

# company announcement

## **Wegovy™ recommended for approval for the treatment of obesity by the European regulatory authorities**

**Bagsværd, Denmark, 11 November 2021** – Novo Nordisk today announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion, recommending marketing authorisation for Wegovy™ for chronic weight management in adults with obesity.

Wegovy™ is a once-weekly semaglutide 2.4 mg injection for chronic weight management in adults living with obesity (initial BMI $\geq$ 30 kg/m<sup>2</sup>) or overweight (initial BMI $\geq$ 27 kg/m<sup>2</sup>) with at least one weight-related comorbidity such as high blood pressure, heart disease or type 2 diabetes.

The positive CHMP opinion is based on results from the STEP phase 3a clinical trial programme. Across the trials in people with obesity or overweight without type 2 diabetes, an average weight loss of 17-18%<sup>1</sup> sustained over 68 weeks was reported for those treated with Wegovy™. Wegovy™ demonstrated a safe and well-tolerated profile across the programme, with the most common adverse events being gastrointestinal.

“With the unprecedented and sustained weight loss for an anti-obesity medication, Wegovy™ has the potential to transform obesity management and help millions of people living with obesity,” said Martin Holst Lange, executive vice president, Development at Novo Nordisk. “We are looking forward to driving change for people with obesity by introducing Wegovy™ in Europe next year.”

Novo Nordisk expects to receive final marketing authorisation from the European Commission in approximately two months.

Wegovy™ was launched in the US in June 2021 following approval by the U.S. Food and Drug Administration (FDA). In September 2021, Wegovy™ was approved by the UK Medicines and Health products Regulations Agency (MHRA). Novo Nordisk expects to launch Wegovy™ in Europe in the second half of 2022.

## **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 of 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 and specifically 53% of the adults living in the EU are considered to be living with overweight.

## **About Wegovy™ (semaglutide 2.4 mg) and STEP**

Semaglutide 2.4 mg is an analogue of the human glucagon-like peptide-1 (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 and UK, as an adjunct to diet and exercise.

The approval is 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 47,000 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](https://www.novonordisk.com), [Facebook](#), [Twitter](#), [LinkedIn](#), [YouTube](#)*

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