company announcement

Semaglutide 7.2 mg s.c. achieved 20.7% weight loss in the STEP UP obesity trial, and 18.7% regardless of treatment adherence

Bagsværd, Denmark, 17 January 2025 – Novo Nordisk today announced headline results from STEP UP, a phase 3b trial in the global STEP programme. STEP UP is a 72-week efficacy and safety trial investigating subcutaneous semaglutide 7.2 mg compared to semaglutide 2.4 mg and placebo, all administered once weekly. The trial included 1,407 randomised adults with obesity. All treatment arms were in conjunction with lifestyle intervention.

The trial achieved its primary endpoint by demonstrating a statistically significant and superior weight loss at week 72 with semaglutide 7.2 mg versus placebo.

When evaluating the effects of treatment if all people adhered to treatment[1] from a mean baseline body weight of 113 kg, people treated with semaglutide 7.2 mg achieved a superior 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. 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 applying the treatment policy estimand[2], people treated with semaglutide 7.2 mg achieved a superior weight loss of 18.7% compared to a reduction of 15.6% with semaglutide 2.4 mg and 3.9% with placebo.

In the trial, semaglutide 7.2 mg appeared to have a safe and well-tolerated profile. The most common adverse events were gastrointestinal, and the vast majority were mild to moderate and diminished over time, consistent with the GLP-1 receptor agonist class.

[1] Based on the trial product estimand: treatment effect if all people adhered to treatment

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

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“We are very pleased to demonstrate 20.7% weight loss and to see that 33% of patients achieved more than 25% weight loss with semaglutide 7.2 mg, with a safety and tolerability profile comparable to semaglutide 2.4 mg,” said Martin Holst Lange, executive vice president for Development at Novo Nordisk. “Results from STEP UP further strengthen the clinical profile of semaglutide for the treatment of obesity, in addition to the health benefits already established with Wegovy®, including cardiovascular risk reduction as seen in SELECT”.

The results from the second semaglutide 7.2 mg phase 3 trial, STEP UP T2D, in adults with type 2 diabetes and obesity are expected within the next few months.

Detailed results from the STEP UP trial are expected to be presented at a scientific conference in 2025.

About the STEP UP trials
Novo Nordisk has initiated two trials investigating the efficacy of semaglutide 7.2mg, STEP UP and STEP UP T2D.

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

The ongoing 72-week STEP UP T2D trial will investigate 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)
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/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 showing the benefits of Wegovy® in reducing the risk of MACE, improving HFpEF-related symptoms and physical function, as well as reducing pain 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 adults and paediatric patients aged 12 years and older with obesity and in adults 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 72,000 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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