Xultophy® reported a better option than basal-bolus insulin therapy to manage type 2 diabetes by participants in the DUAL VII clinical trial

Abu Dhabi, UAE, 5 December 2017 - Once-daily Xultophy® (insulin degludec/liraglutide) was a better option to manage diabetes compared to multiple daily injections of insulin (basal-bolus regimen). This was reported by people with type 2 diabetes whose blood sugar was not controlled on insulin glargine U100 with metformin, and who completed quality-of-life questionnaires as part of the DUAL VII clinical trial. In addition, more people preferred to stay on Xultophy® compared with basal-bolus therapy (84.5% versus 68.1%). These results were presented today at the 2017 International Diabetes Federation Congress in Abu Dhabi, UAE.

"Adding insulin injections at mealtime is an effective option to achieve desired blood glucose levels when basal insulin is not enough, but this raises the level of complexity in the patients’ daily management of their diabetes. It can also lead to an increased risk of hypoglycaemia (low blood sugar) or weight gain”, said Professor Esteban Jódar, University Hospital Quirón Salud, Madrid, Spain. “In the main analysis of the DUAL VII trial, Xultophy® delivered similar glucose reductions to a basal-bolus regimen alongside weight loss, as opposed to weight gain, and fewer episodes of hypoglycaemia. We now see that it also reduces treatment burden.”

In the patient-reported outcomes (PRO) analysis from the DUAL VII clinical trial, 506 adults living with type 2 diabetes assessed their physical health, mental health and a number of diabetes-specific factors. These scores were measured using the validated Treatment-Related Impact Measure-Diabetes (TRIM-D) questionnaire and the Short Form Health Survey 36 v2 (SF-36). The participants in the study treated with Xultophy® reported better experiences for all diabetes-specific factors compared to the ones in the basal-bolus treatment regimen, with the highest improvement in TRIM-D scores given for diabetes management (16.7 versus 6.8), treatment burden (12.4 versus 4.3) and compliance (9.1 versus 3.9). The analysis of the SF-36 questionnaire results found that Xultophy® was associated with a statistically significant higher score compared to basal-bolus insulin regimen for the mental health component of the questionnaire; all other comparisons were non-significant.
“Living with diabetes is a complex situation in itself, and the treatment should not add to this. We are very pleased to see that Xultophy® not only helps people with type 2 diabetes reach their blood glucose targets while reducing the risk of hypoglycaemia and helping them to lose weight, but does this in a simple way”, said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “This is a key component of what innovation in diabetes means to us. It’s about making the lives of people with diabetes as easy as possible.”

About the analysis
This analysis is based on PRO data collected during the DUAL VII clinical trial using different health questionnaires. The TRIM-D questionnaire is specific to diabetes. The SF-36 is a generic health questionnaire used to assess quality of life measures. Motivation to stay on treatment was measured using an additional motivation questionnaire.1

In DUAL VII, Xultophy® induced greater improvements in PROs, mainly in outcome measures related to diabetes management, treatment burden and compliance versus basal-bolus therapy in people with HbA1c 7.0-10% switched from insulin glargine U100 with metformin. People on Xultophy® had an equal reduction in HbA1c, a lower rate of hypoglycaemia, fewer injections per day and weight loss versus basal-bolus insulin treatment. Improvement in the PRO measurements with Xultophy® corresponded with desirable clinical outcomes. The open-label nature of the trial was a limitation and could have influenced the results.1

Changes in PRO scores were calculated from baseline after 26 weeks of treatment. Per definition, PRO data came directly from patients, without interpretation of the patient’s response by a clinician or anyone else.2

About DUAL VII
DUAL VII was a phase 3b, 26-week, randomised, open-label, multicentre trial conducted in 12 countries including 506 patients.3 The trial was designed to investigate the safety and efficacy of Xultophy® versus basal-bolus therapy in adults with type 2 diabetes previously treated with insulin glargine U100 and metformin.3

About Xultophy®
Xultophy® is a once-daily single injection fixed-ratio combination of long-acting insulin degludec and the glucagon-like peptide-1(GLP-1) receptor agonist liraglutide in one pen. It 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 a GLP-1 receptor agonist or basal insulin do not provide adequate glycaemic control. Xultophy® can be administered at any time of the day with or without meals, preferably at the same time of the day.4
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 obesity, haemophilia, growth disorders and other serious chronic diseases. Headquartered in Denmark, Novo Nordisk employs approximately 41,700 people in 77 countries and markets its products in more than 165 countries. For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube

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