

company announcement

Novo Nordisk files for US FDA regulatory approval of once-weekly semaglutide 2.4 mg for weight management

Bagsværd, Denmark, 4 December 2020 – Novo Nordisk today announced the submission of a new drug application (NDA) to the US Food and Drug Administration (FDA) for subcutaneous semaglutide 2.4 mg, a once-weekly glucagon-like peptide-1 (GLP-1) analogue for chronic weight management. A priority review voucher has been applied to the NDA, leading to an anticipated review time of six months from the submission date, according to standard FDA review timelines.

The potential indication is for the treatment of adults with obesity (BMI \geq 30 kg/m²) or overweight (BMI \geq 27 kg/m²) with at least one weight-related comorbidity, as an adjunct to reduced-calorie diet and increased physical activity.

The submission is based on the results from the STEP phase 3a clinical trial programme, which included more than 4,500 adults with obesity or overweight. Across the STEP programme, people with obesity treated with once-weekly semaglutide 2.4 mg achieved a statistically significant and superior reduction in body weight compared to placebo. Across STEP 1, 3 and 4 a weight loss of 15-18% was reported for people treated with semaglutide 2.4 mg. Furthermore, once-weekly semaglutide 2.4 mg appeared to have a safe and well-tolerated profile. The most common side effects were gastrointestinal and were transient, and mild or moderate in severity.

"Obesity is associated with a wide range of serious complications, yet many healthcare providers still do not have sufficient medical options available to help people with this chronic disease," said Mads Krogsgaard Thomsen, executive vice president and chief scientific officer of Novo Nordisk. "We are excited about the regulatory filing of semaglutide 2.4 mg in the US and we believe once-weekly semaglutide 2.4 mg has the potential to transform the medical management of obesity."

About obesity and subcutaneous 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, non-alcoholic fatty liver disease and cancer.

Once-weekly subcutaneous semaglutide 2.4 mg is being investigated by Novo Nordisk as a potential treatment for 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 subcutaneous semaglutide 2.4 mg in obesity. The global 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 subcutaneous semaglutide 2.4 mg versus placebo in 1,961 adults with obesity or overweight. For more information, please read the company announcement [here](#)

STEP 2 – a 68-week safety and efficacy trial of subcutaneous semaglutide 2.4 mg versus placebo and once-weekly subcutaneous semaglutide 1.0 mg in 1,210 adults with type 2 diabetes and either obesity or overweight. For more information, please read the company announcement [here](#)

STEP 3 – a 68-week safety and efficacy trial of subcutaneous semaglutide 2.4 mg versus placebo in combination with intensive behavioural treatment in 611 adults with obesity or overweight. For more information, please read the company announcement [here](#)

STEP 4 – a 68-week safety and efficacy trial of subcutaneous 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. For more information, please read the company announcement [here](#)

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 44,000 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](#), [Twitter](#), [LinkedIn](#), [YouTube](#).

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