**Press Release**

**Significant blood sugar improvement with Xultophy® compared to insulin glargine U-100 when used as add-on to oral diabetes medications**

Adults with type 2 diabetes treated with Xultophy® (insulin degludec and liraglutide injection) also experienced no change in body weight, lower rates of hypoglycaemia and a lower insulin dose at 26 weeks.

**Bagsværd, Denmark, 23 June 2018** – Xultophy® (insulin degludec and liraglutide injection) provided superior blood sugar reduction (HbA1c) compared to insulin glargine U-100 (1.94% vs 1.68% respectively; \( p < 0.0001 \)) when used as an add-on to an SGLT-2i (an oral diabetes medication), according to results from the DUAL IX study presented today at the American Diabetes Association’s 78th Scientific Sessions (ADA) in Orlando, US.¹

Results from some of the secondary endpoints in DUAL IX included change from baseline in body weight, severe or blood glucose confirmed symptomatic hypoglycaemic events and daily insulin dose at 26 weeks. Mean body weight remained unchanged in the Xultophy® study group versus a 2.0 kg weight gain with insulin glargine U-100. Treatment with Xultophy® demonstrated a 58% lower rate of hypoglycaemia versus insulin glargine U-100 (0.37 events/patient-year of exposure vs 0.90 events/patient-year of exposure respectively; \( p=0.0035 \)). The average total daily insulin dose was significantly less with Xultophy® than insulin glargine U-100 (36 units per day vs 54 units per day respectively; \( p<0.0001 \)).¹

“Type 2 diabetes is a progressive disease that often requires treatment intensification,” said Dr Athena Philis-Tsimikas, DUAL IX lead investigator and corporate vice president, Scripps Whittier Diabetes Institute. “Xultophy® may be an appropriate treatment option for those adults who are unable to meet their blood sugar goals on their current medication.”

Adverse events were similar across both treatment groups; the most common adverse events (≥5%) in the Xultophy® treated patients included viral upper respiratory tract infection, headaches, back pain, increased lipase and nausea. The safety profile of Xultophy® in DUAL IX was consistent with previous Xultophy® clinical trials.¹
Additional DUAL IX patient-reported outcomes will be presented on Monday 25 June at ADA:

- Patient-Reported Outcomes for Insulin Degludec/Liraglutide (IDegLira) vs Insulin Glargine (IGlar U-100) as Add-On to Sodium-Glucose Co-Transporter-2 Inhibitor (SGLT2i) ± Oral Antidiabetic Drug (OAD) Therapy in Patients with Type 2 Diabetes: DUAL IX Trial (Poster Presentation 101-LB)

**About DUAL IX**

DUAL IX was a phase 3b, 26-week, randomised, open-label, multicentre trial conducted in 11 countries including 420 patients. The trial was designed to investigate the safety and efficacy of Xultophy® versus insulin glargine U-100 as add-on therapy in adults uncontrolled on sodium-glucose co-transporter-2 inhibitor (SGLT-2i) treatment with or without additional oral antidiabetic drug therapy. A hypoglycaemic event in DUAL IX was defined as an event requiring assistance from another person or blood glucose (BG) confirmed (less than 56 mg/dL) with symptoms consistent with hypoglycaemia.

**About Xultophy®**

Xultophy® is a once-daily fixed-ratio combination injection of insulin degludec, a long-acting human insulin analogue, and liraglutide, a glucagon-like peptide 1 (GLP-1) receptor agonist. In Europe, Xultophy® is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise in addition to other oral medicinal products for the treatment of diabetes.

In the US, Xultophy® is called Xultophy® 100/3.6, and is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes inadequately controlled on basal insulin (less than 50 U daily) or liraglutide (less than or equal to 1.8 mg daily). In the US, Xultophy® 100/3.6 is not indicated for use as an add-on to oral diabetes medications.

**About Novo Nordisk**

Novo Nordisk is a global healthcare company with 95 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat obesity, haemophilia, growth disorders and other serious chronic diseases. Headquartered in Denmark, Novo Nordisk employs approximately 42,700 people in 79 countries and markets its products in more than 170 countries. For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube.
Further information

Media:
Katrine Sperling  +45 4442 6718  krsp@novonordisk.com
Åsa Josefsson  +45 3079 7708  aajf@novonordisk.com
Michael Bachner (US)  +1 609 664 7308  mzyb@novonordisk.com

Investors:
Peter Hugreff Ankersen  +45 3075 9085  phak@novonordisk.com
Anders Mikkelsen  +45 3079 4461  armk@novonordisk.com
Christina Kjær  +45 3079 3009  cnje@novonordisk.com

References