press release

New Wegovy® dose submitted to European Medicines Agency for approval, with 1 in 3 trial participants achieving 25% or more weight loss

Bagsværd, Denmark, 8 July 2025 – Novo Nordisk today announced the submission of an application to the European Medicines Agency (EMA) for approval of a new, higher dose of its obesity treatment, Wegovy® (subcutaneous semaglutide 7.2 mg). This marks another significant milestone in the company's goal to provide a broad portfolio of innovative and person-centric solutions to support people living with obesity, as part of their journey towards better health.

The submission to the EMA is based on clinical data from the STEP UP and STEP UP T2D trials, investigating the efficacy and safety of semaglutide 7.2 mg in adults with obesity in STEP UP, and adults with obesity and type 2 diabetes in STEP UP T2D.[1] In the STEP UP trial, the new dose of Wegovy® (semaglutide 7.2 mg) demonstrated a substantial average weight loss of 21% in people with obesity, with a third of participants losing 25% or more of their body weight compared with placebo.[1*] Data also indicated that semaglutide 7.2 mg had a well-tolerated safety profile consistent with semaglutide 2.4 mg and the previous, robust, Novo Nordisk semaglutide trials.[1]

"The submission of this new dose of Wegovy® is another step forward in providing innovative solutions that meet the specific needs of people with obesity," said Ludovic Helfgott, executive vice president and head of Product & Portfolio Strategy at Novo Nordisk. "This new dose was developed as a tailored option for people in need of additional support to achieve meaningful, sustained weight loss. With a reaffirmed safety and tolerability profile, we strongly believe in its potential to help even more people with obesity reach their individual weight loss as well as their broader health goals, including improvements in cardiovascular and kidney health, liver disease, type 2 diabetes and mobility through knee osteoarthritis pain reduction."

In addition to the submission to the EMA, Novo Nordisk aims to make the higher dose of Wegovy® widely available throughout the EU.

* Based on the trial product estimand: treatment effect if all people adhered to treatment.

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About the STEP UP trials

Novo Nordisk has completed two trials, STEP UP and STEP UP T2D, investigating the efficacy and safety of semaglutide 7.2 mg in people with obesity with or without type 2 diabetes.

The 72-week STEP UP trial was a randomised, double-blinded, parallel-group, placebo-controlled, superiority trial designed to evaluate the efficacy and safety of semaglutide 7.2 mg compared to semaglutide 2.4 mg and placebo as an adjunct to lifestyle intervention. The trial included 1,407 adults with a BMI ≥30 kg/m^2 without diabetes. The primary objective was to demonstrate the superiority of semaglutide 7.2 mg against placebo on weight loss. Key confirmatory secondary endpoints included the number of participants achieving 10%, 15%, 20% and 25% weight loss, respectively.

The 72-week STEP UP T2D trial investigated semaglutide 7.2 mg in 512 adults with obesity and type 2 diabetes, with the primary objective to demonstrate superiority of semaglutide 7.2 mg against placebo on weight loss.

About Wegovy®

Semaglutide 2.4 mg is marketed under the brand name Wegovy®. In the EU, Wegovy® is indicated as an adjunct to a reduced calorie diet and increased physical activity for weight management in adults with a BMI of 30 kg/m^2 or greater (obesity) or adults with a BMI of 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition. In the EU, Wegovy® is also indicated for paediatric patients aged 12 years and older with an initial BMI at the 95th percentile or greater for age and gender (obesity) and body weight above 60 kg. The clinical section of the label also includes data on Wegovy® major adverse cardiovascular events (MACE) risk reduction, improvements in HFpEF-related symptoms and physical function, as well as pain reduction related to knee osteoarthritis.

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 77,400 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.com, Facebook, Instagram, X, LinkedIn and YouTube.

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References

1. Wharton, S, et al. (2025). Once-weekly semaglutide 7.2 mg in adults with obesity: the randomised, controlled, phase 3b STEP UP trial. 1966-LB poster. American Diabetes Association (ADA) 85th Scientific Sessions, Chicago, US, June 20 – 23, 2025.