company announcement

Novo Nordisk receives US FDA approval for Xultophy® 100/3.6

Bagsværd, Denmark, 21 November 2016 – Novo Nordisk today announced that the US Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for Xultophy® 100/3.6. Xultophy® 100/3.6 is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus inadequately controlled on basal insulin (less than 50 units daily) or liraglutide (less than or equal to 1.8 mg daily).

Xultophy® 100/3.6, the approved brand name for IDegLira in the US, is a once-daily, single injection fixed combination of long-acting insulin degludec (Tresiba®) and the GLP-1 analogue liraglutide (Victoza®). In the DUAL phase 3 clinical trial programme, Xultophy® 100/3.6 consistently showed an improvement of glycaemic control in adults with type 2 diabetes uncontrolled on liraglutide or basal insulin therapy. For adults inadequately controlled on insulin glargine U100, treatment with Xultophy® 100/3.6 demonstrated a reduction in HbA_{1c} of 1.7% after 26 weeks. Xultophy® 100/3.6 can be taken at the same time each day with or without food and will be available in a prefilled pen.

"We are pleased with the approval of Xultophy® 100/3.6 and look forward to launching it in the US in the first half of 2017", said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "We believe Xultophy® 100/3.6 offers significant benefits and is an important and convenient treatment option especially for people not achieving sufficient glycaemic control with basal insulin".

The approval follows the recommendation of the FDA's Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC), which voted 16–0 in favour of an approval of Xultophy® 100/3.6 for the treatment of adults with type 2 diabetes, at its meeting on 24 May 2016.

About Xultophy® 100/3.6

Xultophy® 100/3.6 is a once-daily, single injection fixed combination of long-acting insulin degludec (Tresiba®) and the GLP-1 analogue liraglutide (Victoza®). The Xultophy®

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100/3.6 pen delivers doses from 10 to 50 units with each injection. Each unit of Xultophy® 100/3.6 contains 1 unit of insulin degludec and 0.036 mg of liraglutide.

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 42,600 people in 75 countries and markets its products in more than 180 countries. Novo Nordisk's B shares are listed on Nasdaq Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube

Further information

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