

# company announcement

## **Semaglutide 2.4 mg demonstrates superior and sustained weight loss versus placebo and in addition a 17.4% weight loss after 68 weeks in STEP 4 trial**

**Bagsværd, Denmark, 13 May 2020** – Novo Nordisk today announced headline results from STEP 4, the first completed phase 3a trial in the STEP programme. STEP 4 is a randomised, double-blind, multicentre, placebo-controlled, withdrawal trial exploring sustained weight management with semaglutide vs placebo. The 68-week trial investigated the effect of once-weekly subcutaneous (sc) semaglutide 2.4 mg on body weight in 902 people with obesity or overweight with comorbidities. After the 20-week run-in period, the 803 people reaching the target dose of semaglutide 2.4 mg had reduced their mean body weight from 107.2 kg to 96.1 kg and were randomised to continued treatment with either once-weekly sc semaglutide 2.4 mg or placebo for 48 weeks.

The trial achieved its primary objective by demonstrating that in all people randomised<sup>1</sup>, continued treatment with sc semaglutide 2.4 mg for 48 weeks (after the run-in period) resulted in an additional mean weight loss of 7.9%, from a mean baseline body weight at randomisation of 96.1 kg, whereas people on placebo regained 6.9% of the body weight. The treatment difference was statistically significant. People who received sc semaglutide 2.4 mg for 68 weeks (run-in period plus 48 weeks) achieved a total weight loss of 17.4%.

When evaluating the effects of treatment if taken as intended<sup>2</sup>, people who continued treatment with sc semaglutide 2.4 mg achieved an additional mean weight loss of 8.8% whereas people on placebo regained 6.5%. The treatment difference was statistically significant. People who stayed on sc semaglutide 2.4 mg for 68 weeks achieved a weight loss of 18.2%.

In the trial, sc semaglutide 2.4 mg appeared to have a safe and well-tolerated profile. The most common adverse events among people treated with sc semaglutide 2.4 mg

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

<sup>2</sup> 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

were gastrointestinal events. As seen previously with GLP-1 receptor agonists, most events were transient and mild or moderate in severity.

“Achieving sustained weight loss without medical therapy is known to be very challenging. STEP 4 shows that people continuing treatment with semaglutide achieved a further substantial weight loss while people switching to placebo, on the other hand, regained a significant amount of weight,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk and continues, “this highlights that obesity is a chronic disease requiring sustained treatment, and we look forward to sharing additional results from the ongoing STEP programme”.

### **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 4 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 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 have reached the target dose of 2.4 mg after a 20-week run-in.

*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](http://novonordisk.com), [Facebook](#), [Twitter](#), [LinkedIn](#), [YouTube](#).*

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