

# company announcement

## **Ozempic® 2.0 mg recommended for approval for the treatment of type 2 diabetes by the European Medicines Agency**

**Bagsværd, Denmark**, 12 November 2021 – Novo Nordisk today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending a label extension 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 positive opinion 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<sub>1c</sub> 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.

“The recommendation for the EU label extension of Ozempic® with the 2.0 mg dose is an important step towards offering additional options to people with type 2 diabetes who need treatment intensification to achieve their individualised glycaemic targets,” said Martin Lange, executive vice president, Development at Novo Nordisk.

Novo Nordisk expects a final approval by the European Commission within approximately two months, and Ozempic® 2.0 mg will be launched in the EU in the first half of 2022. The label expansion for semaglutide 2.0 mg is under regulatory review in the US.

### **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](#).

*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 47,000 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](http://novonordisk.com), [Facebook](#), [Twitter](#), [LinkedIn](#) and [YouTube](#).*

## **Further information**

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