

company announcement

Wegovy™ (semaglutide 2.4 mg), the first and only once-weekly GLP-1 therapy for weight management, approved in the US

Bagsværd, Denmark, 4 June 2021 – Novo Nordisk today announced that the US Food and Drug Administration (FDA) has approved Wegovy™ (the brand name for once-weekly semaglutide 2.4 mg injection in the US) for chronic weight management. Wegovy™ is indicated as an adjunct to diet and exercise for chronic weight management in adults with obesity (initial BMI \geq 30 kg/m²) or overweight (initial BMI \geq 27 kg/m²) with at least one weight-related comorbidity.

Wegovy™ is the first and only once-weekly glucagon-like peptide-1 (GLP-1) receptor agonist therapy approved for weight management for people living with obesity. The approval is based on the results from the STEP phase 3a clinical trial programme. Across the trials in people without type 2 diabetes, an average weight loss of 17-18%¹ sustained over 68 weeks was reported for people with obesity treated with Wegovy™. Wegovy™ demonstrated a safe and well-tolerated profile across the programme, with the most common adverse events being gastrointestinal.

“The approval of Wegovy™ in the US brings great promise to people with obesity. Despite the best efforts to lose weight, many people with obesity struggle to achieve and maintain weight loss due to physiological responses that favour weight regain,” said Martin Holst Lange, executive vice president, Development at Novo Nordisk. “The unprecedented weight loss for an anti-obesity medication marks a new era in the treatment of obesity, and we now look forward to making Wegovy™ available to people living with obesity in the US”.

Novo Nordisk expects to launch Wegovy™ in the United States later in June 2021.

¹ 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. When using a treatment policy estimand, 15-17% weight loss was reported.

Conference call

On 7 June at 8.30 CEST, corresponding to 2.30 am EDT, a conference call for investors will be held. Investors will be able to listen in via a link on the investor section of novonordisk.com.

About obesity

Obesity is a chronic disease that requires long-term management. It is associated with many serious health complications 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 certain types of cancer. The current COVID-19 pandemic has highlighted that obesity also increases the risk for severe illness and hospitalisation due to COVID-19.

The global increase in the prevalence of obesity is a public health issue that has severe cost implications to healthcare systems. Approximately 650 million adults are estimated to live with obesity worldwide.

About Wegovy™ (semaglutide 2.4 mg) and STEP

Semaglutide 2.4 mg is a GLP-1 receptor agonist, with 94% similarity to naturally occurring human GLP-1 hormone. It induces weight loss by reducing hunger, increasing feeling of fullness and thereby helping people eat less and reduce their calorie intake. Once-weekly semaglutide 2.4 mg injection is approved for the treatment of adults with obesity or overweight in the US, in addition to diet and exercise.

Semaglutide 2.4 mg for weight management is currently under regulatory review in the EU and other countries. The submissions are based on the results from the STEP (Semaglutide Treatment Effect in People with obesity) phase 3 clinical development programme. The global clinical phase 3a programme consists of four trials and enrolled approximately 4,500 adults with overweight or obesity.

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 45,800 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

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