

company announcement

Semaglutide 2.4 mg shows superior weight loss versus placebo in the phase 3 trials STEP 2 and STEP 3, thereby successfully completing the programme

Bagsværd, Denmark, 12 June 2020 – Novo Nordisk today announced headline results from the final two phase 3a clinical trials investigating once-weekly subcutaneous (sc) semaglutide 2.4 mg for weight management. STEP 2 in adults with obesity and type 2 diabetes (T2D) and STEP 3 as an adjunct to intensive behavioural therapy (IBT) in adults with obesity.

STEP 2 (obesity and type 2 diabetes)

STEP 2 is a 68-week randomised, double-blind, multicentre, placebo-controlled trial. The trial compared the efficacy and safety of once-weekly sc semaglutide 2.4 mg after 68 weeks to placebo and once-weekly sc semaglutide 1.0 mg. Treatment was provided in conjunction with lifestyle intervention, in 1,210 adults with T2D and either obesity or overweight with comorbidities.

The trial met both primary endpoints. In all people randomised¹, a statistically significant greater weight loss of 9.6% was achieved at 68 weeks with sc semaglutide 2.4 mg, from a mean baseline bodyweight of 99.8 kg, compared to placebo (3.4% weight loss) and sc semaglutide 1.0 mg (7.0% weight loss). 68.8% of those who received sc semaglutide 2.4 mg achieved a weight loss of 5% or more after 68 weeks, compared to 28.5% with placebo.

When evaluating the effects of treatment if taken as intended², people treated with sc semaglutide 2.4 mg achieved a weight loss of 10.6%, compared to a 3.1% weight loss with placebo and 7.5% weight loss with semaglutide 1.0 mg at 68 weeks. 73.2% of those who stayed on sc semaglutide 2.4 mg for 68 weeks achieved a weight loss of 5% or more, compared to 27.6% with placebo.

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

STEP 3 (adjunct to intensive behavioural therapy)

STEP 3 is a 68-week randomised, double-blind, multicentre, placebo-controlled trial. The trial investigated the effect of once-weekly sc semaglutide 2.4 mg after 68 weeks compared to placebo in 611 adults with obesity or overweight with comorbidities. Both treatments were in conjunction with IBT, defined as weekly behavioural support, dietician counselling and reduced calorie diet.

The trial met both of its primary endpoints. In all people randomised¹, a statistically significantly greater weight loss of 16.0% was achieved with sc semaglutide 2.4 mg as an adjunct to IBT, from a mean baseline bodyweight of 105.8 kg, compared to a 5.7% weight loss with placebo plus IBT after the 68-week treatment period. 86.6% of those treated with sc semaglutide 2.4 mg achieved a weight loss of 5% or more after 68 weeks as an adjunct to IBT, compared to 47.6% with placebo plus IBT.

When evaluating the effects of treatment if taken as intended², people treated with sc semaglutide 2.4 mg plus IBT achieved a weight loss of 17.6%, compared to a 5.0% weight loss with placebo plus IBT. 89.8% of those who received sc semaglutide 2.4 mg plus IBT achieved a weight loss of 5% or more after 68 weeks, compared to 50.0% with placebo plus IBT.

In both STEP 2 and STEP 3, sc semaglutide 2.4 mg appeared to have a safe and well-tolerated profile, consistent with previous findings. 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.

“These results continue to build on the highly impressive weight loss reported previously in STEP 1 and 4. Altogether, the results indicate that semaglutide 2.4 mg will play a key role in improving the treatment of people with obesity,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “We have now reported on all the four trials in the STEP programme and we look forward to sharing the results with regulatory authorities.”

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 T2D, 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 and has 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. The results were reported on 4 June.

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 have reached the target dose of 2.4 mg after a 20-week run-in. The results were reported on 13 May.

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.

Further information

Media:

Mette Kruse Danielsen	+45 3079 3883	mkd@novonordisk.com
Ken Inchausti (US)	+1 609 240 9429	kiau@novonordisk.com

Investors:

Daniel Muusmann Bohsen	+45 3075 2175	dabo@novonordisk.com
Valdemar Borum Svarrer	+45 3079 0301	jvls@novonordisk.com
Ann Søndermølle Rendbæk	+45 3075 2253	arnd@novonordisk.com
Mark Joseph Root	+45 3079 4211	mjhr@novonordisk.com
Kristoffer Due Berg (US)	+1 609 235 2989	krdb@novonordisk.com