FDA approves inclusion of data on cardiovascular outcomes and severe hypoglycaemia in the Tresiba® label

Bagsværd, Denmark, 26 March 2018 - Novo Nordisk today announced that the US Food and Drug Administration (FDA) has approved an update to the US prescribing information for Tresiba® (insulin degludec) to include data from the DEVOTE trial.

The DEVOTE trial included 7,637 adults with type 2 diabetes at high cardiovascular risk and demonstrated non-inferiority of Tresiba® compared to insulin glargine U100 with regards to major adverse cardiovascular events (MACE) with a hazard ratio of 0.91. MACE was defined as first occurrence of cardiovascular death, non-fatal myocardial infarction or non-fatal stroke.

As a pre-specified secondary end-point, treatment with Tresiba® resulted in 40% statistically significant lower rate of severe hypoglycaemia compared to insulin glargine U100. The glycaemic control between the two groups was similar at baseline and throughout the trial. The Tresiba® label was updated to reflect safety outcomes from the trial, the cardiovascular safety as well as the severe hypoglycaemia data.

Furthermore, supplemental applications were submitted to the FDA in September 2016 for including data from the two SWITCH phase 3b trials in the label for Tresiba®. Following interactions with FDA, Novo Nordisk has withdrawn the applications related to the data from the SWITCH trials.

"It is well known that the fear of severe hypoglycaemia is a barrier to achieving good glycaemic control for many people with diabetes," said Mads Krosggaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "We are therefore very pleased that the FDA has approved the updated label for Tresiba® as the only basal insulin to be labelled with a lower rate of severe hypoglycaemia compared to insulin glargine U100."

The EU label for Tresiba® was updated in 2017 to reflect both the cardiovascular outcomes as well as the severe hypoglycaemia data of this long-acting basal insulin.
About DEVOTE
DEVOTE is a multinational, double-blinded clinical trial which investigated the cardiovascular safety of Tresiba® compared with insulin glargine U100 over 104 weeks. DEVOTE is the first cardiovascular outcomes trial (CVOT) comparing two basal insulins and enrolled 7,637 people with type 2 diabetes. All participants were inadequately controlled with type 2 diabetes and atherosclerotic cardiovascular disease and were already receiving standard of care to reduce their cardiovascular risk. The trial demonstrated that Tresiba® does not increase cardiovascular risk compared with insulin glargine U100, and provides a significant reduction in the rate of severe hypoglycaemia at similar levels of glycaemic control.

About SWITCH 1 and 2
The two phase 3b, 2x32-weeks randomised, double-blind, cross-over, treat-to-target trials were initiated in January 2014 to compare the safety profile and efficacy of Tresiba® and insulin glargine U100. In the trials, adults were treated for a 16-week titration period followed by a 16-week maintenance period and subsequently switched to the comparator drug. The overall objective was to document the hypoglycaemia profile in type 1 diabetes and type 2 diabetes, respectively. In SWITCH 1, 501 people with type 1 diabetes were randomised to cross-over treatment with Tresiba® and insulin glargine U100 in combination with insulin aspart. In SWITCH 2, 721 people with type 2 diabetes were randomised to cross-over treatment with Tresiba® and insulin glargine U100 in combination with oral antidiabetic drugs.

About Tresiba®
Tresiba® (insulin degludec) is a once-daily basal insulin that provides a duration of action beyond 42 hours with a flat and stable glucose-lowering effect. It provides low variability in blood glucose levels and a lower risk of overall, nocturnal and severe hypoglycaemia vs insulin glargine U100. On occasions when administration at the same time of day is not possible, Tresiba® allows for flexibility in day-to-day dosing time with a minimum of eight hours between injections. Tresiba® received its first regulatory approval in September 2012 and has since been approved in more than 80 countries globally. Tresiba® was approved by the FDA on 26 September 2015 and it is now commercially available in more than 50 countries.
Novo Nordisk is a global healthcare company with 95 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 42,100 people in 79 countries and markets its products in more than 170 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

Media:
Katrine Sperling +45 3079 6718 krsp@novonordisk.com
Ken Inchausti (US) +1 609 786 8316 kiau@novonordisk.com

Investors:
Peter Hugreff Ankersen +45 3075 9085 phak@novonordisk.com
Anders Mikkelsen +45 3079 4461 armk@novonordisk.com
Christina Kjær +45 3079 3009 cnje@novonordisk.com