29	1	(0.5)	3	0.86
Mild impairment	1	(0.4)	3	0.86	0			
Moderate or severe impairment	0				0			
Neuropathy peripheral								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.57	2	(0.9)	2	0.60

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	0				1	(1.8)	1	1.17
Paraesthesia								
Normal	2	(0.9)	2	0.57	3	(1.4)	3	0.86
Mild impairment	2	(0.9)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	0				1	(1.8)	1	1.17
Parkinsonian gait								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Pineal gland cyst								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Post herpetic neuralgia								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Presyncope								
Normal	2	(0.9)	2	0.57	0			
Mild impairment	0				0			
Moderate or severe impairment	0				2	(3.5)	2	2.34
Sciatica								
Normal	1	(0.4)	1	0.29	3	(1.4)	4	1.15
Mild impairment	2	(0.9)	2	0.57	4	(1.9)	6	1.81
Moderate or severe impairment	0				1	(1.8)	1	1.17
Somnolence								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Stiff leg syndrome								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Syncope								
Normal	4	(1.8)	4	1.15	1	(0.5)	1	0.29
Mild impairment	1	(0.4)	3	0.86	0			
Moderate or severe impairment	0				0			
Tension headache								
Normal	0				0			
Mild impairment	1	(0.4)	2	0.57	0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Thrombotic stroke								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Transient ischaemic attack								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Tremor								
Normal	3	(1.3)	3	0.86	0			
Mild impairment	3	(1.3)	4	1.15	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Trigeminal neuralgia								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Vertebral artery occlusion								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
VIth nerve paralysis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
VIth nerve paresis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Psychiatric disorders								
All								
Normal	9	(4.0)	9	2.58	10	(4.5)	10	2.87
Mild impairment	12	(5.4)	14	4.01	3	(1.4)	3	0.90
Moderate or severe impairment	2	(4.4)	2	2.96	0			
Anxiety								
Normal	1	(0.4)	1	0.29	2	(0.9)	2	0.57
Mild impairment	3	(1.3)	3	0.86	0			
Moderate or severe impairment	0				0			
Depressed mood								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Depression								
Normal	3	(1.3)	3	0.86	3	(1.4)	3	0.86
Mild impairment	4	(1.8)	4	1.15	1	(0.5)	1	0.30

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	0				0			
Insomnia								
Normal	3	(1.3)	3	0.86	2	(0.9)	2	0.57
Mild impairment	5	(2.2)	5	1.43	2	(0.9)	2	0.60
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Mood swings								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nightmare								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Persistent depressive disorder								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Psychotic disorder								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Schizophrenia								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Sleep disorder								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Renal and urinary disorders								
All								
Normal	7	(3.1)	9	2.58	6	(2.7)	8	2.29
Mild impairment	8	(3.6)	10	2.87	16	(7.5)	16	4.81
Moderate or severe impairment	5	(11.1)	5	7.40	6	(10.5)	11	12.87
Acute kidney injury								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Calculus urinary								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Chronic kidney disease								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				3	(5.3)	3	3.51
Diabetic nephropathy								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Dysuria								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	2	(0.9)	2	0.57	3	(1.4)	3	0.90
Moderate or severe impairment	0				0			
Haematuria								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	3	(1.4)	3	0.90
Moderate or severe impairment	0				1	(1.8)	1	1.17
Hypercalciuria								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hypertonic bladder								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Ketonuria								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Microalbuminuria								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nephrolithiasis								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Nocturia								
Normal	0				0			
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Pollakiuria								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.57	1	(0.5)	1	0.30

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	0				1	(1.8)	1	1.17
Pyelocaliectasis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Renal colic								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Renal cyst								
Normal	2	(0.9)	2	0.57	1	(0.5)	1	0.29
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Renal impairment								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	2	(4.4)	2	2.96	1	(1.8)	1	1.17
Ureterolithiasis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Urinary incontinence								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Urinary retention								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	2	2.34
Urinary tract obstruction								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Urine odour abnormal								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Reproductive system and breast disorders								
All								
Normal	4	(1.8)	4	1.15	5	(2.3)	6	1.72
Mild impairment	7	(3.1)	7	2.01	10	(4.7)	14	4.21
Moderate or severe impairment	4	(8.9)	4	5.92	1	(1.8)	2	2.34

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Adenomyosis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Atrophic vulvovaginitis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Balanoposthitis								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Benign prostatic hyperplasia								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	3	(1.4)	3	0.90
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Breast mass								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Breast pain								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Erectile dysfunction								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Galactorrhoea								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Hydrometra								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Menopausal symptoms								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Ovarian cyst								
Normal	0				0			
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Penile rash								
Normal	0				0			
Mild impairment	0				1	(0.5)	3	0.90
Moderate or severe impairment	0				0			
Prostatism								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Prostatitis								
Normal	0				1	(0.5)	2	0.57
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pruritus genital								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Uterine haemorrhage								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Uterine polyp								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Uterine prolapse								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Vaginal prolapse								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Vulval eczema								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Vulval leukoplakia								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Vulvovaginal dryness								
Normal	0				1	(0.5)	1	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. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Vulvovaginal pruritus								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Respiratory, thoracic and mediastinal disorders								
All								
Normal	31	(13.8)	42	12.04	23	(10.4)	31	8.88
Mild impairment	22	(9.9)	31	8.88	19	(8.9)	29	8.73
Moderate or severe impairment	2	(4.4)	3	4.44	6	(10.5)	9	10.53
Acquired diaphragmatic eventration								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Acute pulmonary oedema								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Acute respiratory failure								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Allergic bronchitis								
Normal	0				0			
Mild impairment	0				1	(0.5)	2	0.60
Moderate or severe impairment	0				0			
Asthma								
Normal	1	(0.4)	2	0.57	1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Bronchiectasis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Bronchitis chronic								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Chronic eosinophilic rhinosinusitis								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Chronic obstructive pulmonary disease								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Cough								
Normal	9	(4.0)	10	2.87	3	(1.4)	3	0.86
Mild impairment	5	(2.2)	5	1.43	5	(2.3)	6	1.81
Moderate or severe impairment	0				0			
Dry throat								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Dyspnoea								
Normal	2	(0.9)	2	0.57	3	(1.4)	3	0.86
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	0				1	(1.8)	1	1.17
Dyspnoea exertional								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Emphysema								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Epistaxis								
Normal	0				0			
Mild impairment	0				1	(0.5)	3	0.90
Moderate or severe impairment	0				0			
Haemoptysis								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Interstitial lung disease								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.57	0			
Moderate or severe impairment	0				0			
Laryngeal cyst								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Nasal congestion								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	2	(0.9)	2	0.57	1	(0.5)	1	0.29
Mild impairment	3	(1.3)	4	1.15	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Nasal dryness								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Nasal turbinate hypertrophy								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Oropharyngeal pain								
Normal	7	(3.1)	7	2.01	4	(1.8)	6	1.72
Mild impairment	5	(2.2)	5	1.43	4	(1.9)	6	1.81
Moderate or severe impairment	1	(2.2)	2	2.96	1	(1.8)	1	1.17
Paranasal sinus discomfort								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pleural calcification								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Pleural effusion								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Pleuritic pain								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Pneumothorax								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Productive cough								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Pulmonary embolism								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pulmonary fibrosis								
Normal	1	(0.4)	2	0.57	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Pulmonary mass								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Respiratory disorder								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Respiratory failure								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Rhinitis allergic								
Normal	0				2	(0.9)	6	1.72
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Rhinorrhoea								
Normal	4	(1.8)	4	1.15	1	(0.5)	1	0.29
Mild impairment	2	(0.9)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	0				1	(1.8)	1	1.17
Sinus congestion								
Normal	0				0			
Mild impairment	1	(0.4)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	0				1	(1.8)	1	1.17
Sinus pain								
Normal	0				0			
Mild impairment	1	(0.4)	2	0.57	0			
Moderate or severe impairment	0				0			
Sleep apnoea syndrome								
Normal	2	(0.9)	2	0.57	1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Sneezing								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Throat irritation								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Upper respiratory tract inflammation								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Upper-airway cough syndrome								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Skin and subcutaneous tissue disorders								
All								
Normal	21	(9.4)	24	6.88	16	(7.2)	19	5.44
Mild impairment	30	(13.5)	41	11.75	27	(12.7)	36	10.83
Moderate or severe impairment	8	(17.8)	12	17.76	10	(17.5)	20	23.41
Actinic keratosis								
Normal	0				0			
Mild impairment	1	(0.4)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Alopecia								
Normal	4	(1.8)	4	1.15	1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Alopecia areata								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Angioedema								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Asteatosis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Blister								
Normal	0				0			
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Cellulite								
Normal	0				1	(0.5)	2	0.57
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 - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Chloasma								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Cold sweat								
Normal	0				0			
Mild impairment	2	(0.9)	3	0.86	1	(0.5)	1	0.30
Moderate or severe impairment	0				1	(1.8)	1	1.17
Cold urticaria								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Dermal cyst								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Dermatitis								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				3	(1.4)	3	0.90
Moderate or severe impairment	0				0			
Dermatitis allergic								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Dermatitis contact								
Normal	2	(0.9)	2	0.57	2	(0.9)	2	0.57
Mild impairment	3	(1.3)	4	1.15	3	(1.4)	3	0.90
Moderate or severe impairment	1	(2.2)	2	2.96	2	(3.5)	3	3.51
Diabetic foot								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Drug eruption								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	1	(1.8)	1	1.17
Dry skin								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	2	(0.9)	2	0.57	0			
Moderate or severe impairment	0				0			
Ecchymosis								
Normal	0				2	(0.9)	2	0.57
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Eczema								
Normal	3	(1.3)	3	0.86	0			
Mild impairment	5	(2.2)	5	1.43	1	(0.5)	1	0.30
Moderate or severe impairment	0				3	(5.3)	3	3.51
Eczema nummular								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Erythema								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Granuloma annulare								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Haemorrhage subcutaneous								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Hyperhidrosis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	2	(0.9)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Hyperkeratosis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Ingrowing nail								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Lentigo								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Lipodystrophy acquired								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Lipohypertrophy								
Normal	0				0			
Mild impairment	0				2	(0.9)	2	0.60

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	0				0			
Macule								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Miliaria								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.57	2	(0.9)	2	0.60
Moderate or severe impairment	1	(2.2)	2	2.96	3	(5.3)	3	3.51
Myxoid cyst								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Night sweats								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Onychalgia								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Pruritus								
Normal	2	(0.9)	4	1.15	1	(0.5)	1	0.29
Mild impairment	2	(0.9)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	0				2	(3.5)	2	2.34
Psoriasis								
Normal	0				0			
Mild impairment	2	(0.9)	2	0.57	0			
Moderate or severe impairment	0				0			
Purpura								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Rash								
Normal	0				4	(1.8)	4	1.15
Mild impairment	2	(0.9)	2	0.57	3	(1.4)	3	0.90
Moderate or severe impairment	0				1	(1.8)	1	1.17
Rosacea								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Skin exfoliation								
Normal	1	(0.4)	1	0.29	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Skin fissures								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Skin irritation								
Normal	0				0			
Mild impairment	2	(0.9)	3	0.86	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Skin lesion								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				1	(1.8)	1	1.17
Skin ulcer								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Urticaria								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	2	0.57	3	(1.4)	3	0.90
Moderate or severe impairment	0				1	(1.8)	1	1.17
Urticaria contact								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Urticaria thermal								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Surgical and medical procedures								
All								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Removal of foreign body								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Vascular disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
Normal	19	(8.5)	23	6.59	13	(5.9)	17	4.87
Mild impairment	17	(7.6)	20	5.73	26	(12.2)	28	8.43
Moderate or severe impairment	4	(8.9)	6	8.88	4	(7.0)	4	4.68
Aneurysm								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Aortic arteriosclerosis								
Normal	2	(0.9)	2	0.57	1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Aortic stenosis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Arteriosclerosis								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Blood pressure inadequately controlled								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Brachiocephalic arteriosclerosis								
Normal	1	(0.4)	1	0.29	1	(0.5)	1	0.29
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Diabetic vascular disorder								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Flushing								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Haematoma								
Normal	2	(0.9)	2	0.57	1	(0.5)	1	0.29
Mild impairment	2	(0.9)	2	0.57	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Hypertension								
Normal	6	(2.7)	6	1.72	4	(1.8)	5	1.43
Mild impairment	6	(2.7)	6	1.72	9	(4.2)	9	2.71
Moderate or severe impairment	3	(6.7)	3	4.44	3	(5.3)	3	3.51

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hypertensive angiopathy								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	1	(0.4)	1	0.29	2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Hypertensive crisis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Hypertensive urgency								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Hypotension								
Normal	3	(1.3)	3	0.86	1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				1	(1.8)	1	1.17
Iliac artery stenosis								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Intermittent claudication								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Macroangiopathy								
Normal	0				0			
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	0				0			
Peripheral arterial occlusive disease								
Normal	1	(0.4)	2	0.57	3	(1.4)	3	0.86
Mild impairment	0				2	(0.9)	2	0.60
Moderate or severe impairment	0				0			
Peripheral artery occlusion								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Peripheral artery stenosis								
Normal	1	(0.4)	2	0.57	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Peripheral coldness								
Normal	0				0			
Mild impairment	4	(1.8)	4	1.15	1	(0.5)	1	0.30

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90), and moderate or severe impairment (eGFR<60); moderate (30<=eGFR<60) and severe (eGFR<30) impairment were combined due to low numbers. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate or severe impairment	0				0			
Peripheral vascular disorder								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Peripheral venous disease								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				1	(0.5)	1	0.30
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Post thrombotic syndrome								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Secondary hypertension								
Normal	1	(0.4)	1	0.29	0			
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Superficial vein thrombosis								
Normal	0				0			
Mild impairment	1	(0.4)	1	0.29	0			
Moderate or severe impairment	0				0			
Thrombophlebitis								
Normal	0				1	(0.5)	1	0.29
Mild impairment	0				0			
Moderate or severe impairment	0				0			
Thrombosis								
Normal	0				0			
Mild impairment	0				0			
Moderate or severe impairment	1	(2.2)	1	1.48	0			
Varicose vein								
Normal	0				1	(0.5)	1	0.29
Mild impairment	1	(0.4)	1	0.29	1	(0.5)	1	0.30
Moderate or severe impairment	1	(2.2)	1	1.48	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. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt; variable(s): ONTRDURY GFRGR3; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR3; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"
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7.24.24 Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	197				190			
Mild impairment	88				93			
Moderate impairment	5				9			
PYE (years)								
Normal	205.47				199.83			
Mild impairment	89.22				99.88			
Moderate impairment	5.46				9.87			
Events								
Normal	161	(81.7)	623	303.20	148	(77.9)	598	299.25
Mild impairment	75	(85.2)	329	368.75	80	(86.0)	518	518.62
Moderate impairment	4	(80.0)	13	237.89	8	(88.9)	30	303.95

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blood and lymphatic system disorders								
All								
Normal	4	(2.0)	5	2.43	3	(1.6)	3	1.50
Mild impairment	3	(3.4)	3	3.36	2	(2.2)	3	3.00
Moderate impairment	0				0			
Anaemia								
Normal	3	(1.5)	3	1.46	0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Blood loss anaemia								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Iron deficiency anaemia								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				1	(1.1)	2	2.00
Moderate impairment	0				0			
Lymphadenitis								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Lymphadenopathy								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Splenomegaly								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Thrombocytopenia								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Cardiac disorders								
All								
Normal	6	(3.0)	8	3.89	5	(2.6)	7	3.50
Mild impairment	10	(11.4)	10	11.21	6	(6.5)	8	8.01
Moderate impairment	0				0			
Acute myocardial infarction								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Angina pectoris								
Normal	2	(1.0)	2	0.97	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Angina unstable								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Aortic valve incompetence								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Atrial fibrillation								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Bundle branch block right								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Cardiac failure congestive								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Cardiomegaly								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Cardiovascular disorder								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Conduction disorder								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Coronary artery disease								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Left ventricular hypertrophy								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	1	1.00
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mitral valve incompetence								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Myocardial infarction								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Myocardial ischaemia								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Palpitations								
Normal	0				2	(1.1)	3	1.50
Mild impairment	3	(3.4)	3	3.36	2	(2.2)	2	2.00
Moderate impairment	0				0			
Tachycardia								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Tricuspid valve incompetence								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Ventricular extrasystoles								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	2	(2.3)	2	2.24	0			
Moderate impairment	0				0			
Congenital, familial and genetic disorders								
All								
Normal	0				0			
Mild impairment	2	(2.3)	2	2.24	0			
Moderate impairment	0				0			
Arteriovenous malformation								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Colour blindness								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
Normal	1	(0.5)	1	0.49	2	(1.1)	2	1.00
Mild impairment	1	(1.1)	1	1.12	2	(2.2)	2	2.00
Moderate impairment	0				0			
Deafness neurosensory								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Ear pain								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Tinnitus								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Tympanic membrane perforation								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Vertigo								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	1	1.00
Moderate impairment	0				0			
Autoimmune thyroiditis								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Hypogonadism								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Hypothyroidism								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Thyroiditis chronic								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Eye disorders								
All								
Normal	20	(10.2)	29	14.11	24	(12.6)	35	17.51
Mild impairment	23	(26.1)	33	36.99	19	(20.4)	28	28.03
Moderate impairment	0				3	(33.3)	3	30.40
Angle closure glaucoma								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Arteriosclerotic retinopathy								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Astigmatism								
Normal	1	(0.5)	1	0.49	2	(1.1)	2	1.00
Mild impairment	0				0			
Moderate impairment	0				0			
Cataract								
Normal	1	(0.5)	1	0.49	2	(1.1)	2	1.00
Mild impairment	5	(5.7)	5	5.60	2	(2.2)	3	3.00
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cataract nuclear								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Conjunctival haemorrhage								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Corneal erosion								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Diabetic retinal oedema								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				1	(11.1)	1	10.13
Diabetic retinopathy								
Normal	11	(5.6)	15	7.30	15	(7.9)	17	8.51
Mild impairment	13	(14.8)	13	14.57	9	(9.7)	10	10.01
Moderate impairment	0				2	(22.2)	2	20.26
Dry eye								
Normal	0				1	(0.5)	1	0.50
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Eczema eyelids								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Epiretinal membrane								
Normal	2	(1.0)	2	0.97	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Eye pain								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Glaucoma								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	3	(3.2)	3	3.00
Moderate impairment	0				0			
Macular oedema								
Normal	2	(1.0)	2	0.97	1	(0.5)	1	0.50
Mild impairment	2	(2.3)	3	3.36	0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Myopia								
Normal	0				2	(1.1)	2	1.00
Mild impairment	0				0			
Moderate impairment	0				0			
Non-proliferative retinopathy								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	2	(2.3)	2	2.24	1	(1.1)	1	1.00
Moderate impairment	0				0			
Ocular hypertension								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				1	(1.1)	2	2.00
Moderate impairment	0				0			
Photopsia								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Posterior capsule opacification								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	2	2.00
Moderate impairment	0				0			
Presbyopia								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Pterygium								
Normal	0				1	(0.5)	2	1.00
Mild impairment	0				0			
Moderate impairment	0				0			
Retinal drusen								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Retinal haemorrhage								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Retinal vascular disorder								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Retinopathy								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Retinopathy hypertensive								
Normal	2	(1.0)	2	0.97	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Strabismus								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Vision blurred								
Normal	0				0			
Mild impairment	2	(2.3)	2	2.24	0			
Moderate impairment	0				0			
Visual acuity reduced								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Vitreous detachment								
Normal	0				0			
Mild impairment	0				2	(2.2)	2	2.00
Moderate impairment	0				0			
Vitreous floaters								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Gastrointestinal disorders								
All								
Normal	25	(12.7)	50	24.33	25	(13.2)	47	23.52
Mild impairment	21	(23.9)	30	33.62	16	(17.2)	26	26.03
Moderate impairment	1	(20.0)	1	18.30	1	(11.1)	2	20.26
Abdominal discomfort								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	1	1.00
Moderate impairment	0				0			
Abdominal distension								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	1	(1.1)	2	2.24	0			
Moderate impairment	0				0			
Abdominal pain								
Normal	4	(2.0)	4	1.95	0			
Mild impairment	3	(3.4)	3	3.36	1	(1.1)	1	1.00
Moderate impairment	0				0			
Abdominal pain upper								
Normal	2	(1.0)	3	1.46	1	(0.5)	1	0.50

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	1	1.00
Moderate impairment	0				0			
Anal fissure								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Change of bowel habit								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Chronic gastritis								
Normal	0				1	(0.5)	1	0.50
Mild impairment	1	(1.1)	1	1.12	2	(2.2)	2	2.00
Moderate impairment	0				0			
Constipation								
Normal	2	(1.0)	3	1.46	2	(1.1)	2	1.00
Mild impairment	0				0			
Moderate impairment	0				0			
Dental caries								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Diarrhoea								
Normal	6	(3.0)	9	4.38	3	(1.6)	3	1.50
Mild impairment	4	(4.5)	4	4.48	3	(3.2)	4	4.00
Moderate impairment	0				0			
Diverticulum intestinal								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Duodenitis								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Dyspepsia								
Normal	2	(1.0)	2	0.97	0			
Mild impairment	1	(1.1)	1	1.12	2	(2.2)	2	2.00
Moderate impairment	0				0			
Enteritis								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Faeces soft								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	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 (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate impairment	0				0			
Flatulence								
Normal	2	(1.0)	2	0.97	0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Food poisoning								
Normal	0				2	(1.1)	2	1.00
Mild impairment	0				0			
Moderate impairment	1	(20.0)	1	18.30	0			
Gastric polyps								
Normal	0				0			
Mild impairment	0				2	(2.2)	2	2.00
Moderate impairment	0				0			
Gastritis								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Gastritis erosive								
Normal	0				0			
Mild impairment	0				2	(2.2)	2	2.00
Moderate impairment	0				0			
Gastrointestinal haemorrhage								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Gastrooesophageal reflux disease								
Normal	0				2	(1.1)	2	1.00
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Gastrooesophageal sphincter insufficiency								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Gingival recession								
Normal	0				1	(0.5)	2	1.00
Mild impairment	0				0			
Moderate impairment	0				0			
Gingival ulceration								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Haematochezia								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Haemorrhoids								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Hiatus hernia								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Impaired gastric emptying								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	1	(1.1)	2	2.24	0			
Moderate impairment	0				0			
Irritable bowel syndrome								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Lumbar hernia								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Mouth ulceration								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Nausea								
Normal	7	(3.6)	7	3.41	5	(2.6)	5	2.50
Mild impairment	2	(2.3)	2	2.24	4	(4.3)	4	4.00
Moderate impairment	0				1	(11.1)	1	10.13
Odynophagia								
Normal	0				1	(0.5)	2	1.00
Mild impairment	0				0			
Moderate impairment	0				0			
Oesophagitis								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Pancreatic failure								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Pancreatitis								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): ONTRDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pneumatosis intestinalis								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Proctitis ulcerative								
Normal	0				1	(0.5)	2	1.00
Mild impairment	0				0			
Moderate impairment	0				0			
Toothache								
Normal	2	(1.0)	3	1.46	3	(1.6)	6	3.00
Mild impairment	2	(2.3)	3	3.36	0			
Moderate impairment	0				0			
Vomiting								
Normal	9	(4.6)	10	4.87	7	(3.7)	7	3.50
Mild impairment	2	(2.3)	2	2.24	2	(2.2)	2	2.00
Moderate impairment	0				1	(11.1)	1	10.13
General disorders and administration site conditions								
All								
Normal	28	(14.2)	42	20.44	34	(17.9)	50	25.02
Mild impairment	26	(29.5)	41	45.95	26	(28.0)	127	127.15
Moderate impairment	1	(20.0)	1	18.30	5	(55.6)	6	60.79
Asthenia								
Normal	1	(0.5)	1	0.49	2	(1.1)	2	1.00
Mild impairment	0				0			
Moderate impairment	0				1	(11.1)	1	10.13
Chest pain								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				1	(11.1)	1	10.13
Chills								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Complication associated with device								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Cyst								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Facial discomfort								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Facial pain								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Fatigue								
Normal	3	(1.5)	3	1.46	3	(1.6)	3	1.50
Mild impairment	3	(3.4)	4	4.48	1	(1.1)	1	1.00
Moderate impairment	1	(20.0)	1	18.30	1	(11.1)	1	10.13
Hunger								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	2	2.00
Moderate impairment	0				0			
Hyperthermia								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Illness								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Inflammation								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Influenza like illness								
Normal	3	(1.5)	3	1.46	2	(1.1)	2	1.00
Mild impairment	1	(1.1)	1	1.12	2	(2.2)	2	2.00
Moderate impairment	0				0			
Injection site mass								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Injection site pain								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Injection site urticaria								
Normal	1	(0.5)	2	0.97	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Malaise								
Normal	3	(1.5)	3	1.46	0			
Mild impairment	1	(1.1)	1	1.12	5	(5.4)	84	84.10

%: 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 (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): ONTRDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate impairment	0				0			
Medical device site bruise								
Normal	0				1	(0.5)	1	0.50
Mild impairment	2	(2.3)	2	2.24	1	(1.1)	1	1.00
Moderate impairment	0				0			
Medical device site dermatitis								
Normal	3	(1.5)	4	1.95	2	(1.1)	3	1.50
Mild impairment	2	(2.3)	2	2.24	4	(4.3)	6	6.01
Moderate impairment	0				0			
Medical device site erythema								
Normal	1	(0.5)	1	0.49	3	(1.6)	4	2.00
Mild impairment	1	(1.1)	2	2.24	1	(1.1)	2	2.00
Moderate impairment	0				1	(11.1)	1	10.13
Medical device site haematoma								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Medical device site haemorrhage								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Medical device site inflammation								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Medical device site irritation								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Medical device site pain								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Medical device site pruritus								
Normal	1	(0.5)	1	0.49	4	(2.1)	4	2.00
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Medical device site rash								
Normal	2	(1.0)	2	0.97	4	(2.1)	4	2.00
Mild impairment	5	(5.7)	6	6.72	7	(7.5)	8	8.01
Moderate impairment	0				0			
Medical device site reaction								
Normal	2	(1.0)	2	0.97	1	(0.5)	1	0.50
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	1	1.00
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Medical device site vesicles								
Normal	1	(0.5)	2	0.97	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Nodule								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Non-cardiac chest pain								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Oedema								
Normal	0				1	(0.5)	1	0.50
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Oedema peripheral								
Normal	2	(1.0)	2	0.97	1	(0.5)	1	0.50
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Pain								
Normal	3	(1.5)	3	1.46	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				1	(11.1)	1	10.13
Peripheral swelling								
Normal	0				0			
Mild impairment	0				2	(2.2)	2	2.00
Moderate impairment	0				0			
Pyrexia								
Normal	7	(3.6)	9	4.38	11	(5.8)	12	6.01
Mild impairment	9	(10.2)	13	14.57	8	(8.6)	12	12.01
Moderate impairment	0				1	(11.1)	1	10.13
Swelling face								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Vaccination site discomfort								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Vaccination site joint pain								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vaccination site lymphadenopathy								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Vaccination site pain								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Vaccination site swelling								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hepatobiliary disorders								
All								
Normal	3	(1.5)	3	1.46	3	(1.6)	3	1.50
Mild impairment	2	(2.3)	3	3.36	3	(3.2)	3	3.00
Moderate impairment	0				0			
Cholecystitis chronic								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Gallbladder disorder								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Gallbladder polyp								
Normal	0				1	(0.5)	1	0.50
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	1	1.00
Moderate impairment	0				0			
Hepatic calcification								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Hepatic function abnormal								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Hepatic steatosis								
Normal	2	(1.0)	2	0.97	0			
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	1	1.00
Moderate impairment	0				0			
Hypertransaminasaemia								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
Normal	3	(1.5)	3	1.46	4	(2.1)	4	2.00
Mild impairment	1	(1.1)	1	1.12	2	(2.2)	2	2.00
Moderate impairment	1	(20.0)	1	18.30	0			
Allergy to arthropod bite								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Allergy to arthropod sting								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Hypersensitivity								
Normal	2	(1.0)	2	0.97	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Seasonal allergy								
Normal	0				3	(1.6)	3	1.50
Mild impairment	1	(1.1)	1	1.12	2	(2.2)	2	2.00
Moderate impairment	1	(20.0)	1	18.30	0			
Infections and infestations								
All								
Normal	114	(57.9)	232	112.91	106	(55.8)	199	99.58
Mild impairment	44	(50.0)	76	85.18	49	(52.7)	96	96.12
Moderate impairment	1	(20.0)	2	36.60	4	(44.4)	8	81.05
Abscess limb								
Normal	0				1	(0.5)	2	1.00
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Acute sinusitis								
Normal	0				2	(1.1)	2	1.00
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Asymptomatic COVID-19								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Beta haemolytic streptococcal infection								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Breast abscess								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Bronchitis								
Normal	3	(1.5)	3	1.46	2	(1.1)	2	1.00
Mild impairment	2	(2.3)	2	2.24	1	(1.1)	2	2.00
Moderate impairment	0				0			
Conjunctivitis								
Normal	2	(1.0)	2	0.97	0			
Mild impairment	2	(2.3)	3	3.36	0			
Moderate impairment	0				0			
Coronavirus infection								
Normal	0				2	(1.1)	2	1.00
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
COVID-19								
Normal	58	(29.4)	63	30.66	63	(33.2)	68	34.03
Mild impairment	17	(19.3)	18	20.17	19	(20.4)	19	19.02
Moderate impairment	0				2	(22.2)	2	20.26
COVID-19 pneumonia								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Cystitis								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	2	(2.3)	2	2.24	2	(2.2)	2	2.00
Moderate impairment	0				0			
Cystitis escherichia								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Ear infection								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Erythema migrans								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Eye infection								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Febrile infection								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Fungal infection								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Fungal skin infection								
Normal	2	(1.0)	2	0.97	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Furuncle								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Gastric infection								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Gastroenteritis								
Normal	8	(4.1)	12	5.84	3	(1.6)	4	2.00
Mild impairment	5	(5.7)	6	6.72	2	(2.2)	2	2.00
Moderate impairment	0				0			
Gastroenteritis viral								
Normal	3	(1.5)	3	1.46	1	(0.5)	1	0.50
Mild impairment	0				2	(2.2)	2	2.00
Moderate impairment	0				0			
Gastrointestinal infection								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				1	(1.1)	3	3.00
Moderate impairment	0				0			
Genital infection fungal								
Normal	1	(0.5)	2	0.97	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Gingival abscess								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Gingivitis								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Herpes zoster								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				2	(2.2)	2	2.00
Moderate impairment	0				0			
Hordeolum								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				3	(3.2)	3	3.00
Moderate impairment	0				0			
Impetigo								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Infected cyst								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Influenza								
Normal	7	(3.6)	8	3.89	4	(2.1)	4	2.00
Mild impairment	1	(1.1)	1	1.12	4	(4.3)	5	5.01
Moderate impairment	0				0			
Laryngitis								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Laryngopharyngitis								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Localised infection								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Lower respiratory tract infection								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Nasopharyngitis								
Normal	37	(18.8)	55	26.77	42	(22.1)	61	30.53
Mild impairment	10	(11.4)	19	21.30	17	(18.3)	21	21.03
Moderate impairment	1	(20.0)	1	18.30	2	(22.2)	2	20.26
Norovirus infection								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Oral herpes								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Otitis externa								
Normal	0				0			
Mild impairment	0				2	(2.2)	2	2.00
Moderate impairment	0				1	(11.1)	1	10.13
Otitis media								
Normal	0				2	(1.1)	2	1.00
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Pericoronitis								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Periodontitis								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	1	1.00
Moderate impairment	0				0			
Pharyngitis								
Normal	5	(2.5)	5	2.43	1	(0.5)	2	1.00
Mild impairment	3	(3.4)	3	3.36	1	(1.1)	1	1.00
Moderate impairment	0				0			
Pneumonia								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				1	(11.1)	1	10.13
Pulpitis dental								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Pyelonephritis acute								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Respiratory tract infection								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Respiratory tract infection viral								
Normal	4	(2.0)	4	1.95	3	(1.6)	3	1.50
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): ONTRDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Rhinitis								
Normal	2	(1.0)	2	0.97	3	(1.6)	3	1.50
Mild impairment	2	(2.3)	2	2.24	2	(2.2)	3	3.00
Moderate impairment	0				0			
Sepsis								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Severe acute respiratory syndrome								
Normal	2	(1.0)	2	0.97	1	(0.5)	1	0.50
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Sinobronchitis								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Sinusitis								
Normal	12	(6.1)	13	6.33	6	(3.2)	6	3.00
Mild impairment	1	(1.1)	1	1.12	3	(3.2)	3	3.00
Moderate impairment	1	(20.0)	1	18.30	0			
Skin infection								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Tinea cruris								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Tinea pedis								
Normal	1	(0.5)	2	0.97	0			
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	1	1.00
Moderate impairment	0				0			
Tonsillitis								
Normal	2	(1.0)	2	0.97	1	(0.5)	1	0.50
Mild impairment	0				1	(1.1)	2	2.00
Moderate impairment	0				0			
Tooth abscess								
Normal	3	(1.5)	3	1.46	0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Tooth infection								
Normal	2	(1.0)	2	0.97	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tracheobronchitis								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Trichophytosis								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Upper respiratory tract infection								
Normal	11	(5.6)	14	6.81	7	(3.7)	9	4.50
Mild impairment	4	(4.5)	4	4.48	4	(4.3)	4	4.00
Moderate impairment	0				0			
Urinary tract infection								
Normal	7	(3.6)	7	3.41	4	(2.1)	4	2.00
Mild impairment	5	(5.7)	5	5.60	3	(3.2)	4	4.00
Moderate impairment	0				1	(11.1)	2	20.26
Vaginal infection								
Normal	1	(0.5)	3	1.46	0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Varicella								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Viral infection								
Normal	1	(0.5)	1	0.49	4	(2.1)	5	2.50
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Viral rhinitis								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Vulvitis								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Vulvovaginal mycotic infection								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Vulvovaginitis								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Injury, poisoning and procedural complications								
All								
Normal	31	(15.7)	42	20.44	35	(18.4)	49	24.52
Mild impairment	12	(13.6)	19	21.30	14	(15.1)	14	14.02
Moderate impairment	0				1	(11.1)	1	10.13
Accidental overdose								
Normal	4	(2.0)	4	1.95	2	(1.1)	2	1.00
Mild impairment	3	(3.4)	4	4.48	0			
Moderate impairment	0				0			
Anaemia postoperative								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Animal bite								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Animal scratch								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Ankle fracture								
Normal	0				0			
Mild impairment	1	(1.1)	3	3.36	0			
Moderate impairment	0				0			
Arthropod bite								
Normal	0				2	(1.1)	2	1.00
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	1	1.00
Moderate impairment	0				0			
Back injury								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Burns first degree								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Chest injury								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Clavicle fracture								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate impairment	0				0			
Concussion								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Contusion								
Normal	0				1	(0.5)	1	0.50
Mild impairment	2	(2.3)	2	2.24	1	(1.1)	1	1.00
Moderate impairment	0				1	(11.1)	1	10.13
Corneal abrasion								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Epicondylitis								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Face injury								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Fall								
Normal	2	(1.0)	2	0.97	2	(1.1)	5	2.50
Mild impairment	0				0			
Moderate impairment	0				0			
Fibula fracture								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Hand fracture								
Normal	1	(0.5)	1	0.49	2	(1.1)	2	1.00
Mild impairment	0				0			
Moderate impairment	0				0			
Heat stroke								
Normal	0				0			
Mild impairment	0				2	(2.2)	2	2.00
Moderate impairment	0				0			
Incorrect dose administered								
Normal	2	(1.0)	2	0.97	0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Intentional underdose								
Normal	0				1	(0.5)	2	1.00
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Joint injury								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Ligament rupture								
Normal	0				0			
Mild impairment	1	(1.1)	2	2.24	0			
Moderate impairment	0				0			
Ligament sprain								
Normal	4	(2.0)	4	1.95	1	(0.5)	1	0.50
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	1	1.00
Moderate impairment	0				0			
Limb injury								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Medication error								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Meniscus injury								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Muscle rupture								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Muscle strain								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Nerve injury								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Overdose								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Post-traumatic neck syndrome								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): ONTRDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Prescribed overdose								
Normal	3	(1.5)	3	1.46	0			
Mild impairment	2	(2.3)	2	2.24	0			
Moderate impairment	0				0			
Procedural pain								
Normal	1	(0.5)	2	0.97	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Product administration error								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Product dispensing error								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Radius fracture								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Road traffic accident								
Normal	2	(1.0)	3	1.46	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Skin abrasion								
Normal	2	(1.0)	3	1.46	0			
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	1	1.00
Moderate impairment	0				0			
Skin laceration								
Normal	1	(0.5)	1	0.49	2	(1.1)	2	1.00
Mild impairment	0				0			
Moderate impairment	0				0			
Stress fracture								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Tendon rupture								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Thermal burn								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Tooth fracture								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Vaccination complication								
Normal	5	(2.5)	5	2.43	7	(3.7)	11	5.50
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	1	1.00
Moderate impairment	0				0			
Venous injury								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Wound								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Wound dehiscence								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Wrist fracture								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Wrong product administered								
Normal	0				4	(2.1)	4	2.00
Mild impairment	0				0			
Moderate impairment	0				0			
Investigations								
All								
Normal	13	(6.6)	15	7.30	13	(6.8)	15	7.51
Mild impairment	4	(4.5)	6	6.72	4	(4.3)	4	4.00
Moderate impairment	2	(40.0)	3	54.90	0			
Angiogram								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Aspartate aminotransferase increased								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Blood cholesterol increased								
Normal	0				1	(0.5)	1	0.50
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blood glucose fluctuation								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Blood glucose increased								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Blood pressure increased								
Normal	2	(1.0)	3	1.46	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Blood testosterone decreased								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Blood triglycerides increased								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Blood uric acid increased								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Body temperature increased								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Cardiac murmur								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Electrocardiogram abnormal								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Electrocardiogram T wave abnormal								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(20.0)	1	18.30	0			
Eosinophil count increased								
Normal	0				1	(0.5)	2	1.00
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Glomerular filtration rate decreased								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(20.0)	1	18.30	0			
Haemoglobin decreased								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Heart rate increased								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Hepatic enzyme increased								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Hepatitis B virus test positive								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Lipids abnormal								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Low density lipoprotein increased								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Mycobacterium tuberculosis complex test positive								
Normal	2	(1.0)	2	0.97	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Occult blood positive								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	1	1.00
Moderate impairment	0				0			
Platelet count decreased								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Pulse absent								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
SARS-CoV-2 test positive								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				4	(2.1)	4	2.00
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Serum ferritin decreased								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(20.0)	1	18.30	0			
Weight decreased								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Weight increased								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
White blood cell count decreased								
Normal	0				1	(0.5)	1	0.50
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Metabolism and nutrition disorders								
All								
Normal	14	(7.1)	17	8.27	10	(5.3)	11	5.50
Mild impairment	3	(3.4)	6	6.72	6	(6.5)	8	8.01
Moderate impairment	1	(20.0)	1	18.30	0			
Decreased appetite								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Dehydration								
Normal	0				0			
Mild impairment	0				1	(1.1)	2	2.00
Moderate impairment	0				0			
Diabetic dyslipidaemia								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Diabetic ketoacidosis								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Dyslipidaemia								
Normal	0				0			
Mild impairment	0				2	(2.2)	2	2.00
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): ONTRDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hypercholesterolaemia								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Hyperlipidaemia								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	1	(20.0)	1	18.30	0			
Hyperuricaemia								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Hypoglycaemia								
Normal	7	(3.6)	9	4.38	3	(1.6)	3	1.50
Mild impairment	3	(3.4)	6	6.72	1	(1.1)	2	2.00
Moderate impairment	0				0			
Hypokalaemia								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Hyponatraemia								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Insulin resistance								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Iron deficiency								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Obesity								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Vitamin D deficiency								
Normal	1	(0.5)	1	0.49	3	(1.6)	3	1.50
Mild impairment	0				0			
Moderate impairment	0				0			
Musculoskeletal and connective tissue 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 (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	33	(16.8)	42	20.44	29	(15.3)	59	29.52
Mild impairment	12	(13.6)	16	17.93	25	(26.9)	37	37.04
Moderate impairment	0				2	(22.2)	3	30.40
Acquired claw toe								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Arthralgia								
Normal	9	(4.6)	10	4.87	8	(4.2)	9	4.50
Mild impairment	3	(3.4)	3	3.36	5	(5.4)	5	5.01
Moderate impairment	0				2	(22.2)	2	20.26
Arthritis								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Back pain								
Normal	5	(2.5)	5	2.43	11	(5.8)	25	12.51
Mild impairment	0				5	(5.4)	5	5.01
Moderate impairment	0				1	(11.1)	1	10.13
Bursitis								
Normal	0				1	(0.5)	1	0.50
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Chondromalacia								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Flank pain								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Foot deformity								
Normal	1	(0.5)	1	0.49	1	(0.5)	2	1.00
Mild impairment	0				0			
Moderate impairment	0				0			
Groin pain								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Intervertebral disc protrusion								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				1	(1.1)	2	2.00
Moderate impairment	0				0			
Limb discomfort								
Normal	2	(1.0)	2	0.97	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	0				0			
Moderate impairment	0				0			
Limb mass								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Muscle spasms								
Normal	2	(1.0)	3	1.46	0			
Mild impairment	2	(2.3)	2	2.24	1	(1.1)	1	1.00
Moderate impairment	0				0			
Muscular weakness								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Musculoskeletal stiffness								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Myalgia								
Normal	2	(1.0)	2	0.97	4	(2.1)	4	2.00
Mild impairment	1	(1.1)	1	1.12	4	(4.3)	7	7.01
Moderate impairment	0				0			
Myopathy								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Neck pain								
Normal	2	(1.0)	2	0.97	2	(1.1)	2	1.00
Mild impairment	0				0			
Moderate impairment	0				0			
Nodal osteoarthritis								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Osteoarthritis								
Normal	3	(1.5)	3	1.46	1	(0.5)	1	0.50
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	1	1.00
Moderate impairment	0				0			
Pain in extremity								
Normal	5	(2.5)	5	2.43	7	(3.7)	7	3.50
Mild impairment	3	(3.4)	3	3.36	6	(6.5)	6	6.01
Moderate impairment	0				0			
Periarthritis								
Normal	2	(1.0)	2	0.97	2	(1.1)	2	1.00
Mild impairment	0				2	(2.2)	2	2.00

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): ONTRDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate impairment	0				0			
Rheumatoid arthritis								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Rotator cuff syndrome								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Spinal stenosis								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Synovial cyst								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	1	1.00
Moderate impairment	0				0			
Tendonitis								
Normal	0				1	(0.5)	1	0.50
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Tenosynovitis								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Trigger finger								
Normal	2	(1.0)	2	0.97	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
Normal	5	(2.5)	5	2.43	3	(1.6)	3	1.50
Mild impairment	3	(3.4)	3	3.36	2	(2.2)	3	3.00
Moderate impairment	0				0			
Benign neoplasm of thyroid gland								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Benign renal neoplasm								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Colon adenoma								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Eye naevus								
Normal	0				2	(1.1)	2	1.00
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Haemangioma of liver								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Lipoma								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Melanocytic naevus								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Myeloproliferative neoplasm								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Seborrhoeic keratosis								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Skin papilloma								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Uterine leiomyoma								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Nervous system disorders								
All								
Normal	28	(14.2)	45	21.90	19	(10.0)	27	13.51
Mild impairment	10	(11.4)	25	28.02	18	(19.4)	90	90.11
Moderate impairment	2	(40.0)	2	36.60	2	(22.2)	2	20.26
Ageusia								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate impairment	0				0			
Autonomic nervous system imbalance								
Normal	1	(0.5)	2	0.97	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Burning sensation								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	1	(20.0)	1	18.30	0			
Carpal tunnel syndrome								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Cerebral haemorrhage								
Normal	0				0			
Mild impairment	1	(1.1)	2	2.24	0			
Moderate impairment	0				0			
Cerebral infarction								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Cervicobrachial syndrome								
Normal	2	(1.0)	2	0.97	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Diabetic neuropathy								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Disturbance in attention								
Normal	0				0			
Mild impairment	1	(1.1)	11	12.33	0			
Moderate impairment	0				0			
Dizziness								
Normal	1	(0.5)	1	0.49	2	(1.1)	2	1.00
Mild impairment	1	(1.1)	2	2.24	3	(3.2)	4	4.00
Moderate impairment	0				0			
Dizziness postural								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Encephalopathy								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Haemorrhage intracranial								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Headache								
Normal	14	(7.1)	24	11.68	10	(5.3)	13	6.51
Mild impairment	3	(3.4)	3	3.36	6	(6.5)	9	9.01
Moderate impairment	0				0			
Hemiparesis								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Hypoaesthesia								
Normal	2	(1.0)	3	1.46	0			
Mild impairment	0				2	(2.2)	2	2.00
Moderate impairment	0				0			
Hypoglycaemic seizure								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Hypoglycaemic unconsciousness								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(11.1)	1	10.13
Hypotonia								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
IIIrd nerve paralysis								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Ischaemic stroke								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(11.1)	1	10.13
Loss of consciousness								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Loss of proprioception								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Migraine								
Normal	3	(1.5)	4	1.95	1	(0.5)	2	1.00
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	1	1.00
Moderate impairment	0				0			
Neuropathy peripheral								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Optic neuritis								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Post herpetic neuralgia								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Presyncope								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Radiculopathy								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Restless legs syndrome								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Sinus headache								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Somnolence								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	1	(20.0)	1	18.30	0			
Syncope								
Normal	2	(1.0)	2	0.97	0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Tension headache								
Normal	0				1	(0.5)	2	1.00
Mild impairment	0				0			
Moderate impairment	0				0			
Tremor								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				1	(0.5)	1	0.50
Mild impairment	1	(1.1)	1	1.12	3	(3.2)	67	67.08
Moderate impairment	0				0			
Pregnancy, puerperium and perinatal conditions								
All								
Normal	2	(1.0)	2	0.97	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Abortion spontaneous								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Abortion threatened								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Psychiatric disorders								
All								
Normal	6	(3.0)	6	2.92	10	(5.3)	13	6.51
Mild impairment	2	(2.3)	2	2.24	1	(1.1)	1	1.00
Moderate impairment	0				0			
Alcohol abuse								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Anxiety								
Normal	1	(0.5)	1	0.49	4	(2.1)	4	2.00
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Anxiety disorder								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Attention deficit hyperactivity disorder								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Depressed mood								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Depression								
Normal	0				5	(2.6)	5	2.50
Mild impairment	0				0			
Moderate impairment	0				0			
Insomnia								
Normal	1	(0.5)	1	0.49	2	(1.1)	2	1.00
Mild impairment	0				0			
Moderate impairment	0				0			
Major depression								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Sleep disorder								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Stress								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Renal and urinary disorders								
All								
Normal	5	(2.5)	5	2.43	1	(0.5)	1	0.50
Mild impairment	2	(2.3)	2	2.24	3	(3.2)	6	6.01
Moderate impairment	0				1	(11.1)	1	10.13
Acute kidney injury								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				1	(11.1)	1	10.13
Chronic kidney disease								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Diabetic nephropathy								
Normal	0				0			
Mild impairment	0				2	(2.2)	2	2.00
Moderate impairment	0				0			
Dysuria								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Hydrocalyx								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate impairment	0				0			
Hypertensive nephropathy								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Microalbuminuria								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Pollakiuria								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Proteinuria								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Renal cyst								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Renal pain								
Normal	2	(1.0)	2	0.97	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Reproductive system and breast disorders								
All								
Normal	5	(2.5)	5	2.43	5	(2.6)	7	3.50
Mild impairment	4	(4.5)	5	5.60	2	(2.2)	2	2.00
Moderate impairment	0				1	(11.1)	1	10.13
Atrophic vulvovaginitis								
Normal	0				0			
Mild impairment	0				0			
Moderate impairment	0				1	(11.1)	1	10.13
Benign prostatic hyperplasia								
Normal	0				0			
Mild impairment	2	(2.3)	2	2.24	1	(1.1)	1	1.00
Moderate impairment	0				0			
Dysmenorrhoea								
Normal	1	(0.5)	1	0.49	2	(1.1)	2	1.00
Mild impairment	0				0			
Moderate impairment	0				0			
Ectropion of cervix								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Erectile dysfunction								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Fibrocystic breast disease								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Heavy menstrual bleeding								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Menstruation irregular								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Ovarian cyst								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Ovarian disorder								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Penile pain								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Premenstrual syndrome								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Prostatic cyst								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Prostatitis								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Prostatomegaly								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Respiratory, thoracic and mediastinal disorders								
All								
Normal	24	(12.2)	32	15.57	23	(12.1)	38	19.02
Mild impairment	11	(12.5)	21	23.54	13	(14.0)	18	18.02
Moderate impairment	1	(20.0)	1	18.30	1	(11.1)	1	10.13
Acute respiratory failure								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Allergic cough								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Asthma								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Bronchial hyperreactivity								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Cough								
Normal	3	(1.5)	3	1.46	9	(4.7)	13	6.51
Mild impairment	6	(6.8)	9	10.09	2	(2.2)	2	2.00
Moderate impairment	0				0			
Cough variant asthma								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Dysphonia								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Dyspnoea								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	1	1.00
Moderate impairment	0				0			
Dyspnoea exertional								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	1	1.00
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Epiglottic oedema								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Epistaxis								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	2	(2.3)	2	2.24	0			
Moderate impairment	0				0			
Hiccups								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Nasal congestion								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Oropharyngeal discomfort								
Normal	0				0			
Mild impairment	0				2	(2.2)	2	2.00
Moderate impairment	0				0			
Oropharyngeal pain								
Normal	7	(3.6)	8	3.89	8	(4.2)	9	4.50
Mild impairment	1	(1.1)	1	1.12	2	(2.2)	2	2.00
Moderate impairment	0				0			
Pleurisy								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				1	(11.1)	1	10.13
Productive cough								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				2	(2.2)	3	3.00
Moderate impairment	0				0			
Pulmonary congestion								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Pulmonary mass								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Respiratory disorder								
Normal	4	(2.0)	4	1.95	2	(1.1)	2	1.00
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

adsl.xpt; variable(s): ONTRDURY GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6"
adae.xpt; variable(s): AEBODSYS AEDECOD GFRGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 6" & (ANL02FL) == "Y" & (ANELFL) == "Y"

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Rhinitis allergic								
Normal	2	(1.0)	2	0.97	1	(0.5)	1	0.50
Mild impairment	1	(1.1)	2	2.24	1	(1.1)	1	1.00
Moderate impairment	0				0			
Rhinorrhoea								
Normal	3	(1.5)	4	1.95	6	(3.2)	7	3.50
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Sinus congestion								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				2	(2.2)	2	2.00
Moderate impairment	1	(20.0)	1	18.30	0			
Sleep apnoea syndrome								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Sneezing								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Throat irritation								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Upper-airway cough syndrome								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Skin and subcutaneous tissue disorders								
All								
Normal	24	(12.2)	28	13.63	19	(10.0)	22	11.01
Mild impairment	11	(12.5)	13	14.57	19	(20.4)	30	30.04
Moderate impairment	1	(20.0)	1	18.30	2	(22.2)	2	20.26
Alopecia								
Normal	2	(1.0)	2	0.97	0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Alopecia areata								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Angioedema								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Moderate impairment	0				0			
Chronic spontaneous urticaria								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Cold sweat								
Normal	0				0			
Mild impairment	0				4	(4.3)	9	9.01
Moderate impairment	0				1	(11.1)	1	10.13
Dermal cyst								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				2	(2.2)	2	2.00
Moderate impairment	0				0			
Dermatitis								
Normal	3	(1.5)	4	1.95	1	(0.5)	2	1.00
Mild impairment	2	(2.3)	3	3.36	2	(2.2)	2	2.00
Moderate impairment	0				0			
Dermatitis allergic								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Dermatitis atopic								
Normal	1	(0.5)	1	0.49	2	(1.1)	2	1.00
Mild impairment	0				0			
Moderate impairment	0				0			
Dermatitis contact								
Normal	2	(1.0)	2	0.97	1	(0.5)	1	0.50
Mild impairment	2	(2.3)	2	2.24	6	(6.5)	6	6.01
Moderate impairment	0				0			
Dry skin								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	1	1.00
Moderate impairment	0				0			
Eczema								
Normal	0				2	(1.1)	2	1.00
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Eczema asteatotic								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Erythema								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Erythema multiforme								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Hidradenitis								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Hyperkeratosis								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Ingrowing nail								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Ingrown hair								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Lichen sclerosus								
Normal	2	(1.0)	2	0.97	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Macule								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Miliaria								
Normal	0				1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				1	(11.1)	1	10.13
Pruritus								
Normal	0				1	(0.5)	1	0.50
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	1	1.00
Moderate impairment	0				0			
Psoriasis								
Normal	0				1	(0.5)	1	0.50
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Rash								
Normal	3	(1.5)	3	1.46	1	(0.5)	1	0.50
Mild impairment	1	(1.1)	1	1.12	1	(1.1)	1	1.00
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Rash erythematous								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Seborrhoeic dermatitis								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Skin fissures								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Skin irritation								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	1	(20.0)	1	18.30	0			
Skin lesion								
Normal	0				1	(0.5)	1	0.50
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Skin reaction								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Skin ulcer								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Telangiectasia								
Normal	1	(0.5)	1	0.49	1	(0.5)	1	0.50
Mild impairment	0				0			
Moderate impairment	0				0			
Urticaria								
Normal	0				2	(1.1)	2	1.00
Mild impairment	0				2	(2.2)	2	2.00
Moderate impairment	0				0			
Urticaria papular								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Vitiligo								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Xeroderma								

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Surgical and medical procedures								
All								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	3	(3.4)	3	3.36	0			
Moderate impairment	0				0			
Cardiac ablation								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Skin neoplasm excision								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Tooth extraction								
Normal	0				0			
Mild impairment	1	(1.1)	1	1.12	0			
Moderate impairment	0				0			
Wisdom teeth removal								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline renal function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vascular disorders								
All								
Normal	4	(2.0)	4	1.95	2	(1.1)	2	1.00
Mild impairment	7	(8.0)	7	7.85	8	(8.6)	9	9.01
Moderate impairment	0				0			
Aortic aneurysm								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Arteriosclerosis								
Normal	1	(0.5)	1	0.49	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Brachiocephalic artery stenosis								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Hypertension								
Normal	1	(0.5)	1	0.49	2	(1.1)	2	1.00
Mild impairment	7	(8.0)	7	7.85	5	(5.4)	5	5.01
Moderate impairment	0				0			
Hypertensive crisis								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			
Hypotension								
Normal	2	(1.0)	2	0.97	0			
Mild impairment	0				0			
Moderate impairment	0				0			
Varicose vein								
Normal	0				0			
Mild impairment	0				1	(1.1)	1	1.00
Moderate impairment	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eGFR: Estimated glomerular filtration rate (mL/min/1.73m^2), N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Categories are coded as normal (eGFR>=90), mild impairment (60<=eGFR<90) and moderate (30<=eGFR<60). MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

7.24.25 Adverse events by baseline hepatic function - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	470				458			
Impaired	1				1			
Missing	21				33			
PYE (years)								
Normal	732.59				712.54			
Impaired	0.31				1.59			
Missing	32.59				52.62			
Events								
Normal	380	(80.9)	1795	245.02	360	(78.6)	1635	229.46
Impaired	0				1	(100.0)	5	314.33
Missing	17	(81.0)	87	266.92	28	(84.8)	183	347.75
Serious								
Yes								
Normal	62	(13.2)	92	12.56	65	(14.2)	112	15.72
Impaired	0				1	(100.0)	2	125.73
Missing	2	(9.5)	3	9.20	5	(15.2)	5	9.50
No								
Normal	370	(78.7)	1703	232.46	351	(76.6)	1523	213.74
Impaired	0				1	(100.0)	3	188.60
Missing	17	(81.0)	84	257.72	28	(84.8)	178	338.25
Missing								
Normal	0				0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severity								
Severe								
Normal	25	(5.3)	37	5.05	35	(7.6)	60	8.42
Impaired	0				0			
Missing	1	(4.8)	1	3.07	1	(3.0)	1	1.90
Moderate								
Normal	184	(39.1)	386	52.69	171	(37.3)	378	53.05
Impaired	0				1	(100.0)	1	62.87
Missing	8	(38.1)	15	46.02	11	(33.3)	18	34.20
Mild								
Normal	337	(71.7)	1372	187.28	314	(68.6)	1197	167.99
Impaired	0				1	(100.0)	4	251.46
Missing	14	(66.7)	71	217.83	25	(75.8)	164	311.64
Missing								
Normal	0				0			
Impaired	0				0			
Missing	0				0			
Related to basal insulin								
Probable								
Normal	30	(6.4)	43	5.87	29	(6.3)	44	6.18
Impaired	0				1	(100.0)	1	62.87
Missing	0				3	(9.1)	6	11.40
Possible								
Normal	45	(9.6)	66	9.01	34	(7.4)	53	7.44
Impaired	0				0			
Missing	1	(4.8)	1	3.07	5	(15.2)	7	13.30
Unlikely								
Normal	375	(79.8)	1684	229.87	349	(76.2)	1532	215.00
Impaired	0				1	(100.0)	4	251.46
Missing	17	(81.0)	86	263.85	28	(84.8)	170	323.05
Missing								
Normal	2	(0.4)	2	0.27	5	(1.1)	6	0.84
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to technical complaint for basal insulin								
Yes								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
No								
Normal	380	(80.9)	1794	244.88	359	(78.4)	1628	228.48
Impaired	0				1	(100.0)	5	314.33
Missing	17	(81.0)	87	266.92	28	(84.8)	183	347.75
NA								
Normal	0				0			
Impaired	0				0			
Missing	0				0			
Missing								
Normal	1	(0.2)	1	0.14	5	(1.1)	6	0.84
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
Normal	5	(1.1)	7	0.96	3	(0.7)	7	0.98
Impaired	0				0			
Missing	0				0			
Not recovered/not resolved								
Normal	205	(43.6)	493	67.30	197	(43.0)	384	53.89
Impaired	0				1	(100.0)	1	62.87
Missing	8	(38.1)	15	46.02	18	(54.5)	62	117.82
Recovered/resolved with sequelae								
Normal	9	(1.9)	9	1.23	8	(1.7)	8	1.12
Impaired	0				0			
Missing	0				0			
Recovering/resolving								
Normal	20	(4.3)	27	3.69	27	(5.9)	35	4.91
Impaired	0				1	(100.0)	2	125.73
Missing	1	(4.8)	1	3.07	2	(6.1)	2	3.80
Recovered/resolved								
Normal	339	(72.1)	1259	171.86	324	(70.7)	1201	168.55
Impaired	0				1	(100.0)	2	125.73
Missing	15	(71.4)	71	217.83	26	(78.8)	119	226.13
Unknown								
Normal	0				0			
					0			
Impaired	0				0			
					0			
Missing	0				0			
					0			
Missing								
Normal	0				0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

adsl.xpt ; variable(s): ONTRDURY CPCLGR1 ; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & ANELFL == "Y" & ANL02FL == "Y"
nn1436/nn1436-japan/submission_ext_20230612_er
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7.24.26 Adverse events by baseline hepatic function - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	281				285			
Impaired	1				0			
Missing	8				7			
PYE (years)								
Normal	290.73				302.22			
Impaired	1.10				0			
Missing	8.33				7.36			
Events								
Normal	232	(82.6)	890	306.13	229	(80.4)	1100	363.97
Impaired	0				0			
Missing	8	(100.0)	75	899.93	7	(100.0)	46	624.82
Serious								
Yes								
Normal	21	(7.5)	33	11.35	19	(6.7)	23	7.61
Impaired	0				0			
Missing	3	(37.5)	6	71.99	1	(14.3)	2	27.17
No								
Normal	229	(81.5)	857	294.78	229	(80.4)	1077	356.36
Impaired	0				0			
Missing	8	(100.0)	69	827.93	7	(100.0)	44	597.66
Missing								
Normal	0				0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Severity								
Severe								
Normal	18	(6.4)	22	7.57	8	(2.8)	8	2.65
Impaired	0				0			
Missing	2	(25.0)	6	71.99	1	(14.3)	2	27.17
Moderate								
Normal	76	(27.0)	147	50.56	77	(27.0)	143	47.32
Impaired	0				0			
Missing	7	(87.5)	32	383.97	5	(71.4)	16	217.33
Mild								
Normal	213	(75.8)	721	248.00	212	(74.4)	949	314.01
Impaired	0				0			
Missing	6	(75.0)	37	443.96	7	(100.0)	28	380.33
Missing								
Normal	0				0			
Impaired	0				0			
Missing	0				0			
Related to basal insulin								
Probable								
Normal	20	(7.1)	25	8.60	11	(3.9)	12	3.97
Impaired	0				0			
Missing	0				0			
Possible								
Normal	30	(10.7)	36	12.38	21	(7.4)	70	23.16
Impaired	0				0			
Missing	0				1	(14.3)	2	27.17
Unlikely								
Normal	226	(80.4)	828	284.80	227	(79.6)	1018	336.84
Impaired	0				0			
Missing	8	(100.0)	75	899.93	7	(100.0)	44	597.66
Missing								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Related to technical complaint for basal insulin								
Yes								
Normal	0				0			
Impaired	0				0			
Missing	0				0			
No								
Normal	232	(82.6)	889	305.78	229	(80.4)	1100	363.97
Impaired	0				0			
Missing	8	(100.0)	75	899.93	7	(100.0)	46	624.82
NA								
Normal	0				0			
Impaired	0				0			
Missing	0				0			
Missing								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Outcome								
Fatal								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Not recovered/not resolved								
Normal	99	(35.2)	184	63.29	99	(34.7)	204	67.50
Impaired	0				0			
Missing	6	(75.0)	11	131.99	5	(71.4)	13	176.58
Recovered/resolved with sequelae								
Normal	1	(0.4)	2	0.69	3	(1.1)	3	0.99
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Recovering/resolving								
Normal	20	(7.1)	24	8.26	20	(7.0)	25	8.27
Impaired	0				0			
Missing	0				0			
Recovered/resolved								
Normal	213	(75.8)	679	233.55	206	(72.3)	868	287.21
Impaired	0				0			
Missing	8	(100.0)	63	755.94	7	(100.0)	33	448.24
Unknown								
Normal	0				0			
Impaired	0				0			
Missing	0				0			
Missing								
Normal	0				0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

7.24.27 Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	470				458			
Impaired	1				1			
Missing	21				33			
PYE (years)								
Normal	732.59				712.54			
Impaired	0.31				1.59			
Missing	32.59				52.62			
Events								
Normal	380	(80.9)	1795	245.02	360	(78.6)	1635	229.46
Impaired	0				1	(100.0)	5	314.33
Missing	17	(81.0)	87	266.92	28	(84.8)	183	347.75

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blood and lymphatic system disorders								
All								
Normal	15	(3.2)	17	2.32	13	(2.8)	14	1.96
Impaired	0				0			
Missing	0				6	(18.2)	6	11.40
Anaemia								
Normal	10	(2.1)	10	1.37	6	(1.3)	7	0.98
Impaired	0				0			
Missing	0				4	(12.1)	4	7.60
Blood loss anaemia								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Eosinophilia								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Hypochromic anaemia								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Iron deficiency anaemia								
Normal	3	(0.6)	3	0.41	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Lymphadenopathy								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				2	(6.1)	2	3.80
Normochromic normocytic anaemia								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Polycythaemia								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Thrombocytopenia								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Cardiac disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
Normal	43	(9.1)	78	10.65	40	(8.7)	59	8.28
Impaired	0				0			
Missing	1	(4.8)	1	3.07	2	(6.1)	2	3.80
Acute coronary syndrome								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Acute myocardial infarction								
Normal	4	(0.9)	4	0.55	5	(1.1)	5	0.70
Impaired	0				0			
Missing	0				0			
Angina pectoris								
Normal	2	(0.4)	2	0.27	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Angina unstable								
Normal	5	(1.1)	5	0.68	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Aortic valve calcification								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Aortic valve incompetence								
Normal	2	(0.4)	2	0.27	0			
Impaired	0				0			
Missing	0				0			
Arrhythmia								
Normal	0				2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Arteriosclerosis coronary artery								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Atrial fibrillation								
Normal	8	(1.7)	9	1.23	6	(1.3)	9	1.26
Impaired	0				0			
Missing	0				0			
Atrial flutter								
Normal	1	(0.2)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Atrial thrombosis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Atrioventricular block complete								
Normal	0				2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Atrioventricular block first degree								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Atrioventricular block second degree								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Bradycardia								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Bundle branch block left								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Bundle branch block right								
Normal	2	(0.4)	2	0.27	2	(0.4)	3	0.42
Impaired	0				0			
Missing	0				0			
Cardiac dysfunction								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Cardiac failure								
Normal	4	(0.9)	4	0.55	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Cardiac failure chronic								
Normal	3	(0.6)	3	0.41	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Cardiac failure congestive								
Normal	2	(0.4)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cardiac ventricular thrombosis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Cardio-respiratory arrest								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Cardiomyopathy								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Chronic coronary syndrome								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Congestive cardiomyopathy								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Coronary artery disease								
Normal	6	(1.3)	6	0.82	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				0			
Coronary artery occlusion								
Normal	2	(0.4)	2	0.27	0			
Impaired	0				0			
Missing	0				0			
Coronary artery stenosis								
Normal	2	(0.4)	3	0.41	0			
Impaired	0				0			
Missing	0				0			
Diastolic dysfunction								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Left atrial dilatation								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Left ventricular dysfunction								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Left ventricular hypertrophy								
Normal	2	(0.4)	2	0.27	0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Mitral valve incompetence								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Myocardial infarction								
Normal	3	(0.6)	3	0.41	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				0			
Myocardial ischaemia								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Palpitations								
Normal	3	(0.6)	3	0.41	4	(0.9)	5	0.70
Impaired	0				0			
Missing	0				0			
Pericardial effusion								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Pericarditis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Sinus arrhythmia								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Sinus bradycardia								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Sinus tachycardia								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Supraventricular extrasystoles								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Supraventricular tachycardia								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Tachycardia								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Tricuspid valve incompetence								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Ventricular extrasystoles								
Normal	4	(0.9)	4	0.55	1	(0.2)	1	0.14
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Congenital, familial and genetic disorders								
All								
Normal	3	(0.6)	3	0.41	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Congenital syphilitic osteochondritis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Corneal dystrophy								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Dolichocolon								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Hydrocele								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Type V hyperlipidaemia								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Ear and labyrinth disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
Normal	12	(2.6)	13	1.77	12	(2.6)	13	1.82
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Cerumen impaction								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Ear discomfort								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Ear inflammation								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Ear pain								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Eustachian tube dysfunction								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Hypoacusis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Presbyacusis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Tinnitus								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Vertigo								
Normal	6	(1.3)	7	0.96	7	(1.5)	8	1.12
Impaired	0				0			
Missing	0				0			
Vertigo positional								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
Normal	4	(0.9)	4	0.55	6	(1.3)	6	0.84
Impaired	0				0			
Missing	0				2	(6.1)	2	3.80
Goitre								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Hyperplasia adrenal								
Normal	0				2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Hyperprolactinaemia								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Hyperthyroidism								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Hypothyroidism								
Normal	2	(0.4)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Thyroid mass								
Normal	2	(0.4)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Eye disorders								
All								
Normal	86	(18.3)	123	16.79	71	(15.5)	107	15.02
Impaired	0				0			
Missing	3	(14.3)	4	12.27	5	(15.2)	12	22.80
Acquired epiblepharon								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Age-related macular degeneration								
Normal	0				2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Asthenopia								
Normal	2	(0.4)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Astigmatism								
Normal	3	(0.6)	3	0.41	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Blepharitis								
Normal	4	(0.9)	4	0.55	0			
Impaired	0				0			
Missing	0				0			
Blepharitis allergic								
Normal	0				0			
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Cataract								
Normal	17	(3.6)	22	3.00	11	(2.4)	14	1.96
Impaired	0				0			
Missing	1	(4.8)	1	3.07	1	(3.0)	1	1.90
Cataract diabetic								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Cataract nuclear								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Cataract subcapsular								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Chorioretinal disorder								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Conjunctival cyst								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Conjunctival erosion								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Conjunctival haemorrhage								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Conjunctival hyperaemia								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Conjunctivitis allergic								
Normal	3	(0.6)	4	0.55	1	(0.2)	1	0.14
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Corneal opacity								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Dacryoadenitis acquired								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Dermatochalasis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Diabetic retinal oedema								
Normal	1	(0.2)	1	0.14	5	(1.1)	5	0.70
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Diabetic retinopathy								
Normal	36	(7.7)	41	5.60	29	(6.3)	33	4.63
Impaired	0				0			
Missing	0				3	(9.1)	5	9.50
Dry age-related macular degeneration								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Dry eye								
Normal	5	(1.1)	5	0.68	4	(0.9)	4	0.56
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Eye discharge								
Normal	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Eye disorder								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Eye inflammation								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Eye irritation								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Eye pain								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Eyelid ptosis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Giant papillary conjunctivitis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Glaucoma								
Normal	2	(0.4)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Iritis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Macular oedema								
Normal	3	(0.6)	3	0.41	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Myopia								
Normal	2	(0.4)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Non-proliferative retinopathy								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Normal tension glaucoma								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Ocular hypertension								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Open angle glaucoma								
Normal	0				1	(0.2)	2	0.28
Impaired	0				0			
Missing	0				0			
Optic disc vascular disorder								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Optic ischaemic neuropathy								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Photophobia								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Post thrombotic retinopathy								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Posterior capsule opacification								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Presbyopia								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Pterygium								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Punctate keratitis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Retinal aneurysm								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Retinal artery occlusion								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Retinal degeneration								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Retinal detachment								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Retinal drusen								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Retinal haemorrhage								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Retinal tear								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Retinal vascular disorder								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Retinal vein occlusion								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Retinal vein thrombosis								

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Retinopathy								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Retinopathy hypertensive								
Normal	2	(0.4)	2	0.27	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Retinopathy proliferative								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Scintillating scotoma								
Normal	0				1	(0.2)	2	0.28
Impaired	0				0			
Missing	0				0			
Uveitis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Vision blurred								
Normal	2	(0.4)	2	0.27	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Visual impairment								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Vitreous detachment								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Vitreous floaters								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Vitreous haemorrhage								
Normal	0				2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vitreous opacities								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Gastrointestinal disorders								
All								
Normal	105	(22.3)	192	26.21	93	(20.3)	159	22.31
Impaired	0				1	(100.0)	2	125.73
Missing	7	(33.3)	10	30.68	10	(30.3)	17	32.30
Abdominal discomfort								
Normal	2	(0.4)	2	0.27	3	(0.7)	6	0.84
Impaired	0				0			
Missing	0				0			
Abdominal distension								
Normal	8	(1.7)	9	1.23	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Abdominal hernia								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Abdominal pain								
Normal	8	(1.7)	8	1.09	5	(1.1)	5	0.70
Impaired	0				0			
Missing	0				2	(6.1)	2	3.80
Abdominal pain lower								
Normal	1	(0.2)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Abdominal pain upper								
Normal	3	(0.6)	3	0.41	4	(0.9)	4	0.56
Impaired	0				0			
Missing	0				1	(3.0)	2	3.80
Abdominal wall haematoma								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Acid peptic disease								
Normal	0				2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Anal eczema								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Anal fissure								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Anal pruritus								
Normal	0				0			
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Angular cheilitis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Aphthous ulcer								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Ascites								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Barrett's oesophagus								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Chronic gastritis								
Normal	4	(0.9)	4	0.55	6	(1.3)	6	0.84
Impaired	0				0			
Missing	0				0			
Colitis								
Normal	1	(0.2)	1	0.14	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				0			
Colitis ischaemic								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Colitis microscopic								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Constipation								
Normal	8	(1.7)	8	1.09	5	(1.1)	5	0.70
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Crohn's disease								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Dental caries								
Normal	8	(1.7)	10	1.37	1	(0.2)	1	0.14
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Diarrhoea								
Normal	38	(8.1)	53	7.23	21	(4.6)	24	3.37
Impaired	0				0			
Missing	1	(4.8)	1	3.07	5	(15.2)	5	9.50
Diverticulum								
Normal	0				4	(0.9)	4	0.56
Impaired	0				0			
Missing	0				0			
Diverticulum intestinal								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Dry mouth								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Duodenal ulcer								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Duodenitis								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Duodenogastric reflux								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Dyspepsia								
Normal	3	(0.6)	3	0.41	4	(0.9)	4	0.56
Impaired	0				0			
Missing	2	(9.5)	2	6.14	0			
Enteritis								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Enterocolitis								
Normal	3	(0.6)	4	0.55	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Epigastric discomfort								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Erosive duodenitis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Flatulence								
Normal	3	(0.6)	3	0.41	0			
Impaired	0				0			
Missing	0				0			
Food poisoning								
Normal	1	(0.2)	1	0.14	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				0			
Frequent bowel movements								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Gastric disorder								
Normal	0				0			
Impaired	0				1	(100.0)	1	62.87
Missing	0				0			
Gastric polyps								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Gastritis								
Normal	2	(0.4)	2	0.27	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Gastritis erosive								
Normal	0				2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Gastrointestinal disorder								
Normal	0				2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Gastrointestinal haemorrhage								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Gastrointestinal inflammation								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Gastrooesophageal reflux disease								
Normal	8	(1.7)	8	1.09	8	(1.7)	8	1.12
Impaired	0				0			
Missing	0				0			
Haematemesis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Haematochezia								
Normal	2	(0.4)	2	0.27	0			
Impaired	0				0			
Missing	0				0			
Haemorrhoids								
Normal	4	(0.9)	4	0.55	4	(0.9)	4	0.56
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Hiatus hernia								
Normal	0				1	(0.2)	1	0.14
Impaired	0				1	(100.0)	1	62.87
Missing	0				0			
Hyperaesthesia teeth								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Hyperchlorhydria								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Ileus								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Inguinal hernia								
Normal	0				1	(0.2)	2	0.28
Impaired	0				0			
Missing	0				0			
Intestinal obstruction								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Irritable bowel syndrome								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Large intestine polyp								
Normal	2	(0.4)	2	0.27	3	(0.7)	4	0.56
Impaired	0				0			
Missing	0				0			
Loose tooth								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Melaena								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Nausea								
Normal	18	(3.8)	20	2.73	8	(1.7)	9	1.26
Impaired	0				0			
Missing	2	(9.5)	2	6.14	1	(3.0)	2	3.80
Odynophagia								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Oral discomfort								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Pancreatitis								
Normal	2	(0.4)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Pancreatitis acute								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Pancreatitis chronic								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Periodontal disease								
Normal	0				0			
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Periodontal inflammation								
Normal	0				1	(0.2)	2	0.28
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Portal hypertensive gastropathy								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Rectal polyp								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Rectal prolapse								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Salivary gland calculus								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Stomatitis								
Normal	0				2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Tooth disorder								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Tooth impacted								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Tooth loss								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Toothache								
Normal	10	(2.1)	11	1.50	4	(0.9)	4	0.56
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Ulcerative gastritis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Umbilical hernia								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Varices oesophageal								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Vomiting								
Normal	7	(1.5)	7	0.96	10	(2.2)	14	1.96
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
General disorders and administration site conditions								
All								
Normal	86	(18.3)	149	20.34	85	(18.6)	131	18.38
Impaired	0				0			
Missing	5	(23.8)	11	33.75	13	(39.4)	19	36.11
Asthenia								
Normal	5	(1.1)	6	0.82	4	(0.9)	4	0.56
Impaired	0				0			
Missing	0				2	(6.1)	2	3.80
Chest discomfort								
Normal	2	(0.4)	2	0.27	2	(0.4)	2	0.28
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Chest pain								
Normal	4	(0.9)	4	0.55	7	(1.5)	7	0.98
Impaired	0				0			
Missing	0				0			
Chills								
Normal	2	(0.4)	2	0.27	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Cyst								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Death								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Discomfort								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Drug intolerance								
Normal	2	(0.4)	2	0.27	0			
Impaired	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Early satiety								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Effusion								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Fatigue								
Normal	16	(3.4)	18	2.46	6	(1.3)	7	0.98
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Feeling abnormal								
Normal	2	(0.4)	7	0.96	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Feeling hot								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Gait disturbance								
Normal	2	(0.4)	2	0.27	0			
Impaired	0				0			
Missing	0				0			
Hunger								
Normal	5	(1.1)	6	0.82	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Implant site pruritus								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Inflammation								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Influenza like illness								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Injection site bruising								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Injection site dermatitis								
Normal	0				0			
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Injection site erythema								
Normal	1	(0.2)	1	0.14	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Injection site haemorrhage								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Injection site hypersensitivity								
Normal	2	(0.4)	2	0.27	0			
Impaired	0				0			
Missing	0				0			
Injection site hypertrophy								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Injection site mass								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Injection site pain								
Normal	0				2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Injection site reaction								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Injection site urticaria								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Malaise								
Normal	7	(1.5)	9	1.23	8	(1.7)	10	1.40
Impaired	0				0			
Missing	0				2	(6.1)	2	3.80
Mass								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Medical device site bruise								
Normal	5	(1.1)	6	0.82	1	(0.2)	2	0.28

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Medical device site dermatitis								
Normal	2	(0.4)	5	0.68	7	(1.5)	13	1.82
Impaired	0				0			
Missing	0				2	(6.1)	2	3.80
Medical device site discomfort								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Medical device site eczema								
Normal	1	(0.2)	2	0.27	1	(0.2)	2	0.28
Impaired	0				0			
Missing	0				1	(3.0)	2	3.80
Medical device site erythema								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Medical device site haematoma								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Medical device site haemorrhage								
Normal	2	(0.4)	2	0.27	2	(0.4)	2	0.28
Impaired	0				0			
Missing	2	(9.5)	2	6.14	0			
Medical device site hypersensitivity								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	1	(4.8)	2	6.14	0			
Medical device site inflammation								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Medical device site pain								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Medical device site pruritus								
Normal	2	(0.4)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Medical device site reaction								
Normal	1	(0.2)	3	0.41	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Non-cardiac chest pain								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Oedema								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Oedema peripheral								
Normal	8	(1.7)	9	1.23	10	(2.2)	12	1.68
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Pain								
Normal	4	(0.9)	4	0.55	5	(1.1)	6	0.84
Impaired	0				0			
Missing	0				2	(6.1)	2	3.80
Peripheral swelling								
Normal	2	(0.4)	3	0.41	6	(1.3)	6	0.84
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Procedural failure								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Pyrexia								
Normal	26	(5.5)	29	3.96	18	(3.9)	22	3.09
Impaired	0				0			
Missing	1	(4.8)	1	3.07	5	(15.2)	5	9.50
Swelling								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Thirst								
Normal	2	(0.4)	2	0.27	0			
Impaired	0				0			
Missing	0				0			
Vaccination site erythema								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Vaccination site pain								
Normal	5	(1.1)	7	0.96	4	(0.9)	4	0.56
Impaired	0				0			
Missing	0				0			
Vaccination site reaction								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Hepatobiliary disorders								
All								
Normal	13	(2.8)	16	2.18	8	(1.7)	9	1.26
Impaired	0				1	(100.0)	1	62.87
Missing	0				1	(3.0)	1	1.90
Biliary colic								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Cholelithiasis								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Gallbladder cholesterolosis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Hepatic cirrhosis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				1	(100.0)	1	62.87
Missing	0				0			
Hepatic cyst								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Hepatic function abnormal								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Hepatic steatosis								
Normal	8	(1.7)	8	1.09	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Hepatitis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Hypertransaminasaemia								
Normal	1	(0.2)	2	0.27	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Liver disorder								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Non-alcoholic steatohepatitis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Nonalcoholic fatty liver disease								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Steatohepatitis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Immune system disorders								
All								
Normal	7	(1.5)	8	1.09	5	(1.1)	6	0.84
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Allergy to arthropod bite								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Allergy to arthropod sting								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Immunisation reaction								
Normal	0				1	(0.2)	2	0.28
Impaired	0				0			
Missing	0				0			
Seasonal allergy								
Normal	7	(1.5)	7	0.96	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Infections and infestations								
All								
Normal	214	(45.5)	392	53.51	231	(50.4)	413	57.96
Impaired	0				1	(100.0)	1	62.87
Missing	11	(52.4)	23	70.56	20	(60.6)	35	66.51
Abscess								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Acarodermatitis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Acute sinusitis								
Normal	3	(0.6)	3	0.41	0			
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Anal abscess								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Asymptomatic COVID-19								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Bacterial infection								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Balanitis candida								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Body tinea								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Breast abscess								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Breast cellulitis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Bronchitis								
Normal	11	(2.3)	11	1.50	6	(1.3)	7	0.98
Impaired	0				0			
Missing	1	(4.8)	1	3.07	1	(3.0)	1	1.90
Candida infection								
Normal	3	(0.6)	3	0.41	0			
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Cellulitis								
Normal	1	(0.2)	1	0.14	3	(0.7)	3	0.42
Impaired	0				0			
Missing	2	(9.5)	2	6.14	0			
Chlamydial infection								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Chronic hepatitis C								
Normal	0				0			
Impaired	0				1	(100.0)	1	62.87
Missing	0				0			
Chronic sinusitis								
Normal	0				2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Chronic tonsillitis								
Normal	1	(0.2)	1	0.14	3	(0.7)	5	0.70
Impaired	0				0			
Missing	0				0			
Clostridium difficile infection								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Conjunctivitis								
Normal	6	(1.3)	7	0.96	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				0			
Conjunctivitis bacterial								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Coronavirus infection								
Normal	6	(1.3)	6	0.82	6	(1.3)	7	0.98
Impaired	0				0			
Missing	0				0			
COVID-19								
Normal	85	(18.1)	89	12.15	99	(21.6)	106	14.88
Impaired	0				0			
Missing	6	(28.6)	6	18.41	5	(15.2)	5	9.50
COVID-19 pneumonia								
Normal	4	(0.9)	4	0.55	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cystitis								
Normal	5	(1.1)	6	0.82	8	(1.7)	11	1.54
Impaired	0				0			
Missing	0				0			
Dermatophytosis of nail								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Diverticulitis								
Normal	0				3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				2	(6.1)	2	3.80
Ear infection								
Normal	4	(0.9)	4	0.55	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Empyema								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Endophthalmitis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Epididymitis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Erysipelas								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Escherichia urinary tract infection								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Eye infection bacterial								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Folliculitis								
Normal	2	(0.4)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Fungal balanitis								
Normal	0				1	(0.2)	1	0.14

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Fungal infection								
Normal	2	(0.4)	2	0.27	0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Furuncle								
Normal	1	(0.2)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Gastroenteritis								
Normal	6	(1.3)	6	0.82	6	(1.3)	7	0.98
Impaired	0				0			
Missing	0				0			
Gastroenteritis norovirus								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Gastroenteritis viral								
Normal	5	(1.1)	5	0.68	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Gastrointestinal infection								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Genital infection fungal								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Giardiasis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Gingivitis								
Normal	4	(0.9)	5	0.68	2	(0.4)	3	0.42
Impaired	0				0			
Missing	0				0			
Helicobacter gastritis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Helicobacter infection								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hepatitis B								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Herpes dermatitis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Herpes simplex								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Herpes virus infection								
Normal	2	(0.4)	2	0.27	0			
Impaired	0				0			
Missing	0				0			
Herpes zoster								
Normal	6	(1.3)	6	0.82	8	(1.7)	8	1.12
Impaired	0				0			
Missing	0				0			
Hordeolum								
Normal	2	(0.4)	2	0.27	0			
Impaired	0				0			
Missing	0				0			
Infected bite								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Infected skin ulcer								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Influenza								
Normal	0				3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				0			
Intestinal sepsis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Labyrinthitis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Laryngitis								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	2	(0.4)	2	0.27	4	(0.9)	4	0.56
Impaired	0				0			
Missing	0				0			
Laryngopharyngitis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Localised infection								
Normal	2	(0.4)	2	0.27	0			
Impaired	0				0			
Missing	0				0			
Lower respiratory tract infection								
Normal	7	(1.5)	9	1.23	2	(0.4)	4	0.56
Impaired	0				0			
Missing	0				0			
Lyme disease								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Lymphangitis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Mastitis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Mycoplasma infection								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Nail infection								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Nasopharyngitis								
Normal	36	(7.7)	48	6.55	40	(8.7)	49	6.88
Impaired	0				0			
Missing	2	(9.5)	2	6.14	7	(21.2)	7	13.30
Onychomycosis								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Oophoritis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Oral candidiasis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Oral herpes								
Normal	3	(0.6)	3	0.41	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Oral infection								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Orchitis								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Oropharyngeal candidiasis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Osteomyelitis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Osteomyelitis chronic								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Otitis externa								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Otitis media								
Normal	2	(0.4)	2	0.27	1	(0.2)	2	0.28
Impaired	0				0			
Missing	0				0			
Otitis media acute								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Otitis media chronic								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Parotitis								
Normal	0				1	(0.2)	3	0.42
Impaired	0				0			
Missing	0				0			
Peri-implantitis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Pericoronitis								
Normal	0				0			
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Periodontitis								
Normal	1	(0.2)	1	0.14	4	(0.9)	5	0.70
Impaired	0				0			
Missing	1	(4.8)	1	3.07	1	(3.0)	1	1.90
Pharyngitis								
Normal	14	(3.0)	20	2.73	12	(2.6)	17	2.39
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Pharyngitis bacterial								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Pharyngotonsillitis								
Normal	0				4	(0.9)	5	0.70
Impaired	0				0			
Missing	0				0			
Pneumonia								
Normal	4	(0.9)	4	0.55	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				0			
Post procedural infection								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Pulpitis dental								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Purulence								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Pyelonephritis chronic								
Normal	0				1	(0.2)	1	0.14

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Respiratory syncytial virus infection								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Respiratory tract infection								
Normal	4	(0.9)	4	0.55	5	(1.1)	6	0.84
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Respiratory tract infection viral								
Normal	4	(0.9)	4	0.55	3	(0.7)	3	0.42
Impaired	0				0			
Missing	1	(4.8)	4	12.27	0			
Rhinitis								
Normal	7	(1.5)	8	1.09	9	(2.0)	11	1.54
Impaired	0				0			
Missing	0				0			
Rotavirus infection								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Salpingitis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Sepsis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Sinusitis								
Normal	5	(1.1)	6	0.82	7	(1.5)	11	1.54
Impaired	0				0			
Missing	0				0			
Skin bacterial infection								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Skin infection								
Normal	2	(0.4)	2	0.27	0			
Impaired	0				0			
Missing	0				0			
Staphylococcal infection								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Subcutaneous abscess								
Normal	1	(0.2)	1	0.14	1	(0.2)	4	0.56
Impaired	0				0			
Missing	0				0			
Tinea infection								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Tonsillitis								
Normal	2	(0.4)	3	0.41	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Tooth abscess								
Normal	5	(1.1)	5	0.68	4	(0.9)	4	0.56
Impaired	0				0			
Missing	0				0			
Tooth infection								
Normal	2	(0.4)	2	0.27	3	(0.7)	4	0.56
Impaired	0				0			
Missing	0				0			
Tracheitis								
Normal	1	(0.2)	3	0.41	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Upper respiratory tract infection								
Normal	25	(5.3)	37	5.05	18	(3.9)	20	2.81
Impaired	0				0			
Missing	3	(14.3)	3	9.20	4	(12.1)	4	7.60
Urethritis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Urinary tract infection								
Normal	9	(1.9)	12	1.64	18	(3.9)	22	3.09
Impaired	0				0			
Missing	0				3	(9.1)	3	5.70
Vaginal infection								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Varicella								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Viral infection								

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	4	(0.9)	4	0.55	5	(1.1)	5	0.70
Impaired	0				0			
Missing	0				0			
Viral pharyngitis								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Viral upper respiratory tract infection								
Normal	1	(0.2)	1	0.14	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				0			
Vulvovaginal candidiasis								
Normal	2	(0.4)	4	0.55	3	(0.7)	3	0.42
Impaired	0				0			
Missing	1	(4.8)	1	3.07	1	(3.0)	1	1.90
Vulvovaginal mycotic infection								
Normal	1	(0.2)	2	0.27	0			
Impaired	0				0			
Missing	0				0			
Wound infection								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Injury, poisoning and procedural complications								
All								
Normal	84	(17.9)	97	13.24	63	(13.8)	93	13.05
Impaired	0				0			
Missing	5	(23.8)	5	15.34	4	(12.1)	10	19.00
Accidental overdose								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Alcohol poisoning								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Animal bite								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Ankle fracture								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Arthropod bite								
Normal	0				2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Arthropod sting								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Avulsion fracture								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Bone contusion								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Burn oral cavity								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Burns first degree								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Cervical vertebral fracture								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Chillblains								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Concussion								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Contusion								
Normal	4	(0.9)	5	0.68	10	(2.2)	13	1.82
Impaired	0				0			
Missing	1	(4.8)	1	3.07	3	(9.1)	3	5.70
Deafness traumatic								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Endotracheal intubation complication								

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Eye injury								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Fall								
Normal	7	(1.5)	9	1.23	7	(1.5)	8	1.12
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Fibula fracture								
Normal	2	(0.4)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Foot fracture								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Hand fracture								
Normal	2	(0.4)	2	0.27	0			
Impaired	0				0			
Missing	0				0			
Head injury								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Heat illness								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				2	(6.1)	3	5.70
Hip fracture								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Injury								
Normal	4	(0.9)	4	0.55	0			
Impaired	0				0			
Missing	0				0			
Joint injury								
Normal	3	(0.6)	3	0.41	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Ligament sprain								
Normal	3	(0.6)	3	0.41	3	(0.7)	3	0.42
Impaired	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	1	(4.8)	1	3.07	0			
Limb fracture								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Limb injury								
Normal	4	(0.9)	4	0.55	0			
Impaired	0				0			
Missing	0				0			
Lower limb fracture								
Normal	0				2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Meniscus injury								
Normal	3	(0.6)	3	0.41	0			
Impaired	0				0			
Missing	0				0			
Muscle strain								
Normal	1	(0.2)	1	0.14	4	(0.9)	4	0.56
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Overdose								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Patella fracture								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Periprocedural myocardial infarction								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Post procedural fistula								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Post procedural haemorrhage								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Post procedural hypothyroidism								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Post procedural stroke								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Post procedural swelling								
Normal	0				1	(0.2)	2	0.28
Impaired	0				0			
Missing	0				0			
Post-traumatic neck syndrome								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Procedural pain								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Product administration error								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Radius fracture								
Normal	3	(0.6)	3	0.41	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Rib fracture								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Road traffic accident								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Scar								
Normal	0				0			
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Skin abrasion								
Normal	4	(0.9)	4	0.55	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Skin laceration								
Normal	4	(0.9)	4	0.55	0			
Impaired	0				0			
Missing	0				0			
Soft tissue injury								
Normal	0				1	(0.2)	1	0.14

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Spinal column injury								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Spinal cord injury cervical								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Stress fracture								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Subcutaneous haematoma								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Tendon rupture								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Thermal burn								
Normal	1	(0.2)	1	0.14	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				0			
Tooth fracture								
Normal	3	(0.6)	3	0.41	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Traumatic arthritis								
Normal	1	(0.2)	2	0.27	0			
Impaired	0				0			
Missing	0				0			
Traumatic haematoma								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Ulna fracture								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Underdose								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Upper limb fracture								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Vaccination complication								
Normal	12	(2.6)	13	1.77	13	(2.8)	21	2.95
Impaired	0				0			
Missing	0				3	(9.1)	3	5.70
Wound								
Normal	4	(0.9)	4	0.55	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				0			
Wrist fracture								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Investigations								
All								
Normal	35	(7.4)	40	5.46	29	(6.3)	29	4.07
Impaired	0				1	(100.0)	1	62.87
Missing	0				4	(12.1)	6	11.40
Alanine aminotransferase increased								
Normal	2	(0.4)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Aspartate aminotransferase increased								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Blood cholesterol increased								
Normal	3	(0.6)	3	0.41	0			
Impaired	0				0			
Missing	0				0			
Blood creatine increased								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Blood creatine phosphokinase increased								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Blood glucose increased								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Blood potassium increased								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Blood pressure decreased								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Blood pressure increased								
Normal	2	(0.4)	2	0.27	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Blood triglycerides increased								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Body temperature increased								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Cardiac stress test abnormal								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Electrocardiogram change								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Electrocardiogram repolarisation abnormality								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Electrocardiogram T wave inversion								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Glycosylated haemoglobin increased								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Haemoglobin decreased								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	2	3.80

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hepatic enzyme abnormal								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Hepatic enzyme increased								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
International normalised ratio abnormal								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
International normalised ratio decreased								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
International normalised ratio increased								
Normal	1	(0.2)	2	0.27	0			
Impaired	0				0			
Missing	0				0			
Intraocular pressure increased								
Normal	1	(0.2)	2	0.27	0			
Impaired	0				0			
Missing	0				0			
Lipids increased								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Low density lipoprotein increased								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Prostatic specific antigen increased								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Protein urine present								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Pulse absent								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Red blood cell count decreased								
Normal	1	(0.2)	1	0.14	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
SARS-CoV-2 test positive								
Normal	3	(0.6)	3	0.41	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				0			
Serum ferritin decreased								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Transferrin saturation decreased								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Troponin increased								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Weight decreased								
Normal	3	(0.6)	3	0.41	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Weight increased								
Normal	9	(1.9)	9	1.23	8	(1.7)	8	1.12
Impaired	0				1	(100.0)	1	62.87
Missing	0				1	(3.0)	1	1.90
White blood cell count decreased								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Metabolism and nutrition disorders								
All								
Normal	57	(12.1)	64	8.74	60	(13.1)	80	11.23
Impaired	0				0			
Missing	2	(9.5)	2	6.14	3	(9.1)	9	17.10
Adult failure to thrive								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Appetite disorder								
Normal	0				1	(0.2)	2	0.28
Impaired	0				0			
Missing	0				0			
Decreased appetite								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	4	(0.9)	4	0.55	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Dehydration								
Normal	0				0			
Impaired	0				0			
Missing	0				2	(6.1)	2	3.80
Diabetes mellitus								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Diabetes mellitus inadequate control								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Dyslipidaemia								
Normal	13	(2.8)	14	1.91	8	(1.7)	10	1.40
Impaired	0				0			
Missing	1	(4.8)	1	3.07	1	(3.0)	1	1.90
Electrolyte depletion								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Electrolyte imbalance								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Fluid retention								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Gout								
Normal	2	(0.4)	3	0.41	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Hypercalcaemia								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Hypercholesterolaemia								
Normal	2	(0.4)	2	0.27	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				0			
Hyperglycaemia								
Normal	1	(0.2)	1	0.14	7	(1.5)	7	0.98
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Hyperkalaemia								
Normal	6	(1.3)	6	0.82	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Hyperlipidaemia								
Normal	4	(0.9)	4	0.55	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				0			
Hypertriglyceridaemia								
Normal	5	(1.1)	5	0.68	9	(2.0)	9	1.26
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Hyperuricaemia								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Hypoglycaemia								
Normal	7	(1.5)	8	1.09	11	(2.4)	21	2.95
Impaired	0				0			
Missing	0				2	(6.1)	5	9.50
Hypokalaemia								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Hypophosphataemia								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Increased appetite								
Normal	2	(0.4)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Iron deficiency								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Lactic acidosis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Malnutrition								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Metabolic disorder								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Obesity								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Type 2 diabetes mellitus								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Vitamin B12 deficiency								
Normal	3	(0.6)	3	0.41	0			
Impaired	0				0			
Missing	0				0			
Vitamin D deficiency								
Normal	4	(0.9)	5	0.68	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				0			
Zinc deficiency								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Musculoskeletal and connective tissue disorders								
All								
Normal	121	(25.7)	206	28.12	104	(22.7)	166	23.30
Impaired	0				0			
Missing	9	(42.9)	12	36.82	13	(39.4)	18	34.20
Arthralgia								
Normal	26	(5.5)	32	4.37	20	(4.4)	25	3.51
Impaired	0				0			
Missing	4	(19.0)	4	12.27	2	(6.1)	3	5.70
Arthritis								
Normal	2	(0.4)	2	0.27	4	(0.9)	5	0.70
Impaired	0				0			
Missing	0				0			
Axillary mass								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Back disorder								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Back pain								
Normal	37	(7.9)	39	5.32	30	(6.6)	32	4.49
Impaired	0				0			
Missing	3	(14.3)	4	12.27	2	(6.1)	2	3.80
Bone cyst								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Bursitis								
Normal	2	(0.4)	2	0.27	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				0			
Cervical spinal stenosis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Chondrodynia								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Chondropathy								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Coccydynia								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Costochondritis								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Dupuytren's contracture								
Normal	0				2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Exostosis								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Fibromyalgia								
Normal	2	(0.4)	2	0.27	0			
Impaired	0				0			
Missing	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Fistula								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Flank pain								
Normal	0				2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Fracture nonunion								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Gouty arthritis								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Groin pain								
Normal	2	(0.4)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Intervertebral disc disorder								
Normal	2	(0.4)	2	0.27	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Intervertebral disc protrusion								
Normal	7	(1.5)	8	1.09	4	(0.9)	5	0.70
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Intervertebral disc space narrowing								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Joint effusion								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Joint swelling								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Ligamentitis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Limb deformity								
Normal	0				1	(0.2)	1	0.14

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Lordosis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Lumbar spinal stenosis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Mastication disorder								
Normal	0				1	(0.2)	2	0.28
Impaired	0				0			
Missing	0				0			
Muscle contracture								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Muscle spasms								
Normal	12	(2.6)	12	1.64	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Muscular weakness								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Musculoskeletal chest pain								
Normal	3	(0.6)	3	0.41	1	(0.2)	1	0.14
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Musculoskeletal pain								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Musculoskeletal stiffness								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Myalgia								
Normal	3	(0.6)	3	0.41	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Myositis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Neck pain								
Normal	6	(1.3)	6	0.82	8	(1.7)	8	1.12
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Osteoarthritis								
Normal	19	(4.0)	21	2.87	13	(2.8)	16	2.25
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Osteochondrosis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Osteopenia								
Normal	2	(0.4)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Pain in extremity								
Normal	18	(3.8)	23	3.14	12	(2.6)	15	2.11
Impaired	0				0			
Missing	0				2	(6.1)	2	3.80
Periarthritis								
Normal	6	(1.3)	6	0.82	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				2	(6.1)	2	3.80
Plantar fasciitis								
Normal	5	(1.1)	6	0.82	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Polyarthritis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Rotator cuff syndrome								
Normal	3	(0.6)	3	0.41	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Scoliosis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Spinal osteoarthritis								
Normal	3	(0.6)	3	0.41	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Spinal pain								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	1	(0.2)	1	0.14	4	(0.9)	4	0.56
Impaired	0				0			
Missing	0				0			
Spinal stenosis								
Normal	2	(0.4)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Spondylolisthesis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Synovial cyst								
Normal	2	(0.4)	2	0.27	0			
Impaired	0				0			
Missing	0				0			
Tendon calcification								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Tendonitis								
Normal	2	(0.4)	2	0.27	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Tenosynovitis								
Normal	1	(0.2)	1	0.14	4	(0.9)	5	0.70
Impaired	0				0			
Missing	0				2	(6.1)	2	3.80
Tenosynovitis stenosans								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Torticollis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Trigger finger								
Normal	3	(0.6)	3	0.41	3	(0.7)	6	0.84
Impaired	0				0			
Missing	0				0			
Vertebral osteophyte								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			

Neoplasms benign, malignant and
unspecified (incl cysts and polyps)

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
Normal	17	(3.6)	19	2.59	7	(1.5)	11	1.54
Impaired	0				0			
Missing	2	(9.5)	2	6.14	2	(6.1)	2	3.80
Acrochordon								
Normal	0				0			
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Basal cell carcinoma								
Normal	2	(0.4)	2	0.27	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Colon adenoma								
Normal	2	(0.4)	2	0.27	0			
Impaired	0				0			
Missing	0				0			
Colon cancer								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Dysplastic naevus								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Glioblastoma multiforme								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Haemangioma of liver								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Hepatocellular carcinoma								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Hypergammaglobulinaemia benign monoclonal								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Lipoma								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Lung adenocarcinoma								

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Malignant melanoma in situ								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Metastases to liver								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Metastatic renal cell carcinoma								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Neoplasm skin								
Normal	0				0			
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Oral fibroma								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Ovarian cancer metastatic								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Pancreatic carcinoma metastatic								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Pancreatic neoplasm								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Prostate cancer								
Normal	2	(0.4)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Seborrhoeic keratosis								
Normal	2	(0.4)	3	0.41	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Skin papilloma								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Small cell lung cancer								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Squamous cell carcinoma								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Uterine leiomyoma								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Nervous system disorders								
All								
Normal	81	(17.2)	120	16.38	71	(15.5)	99	13.89
Impaired	0				0			
Missing	3	(14.3)	5	15.34	9	(27.3)	16	30.40
Ageusia								
Normal	0				0			
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Anosmia								
Normal	0				0			
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Balance disorder								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Brain injury								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Burning sensation								
Normal	3	(0.6)	3	0.41	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Carotid arteriosclerosis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Carotid artery stenosis								
Normal	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Carpal tunnel syndrome								
Normal	4	(0.9)	4	0.55	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				0			
Cerebral arteriosclerosis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Cerebral atrophy								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Cerebral haemorrhage								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Cerebral infarction								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Cerebrovascular accident								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Cerebrovascular disorder								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Cervical radiculopathy								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Cognitive disorder								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Diabetic neuropathy								
Normal	3	(0.6)	3	0.41	5	(1.1)	5	0.70
Impaired	0				0			
Missing	0				0			
Dizziness								
Normal	15	(3.2)	21	2.87	13	(2.8)	14	1.96
Impaired	0				0			
Missing	0				2	(6.1)	2	3.80

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Dizziness postural								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Dysgeusia								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Essential tremor								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Headache								
Normal	20	(4.3)	26	3.55	18	(3.9)	28	3.93
Impaired	0				0			
Missing	2	(9.5)	2	6.14	3	(9.1)	4	7.60
Hypoaesthesia								
Normal	6	(1.3)	8	1.09	4	(0.9)	5	0.70
Impaired	0				0			
Missing	0				0			
Hypoglycaemic unconsciousness								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Ischaemic stroke								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Lethargy								
Normal	0				2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Lumbar radiculopathy								
Normal	2	(0.4)	2	0.27	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				0			
Memory impairment								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Mental impairment								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Metabolic encephalopathy								

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Migraine								
Normal	3	(0.6)	3	0.41	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Movement disorder								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Muscle tone disorder								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Neuralgia								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Neuroglycopenia								
Normal	2	(0.4)	4	0.55	1	(0.2)	3	0.42
Impaired	0				0			
Missing	0				0			
Neuropathy peripheral								
Normal	2	(0.4)	2	0.27	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				0			
Paraesthesia								
Normal	4	(0.9)	4	0.55	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				2	(6.1)	2	3.80
Parkinsonian gait								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Pineal gland cyst								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Post herpetic neuralgia								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Presyncope								
Normal	2	(0.4)	2	0.27	2	(0.4)	2	0.28
Impaired	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Sciatica								
Normal	3	(0.6)	3	0.41	5	(1.1)	5	0.70
Impaired	0				0			
Missing	0				3	(9.1)	6	11.40
Somnolence								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Stiff leg syndrome								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Syncope								
Normal	5	(1.1)	7	0.96	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Tension headache								
Normal	2	(0.4)	3	0.41	0			
Impaired	0				0			
Missing	0				0			
Thrombotic stroke								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Transient ischaemic attack								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Tremor								
Normal	6	(1.3)	7	0.96	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Trigeminal neuralgia								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Vertebral artery occlusion								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
VIth nerve paralysis								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
VIth nerve paresis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Psychiatric disorders								
All								
Normal	22	(4.7)	24	3.28	12	(2.6)	12	1.68
Impaired	0				0			
Missing	1	(4.8)	1	3.07	1	(3.0)	1	1.90
Anxiety								
Normal	4	(0.9)	4	0.55	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Depressed mood								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Depression								
Normal	6	(1.3)	6	0.82	4	(0.9)	4	0.56
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Insomnia								
Normal	9	(1.9)	9	1.23	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Mood swings								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Nightmare								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Persistent depressive disorder								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Psychotic disorder								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Schizophrenia								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Sleep disorder								
Normal	2	(0.4)	2	0.27	0			
Impaired	0				0			
Missing	0				0			
Renal and urinary disorders								
All								
Normal	20	(4.3)	24	3.28	23	(5.0)	30	4.21
Impaired	0				0			
Missing	0				5	(15.2)	5	9.50
Acute kidney injury								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Calculus urinary								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Chronic kidney disease								
Normal	1	(0.2)	1	0.14	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Diabetic nephropathy								
Normal	2	(0.4)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Dysuria								
Normal	3	(0.6)	3	0.41	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Haematuria								
Normal	1	(0.2)	1	0.14	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Hypercalciuria								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Hypertonic bladder								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Ketonuria								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Microalbuminuria								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Nephrolithiasis								
Normal	2	(0.4)	2	0.27	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Nocturia								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Pollakiuria								
Normal	2	(0.4)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Pyelocaliectasis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Renal colic								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Renal cyst								
Normal	2	(0.4)	2	0.27	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Renal impairment								
Normal	2	(0.4)	2	0.27	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				0			
Ureterolithiasis								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Urinary incontinence								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Urinary retention								
Normal	0				1	(0.2)	2	0.28
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Urinary tract obstruction								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Urine odour abnormal								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Reproductive system and breast disorders								
All								
Normal	14	(3.0)	14	1.91	12	(2.6)	18	2.53
Impaired	0				0			
Missing	1	(4.8)	1	3.07	4	(12.1)	4	7.60
Adenomyosis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Atrophic vulvovaginitis								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Balanoposthitis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Benign prostatic hyperplasia								
Normal	2	(0.4)	2	0.27	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				0			
Breast mass								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Breast pain								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Erectile dysfunction								
Normal	3	(0.6)	3	0.41	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Galactorrhoea								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hydrometra								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Menopausal symptoms								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Ovarian cyst								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Penile rash								
Normal	0				1	(0.2)	3	0.42
Impaired	0				0			
Missing	0				0			
Prostatism								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Prostatitis								
Normal	0				1	(0.2)	2	0.28
Impaired	0				0			
Missing	0				0			
Pruritus genital								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Uterine haemorrhage								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Uterine polyp								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Uterine prolapse								
Normal	0				0			
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Vaginal prolapse								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Vulval eczema								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Vulval leukoplakia								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Vulvovaginal dryness								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Vulvovaginal pruritus								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Respiratory, thoracic and mediastinal disorders								
All								
Normal	51	(10.9)	70	9.56	44	(9.6)	63	8.84
Impaired	0				0			
Missing	4	(19.0)	6	18.41	4	(12.1)	6	11.40
Acquired diaphragmatic eventration								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Acute pulmonary oedema								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Acute respiratory failure								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Allergic bronchitis								
Normal	0				1	(0.2)	2	0.28
Impaired	0				0			
Missing	0				0			
Asthma								
Normal	1	(0.2)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Bronchiectasis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Bronchitis chronic								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Chronic eosinophilic rhinosinusitis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Chronic obstructive pulmonary disease								
Normal	2	(0.4)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Cough								
Normal	13	(2.8)	14	1.91	8	(1.7)	9	1.26
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Dry throat								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Dyspnoea								
Normal	1	(0.2)	1	0.14	5	(1.1)	5	0.70
Impaired	0				0			
Missing	1	(4.8)	1	3.07	1	(3.0)	1	1.90
Dyspnoea exertional								
Normal	2	(0.4)	2	0.27	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Emphysema								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Epistaxis								
Normal	0				1	(0.2)	3	0.42
Impaired	0				0			
Missing	0				0			
Haemoptysis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Interstitial lung disease								
Normal	2	(0.4)	2	0.27	0			
Impaired	0				0			
Missing	0				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). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Nasal congestion								
Normal	4	(0.9)	5	0.68	2	(0.4)	2	0.28
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Nasal dryness								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Nasal turbinate hypertrophy								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Oropharyngeal pain								
Normal	11	(2.3)	12	1.64	5	(1.1)	9	1.26
Impaired	0				0			
Missing	2	(9.5)	2	6.14	4	(12.1)	4	7.60
Paranasal sinus discomfort								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Pleural calcification								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Pleural effusion								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Pleuritic pain								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Pneumothorax								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Productive cough								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Pulmonary embolism								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Pulmonary fibrosis								
Normal	1	(0.2)	2	0.27	0			
Impaired	0				0			
Missing	0				0			
Pulmonary mass								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Respiratory disorder								
Normal	1	(0.2)	1	0.14	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				0			
Respiratory failure								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Rhinitis allergic								
Normal	0				2	(0.4)	6	0.84
Impaired	0				0			
Missing	0				0			
Rhinorrhoea								
Normal	5	(1.1)	5	0.68	3	(0.7)	3	0.42
Impaired	0				0			
Missing	1	(4.8)	1	3.07	0			
Sinus congestion								
Normal	1	(0.2)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Sinus pain								
Normal	1	(0.2)	2	0.27	0			
Impaired	0				0			
Missing	0				0			
Sleep apnoea syndrome								
Normal	3	(0.6)	3	0.41	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Sneezing								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Throat irritation								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Upper respiratory tract inflammation								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Upper-airway cough syndrome								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Skin and subcutaneous tissue disorders								
All								
Normal	58	(12.3)	74	10.10	48	(10.5)	67	9.40
Impaired	0				0			
Missing	1	(4.8)	3	9.20	5	(15.2)	8	15.20
Actinic keratosis								
Normal	1	(0.2)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Alopecia								
Normal	6	(1.3)	6	0.82	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Alopecia areata								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Angioedema								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Asteatosis								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Blister								
Normal	0				2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Cellulite								
Normal	0				1	(0.2)	2	0.28
Impaired	0				0			
Missing	0				0			
Chloasma								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cold sweat								
Normal	2	(0.4)	3	0.41	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Cold urticaria								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Dermal cyst								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Dermatitis								
Normal	1	(0.2)	1	0.14	4	(0.9)	4	0.56
Impaired	0				0			
Missing	0				0			
Dermatitis allergic								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Dermatitis contact								
Normal	6	(1.3)	8	1.09	7	(1.5)	8	1.12
Impaired	0				0			
Missing	0				0			
Diabetic foot								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Drug eruption								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Dry skin								
Normal	3	(0.6)	3	0.41	0			
Impaired	0				0			
Missing	0				0			
Ecchymosis								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Eczema								
Normal	8	(1.7)	8	1.09	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Eczema nummular								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Erythema								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Granuloma annulare								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Haemorrhage subcutaneous								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Hyperhidrosis								
Normal	4	(0.9)	4	0.55	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Hyperkeratosis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Ingrowing nail								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				2	(6.1)	2	3.80
Lentigo								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Lipodystrophy acquired								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Lipohypertrophy								
Normal	0				2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Macule								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Miliaria								
Normal	3	(0.6)	4	0.55	3	(0.7)	3	0.42
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				2	(6.1)	2	3.80
Myxoid cyst								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Night sweats								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Onychalgia								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Pruritus								
Normal	3	(0.6)	3	0.41	3	(0.7)	3	0.42
Impaired	0				0			
Missing	1	(4.8)	3	9.20	1	(3.0)	1	1.90
Psoriasis								
Normal	2	(0.4)	2	0.27	0			
Impaired	0				0			
Missing	0				0			
Purpura								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Rash								
Normal	2	(0.4)	2	0.27	8	(1.7)	8	1.12
Impaired	0				0			
Missing	0				0			
Rosacea								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Skin exfoliation								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Skin fissures								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Skin irritation								
Normal	2	(0.4)	3	0.41	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Skin lesion								
Normal	2	(0.4)	2	0.27	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				1	(3.0)	1	1.90
Skin ulcer								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Urticaria								
Normal	1	(0.2)	2	0.27	5	(1.1)	5	0.70
Impaired	0				0			
Missing	0				0			
Urticaria contact								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Urticaria thermal								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Surgical and medical procedures								
All								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Removal of foreign body								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Vascular disorders								
All								
Normal	39	(8.3)	48	6.55	41	(9.0)	47	6.60
Impaired	0				0			
Missing	1	(4.8)	1	3.07	2	(6.1)	2	3.80
Aneurysm								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Aortic arteriosclerosis								
Normal	3	(0.6)	3	0.41	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Aortic stenosis								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Arteriosclerosis								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Blood pressure inadequately controlled								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Brachiocephalic arteriosclerosis								
Normal	1	(0.2)	1	0.14	3	(0.7)	3	0.42
Impaired	0				0			
Missing	0				0			
Diabetic vascular disorder								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Flushing								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Haematoma								
Normal	4	(0.9)	4	0.55	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Hypertension								
Normal	14	(3.0)	14	1.91	14	(3.1)	15	2.11
Impaired	0				0			
Missing	1	(4.8)	1	3.07	2	(6.1)	2	3.80
Hypertensive angiopathy								
Normal	2	(0.4)	2	0.27	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Hypertensive crisis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Hypertensive urgency								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Hypotension								
Normal	3	(0.6)	3	0.41	2	(0.4)	2	0.28
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Iliac artery stenosis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Intermittent claudication								
Normal	1	(0.2)	1	0.14	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Macroangiopathy								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Peripheral arterial occlusive disease								
Normal	1	(0.2)	2	0.27	5	(1.1)	5	0.70
Impaired	0				0			
Missing	0				0			
Peripheral artery occlusion								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Peripheral artery stenosis								
Normal	1	(0.2)	2	0.27	0			
Impaired	0				0			
Missing	0				0			
Peripheral coldness								
Normal	4	(0.9)	4	0.55	1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Peripheral vascular disorder								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Peripheral venous disease								
Normal	1	(0.2)	1	0.14	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			
Post thrombotic syndrome								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Secondary hypertension								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 1 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Superficial vein thrombosis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Thrombophlebitis								
Normal	0				1	(0.2)	1	0.14
Impaired	0				0			
Missing	0				0			
Thrombosis								
Normal	1	(0.2)	1	0.14	0			
Impaired	0				0			
Missing	0				0			
Varicose vein								
Normal	2	(0.4)	2	0.27	2	(0.4)	2	0.28
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IGlar U100.

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adae.xpt; variable(s): AEBODSYS AEDECOD CPCLGR1; criteria: SAFFL == "Y" & STDNM == "ONWARDS 1" & (ANL02FL) == "Y" & (ANELFL) == "Y"
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7.24.28 Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Number of subjects								
Normal	281				285			
Impaired	1				0			
Missing	8				7			
PYE (years)								
Normal	290.73				302.22			
Impaired	1.10				0			
Missing	8.33				7.36			
Events								
Normal	232	(82.6)	890	306.13	229	(80.4)	1100	363.97
Impaired	0				0			
Missing	8	(100.0)	75	899.93	7	(100.0)	46	624.82

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blood and lymphatic system disorders								
All								
Normal	6	(2.1)	7	2.41	5	(1.8)	6	1.99
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Anaemia								
Normal	4	(1.4)	4	1.38	0			
Impaired	0				0			
Missing	0				0			
Blood loss anaemia								
Normal	0				0			
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Iron deficiency anaemia								
Normal	0				2	(0.7)	3	0.99
Impaired	0				0			
Missing	0				0			
Lymphadenitis								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Lymphadenopathy								
Normal	2	(0.7)	2	0.69	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Splenomegaly								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Thrombocytopenia								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Cardiac disorders								
All								
Normal	15	(5.3)	17	5.85	10	(3.5)	13	4.30
Impaired	0				0			
Missing	1	(12.5)	1	12.00	1	(14.3)	2	27.17
Acute myocardial infarction								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Angina pectoris								
Normal	2	(0.7)	2	0.69	0			
Impaired	0				0			
Missing	0				0			
Angina unstable								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				1	(14.3)	1	13.58
Aortic valve incompetence								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Atrial fibrillation								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Bundle branch block right								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Cardiac failure congestive								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Cardiomegaly								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Cardiovascular disorder								
Normal	0				0			
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Conduction disorder								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Coronary artery disease								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Left ventricular hypertrophy								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Mitral valve incompetence								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Myocardial infarction								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Myocardial ischaemia								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(14.3)	1	13.58
Palpitations								
Normal	3	(1.1)	3	1.03	4	(1.4)	5	1.65
Impaired	0				0			
Missing	0				0			
Tachycardia								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Tricuspid valve incompetence								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Ventricular extrasystoles								
Normal	3	(1.1)	3	1.03	0			
Impaired	0				0			
Missing	0				0			
Congenital, familial and genetic disorders								
All								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Arteriovenous malformation								
Normal	0				0			
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Colour blindness								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Ear and labyrinth disorders								
All								
Normal	2	(0.7)	2	0.69	4	(1.4)	4	1.32
Impaired	0				0			
Missing	0				0			
Deafness neurosensory								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Ear pain								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Tinnitus								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Tympanic membrane perforation								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Vertigo								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Endocrine disorders								
All								
Normal	2	(0.7)	2	0.69	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Autoimmune thyroiditis								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Hypogonadism								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Hypothyroidism								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Thyroiditis chronic								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Eye disorders								
All								
Normal	43	(15.3)	62	21.33	43	(15.1)	62	20.51
Impaired	0				0			
Missing	0				3	(42.9)	4	54.33
Angle closure glaucoma								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Arteriosclerotic retinopathy								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Astigmatism								
Normal	1	(0.4)	1	0.34	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Cataract								
Normal	6	(2.1)	6	2.06	3	(1.1)	4	1.32
Impaired	0				0			
Missing	0				1	(14.3)	1	13.58

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Cataract nuclear								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Conjunctival haemorrhage								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Corneal erosion								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Diabetic retinal oedema								
Normal	2	(0.7)	2	0.69	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Diabetic retinopathy								
Normal	24	(8.5)	28	9.63	25	(8.8)	28	9.26
Impaired	0				0			
Missing	0				1	(14.3)	1	13.58
Dry eye								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Eczema eyelids								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Epiretinal membrane								
Normal	2	(0.7)	2	0.69	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Eye pain								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Glaucoma								
Normal	1	(0.4)	1	0.34	3	(1.1)	3	0.99
Impaired	0				0			
Missing	0				0			
Macular oedema								
Normal	4	(1.4)	5	1.72	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Myopia								
Normal	0				2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Non-proliferative retinopathy								
Normal	3	(1.1)	3	1.03	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Ocular hypertension								
Normal	0				2	(0.7)	3	0.99
Impaired	0				0			
Missing	0				0			
Photopsia								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Posterior capsule opacification								
Normal	1	(0.4)	1	0.34	1	(0.4)	2	0.66
Impaired	0				0			
Missing	0				0			
Presbyopia								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Pterygium								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(14.3)	2	27.17
Retinal drusen								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Retinal haemorrhage								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Retinal vascular disorder								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Retinopathy								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Retinopathy hypertensive								
Normal	2	(0.7)	2	0.69	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Strabismus								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Vision blurred								
Normal	2	(0.7)	2	0.69	0			
Impaired	0				0			
Missing	0				0			
Visual acuity reduced								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Vitreous detachment								
Normal	0				2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Vitreous floaters								
Normal	0				2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Gastrointestinal disorders								
All								
Normal	45	(16.0)	74	25.45	40	(14.0)	71	23.49
Impaired	0				0			
Missing	2	(25.0)	7	83.99	2	(28.6)	4	54.33
Abdominal discomfort								
Normal	2	(0.7)	2	0.69	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Abdominal distension								
Normal	2	(0.7)	3	1.03	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Abdominal pain								
Normal	6	(2.1)	6	2.06	1	(0.4)	1	0.33
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Abdominal pain upper								
Normal	3	(1.1)	4	1.38	2	(0.7)	2	0.66
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Anal fissure								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Change of bowel habit								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Chronic gastritis								
Normal	1	(0.4)	1	0.34	3	(1.1)	3	0.99
Impaired	0				0			
Missing	0				0			
Constipation								
Normal	2	(0.7)	3	1.03	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Dental caries								
Normal	1	(0.4)	1	0.34	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Diarrhoea								
Normal	9	(3.2)	12	4.13	4	(1.4)	5	1.65
Impaired	0				0			
Missing	1	(12.5)	1	12.00	2	(28.6)	2	27.17
Diverticulum intestinal								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Duodenitis								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Dyspepsia								
Normal	3	(1.1)	3	1.03	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Enteritis								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Faeces soft								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Flatulence								
Normal	3	(1.1)	3	1.03	0			
Impaired	0				0			
Missing	0				0			
Food poisoning								
Normal	1	(0.4)	1	0.34	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Gastric polyps								
Normal	0				2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Gastritis								
Normal	2	(0.7)	2	0.69	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Gastritis erosive								
Normal	0				2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Gastrointestinal haemorrhage								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Gastrooesophageal reflux disease								
Normal	1	(0.4)	1	0.34	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Gastrooesophageal sphincter insufficiency								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Gingival recession								
Normal	0				1	(0.4)	2	0.66
Impaired	0				0			
Missing	0				0			
Gingival ulceration								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Haematochezia								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Haemorrhoids								
Normal	0				1	(0.4)	1	0.33

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Hiatus hernia								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Impaired gastric emptying								
Normal	2	(0.7)	3	1.03	0			
Impaired	0				0			
Missing	0				0			
Irritable bowel syndrome								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Lumbar hernia								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Mouth ulceration								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Nausea								
Normal	8	(2.8)	8	2.75	9	(3.2)	9	2.98
Impaired	0				0			
Missing	1	(12.5)	1	12.00	1	(14.3)	1	13.58
Odynophagia								
Normal	0				1	(0.4)	2	0.66
Impaired	0				0			
Missing	0				0			
Oesophagitis								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Pancreatic failure								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Pancreatitis								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Pneumatosis intestinalis								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Proctitis ulcerative								
Normal	0				1	(0.4)	2	0.66
Impaired	0				0			
Missing	0				0			
Toothache								
Normal	3	(1.1)	4	1.38	3	(1.1)	6	1.99
Impaired	0				0			
Missing	1	(12.5)	2	24.00	0			
Vomiting								
Normal	10	(3.6)	10	3.44	9	(3.2)	9	2.98
Impaired	0				0			
Missing	1	(12.5)	2	24.00	1	(14.3)	1	13.58
General disorders and administration site conditions								
All								
Normal	53	(18.9)	81	27.86	62	(21.8)	179	59.23
Impaired	0				0			
Missing	2	(25.0)	3	36.00	3	(42.9)	4	54.33
Asthenia								
Normal	1	(0.4)	1	0.34	3	(1.1)	3	0.99
Impaired	0				0			
Missing	0				0			
Chest pain								
Normal	1	(0.4)	1	0.34	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Chills								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Complication associated with device								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Cyst								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Facial discomfort								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Facial pain								
Normal	0				1	(0.4)	1	0.33

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Fatigue								
Normal	6	(2.1)	7	2.41	5	(1.8)	5	1.65
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Hunger								
Normal	1	(0.4)	1	0.34	1	(0.4)	2	0.66
Impaired	0				0			
Missing	0				0			
Hyperthermia								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Illness								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(14.3)	1	13.58
Inflammation								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Influenza like illness								
Normal	4	(1.4)	4	1.38	4	(1.4)	4	1.32
Impaired	0				0			
Missing	0				0			
Injection site mass								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Injection site pain								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Injection site urticaria								
Normal	1	(0.4)	2	0.69	0			
Impaired	0				0			
Missing	0				0			
Malaise								
Normal	4	(1.4)	4	1.38	5	(1.8)	84	27.79
Impaired	0				0			
Missing	0				0			
Medical device site bruise								
Normal	2	(0.7)	2	0.69	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				1	(14.3)	1	13.58

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Medical device site dermatitis								
Normal	5	(1.8)	6	2.06	6	(2.1)	9	2.98
Impaired	0				0			
Missing	0				0			
Medical device site erythema								
Normal	2	(0.7)	3	1.03	5	(1.8)	7	2.32
Impaired	0				0			
Missing	0				0			
Medical device site haematoma								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Medical device site haemorrhage								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Medical device site inflammation								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Medical device site irritation								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Medical device site pain								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Medical device site pruritus								
Normal	1	(0.4)	1	0.34	5	(1.8)	5	1.65
Impaired	0				0			
Missing	0				0			
Medical device site rash								
Normal	7	(2.5)	8	2.75	10	(3.5)	11	3.64
Impaired	0				0			
Missing	0				1	(14.3)	1	13.58
Medical device site reaction								
Normal	3	(1.1)	3	1.03	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Medical device site vesicles								
Normal	1	(0.4)	2	0.69	0			
Impaired	0				0			
Missing	0				0			
Nodule								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Non-cardiac chest pain								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Oedema								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Oedema peripheral								
Normal	3	(1.1)	3	1.03	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Pain								
Normal	2	(0.7)	2	0.69	2	(0.7)	2	0.66
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Peripheral swelling								
Normal	0				2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Pyrexia								
Normal	15	(5.3)	21	7.22	19	(6.7)	24	7.94
Impaired	0				0			
Missing	1	(12.5)	1	12.00	1	(14.3)	1	13.58
Swelling face								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Vaccination site discomfort								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Vaccination site joint pain								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Vaccination site lymphadenopathy								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Vaccination site pain								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Vaccination site swelling								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Hepatobiliary disorders								
All								
Normal	5	(1.8)	6	2.06	6	(2.1)	6	1.99
Impaired	0				0			
Missing	0				0			
Cholecystitis chronic								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Gallbladder disorder								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Gallbladder polyp								
Normal	1	(0.4)	1	0.34	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Hepatic calcification								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Hepatic function abnormal								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Hepatic steatosis								
Normal	3	(1.1)	3	1.03	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Hypertransaminasaemia								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Immune system disorders								
All								
Normal	5	(1.8)	5	1.72	6	(2.1)	6	1.99
Impaired	0				0			
Missing	0				0			
Allergy to arthropod bite								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Allergy to arthropod sting								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Hypersensitivity								
Normal	2	(0.7)	2	0.69	0			
Impaired	0				0			
Missing	0				0			
Seasonal allergy								
Normal	2	(0.7)	2	0.69	5	(1.8)	5	1.65
Impaired	0				0			
Missing	0				0			
Infections and infestations								
All								
Normal	151	(53.7)	281	96.65	153	(53.7)	286	94.63
Impaired	0				0			
Missing	8	(100.0)	29	347.97	6	(85.7)	17	230.91
Abscess limb								
Normal	1	(0.4)	1	0.34	1	(0.4)	2	0.66
Impaired	0				0			
Missing	0				0			
Acute sinusitis								
Normal	0				3	(1.1)	3	0.99
Impaired	0				0			
Missing	0				0			
Asymptomatic COVID-19								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Beta haemolytic streptococcal infection								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(14.3)	1	13.58

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Breast abscess								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Bronchitis								
Normal	5	(1.8)	5	1.72	2	(0.7)	3	0.99
Impaired	0				0			
Missing	0				1	(14.3)	1	13.58
Conjunctivitis								
Normal	4	(1.4)	5	1.72	0			
Impaired	0				0			
Missing	0				0			
Coronavirus infection								
Normal	0				3	(1.1)	3	0.99
Impaired	0				0			
Missing	0				0			
COVID-19								
Normal	70	(24.9)	76	26.14	82	(28.8)	86	28.46
Impaired	0				0			
Missing	5	(62.5)	5	60.00	2	(28.6)	3	40.75
COVID-19 pneumonia								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Cystitis								
Normal	3	(1.1)	3	1.03	3	(1.1)	3	0.99
Impaired	0				0			
Missing	0				0			
Cystitis escherichia								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Ear infection								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Erythema migrans								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Eye infection								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Febrile infection								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Fungal infection								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Fungal skin infection								
Normal	2	(0.7)	2	0.69	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Furuncle								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Gastric infection								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Gastroenteritis								
Normal	13	(4.6)	18	6.19	5	(1.8)	6	1.99
Impaired	0				0			
Missing	0				0			
Gastroenteritis viral								
Normal	2	(0.7)	2	0.69	3	(1.1)	3	0.99
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Gastrointestinal infection								
Normal	1	(0.4)	1	0.34	2	(0.7)	4	1.32
Impaired	0				0			
Missing	0				0			
Genital infection fungal								
Normal	1	(0.4)	2	0.69	0			
Impaired	0				0			
Missing	0				0			
Gingival abscess								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Gingivitis								
Normal	1	(0.4)	1	0.34	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Herpes zoster								
Normal	1	(0.4)	1	0.34	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Hordeolum								
Normal	1	(0.4)	1	0.34	3	(1.1)	3	0.99
Impaired	0				0			
Missing	0				0			
Impetigo								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Infected cyst								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Influenza								
Normal	8	(2.8)	9	3.10	8	(2.8)	9	2.98
Impaired	0				0			
Missing	0				0			
Laryngitis								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Laryngopharyngitis								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Localised infection								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(14.3)	1	13.58
Lower respiratory tract infection								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Nasopharyngitis								
Normal	43	(15.3)	62	21.33	58	(20.4)	79	26.14
Impaired	0				0			
Missing	5	(62.5)	13	155.99	3	(42.9)	5	67.92
Norovirus infection								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Oral herpes								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Otitis externa								
Normal	0				3	(1.1)	3	0.99
Impaired	0				0			
Missing	0				0			
Otitis media								
Normal	0				3	(1.1)	3	0.99
Impaired	0				0			
Missing	0				0			
Pericoronitis								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Periodontitis								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Pharyngitis								
Normal	7	(2.5)	7	2.41	2	(0.7)	3	0.99
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Pneumonia								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Pulpitis dental								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Pyelonephritis acute								
Normal	0				0			
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Respiratory tract infection								
Normal	2	(0.7)	2	0.69	0			
Impaired	0				0			
Missing	0				0			
Respiratory tract infection viral								
Normal	4	(1.4)	4	1.38	3	(1.1)	3	0.99
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Rhinitis								
Normal	4	(1.4)	4	1.38	5	(1.8)	6	1.99
Impaired	0				0			
Missing	0				0			
Sepsis								
Normal	0				0			
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Severe acute respiratory syndrome								
Normal	3	(1.1)	3	1.03	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Sinobronchitis								
Normal	0				0			
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Sinusitis								
Normal	13	(4.6)	14	4.82	8	(2.8)	8	2.65
Impaired	0				0			
Missing	1	(12.5)	1	12.00	1	(14.3)	1	13.58
Skin infection								
Normal	0				2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Tinea cruris								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Tinea pedis								
Normal	2	(0.7)	3	1.03	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Tonsillitis								
Normal	2	(0.7)	2	0.69	2	(0.7)	3	0.99
Impaired	0				0			
Missing	0				0			
Tooth abscess								
Normal	4	(1.4)	4	1.38	0			
Impaired	0				0			
Missing	0				0			
Tooth infection								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Tracheobronchitis								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Trichophytosis								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Upper respiratory tract infection								
Normal	14	(5.0)	17	5.85	10	(3.5)	11	3.64
Impaired	0				0			
Missing	1	(12.5)	1	12.00	1	(14.3)	2	27.17
Urinary tract infection								
Normal	10	(3.6)	10	3.44	6	(2.1)	8	2.65
Impaired	0				0			
Missing	2	(25.0)	2	24.00	2	(28.6)	2	27.17
Vaginal infection								
Normal	1	(0.4)	3	1.03	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Varicella								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Viral infection								
Normal	1	(0.4)	1	0.34	5	(1.8)	6	1.99
Impaired	0				0			
Missing	0				0			
Viral rhinitis								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Vulvitis								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Vulvovaginal mycotic infection								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(14.3)	1	13.58
Vulvovaginitis								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Injury, poisoning and procedural complications								
All								
Normal	41	(14.6)	59	20.29	46	(16.1)	60	19.85
Impaired	0				0			
Missing	2	(25.0)	2	24.00	4	(57.1)	4	54.33
Accidental overdose								
Normal	7	(2.5)	8	2.75	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Anaemia postoperative								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(14.3)	1	13.58
Animal bite								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Animal scratch								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(14.3)	1	13.58
Ankle fracture								
Normal	1	(0.4)	3	1.03	0			
Impaired	0				0			
Missing	0				0			
Arthropod bite								
Normal	1	(0.4)	1	0.34	3	(1.1)	3	0.99
Impaired	0				0			
Missing	0				0			
Back injury								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Burns first degree								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Chest injury								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Clavicle fracture								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Concussion								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Contusion								
Normal	2	(0.7)	2	0.69	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				1	(14.3)	1	13.58
Corneal abrasion								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Epicondylitis								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Face injury								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Fall								
Normal	2	(0.7)	2	0.69	2	(0.7)	5	1.65
Impaired	0				0			
Missing	0				0			
Fibula fracture								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Hand fracture								
Normal	1	(0.4)	1	0.34	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Heat stroke								
Normal	0				2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Incorrect dose administered								
Normal	3	(1.1)	3	1.03	0			
Impaired	0				0			
Missing	0				0			
Intentional underdose								
Normal	0				1	(0.4)	2	0.66
Impaired	0				0			
Missing	0				0			
Joint injury								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Ligament rupture								
Normal	1	(0.4)	2	0.69	0			
Impaired	0				0			
Missing	0				0			
Ligament sprain								
Normal	4	(1.4)	4	1.38	2	(0.7)	2	0.66
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Limb injury								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Medication error								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Meniscus injury								
Normal	0				0			
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Muscle rupture								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Muscle strain								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Nerve injury								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Overdose								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Post-traumatic neck syndrome								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Prescribed overdose								
Normal	5	(1.8)	5	1.72	0			
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Procedural pain								
Normal	1	(0.4)	2	0.69	0			
Impaired	0				0			
Missing	0				0			
Product administration error								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Product dispensing error								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Radius fracture								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Road traffic accident								
Normal	2	(0.7)	3	1.03	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Skin abrasion								
Normal	3	(1.1)	4	1.38	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Skin laceration								
Normal	1	(0.4)	1	0.34	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Stress fracture								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Tendon rupture								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Thermal burn								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Tooth fracture								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vaccination complication								
Normal	6	(2.1)	6	2.06	8	(2.8)	12	3.97
Impaired	0				0			
Missing	0				0			
Venous injury								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(14.3)	1	13.58
Wound								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Wound dehiscence								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Wrist fracture								
Normal	0				2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Wrong product administered								
Normal	0				4	(1.4)	4	1.32
Impaired	0				0			
Missing	0				0			
Investigations								
All								
Normal	19	(6.8)	24	8.26	15	(5.3)	16	5.29
Impaired	0				0			
Missing	0				2	(28.6)	3	40.75
Angiogram								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Aspartate aminotransferase increased								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Blood cholesterol increased								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Blood glucose fluctuation								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Blood glucose increased								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Blood pressure increased								
Normal	2	(0.7)	3	1.03	0			
Impaired	0				0			
Missing	0				0			
Blood testosterone decreased								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Blood triglycerides increased								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Blood uric acid increased								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Body temperature increased								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Cardiac murmur								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(14.3)	1	13.58
Electrocardiogram abnormal								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Electrocardiogram T wave abnormal								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Eosinophil count increased								
Normal	0				0			
Impaired	0				0			
Missing	0				1	(14.3)	2	27.17
Glomerular filtration rate decreased								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Haemoglobin decreased								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Heart rate increased								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Hepatic enzyme increased								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Hepatitis B virus test positive								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Lipids abnormal								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Low density lipoprotein increased								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Mycobacterium tuberculosis complex test positive								
Normal	2	(0.7)	2	0.69	0			
Impaired	0				0			
Missing	0				0			
Occult blood positive								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Platelet count decreased								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Pulse absent								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
SARS-CoV-2 test positive								
Normal	0				5	(1.8)	5	1.65
Impaired	0				0			
Missing	0				0			
Serum ferritin decreased								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			

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Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Weight decreased								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Weight increased								
Normal	2	(0.7)	2	0.69	0			
Impaired	0				0			
Missing	0				0			
White blood cell count decreased								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Metabolism and nutrition disorders								
All								
Normal	17	(6.0)	23	7.91	15	(5.3)	18	5.96
Impaired	0				0			
Missing	1	(12.5)	1	12.00	1	(14.3)	1	13.58
Decreased appetite								
Normal	1	(0.4)	1	0.34	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Dehydration								
Normal	0				1	(0.4)	2	0.66
Impaired	0				0			
Missing	0				0			
Diabetic dyslipidaemia								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Diabetic ketoacidosis								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Dyslipidaemia								
Normal	0				2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Hypercholesterolaemia								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Hyperlipidaemia								
Normal	2	(0.7)	2	0.69	1	(0.4)	1	0.33

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Hyperuricaemia								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Hypoglycaemia								
Normal	10	(3.6)	15	5.16	4	(1.4)	5	1.65
Impaired	0				0			
Missing	0				0			
Hypokalaemia								
Normal	0				0			
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Hyponatraemia								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Insulin resistance								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Iron deficiency								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Obesity								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Vitamin D deficiency								
Normal	1	(0.4)	1	0.34	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				1	(14.3)	1	13.58
Musculoskeletal and connective tissue disorders								
All								
Normal	41	(14.6)	51	17.54	54	(18.9)	95	31.43
Impaired	0				0			
Missing	4	(50.0)	7	83.99	2	(28.6)	4	54.33
Acquired claw toe								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Arthralgia								
Normal	11	(3.9)	11	3.78	15	(5.3)	16	5.29
Impaired	0				0			
Missing	1	(12.5)	2	24.00	0			
Arthritis								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Back pain								
Normal	5	(1.8)	5	1.72	17	(6.0)	31	10.26
Impaired	0				0			
Missing	0				0			
Bursitis								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				1	(14.3)	1	13.58
Chondromalacia								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Flank pain								
Normal	0				0			
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Foot deformity								
Normal	1	(0.4)	1	0.34	1	(0.4)	2	0.66
Impaired	0				0			
Missing	0				0			
Groin pain								
Normal	0				2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Intervertebral disc protrusion								
Normal	0				2	(0.7)	3	0.99
Impaired	0				0			
Missing	0				0			
Limb discomfort								
Normal	2	(0.7)	2	0.69	0			
Impaired	0				0			
Missing	0				0			
Limb mass								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Muscle spasms								
Normal	4	(1.4)	5	1.72	1	(0.4)	1	0.33

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Muscular weakness								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Musculoskeletal stiffness								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Myalgia								
Normal	3	(1.1)	3	1.03	8	(2.8)	11	3.64
Impaired	0				0			
Missing	0				0			
Myopathy								
Normal	0				0			
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Neck pain								
Normal	1	(0.4)	1	0.34	2	(0.7)	2	0.66
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Nodal osteoarthritis								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Osteoarthritis								
Normal	2	(0.7)	2	0.69	1	(0.4)	1	0.33
Impaired	0				0			
Missing	2	(25.0)	2	24.00	1	(14.3)	1	13.58
Pain in extremity								
Normal	8	(2.8)	8	2.75	11	(3.9)	11	3.64
Impaired	0				0			
Missing	0				2	(28.6)	2	27.17
Periarthritis								
Normal	2	(0.7)	2	0.69	4	(1.4)	4	1.32
Impaired	0				0			
Missing	0				0			
Rheumatoid arthritis								
Normal	1	(0.4)	1	0.34	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Rotator cuff syndrome								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Spinal stenosis								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Synovial cyst								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Tendonitis								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Tenosynovitis								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Trigger finger								
Normal	2	(0.7)	2	0.69	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
All								
Normal	8	(2.8)	8	2.75	5	(1.8)	6	1.99
Impaired	0				0			
Missing	0				0			
Benign neoplasm of thyroid gland								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Benign renal neoplasm								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Colon adenoma								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Eye naevus								
Normal	1	(0.4)	1	0.34	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Haemangioma of liver								
Normal	1	(0.4)	1	0.34	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Lipoma								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Melanocytic naevus								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Myeloproliferative neoplasm								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Seborrhoeic keratosis								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Skin papilloma								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Uterine leiomyoma								
Normal	0				2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Nervous system disorders								
All								
Normal	38	(13.5)	62	21.33	38	(13.3)	118	39.04
Impaired	0				0			
Missing	2	(25.0)	10	119.99	1	(14.3)	1	13.58
Ageusia								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Autonomic nervous system imbalance								
Normal	1	(0.4)	2	0.69	0			
Impaired	0				0			
Missing	0				0			
Burning sensation								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Carpal tunnel syndrome								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Cerebral haemorrhage								
Normal	0				0			
Impaired	0				0			
Missing	1	(12.5)	2	24.00	0			
Cerebral infarction								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Cervicobrachial syndrome								
Normal	2	(0.7)	2	0.69	0			
Impaired	0				0			
Missing	0				0			
Diabetic neuropathy								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Disturbance in attention								
Normal	1	(0.4)	11	3.78	0			
Impaired	0				0			
Missing	0				0			
Dizziness								
Normal	2	(0.7)	3	1.03	5	(1.8)	6	1.99
Impaired	0				0			
Missing	0				0			
Dizziness postural								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Encephalopathy								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Haemorrhage intracranial								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Headache								
Normal	16	(5.7)	21	7.22	15	(5.3)	21	6.95
Impaired	0				0			
Missing	1	(12.5)	6	71.99	1	(14.3)	1	13.58
Hemiparesis								
Normal	0				0			
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	1	(12.5)	1	12.00	0			
Hypoaesthesia								
Normal	2	(0.7)	3	1.03	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Hypoglycaemic seizure								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Hypoglycaemic unconsciousness								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Hypotonia								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
IIIrd nerve paralysis								
Normal	0				0			
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Ischaemic stroke								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Loss of consciousness								
Normal	1	(0.4)	1	0.34	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Loss of proprioception								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Migraine								
Normal	4	(1.4)	5	1.72	2	(0.7)	3	0.99
Impaired	0				0			
Missing	0				0			
Neuropathy peripheral								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Optic neuritis								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Post herpetic neuralgia								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Presyncope								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Radiculopathy								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Restless legs syndrome								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Sinus headache								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Somnolence								
Normal	2	(0.7)	2	0.69	0			
Impaired	0				0			
Missing	0				0			
Syncope								
Normal	3	(1.1)	3	1.03	0			
Impaired	0				0			
Missing	0				0			
Tension headache								
Normal	0				1	(0.4)	2	0.66
Impaired	0				0			
Missing	0				0			
Tremor								
Normal	1	(0.4)	1	0.34	4	(1.4)	68	22.50
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Pregnancy, puerperium and perinatal conditions								
All								
Normal	2	(0.7)	2	0.69	0			
Impaired	0				0			
Missing	0				0			
Abortion spontaneous								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Abortion threatened								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Psychiatric disorders								
All								
Normal	7	(2.5)	7	2.41	9	(3.2)	12	3.97
Impaired	0				0			
Missing	1	(12.5)	1	12.00	2	(28.6)	2	27.17
Alcohol abuse								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Anxiety								
Normal	1	(0.4)	1	0.34	4	(1.4)	4	1.32
Impaired	0				0			
Missing	0				1	(14.3)	1	13.58
Anxiety disorder								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Attention deficit hyperactivity disorder								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Depressed mood								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Depression								
Normal	0				4	(1.4)	4	1.32
Impaired	0				0			
Missing	0				1	(14.3)	1	13.58

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Insomnia								
Normal	1	(0.4)	1	0.34	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Major depression								
Normal	0				0			
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Sleep disorder								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Stress								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Renal and urinary disorders								
All								
Normal	6	(2.1)	6	2.06	5	(1.8)	8	2.65
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Acute kidney injury								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Chronic kidney disease								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Diabetic nephropathy								
Normal	0				2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Dysuria								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Hydrocalyx								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Hypertensive nephropathy								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Microalbuminuria								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Pollakiuria								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Proteinuria								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Renal cyst								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Renal pain								
Normal	2	(0.7)	2	0.69	0			
Impaired	0				0			
Missing	0				0			
Reproductive system and breast disorders								
All								
Normal	8	(2.8)	9	3.10	8	(2.8)	10	3.31
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Atrophic vulvovaginitis								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Benign prostatic hyperplasia								
Normal	2	(0.7)	2	0.69	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Dysmenorrhoea								
Normal	1	(0.4)	1	0.34	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Ectropion of cervix								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Erectile dysfunction								
Normal	1	(0.4)	1	0.34	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Fibrocystic breast disease								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Heavy menstrual bleeding								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Menstruation irregular								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Ovarian cyst								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Ovarian disorder								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Penile pain								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Premenstrual syndrome								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Prostatic cyst								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Prostatitis								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Prostatomegaly								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Respiratory, thoracic and mediastinal disorders								

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
All								
Normal	34	(12.1)	47	16.17	37	(13.0)	57	18.86
Impaired	0				0			
Missing	2	(25.0)	7	83.99	0			
Acute respiratory failure								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Allergic cough								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Asthma								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Bronchial hyperreactivity								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Cough								
Normal	8	(2.8)	10	3.44	11	(3.9)	15	4.96
Impaired	0				0			
Missing	1	(12.5)	2	24.00	0			
Cough variant asthma								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Dysphonia								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Dyspnoea								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Dyspnoea exertional								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Epiglottic oedema								
Normal	0				0			
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Epistaxis								
Normal	2	(0.7)	2	0.69	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Hiccups								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Nasal congestion								
Normal	2	(0.7)	2	0.69	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Oropharyngeal discomfort								
Normal	0				2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Oropharyngeal pain								
Normal	7	(2.5)	8	2.75	10	(3.5)	11	3.64
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Pleurisy								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Productive cough								
Normal	0				3	(1.1)	4	1.32
Impaired	0				0			
Missing	0				0			
Pulmonary congestion								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Pulmonary mass								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Respiratory disorder								
Normal	4	(1.4)	4	1.38	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Rhinitis allergic								
Normal	3	(1.1)	4	1.38	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Rhinorrhoea								
Normal	3	(1.1)	4	1.38	7	(2.5)	8	2.65
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Sinus congestion								
Normal	2	(0.7)	2	0.69	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Sleep apnoea syndrome								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Sneezing								
Normal	0				0			
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Throat irritation								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Upper-airway cough syndrome								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Skin and subcutaneous tissue disorders								
All								
Normal	34	(12.1)	40	13.76	40	(14.0)	54	17.87
Impaired	0				0			
Missing	2	(25.0)	2	24.00	0			
Alopecia								
Normal	2	(0.7)	2	0.69	0			
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Alopecia areata								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Angioedema								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Chronic spontaneous urticaria								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Cold sweat								
Normal	0				5	(1.8)	10	3.31
Impaired	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Missing	0				0			
Dermal cyst								
Normal	1	(0.4)	1	0.34	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Dermatitis								
Normal	5	(1.8)	7	2.41	3	(1.1)	4	1.32
Impaired	0				0			
Missing	0				0			
Dermatitis allergic								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Dermatitis atopic								
Normal	1	(0.4)	1	0.34	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Dermatitis contact								
Normal	4	(1.4)	4	1.38	7	(2.5)	7	2.32
Impaired	0				0			
Missing	0				0			
Dry skin								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Eczema								
Normal	0				3	(1.1)	3	0.99
Impaired	0				0			
Missing	0				0			
Eczema asteatotic								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Erythema								
Normal	0				2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Erythema multiforme								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Hidradenitis								
Normal	0				0			
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Hyperkeratosis								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Ingrowing nail								
Normal	1	(0.4)	1	0.34	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Ingrown hair								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Lichen sclerosus								
Normal	2	(0.7)	2	0.69	0			
Impaired	0				0			
Missing	0				0			
Macule								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Miliaria								
Normal	0				2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Pruritus								
Normal	1	(0.4)	1	0.34	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Psoriasis								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Rash								
Normal	4	(1.4)	4	1.38	2	(0.7)	2	0.66
Impaired	0				0			
Missing	0				0			
Rash erythematous								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Seborrhoeic dermatitis								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Skin fissures								
Normal	1	(0.4)	1	0.34	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Impaired	0				0			
Missing	0				0			
Skin irritation								
Normal	2	(0.7)	2	0.69	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Skin lesion								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Skin reaction								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Skin ulcer								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Telangiectasia								
Normal	1	(0.4)	1	0.34	1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Urticaria								
Normal	0				4	(1.4)	4	1.32
Impaired	0				0			
Missing	0				0			
Urticaria papular								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Vitiligo								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Xeroderma								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Surgical and medical procedures								
All								
Normal	4	(1.4)	4	1.38	0			
Impaired	0				0			
Missing	0				0			
Cardiac ablation								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Skin neoplasm excision								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Tooth extraction								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Wisdom teeth removal								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

Adverse events by baseline hepatic function, system organ class and preferred term - ONWARDS 6 (extension part) - on-treatment - summary - safety analysis set

	Insulin icodec				Daily basal insulin			
	N	(%)	E	R	N	(%)	E	R
Vascular disorders								
All								
Normal	10	(3.6)	10	3.44	10	(3.5)	11	3.64
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Aortic aneurysm								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Arteriosclerosis								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	0				0			
Brachiocephalic artery stenosis								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Hypertension								
Normal	8	(2.8)	8	2.75	7	(2.5)	7	2.32
Impaired	0				0			
Missing	0				0			
Hypertensive crisis								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			
Hypotension								
Normal	1	(0.4)	1	0.34	0			
Impaired	0				0			
Missing	1	(12.5)	1	12.00	0			
Varicose vein								
Normal	0				1	(0.4)	1	0.33
Impaired	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Daily basal insulin: IDeg.

インスリン イコデク（遺伝子組換え）

2.7.5 参考文献

ノボ ノルディスク ファーマ株式会社

2.7.5.1 参考文献

参考文献は、Module 2.5、Module 2.7.1、Module 2.7.2、Module 2.7.3 及び Module 2.7.4 の参考文献の項にそれぞれ示した。