

company announcement

Ozempic® 2.0 mg approved in the US for the treatment of type 2 diabetes

Bagsværd, Denmark, 28 March 2022 – Novo Nordisk today announced that the US Food and Drug Administration (FDA) has approved a 2.0 mg dose of Ozempic® (once-weekly semaglutide subcutaneous injection), a glucagon-like peptide-1 (GLP-1) analogue for the treatment of adults with type 2 diabetes. Ozempic® is now approved in the US at 0.5 mg, 1.0 mg and 2.0 mg doses for the treatment of type 2 diabetes in adults. Further, Ozempic® is indicated to reduce the risk of major cardiovascular events such as heart attack, stroke or death in adults with type 2 diabetes and known heart disease.

The FDA approval is based on the results from the SUSTAIN FORTE trial. 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 to have a safe and well-tolerated profile. The most common adverse events were gastrointestinal. Compared to semaglutide 1.0 mg, the gastrointestinal adverse events were similar for semaglutide 2.0 mg.

“We are pleased with the FDA approval for a higher 2.0 mg dose of Ozempic®, which further supports our purpose of driving change in diabetes care” said Martin Lange, executive vice president, Development at Novo Nordisk. “The approval of the 2.0 mg dose allows more people with type 2 diabetes to achieve and maintain individualised glycaemic targets and remain on the same medication for longer as their needs evolve.”

Novo Nordisk expects to launch Ozempic® 2.0 mg in the United States in the second quarter of 2022. Ozempic® 2.0 mg is now approved in the US, the EU, Canada and Switzerland.

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 47,800 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](https://www.novonordisk.com), [Facebook](#), [Twitter](#), [LinkedIn](#) and [YouTube](#).

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