

company announcement

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

Bagsværd, Denmark, 29 December 2020 – Novo Nordisk today announced the submission of a label extension application to the European Medicines Agency (EMA) 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 EU in 0.5 mg and 1.0 mg doses for the treatment of type 2 diabetes in adults.

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} at week 40 compared to semaglutide 1.0 mg. In the trial, both doses of semaglutide appeared safe and well-tolerated. 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.

“Following the announcement of the headline results in November, we have expeditiously prepared the submission file. The submission in the EU represents an important milestone for people living with type 2 diabetes who have poor glycaemic control and need treatment intensification” said Mads Krogsgaard Thomsen, executive vice president and chief scientific officer of Novo Nordisk. “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.

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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