IDegLira improves glycaemic control throughout the day with no weight gain and a low rate of hypoglycaemia*

Barcelona, Spain, 27 September 2013 – Today, phase 3 data from the investigational therapy IDegLira [Tresiba® (insulin degludec)/Victoza® (liraglutide injection)] were presented at the 49th Annual European Association for the Study of Diabetes (EASD) Congress. Data from the DUAL™ I trial show IDegLira demonstrates a statistically significant greater reduction in blood sugar levels (HbA1c) compared to insulin degludec or liraglutide alone, with no weight gain and a low rate of hypoglycaemia compared to insulin degludec in adults with type 2 diabetes. These results were also supported by data showing once-daily IDegLira provides statistically greater reductions in postprandial glucose following all three main meals of the day (breakfast, lunch and dinner) compared to insulin degludec.

IDegLira is a once-daily, single-administration basal insulin/GLP-1 analogue combination being developed for the treatment of type 2 diabetes in adults.

"The efficacy of IDegLira demonstrated by the DUAL™ I data is exciting. It combines the clinical advantages, yet mitigates the principal side effects of insulin degludec and liraglutide," said Professor Stephen Gough, University of Oxford and Oxford University Hospitals NHS Trust, lead investigator of the study. "DUAL™ I shows how patients can achieve an average final HbA1c of 6.4% with no weight gain and a low rate of hypoglycaemia."

The DUAL™ I trial evaluated IDegLira in people with type 2 diabetes inadequately controlled on oral antidiabetic (OAD) medications compared to insulin degludec or liraglutide (1.8 mg) alone:¹

- IDegLira showed a statistically significant mean HbA1c reduction of 1.9% (from baseline of 8.3%) achieving its primary endpoint of superiority versus liraglutide and non-inferiority versus insulin degludec (-1.3% and -1.4%, p<0.0001, respectively)
• 81% of patients treated with IDegLira reached the HbA1c goal of <7%, and 70% reached ≤6.5% versus liraglutide alone (60% and 41%, respectively) and insulin degludec alone (65% and 48% respectively)
• IDegLira resulted in a mean weight reduction of ~0.5 kg and a 32% lower rate of confirmed hypoglycaemia versus insulin degludec (p<0.0001; 1.8 versus 2.6 events per patient per year) whereas liraglutide, as expected, was associated with less hypoglycaemia and greater weight reduction.

The effects of IDegLira on fasting and postprandial glucose levels resulted in a substantial overall improvement in glycaemic control as compared to its individual components.² IDegLira reduced the postprandial increments significantly more than insulin degludec following all three main meals. The reduction in postprandial increments seen for IDegLira and liraglutide were similar.² Furthermore, IDegLira resulted in significantly better control of postprandial blood glucose following a standardised mixed meal compared to insulin degludec.³

The most frequently reported adverse events seen with IDegLira in the DUAL™ I trial are consistent with its individual components.

**About the DUAL™ clinical programme**

DUAL™ (DUal Action of Liraglutide and Insulin Degludec in Type 2 Diabetes) consists of two phase 3a trials encompassing around 2,000 people with type 2 diabetes.

DUAL™ I (around 1,600 people randomised) – a 26-week randomised, open-label trial comparing the efficacy and safety of IDegLira, insulin degludec and liraglutide in people with type 2 diabetes inadequately controlled with metformin with or without pioglitazone.

DUAL™ II (around 400 people randomised) – a 26-week randomised, double-blinded trial comparing IDegLira and insulin degludec in people with type 2 diabetes inadequately controlled on basal insulin in combination with 1–2 oral anti-diabetic agents. In this trial, the maximum dose of insulin degludec was fixed in both treatment arms to investigate the additional impact of the liraglutide component of IDegLira on glucose control.

**About IDegLira (insulin degludec/liraglutide)**

IDegLira is a combination of insulin degludec (Tresiba®), a once-daily basal insulin analogue with an ultra-long duration of action, and liraglutide (Victoza®), the once-daily human GLP-1 analogue, which is being developed for the treatment of type 2 diabetes. IDegLira is administered once daily independent of meals and provides improved overall glycaemic control versus insulin degludec or liraglutide alone, with no weight gain and a low rate of hypoglycaemia compared to insulin degludec. IDegLira is being investigated in a phase 3 clinical trial programme; DUAL™ I. Novo Nordisk submitted the regulatory filing for IDegLira in the EU in June 2013.
About Tresiba® (insulin degludec)

Tresiba® is the global brand name for insulin degludec, a basal insulin discovered and developed by Novo Nordisk. Tresiba® provides an ultra-long duration of action beyond 42 hours, allowing for flexibility in day-to-day dosing time, when needed, with a minimum of eight hours between injections, without compromising efficacy or risk of hypoglycaemia. Tresiba® has been studied in a large-scale clinical trial programme, BEGIN™, examining its impact on glucose control, hypoglycaemia and the possibility to flexibly adjust insulin degludec dosing time to suit patient needs. Tresiba® has been approved in the EU, Japan, Mexico, Norway, Switzerland, Iceland and India.

About Victoza®

Victoza® (liraglutide) is a human glucagon-like peptide-1 (GLP-1) analogue with an amino acid sequence 97% similar to endogenous human GLP-1. Like natural GLP-1, Victoza® works by stimulating the beta cells to release insulin and suppressing glucagon secretion from the alpha cells only when blood sugar levels are high. Due to this glucose-dependent mechanism of action, Victoza® is associated with a low rate of hypoglycaemia. In addition, Victoza® reduces body weight and body fat mass through mechanisms involving reduced appetite and lowered food intake.

Victoza® was launched in the EU in 2009 and is commercially available in more than 60 countries globally. Currently, there are more than 750,000 Victoza® patients worldwide. In the US, Victoza® was approved on 25 January 2010 as an adjunct to diet and exercise to improve blood sugar control in adults with type 2 diabetes.

Headquartered in Denmark, Novo Nordisk is a global healthcare company with 90 years of innovation and leadership in diabetes care. The company also has leading positions within haemophilia care, growth hormone therapy and hormone replacement therapy. Headquartered in Denmark, Novo Nordisk employs approximately 36,000 employees in 75 countries, and markets its products in more than 180 countries. For more information, visit novonordisk.com.

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Hypoglycaemia has primarily been observed when Victoza® is combined with a sulphonylurea

* IDegLira improves glycaemic control throughout the day compared to insulin degludec or liraglutide alone, with a low rate of hypoglycaemia and no weight gain compared to insulin degludec

References

1. Gough SCL, et al. IDegLira, a Novel Fixed Ratio Combination of Insulin Degludec and Liraglutide, is Efficacious and Safe in Subjects with Type 2 Diabetes: A Large, Randomized Phase 3 Trial. Oral presentation (OP 37) at the 49th Annual European Association for the Study of Diabetes (EASD) Congress, 27 September 2013.

2. Buse JB, et al. Postprandial glycaemic control following a fixed ratio combination of insulin degludec and liraglutide compared to each component individually in patients with T2D. Poster presentation (PS 084) at the 49th Annual European Association for the Study of Diabetes (EASD) Congress, 26 September 2013.