press release

Not intended for UK media

New Xultophy® (IDegLira) data show rapid and predictable glycaemic improvements in people with type 2 diabetes

Analyses of DUAL™ trial data compared Xultophy® (IDegLira) to insulin degludec and liraglutide alone in both insulin-naïve and insulin-treated patients

Vienna, Austria, **19 September 2014** – New analyses of phase 3a DUAL™ clinical data show that adults with type 2 diabetes treated with Xultophy® (IDegLira), the once-daily single injection combination of Tresiba® (insulin degludec) and Victoza® (liraglutide), resulted in rapid and substantial improvement in glycaemic control, with a beneficial weight profile, as early as 4 weeks after initiation in both insulin-naïve and insulin-treated patients compared to its individual components.

Xultophy® treated patients also had a greater likelihood of reaching both pre-prandial (before meal) and post-prandial (after meal) blood glucose targets compared with either insulin degludec or liraglutide, suggesting increased predictability with treatment. Data from the 52-week DUAL™ I and the 26-week DUAL™ II clinical trials were presented at the 50th European Association for the Study of Diabetes (EASD) annual meeting.

"These new findings indicate that IDegLira could have a significant positive impact on how people with type 2 diabetes view their treatment progress, which could improve clinical outcomes," said Professor Tina Vilsbøll, Gentofte Hospital, University of Copenhagen, Denmark. "Getting to glycaemic target faster and with more predictable control motivates patients to adhere to therapy and proactively manage their disease."

In the DUAL™ I clinical trial, the proportion of people achieving fasting plasma glucose ≤7.2 mmol/L at Week 4 and glycated haemoglobin (HbA_{1c}) <7% at Week 8 was greater with Xultophy® (76%; 57%, respectively) than with insulin degludec (62%; 38%) or with liraglutide (62%; 47%). At Weeks 4, 8 and 12 in DUAL™ I, treatment with Xultophy® also resulted in significant weight loss compared with insulin degludec, which was associated with a small overall weight gain ($p<0.0001$ at Weeks 4, 8 and 12). Weight loss with Xultophy® was less than that achieved with liraglutide 1.8 mg alone. Results

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from DUAL™ II were consistent with DUAL™ I findings for Xultophy® and insulin degludec.[1]

Results showed Xultophy® enabled more patients to reach the recommended pre- and post-prandial target ranges, compared with administration of its individual components. The proportion of people with type 2 diabetes at the end of the trials with breakfast, lunch and dinner post-prandial blood glucose values within the target of <9 mmol/L was significantly higher with Xultophy® treatment (DUAL™ I: 51%; DUAL™ II: 37%) than with insulin degludec treatment (DUAL™ I: 38%; DUAL™ II: 25%) or with liraglutide (DUAL™ I: 36%).[2]

The likelihood of achieving all four pre-prandial blood glucose values (before meals and bedtime) within the recommended range of ≥3.9 to ≤7.2 mmol/L was also significantly greater with Xultophy® treatment (DUAL™ I: 48%; DUAL™II: 44%) than with insulin degludec treatment (DUAL™ I: 41%; DUAL™ II: 27%) or with liraglutide treatment (DUAL™ I: 32%), which suggests the predictability of glycaemic control within one day is increased with Xultophy®.[2]

In the clinical trial programme for Xultophy® there were no apparent differences between Xultophy®, insulin degludec and liraglutide with respect to adverse events and standard safety parameters.[3,4]

About Xultophy® (IDegLira)
Xultophy® is a once-daily, single-injection combination product consisting of Tresiba® (insulin degludec 50 units), a once-daily basal insulin analogue with an ultra-long duration of action, and Victoza® (liraglutide 1.8 mg), the once-daily human GLP-1 analogue. Xultophy® is administered independently of meals and has shown consistent results in improving glycaemic control in both insulin-naïve people as well as people with type 2 diabetes who are uncontrolled on basal insulin. For people uncontrolled on basal insulin therapy, Xultophy® has demonstrated a significant reduction in HbA_{1c} of 1.9%, with a mean weight loss of 2.7 kg and a low rate of hypoglycaemia comparable to that of insulin degludec.[3] Xultophy® is being investigated in the clinical trial programme, DUAL™.

Xultophy® was approved in Switzerland on 12 September 2014 and granted marketing authorisation by the European Commission for all 27 European Union member states on 18 September 2014.

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

DUAL™ I (1,663 people) – a 26-week, randomised, parallel, three-arm, open-label, multicentre trial conducted at 271 sites across 19 countries. The trial compared the efficacy and safety of Xultophy® versus insulin degludec and liraglutide alone, in insulin-naïve adults with type 2 diabetes uncontrolled with metformin with or without

pioglitazone. A 26-week extension phase of the main trial was conducted to generate longer-term safety and efficacy data. The topline results for DUAL™ I were reported in 2012.

DUAL™ II (398 people) – a 26-week, randomised, parallel, two-arm, double-blinded, multicentre trial conducted at 75 sites across 7 countries. The trial compared the efficacy and safety of Xultophy® and insulin degludec once daily, both added on to metformin in adults with type 2 diabetes uncontrolled on basal insulin (20–40 units) in combination with metformin with or without sulfonylureas/glinides. Sulfonylureas and glinides were discontinued at randomisation. In this trial, the allowed maximum dose of insulin degludec in the treatment arms was 50 units so that the contribution of the liraglutide component of Xultophy® on glycaemic control could be demonstrated. The topline results for DUAL™ II were reported in 2012.

About Novo Nordisk

Headquartered in Denmark, Novo Nordisk is a global healthcare company with more than 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. Novo Nordisk employs approximately 40,700 employees in 75 countries, and markets its products in more than 180 countries. For more information, visit novonordisk.com.

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