company announcement

Ozempic® (semaglutide) approved in the US

Bagsværd, Denmark, 5 December 2017 - Novo Nordisk today announced that the US Food and Drug Administration (FDA) has approved Ozempic® (semaglutide injection). Ozempic® is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus.

Ozempic®, the approved brand name for once-weekly semaglutide in the US, is a glucagon-like peptide 1 (GLP-1) receptor agonist. The approval of Ozempic® is based on the results from the SUSTAIN clinical trial programme and follows a positive recommendation from an FDA Advisory Committee meeting on 18 October 2017. In people with type 2 diabetes, Ozempic® produced clinically meaningful and statistically significant reductions in HbA_{1c} compared with placebo, sitagliptin, exenatide extended-release and insulin glargine U100. Furthermore, in the trials, treatment with Ozempic® resulted in statistically significant reductions in body weight. Ozempic® demonstrated a safe and well-tolerated profile across the SUSTAIN programme with the most common adverse event being mild to moderate nausea, which diminished over time.

Ozempic® is approved for use in two therapeutic dosages, 0.5 mg and 1 mg, and will be launched in the Ozempic® Pen, the latest generation of Novo Nordisk prefilled devices.

Novo Nordisk will, as part of the post-approval requirements, conduct a paediatric trial in adolescents under 18 years of age and will add Ozempic® to the 15-year MTC (medullary thyroid carcinoma) registry that is being conducted for all other long-acting GLP-1 products.

"We are very excited about the first approval of Ozempic® and look forward to making this important innovation available to people in the US with type 2 diabetes in the beginning of 2018," said Mads Krogsgaard Thomsen, executive vice president and chief science officer. "Type 2 diabetes is a complex disease, but with the unique clinical profile of Ozempic®, we believe it has the potential to set a new standard for the treatment of the disease."

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Conference call

On 6 December 2017 at 12.00 pm CET, corresponding to 6.00 am EST, a conference call for investors will be held. Investors will be able to listen in via a link on the investor section of novonordisk.com.

About Ozempic®

Ozempic® (semaglutide) is a once-weekly analogue of human glucagon-like peptide-1 (GLP-1) that has been developed for the treatment of type 2 diabetes. The review of Ozempic® is based on the SUSTAIN programme, a global clinical development programme that comprises eight phase 3a trials, encompassing more than 8,000 adults with type 2 diabetes. The phase 3a programme involves a broad range of people with type 2 diabetes, including some with high cardiovascular risk profiles and people with and without renal disease.

Ozempic® is currently under review by several regulatory agencies, including the European Medicines Agency and the Japanese Pharmaceuticals and Medical Devices Agency.

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. 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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