

press release

New treatment shows significant reduction in blood sugar, body weight change*, and lower rate of hypoglycaemia versus insulin glargine

Gatwick, UK, 08 June 2015

New findings show adults with type 2 diabetes treated with Xultophy® ▼ (insulin degludec/liraglutide; IDegLira), demonstrated a significant reduction in blood sugar (measured by HbA_{1c}), change in body weight*, and a lower rate of hypoglycaemia compared with patients treated with insulin glargine.¹ Xultophy® is the first ever treatment combining two existing treatments, long acting (basal) insulin (insulin degludec, Tresiba® ▼)² and GLP-1 receptor agonist (liraglutide, Victoza®) in one pen.^{3,4}

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

At 26 weeks of the treat-to-target trial, patients randomised to the Xultophy® treatment achieved a statistically significant mean reduction in HbA_{1c} of 1.8% from baseline (8.4% to 6.6% (63.3mmol/mol to 48.6mmol/mol)) compared with a 1.1% reduction (8.2% to 7.1% (66.1mmol/mol to 54.1mmol/mol)) achieved by patients increasing their dose of insulin glargine (p<0.001).¹ In the Xultophy® group, 72% achieved an HbA_{1c} of <7% at the end of the trial, (versus 47% in the insulin glargine group (p<0.001)).¹ Three times as many Xultophy® patients (39% vs 12%; p<0.001) achieved an HbA_{1c} <7% without hypoglycaemia and weight gain compared to those treated with insulin glargine.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.”

In addition, the Xultophy® group had:

- A 57% lower rate of confirmed hypoglycaemia compared with insulin glargine (2.23 episodes/patient-year versus 5.05 episodes/patient-year; p<0.001)¹

** Xultophy® is not licensed for weight loss. Change in body weight from baseline was a secondary endpoint in DUAL™ V, a 26-week study in patients whose blood sugar was not controlled on insulin glargine and oral diabetes medication.¹*

- A decrease in body weight of 1.4kg (3.0lb) from baseline, compared to an increase of 1.8kg (4.0lb) for patients treated with insulin glargine. A significant difference of 3.2kg (7.1lb) in body weight change between treatment groups ($p < 0.001$)¹
- A significantly lower requirement for insulin than patients treated with insulin glargine, (end-of-trial dose of 41 units of the insulin degludec component in Xultophy[®] versus 66 units of insulin glargine $p < 0.001$).¹

In the DUAL™ V trial, there were similar rates of overall and serious adverse events in the two treatment groups.²

About Xultophy[®]

Xultophy[®] is a co-formulation of insulin degludec (Tresiba[®]), a once-daily basal insulin analogue with a long duration of action,² and liraglutide (Victoza[®]), a once-daily GLP-1 receptor agonist.^{3,4} Xultophy[®] is administered in “dose steps”, where each dose step contains one unit of insulin and 0.036mg of liraglutide. Xultophy[®] is priced lower than the sum of the two individual components, with each dose step costing less than 11 pence. For patients switching to Xultophy[®] from insulin, the starting dose is 16 dose steps, which will cost approximately £1.70 per day.

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} change from baseline as a primary objective, and to subsequently demonstrate superiority in HbA_{1c} reduction from baseline, rate of confirmed hypoglycaemia and change from baseline in body weight compared to insulin glargine. The trial compared the efficacy and safety of Xultophy[®] versus intensification of 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[®] of 50 dose steps (equivalent to 50 units of insulin degludec and 1.8mg of liraglutide) and there was no maximum daily dose of insulin glargine.^{1,5}

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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Date of preparation:
May 2015

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