Adults with type 2 diabetes treated with Xultophy® (IDegLira) were up to 4.5 times more likely to reach glycaemic targets without hypoglycaemia and weight gain vs up-titration with insulin glargine U100

Munich, Germany, 13 September 2016 – Novo Nordisk today presented data showing the odds of reaching fasting plasma glucose (FPG) targets without hypoglycaemia and weight gain were significantly greater for Xultophy® (IDegLira) compared to up-titration with insulin glargine U100 in adults with type 2 diabetes uncontrolled on insulin glargine U100 (20-50 units). Xultophy® is the first once-daily combination of a long-acting insulin (insulin degludec) and a glucagon-like peptide-1 (GLP-1) receptor agonist (liraglutide) in Europe. Results were presented at the 52nd Annual Meeting of the European Association for the Study of Diabetes (EASD) 2016.1

The post-hoc analysis of the DUAL V phase 3b trial was evaluated using a FPG target of 7.2 mmol/L, selected to better reflect targets used in clinical practice.2 Data showed that adults treated with Xultophy® were 4.55 times more likely to reach FPG targets without confirmed hypoglycaemia and weight gain vs up-titration with insulin glargine U100 (41.4% vs 14.3%, p<0.0001).1

The data also demonstrated that significantly more adults achieved HbA1c target of <7% with no hypoglycaemia and no weight gain across baseline HbA1c groups (≤7.5, >7.5–≤8.5 and >8.5%) with Xultophy® vs up-titration with insulin glargine U100 (51% vs 25%; 39% vs 11%; 32% vs 5%; p<0.005 for all).1

In addition, FPG and HbA1c were already significantly reduced at weeks 4, 8 and 12 in adults switching to Xultophy® vs up-titration with insulin glargine U100, demonstrating better glycaemic control shortly after transferring to Xultophy® compared to insulin glargine U100.1

“This analysis of DUAL V indicates that Xultophy® is effective in helping patients achieve glycaemic control with a lower risk of hypoglycaemia and weight gain compared to up-
titration with insulin glargine U100, based on targets used in clinical practice,” said Dr. Ildiko Lingvay, Associate Professor of Internal Medicine and Clinical Science at UT Southwestern Medical Center. “The data demonstrate improvements in glycaemic control as early as four weeks after treatment initiation.”

Also presented at EASD, Novo Nordisk announced results from DUAL VI demonstrating that using a simpler titration algorithm of once-weekly dose adjustments compared to the twice-weekly adjustments used in previous DUAL trials, results in a non-inferior safety and glycaemic efficacy profile for Xultophy® in insulin-naïve adults with type 2 diabetes.3

*Dr. Lingvay, who is involved with several Novo Nordisk-sponsored clinical trials, including DUAL V, received editorial support and reimbursements from Novo Nordisk in 2016.

About Xultophy®
Xultophy® is a once-daily single injection combination of basal insulin analogue (insulin degludec) and GLP-1 analogue (liraglutide). The maximum dose of Xultophy® is 50 dose steps (equivalent to 50 units of insulin degludec and 1.8 mg of liraglutide).4 Xultophy® has been investigated in six trials in the DUAL clinical trial programme, encompassing more than 3,850 people with type 2 diabetes. Phase 3b trials are still ongoing. Xultophy® was granted marketing authorisation by the European Commission on 18 September 2014 and approved in Switzerland on 12 September 2014.4,5 Xultophy® is not distributed in Germany.

About DUAL V
DUAL V was a phase 3b, 26-week, treat-to-target, randomised, open-label, multicentre trial conducted in 10 countries with 557 patients. The trial was designed to show non-inferiority in HbA1c and to subsequently demonstrate superiority in HbA1c, body weight and rate of hypoglycaemia. The trial compared the efficacy and safety of Xultophy® vs up-titration of insulin glargine U100, both added on to metformin, in adults with type 2 diabetes uncontrolled on insulin glargine (20–50 units). The pre-trial mean dose of insulin glargine was 32 units. Patients could be titrated to the maximum dose of Xultophy® (equivalent to 50 units of insulin degludec and 1.8 mg of liraglutide) and there was no maximum daily dose of insulin glargine.6

About DUAL VI
DUAL VI was a 32-week, open-label, non-inferiority trial to investigate the safety and efficacy of Xultophy® in insulin-naïve adults with type 2 diabetes uncontrolled on metformin ± pioglitazone. In the trial, 420 participants were randomised 1:1 to receive Xultophy®, titrated either once weekly based on the mean of two pre-breakfast plasma glucose (PG) readings (n=210) or twice weekly based on the mean of three pre-breakfast PG readings (i.e. six readings/week, as for DUAL I-V trials; n=210).3
About Novo Nordisk

Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat other serious chronic conditions: haemophilia, growth disorders and obesity. Headquartered in Denmark, Novo Nordisk employs approximately 42,300 people in 75 countries and markets its products in more than 180 countries. For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube.

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References

1. Lingvay I, Norwood P, Begtrup K et al. Patients with T2D Treated with IDegLira Have a Greater Chance of Reaching Glycaemic targets without Hypoglycaemia and Weight Gain than with Insulin Glargine U100 (IGlar U100). Abstract 890 presented at the 52nd European Association for the Study of Diabetes (EASD), Munich, Germany. 13 September 2016.


3. Harris S, Kocsis G, Prager T et al. Safety and efficacy of IDegLira titrated once weekly (1W) vs twice weekly (2W) in patients with T2D uncontrolled on oral antidiabetic drugs: DUAL VI study. Abstract 908 presented at the 52nd European Association for the Study of Diabetes (EASD), Munich, Germany. 15 September 2016.

