

press release

Higher dose of Wegovy[®] provided average weight loss of 21% in people with obesity – with a third achieving 25% or more – according to data presented at ADA

- Results from the phase 3b STEP UP trial showed that a higher dose of Wegovy[®] (semaglutide 7.2 mg) delivered 21% weight loss in people with obesity, with a third of participants losing 25% or more of their weight, compared to placebo¹
- Safety and tolerability of the higher dose of Wegovy[®] (semaglutide 7.2 mg) was consistent with the currently approved dose (semaglutide 2.4 mg)¹
- The STEP UP data add to the existing evidence base on the value of Wegovy[®] in delivering significant weight loss and health gains for people living with obesity

Bagsværd, Denmark, 21 June 2025 – Novo Nordisk today presented the results from the phase 3b STEP UP trial in people with obesity without diabetes at the American Diabetes Association (ADA) Scientific Sessions, in Chicago, US. In the STEP UP trial, the higher dose of Wegovy[®] (semaglutide 7.2 mg) demonstrated a mean weight loss of 21%, with a third of participants losing 25% or more of their body weight compared to placebo at 72 weeks.¹

"The STEP UP trial demonstrated that we can increase the dose of semaglutide and achieve greater weight loss than previously seen, and in line with semaglutide's established safety profile. This may offer another option to people who do not attain their weight goals," said Sean Wharton, lead study author and medical director of the Wharton Medical Clinic, Canada. "We are already aware that semaglutide can have health benefits for people with heart disease, liver disease, knee osteoarthritis, type 2 diabetes and prediabetes. These findings help to give patients with obesity more options for improvements in their weight and overall health."

STEP UP co-primary endpoints at 72 weeks*1:

	semaglutide 7.2 mg	semaglutide 2.4 mg	Placebo
Weight loss	20.7%	17.5%	2.4%
5% or more weight loss	93.2%	92.5%	35.7%

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When evaluating the effect of treatment regardless of treatment adherence, people receiving semaglutide 7.2 mg achieved 18.7% weight loss vs 3.9% with placebo, and 90.7% achieved 5% or more weight loss with semaglutide 7.2 mg vs 36.8% on placebo.

"With these results, semaglutide reaffirms its significant weight loss for people with obesity. The STEP UP trial delivers a substantial weight loss of over 20%, in addition to health benefits previously demonstrated with semaglutide," said Ludovic Helfgott, executive vice president of Product & Portfolio Strategy at Novo Nordisk. "As pioneers in obesity, we continue to develop new innovative treatments to fit the needs and preferences of people living with obesity. This includes maximising the value of semaglutide for individuals, healthcare systems and society, and developing a new oral formulation of Wegovy[®] that, pending FDA approval, can become the first GLP-1 pill to offer double-digit weight loss."

In the STEP UP trial, semaglutide 7.2 mg demonstrated a well-tolerated safety profile consistent with previous Novo Nordisk semaglutide trials.¹ The most common adverse events were gastrointestinal, and the vast majority were mild to moderate during dose escalation and diminished over time, consistent with the GLP-1 class.¹ In STEP UP, 3.3% of people treated with semaglutide 7.2 mg discontinued due to gastrointestinal adverse events, compared to 2.0% with semaglutide 2.4 mg and 0% with placebo.¹

Novo Nordisk expects to file the higher dose of Wegovy[®] for a label update in the EU in the second half of 2025, followed by regulatory submissions in other markets where Wegovy[®] is already approved.

STEP UP selected confirmatory secondary endpoints at 72 weeks*1:

	semaglutide 7.2 mg	semaglutide 2.4 mg	Placebo
10% or more weight loss	86.0%	77.6%	20.0%
15% or more weight loss	70.4%	57.5%	7.9%
20% or more weight loss	50.9%	35.1%	2.9%
25% or more weight loss	33.2%	16.7%	0%

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

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, placebocontrolled, superiority trial designed to evaluate the efficacy and safety of semaglutide 7.2 mg

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compared to semaglutide 2.4 mg and placebo as an adjunct to lifestyle intervention. The trial included 1,407 adults with a BMI \geq 30 kg/m² without diabetes. The primary objective was to demonstrate 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/m² or greater (obesity) or adults with a BMI of 27 kg/m² 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.

In the US, Wegovy[®] is indicated in combination with a reduced calorie diet and increased physical activity to reduce the risk of MACE in adults with established cardiovascular disease and either obesity or overweight, as well as to reduce excess body weight and maintain weight reduction long term in paediatric patients aged 12 years and older with obesity and in adults with obesity or with overweight in the presence of at least one weight-related comorbid condition.

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 <u>novonordisk.com</u>, <u>Facebook</u>, <u>Instagram</u>, <u>X</u>, <u>LinkedIn</u> and <u>YouTube</u>.

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References

 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, 2025.17.

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