company announcement

Novo Nordisk files for regulatory approval in the US of once-weekly semaglutide 2.0 mg for the treatment of type 2 diabetes

Bagsværd, Denmark, 20 January 2021 – Novo Nordisk today announced the submission of a label expansion application to the US Food and Drug Administration (FDA) for the existing marketing authorisation for Ozempic®, a once-weekly glucagon-like peptide-1 (GLP-1) analogue, to introduce a new dose of 2.0 mg. Ozempic® is currently approved in the US in 0.5 mg and 1.0 mg doses for the treatment of type 2 diabetes in adults and to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease. The submission follows the application on 29 December 2020 for label extension to the European Medicines Agency (EMA).

The submission is based on the results from the SUSTAIN FORTE trial, which included 961 people with type 2 diabetes in need of treatment intensification. In the trial, people treated with semaglutide 2.0 mg achieved a statistically significant and superior reduction in HbA_{1c} compared to semaglutide 1.0 mg. In the trial, both doses of semaglutide appeared to have safe and well-tolerated profiles. The most common adverse events were gastrointestinal, the vast majority were mild to moderate and diminished over time and were consistent with the GLP-1 receptor agonist class. Compared to semaglutide 1.0 mg, the gastrointestinal adverse events were similar for semaglutide 2.0 mg.

“We are excited about the regulatory submission of semaglutide 2.0 mg to the FDA,” said Mads Krogsgaard Thomsen, executive vice president and chief scientific officer of Novo Nordisk. “In the SUSTAIN programme most people achieved the treatment target of HbA_{1c} levels below 7%. However, some patients need treatment intensification and with the 2.0 mg dose, more people with type 2 diabetes will be able to achieve treatment target”.

About the SUSTAIN clinical programme
The SUSTAIN clinical development programme for once-weekly subcutaneous semaglutide injection currently comprises 11 phase 3 global clinical trials, including a cardiovascular outcomes trial, involving more than 11,000 adults with type 2 diabetes.

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For more information about the SUSTAIN FORTE trial, please read the headline results here

About Novo Nordisk

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat diabetes and other serious chronic diseases such as obesity and rare blood and endocrine disorders. We do so by pioneering scientific breakthroughs, expanding access to our medicines and working to prevent and ultimately cure disease. Novo Nordisk employs about 44,000 people in 80 countries and markets its products in around 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

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