

# company announcement

## Wegovy® pill approved in the US as first oral GLP-1 for weight management

- Wegovy® pill showed a mean weight loss of 16.6% in the OASIS 4 trial<sup>1</sup>
- Wegovy® pill is indicated to reduce excess body weight and maintain weight reduction long-term and to reduce the risk of major adverse cardiovascular events\*
- Novo Nordisk expects to launch Wegovy® pill in the US in early January 2026

**Bagsværd, Denmark, 22 December 2025** – Novo Nordisk today announced that the US Food and Drug Administration (FDA) has approved the Wegovy® pill (once-daily oral semaglutide 25 mg) to reduce excess body weight and maintain weight reduction long term and to reduce the risk of major adverse cardiovascular events\*.

The Wegovy® pill is the first oral glucagon-like peptide-1 (GLP-1) receptor agonist therapy approved for weight management. The approval is based on the OASIS trial programme and the SELECT trial<sup>2</sup>. In the OASIS 4 trial, oral semaglutide 25 mg taken once daily demonstrated 16.6% mean weight loss when treatment was adhered to in adult participants with obesity or overweight with one or more comorbidities<sup>1</sup>. The weight loss achieved with the Wegovy® pill is similar to that of injectable Wegovy® 2.4 mg. Furthermore, one in three people experienced 20% or greater weight loss in the OASIS 4 trial<sup>1</sup>. The well-known safety and tolerability profile of semaglutide was reaffirmed with the Wegovy® pill in the OASIS-4 trial, which was comparable to previous trials with semaglutide for weight management.

“The pill is here. With today’s approval of the Wegovy® pill, patients will have a convenient, once-daily pill that can help them lose as much weight as the original Wegovy® injection,” said Mike Doustdar, president and CEO of Novo Nordisk. “As the first oral GLP-1 treatment for people

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\*CV death, non-fatal myocardial infarction, or non-fatal stroke

<sup>1</sup>Based on the trial product estimand: treatment effect if all people adhered to treatment

<sup>2</sup>Supported with data from the STEP trial programme and the PIONEER PLUS trial

living with overweight or obesity, the Wegovy® pill provides patients with a new, convenient treatment option that can help patients start or continue their weight loss journey. No other current oral GLP-1 treatment can match the weight loss delivered by the Wegovy® pill, and we are very excited for what this will mean for patients in the US”.

Novo Nordisk expects to launch the Wegovy® pill in the US in early January 2026. Novo Nordisk has submitted oral semaglutide 25 mg once-daily for obesity to the European Medicines Agency (EMA) and other regulatory authorities during the second half of 2025.

### **About the OASIS trial programme**

OASIS was a phase 3 clinical development programme with once-daily oral semaglutide 25 mg and 50 mg in obesity. The global clinical phase 3 programme consisted of four trials, enrolling approximately 1,300 adults with obesity or overweight with one or more comorbidities.

OASIS 4 was a 64-week efficacy and safety phase 3b trial of once-daily oral semaglutide 25 mg versus placebo in 307 adults with obesity or overweight with one or more comorbidities.

### **About Wegovy®**

Wegovy® is now approved as once-daily Wegovy® pill (semaglutide tablet 25 mg) and once-weekly Wegovy® injection (semaglutide injectable 2.4 mg) by the FDA. The approval of Wegovy® pill is based on a New Drug Application to reduce excess body weight in adults with obesity or overweight with at least one weight-related medical condition.

Wegovy® is approved as a once-weekly injection by the EMA and widely by other regulatory authorities. The Wegovy® pill is currently pending marketing approval from the EMA and other regulatory authorities.

Wegovy® is indicated to reduce excess body weight and maintain weight reduction long term in adults with obesity or overweight and in the presence of at least one weight-related comorbid condition, and approved by the FDA to reduce the risk of major adverse cardiovascular events, such as death, heart attack or stroke in adults with known heart disease and either obesity or overweight. Furthermore, Wegovy® injection is indicated to reduce excess body weight and maintain weight reduction long term in paediatric patients aged 12 years and older, and approved by the FDA for the treatment of MASH in adults with moderate to advanced liver scarring (fibrosis), but not with cirrhosis of the liver.

### **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 serious chronic diseases built upon our heritage in diabetes. We do so by pioneering scientific breakthroughs, expanding access to our medicines and working to prevent and ultimately cure disease. Novo Nordisk*

*employs about 78,500 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://novonordisk.com), [Facebook](#), [Instagram](#), [X](#), [LinkedIn](#) and [YouTube](#).*

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