press release

New Xultophy® (IDegLira) phase 3b study showed statistically significant HbA_{1c} reduction, body weight change and lower rate of hypoglycaemia versus insulin glargine

Boston, US, **7 June 2015** – New phase 3b findings showed adults with type 2 diabetes treated with Xultophy® (IDegLira), a once-daily, single-injection combination of insulin degludec and liraglutide, demonstrated statistically significant reduction in HbA_{1c} (average blood glucose over the previous three months), change in body weight and a lower rate of hypoglycaemia compared with patients treated with insulin glargine.[1]

Findings from the phase 3b DUAL™ V 26-week trial that compared the efficacy and safety of Xultophy® versus insulin glargine, both added on to metformin, in patients with type 2 diabetes uncontrolled on insulin glargine (20–50 units/day), were presented today at the 75th Annual Scientific Sessions of the American Diabetes Association (ADA) in Boston, Massachusetts, United States.[1]

At 26 weeks, patients randomised to Xultophy® treatment achieved a statistically significant mean reduction in HbA_{1c} of 1.8% from baseline (8.4% to 6.6%) compared with a 1.1% reduction (8.2% to 7.1%) achieved by patients who further increased their dose of insulin glargine ($p<0.001$).[1] In the Xultophy® group, 72% of patients achieved an HbA_{1c} of <7% at the end of the trial, compared with 47% of patients in the insulin glargine group ($p<0.001$).[1] Furthermore, 39% of patients treated with Xultophy® achieved an HbA_{1c} <7% without hypoglycaemia and weight gain versus 12% treated with insulin glargine ($p<0.001$).[1]

"The results demonstrated that IDegLira treatment could positively impact patients who are not in control on their current basal insulin therapy," said Professor John Buse, University of North Carolina School of Medicine, Chapel Hill, North Carolina, US. "IDegLira patients achieved an end of trial mean HbA_{1c} of 6.6% while still experiencing weight reduction, and had significantly less hypoglycaemia than patients taking higher doses of insulin glargine."

There was a 57% lower rate of confirmed hypoglycaemia with Xultophy® compared with insulin glargine (2.23 episodes/patient-year vs 5.05 episodes/patient-year; $p<0.001$).[1] Additionally, there was a significant difference of 3.2 kg (7.1 lb) in change in body weight

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between treatment groups (p<0.001); body weight decreased by 1.4 kg (3.0 lb) from baseline for patients treated with Xultophy® and increased by 1.8 kg (4.0 lb) for patients treated with insulin glargine.[1] Patients treated with Xultophy® required significantly less insulin than patients treated with insulin glargine, demonstrated by the end-of- trial dose of 41 units of the insulin degludec component in Xultophy® versus 66 units respectively (p<0.001).[1]

In the DUAL™ V trial, there were similar rates of overall and serious adverse events in the two treatment groups.[1]

Also presented during the scientific meeting were additional patient-reported outcomes (PRO) data measured by TRIM-D (Treatment Related Impact Measure-Diabetes) and SF-36 v2 (Short-Form 36 Health Survey version 2) from DUAL™ V:

- Insulin Degludec/Liraglutide (IDegLira) Improves Patient-Reported Impacts in Subjects With Type 2 Diabetes (T2D) Inadequately Controlled on Insulin Glargine (IG) Plus Metformin (Met): DUAL™ V Study (Abstract #2550-PO).

About Xultophy®

Xultophy® is a once-daily single injection combination of Tresiba® (insulin degludec), a once-daily basal insulin analogue with an ultra-long duration of action and Victoza® (liraglutide), a once-daily human GLP-1 analogue.[2] The maximum dose of Xultophy® is 50 dose steps (equivalent to 50 units of insulin degludec and 1.8 mg of liraglutide). Xultophy® is being investigated in the DUAL™ clinical trial programme which includes two phase 3a and a number of phase 3b trials, encompassing more than 3,500 people with type 2 diabetes. Xultophy® was granted marketing authorisation by the European Commission on 18 September 2014 and approved in Switzerland on 12 September 2014.[2,3]

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 HbA_{1c} and to subsequently demonstrate superiority in HbA_{1c}, body weight and hypoglycaemia. The trial compared the efficacy and safety of Xultophy® versus insulin glargine, 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.[1,4]

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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 39,000 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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2. EMA. Xultophy® Summary of Product Characteristics. Available at: http://ec.europa.eu/health/documents/community-register/2014/20140918129550/anx_129550_en.pdf Last accessed: 03.02.2015.
3. SwissMedic. Xultophy®: Information for Professionals. 22.09.2014.
4. ClinicalTrials.gov. NCT01952145. A Trial Comparing the Efficacy and Safety of Insulin Degludec/Liraglutide Versus Insulin Glargine in Subjects With Type 2 Diabetes Mellitus (DUAL™ V). Available at: https://www.clinicaltrials.gov/ct2/show/study/NCT01952145?show_locs=Y#locn Last accessed: 03.02.2015.