

press release

New treatment can help adults with type 2 diabetes achieve better blood sugar control, with fewer treatment-related side effects

Gatwick, UK, 08 June 2015

Novo Nordisk today announced that Xultophy®▼ (insulin degludec/liraglutide; IDegLira), the first ever treatment combining two existing treatments, long acting (basal) insulin (insulin degludec, Tresiba®▼)¹ and GLP-1 receptor agonist (liraglutide, Victoza®)² in one pen, has been launched in the United Kingdom.

Xultophy® is indicated for the treatment of adults with type 2 diabetes mellitus to improve glycaemic control in combination with oral glucose-lowering medicinal products when these alone or combined with basal insulin do not provide adequate glycaemic control.³

Adults with type 2 diabetes taking once-daily Xultophy® (pronounced Zol-toe-fy) had a significant improvement in blood sugar (measured by HbA_{1c}).⁴ Additionally, Xultophy® was shown to have a secondary benefit of weight loss* and a low rate of hypoglycaemia (very low blood sugar), comparable to Tresiba®.⁵

In the UK, nearly three quarters of people with type 2 diabetes on basal insulin regimens fail to reach the recommended target for HbA_{1c} of 58mmol/mol ($\leq 7.5\%$) and are therefore at a greater risk of complications.⁶⁻¹⁰ Despite this, market research data for the year to September 2014 show that two thirds (67%) of people with type 2 diabetes who were prescribed long-acting insulin (as the only insulin) had no change to their insulin prescription during that 12-month period**.¹¹

Insulin is an effective diabetes treatment, but it is often delayed due to the risk or fear of hypoglycaemia – and also possible weight gain.¹² A reduction in HbA_{1c} can provide both a huge personal benefit and a significant cost saving through the reduction of complications. A one percentage point drop in HbA_{1c} can lead to a 37% reduction in microvascular complications, a 14% reduction in myocardial infarctions and a 21% reduction in overall diabetes-related mortality.⁹

Professor Steve Bain, Professor of Medicine (Diabetes) at Swansea University and Clinical Lead for the Diabetes Research Network, Wales, commented: "The availability of Xultophy® is a positive step forward, providing a new treatment option for the many people in the UK with type 2 diabetes who struggle to control their blood sugar. This has the potential to reduce complications and help ease the significant cost burden on the NHS."

** Xultophy® is not licensed for weight loss. Change in body weight from baseline was a secondary endpoint in DUAL™ II, a 26-week study in patients whose blood sugar was not controlled on long-acting insulin and oral diabetes medication.⁴*

*** These patients may or may not have had another diabetes treatment in combination with their current long-acting insulin during this period (MAT Sep 2014).*

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When taking Xultophy® in a Phase III trial over 26 weeks, people struggling to control their blood sugar on long acting insulin and oral diabetes medication were shown to have:

- Significant improvement in blood sugar (1.9% reduction in HbA_{1c})⁵
- Secondary benefits of:
 - Weight loss of 2.7kg from baseline^{5*}
 - Low rate of hypoglycaemia comparable to Tresiba®^{1,5}

Type 2 diabetes affects three million people in the UK and this is expected to rise to five million in 2025.¹³ Type 2 diabetes currently costs the NHS over £10 billion per year, with around 80% of this cost because of often preventable complications.¹⁴ These include blindness, amputations and kidney failure.

Commenting on the availability of Xultophy®, Gwen Hall, Diabetes Specialist Nurse, Haslemere Health Centre, Surrey said: "Many people with type 2 diabetes would benefit from intensifying their basal insulin treatment but face additional barriers in terms of hypoglycaemia, weight gain and a potential increase in the number of daily injections they have to take, meaning their diabetes is not optimally controlled. The data from the clinical trials suggest that once-daily Xultophy® could help to reduce some of the obstacles people face and it is very welcome news that it is available for patients."

Xultophy® is now available in the UK.

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Further information

About Xultophy® (insulin degludec/liraglutide; IDegLira)

Xultophy® is a combination of Tresiba®, (insulin degludec) a once-daily basal insulin analogue with a long duration of action¹ and Victoza® (liraglutide), a once-daily GLP-1 receptor agonist.² 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.

** Xultophy® is not licensed for weight loss. Change in body weight from baseline was a secondary endpoint in DUAL™ II, a 26-week study.⁴*

About the DUAL™ programme

DUAL™ (DUal Action of Liraglutide and insulin degludec in type 2 diabetes) consists of two Phase 3a (DUAL™ I and II) trials encompassing around 2,000 adults with type 2 diabetes and three Phase 3b trials (DUAL™ III, IV and V).

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.⁴

DUAL™ I Extension

26-week extension phase of the main trial was conducted to generate longer-term safety and efficacy data. The results confirmed that the benefits seen in the DUAL™ I trial were sustained up to 52 weeks.¹⁵

DUAL™ II

(398 people) – a 26-week, randomised, parallel, two-arm, double-blinded, multicentre trial conducted at 75 sites across seven countries. The trial compared the efficacy and safety of Xultophy® and Tresiba® 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 sulphonylureas/glinides. Sulphonylureas and glinides were discontinued at randomisation. In this trial, the allowed maximum dose of insulin degludec in the treatment arms was 50 units, so as to be able to demonstrate the contribution of the Victoza® component of Xultophy® on blood glucose control (maximum dose for Xultophy® is 50 dose steps).⁵

In DUAL™ II Xultophy® demonstrated:

- 1.9% HbA_{1c} reduction (-1.9% vs -0.89%; p<0.0001)⁵
- Secondary benefits of:
 - Weight loss of 2.7kg from baseline (-2.7kg vs 0.0kg; p<0.001)⁵
 - Low rate of hypoglycaemia comparable to Tresiba®¹ (1.5 episodes/year versus 2.6 episodes per year; p=0.13)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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