press release

Novo Nordisk files for FDA approval of a higher dose of Wegovy® injection 7.2 mg

- If approved, investigational semaglutide 7.2 mg injection would offer the optionality of a higher dose for greater weight loss potential in adults with obesity[1,2]
- In the STEP UP phase 3 trial, adults with obesity taking semaglutide 7.2 mg as directed lost an average of 20.7% body weight[2,3*]
- The supplemental New Drug Application (sNDA) will be reviewed under the FDA's Commissioner's National Priority voucher (CNPV) pilot, which accelerates review for products addressing major national health priorities[1]

Plainsboro, NJ, US and Bagsværd, Denmark, November 26, 2025 – Today, Novo Nordisk announced the submission of a sNDA to the U.S. Food and Drug Administration (FDA) for a higher dose of semaglutide injection 7.2 mg, to be used along with a reduced-calorie diet and increased physical activity for chronic weight management in adults with obesity.[1] Under the CNPV expedited program, review is expected within 1–2 months following the FDA's acceptance of the filing.

"Our pipeline is rapidly expanding to meet the needs of people living with obesity, and this submission—under the FDA's new expedited review program—marks an exciting step forward," said Anna Windle, PhD, senior vice president, Clinical Development, Medical and Regulatory Affairs, Novo Nordisk. "If approved, semaglutide 7.2 mg would bring patients and healthcare professionals a new option for greater weight loss potential, further underlining the efficacy that the semaglutide molecule can bring. We look forward to working with the FDA to bring this fast-tracked option to the obesity community."

The sNDA includes results from STEP UP, a 72-week phase 3, randomized, double-blind, placebo controlled and active-controlled superiority trial that evaluated the efficacy and safety of once-weekly semaglutide 7.2 mg compared to placebo and semaglutide 2.4 mg, as an adjunct to lifestyle intervention, in 1,407 adults with obesity (BMI ≥30 kg/m^2).[2] Patients with diabetes were excluded.[2]

From a mean baseline body weight of 249 pounds, people treated with semaglutide 7.2 mg in the STEP UP trial achieved an average weight loss of 20.7% after 72 weeks compared to a reduction of 17.5% with semaglutide 2.4 mg and 2.4% with placebo, when patients adhered to

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treatment.[2*] In addition, 33.2% of those who received semaglutide 7.2 mg achieved a weight loss of 25% or more after 72 weeks, compared to 16.7% with semaglutide 2.4 mg and 0.0% with placebo. When assessed to include those who discontinued, people treated with semaglutide 7.2 mg achieved weight loss of 18.7% compared to a reduction of 15.6% with semaglutide 2.4 mg and 3.9% with placebo. 90.7% of participants taking semaglutide 7.2 mg achieved a body weight reduction of greater than or equal to 5%, compared to 89.9% and 36.8% for semaglutide 2.4 mg and placebo, respectively. Also, 31.2% of those who received semaglutide 7.2 mg achieved a weight loss of 25% or more after 72 weeks, compared to 15.3% for semaglutide 2.4 mg and 0.0% for placebo.[2**]

Gastrointestinal adverse events were more common with semaglutide 7.2 mg versus 2.4 mg or placebo, as was dysaesthesia. Serious adverse events were reported by 6.8% of participants with semaglutide 7.2 mg, 10.9% with semaglutide 2.4 mg, and 5.5% with placebo.[2]

The new, higher dose of Wegovy® (semaglutide 7.2 mg) is currently under review with the European Medicines Agency (EMA), in the UK and several other countries. In the EU, Novo Nordisk expects a regulatory decision in Q1 2026.

[*] Based on the trial product estimand; estimated treatment effect if all participants adhered to treatment.

[**] Based on the treatment policy estimand: treatment effect regardless of treatment adherence

About the STEP UP trial

The 72-week STEP UP trial was a randomized, double-blinded, parallel-group, placebo-controlled and active-controlled superiority trial designed to evaluate the efficacy and safety of once-weekly semaglutide 7.2 mg compared to placebo and semaglutide 2.4 mg as an adjunct to lifestyle intervention.[2] 1,407 adults with BMI ≥30 kg/m^2 without diabetes were included in the trial. The primary objective was to demonstrate superiority of semaglutide 7.2 mg against placebo after 72 weeks with respect to the percentage change in body weight and the proportion of participants with weight loss of 5% or greater. Select confirmatory secondary endpoints included proportion of participants achieving greater than or equal to 10%, 15%, 20% and 25% weight loss, with semaglutide 7.2 mg vs placebo. [2]

About obesity

Obesity is a serious chronic, progressive and complex disease that requires long-term management.[4-6] One key misunderstanding is that this is a disease of just lack of willpower, when in fact there is underlying biology that may impede people with obesity from losing weight and keeping it off.[4,6] Obesity is influenced by a variety of factors, including genetics, social determinants of health, and the environment.[7,8]

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About Novo Nordisk

Novo Nordisk is a leading global healthcare company with a heritage of more than 100 years in diabetes care. Building on this foundation, our purpose is to drive change to defeat serious chronic diseases — from diabetes and obesity to rare blood and endocrine disorders — by pioneering scientific breakthroughs, expanding access to medicines, and working to prevent and ultimately cure disease. We are committed to long-term, responsible business practices that deliver financial, social and environmental value. Headquartered in Denmark and operating in around 80 countries, Novo Nordisk employs approximately 78,500 people and markets products in roughly 170 countries. In the United States, Novo Nordisk has a 40-year presence, is headquartered in New Jersey and employs over 10,000 people across more than 10 manufacturing, R&D and corporate locations in eight states plus Washington, D.C. For more information, visit novonordisk.com and novonordisk-us.com, and follow us on Facebook, Instagram, X, LinkedIn and YouTube.

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