

company announcement

Novo Nordisk reports weight loss of 14.9% (16.9% if taken as intended) in STEP 1 trial

Bagsværd, Denmark, 4 June 2020 – Novo Nordisk today announced headline results from STEP 1, a phase 3a trial in the STEP programme. STEP 1 is a 68-week randomised, double-blind, multicentre, placebo-controlled weight management trial. The trial investigated the efficacy and safety of once-weekly subcutaneous (sc) semaglutide 2.4 mg on body weight over 68 weeks compared to placebo in 1,961 adults with obesity or overweight with comorbidities, both in conjunction with lifestyle intervention.

The STEP 1 trial met both primary endpoints. In all people randomised¹, a statistically significant and superior reduction in body weight was achieved with sc semaglutide 2.4 mg compared to placebo after 68 weeks. People treated with sc semaglutide 2.4 mg achieved a weight loss of 14.9%, from a mean baseline body weight of 105.3 kg, compared to a 2.4% weight loss with placebo. In addition, 86.4% of those who received sc semaglutide 2.4 mg reached a weight loss of 5% or more after 68 weeks, compared to 31.5% with placebo.

When evaluating the effects of treatment taken as intended², people treated with sc semaglutide 2.4 mg achieved a weight loss of 16.9%, compared to a 2.4% weight loss with placebo after 68 weeks and 92.4% achieved a weight loss of 5% or more, compared to 33.1% with placebo. The treatment differences were statistically significant.

In the trial, sc semaglutide 2.4 mg appeared to have a safe and well-tolerated profile, as seen with previous trials. The most common adverse events among people treated with sc semaglutide 2.4 mg were gastrointestinal events. Most events were transient, and mild or moderate in severity.

“The results from the pivotal STEP 1 trial show that semaglutide 2.4 mg provides unprecedented weight loss after 68 weeks. Further, almost all patients achieved a weight

¹ Based on the treatment policy estimand (primary statistical approach): treatment effect regardless of treatment adherence or initiation of other anti-obesity therapies

² Based on the trial product estimand (secondary statistical approach): treatment effect if all people adhered to treatment and did not initiate other anti-obesity therapies

loss of at least 5%, which is widely recognised as clinically relevant. The results from this trial are very encouraging, boding well for the treatment outlook for people with obesity” says Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “We now look forward to soon sharing additional data from the remaining two STEP clinical trials.”

About obesity and sc semaglutide 2.4 mg for weight management

Obesity is a chronic disease that requires long-term management. It is associated with many serious health consequences and decreased life expectancy. Obesity-related complications are numerous and include type 2 diabetes, heart disease, obstructive sleep apnoea, chronic kidney disease, non-alcoholic fatty liver disease and cancer.

Once-weekly sc semaglutide 2.4 mg is being investigated by Novo Nordisk as a treatment for adults with obesity. Semaglutide is an analogue of the human glucagon-like peptide-1 (GLP-1) hormone. It induces weight loss by reducing hunger, increasing feelings of fullness and thereby helping people eat less and reduce their calorie intake.

About the STEP clinical programme

STEP (Semaglutide Treatment Effect in People with obesity) is a phase 3 clinical development programme with once-weekly sc semaglutide 2.4 mg in obesity. The global clinical phase 3a programme consists of four trials, having enrolled approximately 4,500 adults with overweight or obesity.

STEP 1 – a 68-week safety and efficacy trial of sc semaglutide 2.4 mg versus placebo in 1,961 adults with obesity or overweight.

STEP 2 – a 68-week safety and efficacy trial of sc semaglutide 2.4 mg versus placebo and once-weekly sc semaglutide 1.0 mg once-weekly in 1,210 adults with type 2 diabetes and either obesity or overweight.

STEP 3 – a 68-week safety and efficacy trial of sc semaglutide 2.4 mg versus placebo in combination with intensive behavioural treatment in 611 adults with obesity or overweight.

STEP 4 – a 68-week safety and efficacy trial of sc semaglutide 2.4 mg versus placebo in 803 adults with obesity or overweight who reached the target dose of 2.4 mg after a 20-week run-in. The results were reported on 13 May 2020.

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 diabetes and other serious chronic diseases such as obesity and rare blood and endocrine disorders. We do so by pioneering scientific breakthroughs, expanding access to our medicines and working to prevent and ultimately cure disease. Novo Nordisk employs about 43,100 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](#), [Twitter](#), [LinkedIn](#), [YouTube](#).

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