company announcement

Wegovy® pill (oral semaglutide) recommended by CHMP for approval in the EU as the first oral GLP-1 representing the most efficacious oral obesity treatment in its class

- With a mean weight loss of 16.6%[1], Wegovy® pill demonstrates best-in-class weight-loss efficacy and is the first oral GLP-1 treatment recommended by CHMP for weight management in the EU.
- CHMP recommends Wegovy® pill for approval to reduce excess body weight and maintain long-term weight reduction. The recommendation also includes data from SELECT which demonstrates that Wegovy® reduces the risk of major adverse cardiovascular events (MACE)*, in the label.
- Wegovy® pill is the only oral GLP-1 treatment with no drug-drug restrictions in the label.
- Novo Nordisk plans to launch Wegovy® pill in select markets outside the US in the second half of 2026.

Bagsværd, Denmark, 22 May 2026 – Novo Nordisk today announced that the Committee for Medicinal Products for Human Use (CHMP) under the European Medicines Agency (EMA) has adopted a positive opinion, recommending marketing authorisation of Wegovy® pill (once-daily oral semaglutide 25 mg) to reduce excess body weight and maintain long-term weight reduction. The positive opinion also includes SELECT data in the label, demonstrating that Wegovy® reduces the risk of major adverse cardiovascular events (MACE)*.

Wegovy® pill is the first oral glucagon-like peptide-1 (GLP-1) receptor agonist therapy recommended for approval by CHMP for weight management in the EU. The recommendation is based on the OASIS trial programme and the SELECT[2] trial. 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[1]. The weight loss achieved with 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[1].

*Includes cardiovascular death, non-fatal heart attack (myocardial infarction) or non-fatal stroke.

[1]Based on the trial product estimand from OASIS 4 trial, ie treatment effect if all people adhered to treatment.

[2]Supported with data from the STEP trial programme and the PIONEER PLUS trial.

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The well-known safety and tolerability profile of semaglutide was reaffirmed with Wegovy® pill in the OASIS 4 trial, which was comparable to previous semaglutide trials for weight management. Semaglutide is supported by more than 50 million patient-years of real-world safety data, and notably, the Wegovy® pill label includes no drug–drug restrictions with concomitant medications.

“We are encouraged by CHMP’s positive opinion for Wegovy® pill, bringing the most efficacious oral GLP-1 in its class one step closer to becoming the first approved oral treatment in its class for weight management in the EU”, said Mike Doustdar, president and CEO of Novo Nordisk. “The demand for effective and convenient obesity treatment is already evident in the U.S., where more than 1 million Americans began using Wegovy® pill within the first four months following launch. We look forward to bringing this innovative medicine to the first markets outside the US in the second half of 2026.”

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®

Once-weekly Wegovy® injection (2.4 mg and 7.2 mg) is approved by the FDA, EMA and other regulatory authorities worldwide. Wegovy® is approved as once-daily Wegovy® pill (semaglutide 25 mg) by the FDA. 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 long-term weight reduction in paediatric patients aged 12 years and older. It is approved by the FDA for the treatment of MASH in adults with moderate to advanced liver scarring (fibrosis), but not in those 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 67,900 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, Instagram, X, LinkedIn and YouTube.

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