company announcement

Wegovy® approved in the US for the treatment of MASH

Bagsværd, Denmark, 15 August 2025 – Novo Nordisk today announced that the US Food and Drug Administration (FDA) has approved an additional indication for Wegovy® (semaglutide 2.4 mg) based on a supplemental New Drug Application (sNDA) for treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) in adults with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis), in combination with a reduced calorie diet and increased physical activity.

The accelerated approval is based on part 1 of the ESSENCE trial, in which Wegovy® demonstrated a statistically significant and superior improvement in liver fibrosis with no worsening of steatohepatitis, as well as resolution of steatohepatitis with no worsening of liver fibrosis compared to placebo.

The clinical data from ESSENCE showed that at week 72, 36.8% of people treated with Wegovy® achieved improvement in liver fibrosis with no worsening of steatohepatitis compared to 22.4% treated with placebo. 62.9% of people treated with Wegovy® achieved resolution of steatohepatitis with no worsening of liver fibrosis compared to 34.3% treated with placebo.

"Wegovy® is now uniquely positioned as the first and only GLP-1 treatment approved for MASH, complementing the already proven weight loss, cardiovascular benefits and extensive body of evidence linked to semaglutide," said Martin Holst Lange, executive vice president, chief scientific officer and head of Research and Development, at Novo Nordisk. "MASH represents a significant health burden, with one in three people with overweight or obesity worldwide affected. In the US alone, around 22 million people are estimated to live with MASH. With the approval of Wegovy® for MASH, we provide a new treatment to people living with MASH that not only halts the disease activity but helps reverse the damage caused to the liver."

As of today, Wegovy® is available in the US for the treatment for MASH.

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About MASH

Metabolic dysfunction-associated steatohepatitis (MASH) is a serious, progressive, metabolic disease affecting the liver, which can be fatal if not properly managed. More than 250 million people live with MASH and the number of individuals in advanced stages of the disease is expected to double by 2030. Of those who are currently overweight or living with obesity, more than one in three are also living with MASH. People living with MASH often experience few or no specific symptoms in the early stages of the disease, which often results in delayed diagnosis. The risk of progression to advanced liver disease, including liver cancer, is higher in people living with MASH than in the general population.

About the ESSENCE trial

ESSENCE is a phase 3 trial evaluating the effect of once-weekly subcutaneous semaglutide 2.4 mg in adults with metabolic dysfunction-associated steatohepatitis with moderate to advanced liver fibrosis (stage 2 or 3). ESSENCE is a two-part trial where 1,200 planned participants were randomised 2:1 to receive semaglutide 2.4 mg or placebo, on top of standard of care for 240 weeks. In part 1, the objective was to demonstrate that treatment with semaglutide 2.4 mg improves liver histology at 72 weeks based on biopsy sampling from the first 800 randomised patients. In part 2, the objective is to demonstrate that treatment with semaglutide 2.4 mg lowers the risk of liver-related clinical events compared to placebo in adults with MASH and moderate to advanced liver fibrosis at 240 weeks.

Based on part 1 of the ESSENCE trial, Novo Nordisk has also filed for regulatory approval in the EU in February 2025, with a subsequent filing in Japan in May 2025. Part 2 of the ESSENCE trial is expected to read out in 2029.

About Wegovy® (semaglutide 2.4 mg)

The FDA initially approved Wegovy® in 2021 with a reduced calorie meal plan and increased physical activity to help adults with obesity, or adults with excess weight (overweight) who also have weight-related medical problems to lose weight and keep the weight off. The indication was expanded in 2022 to include children aged 12 years and older with obesity. In 2024, Wegovy® was approved to reduce the risk of major cardiovascular events such as death, heart attack, or stroke in adults with known heart disease and either obesity or overweight. Today, the FDA granted accelerated approval for Wegovy® for a new patient population for the treatment of MASH in adults with moderate to advanced liver scarring (fibrosis), but not with cirrhosis of the liver.

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 serious chronic diseases built upon our heritage in diabetes. We do so by pioneering scientific breakthroughs, expanding access to our medicines and working to prevent and ultimately cure disease. Novo Nordisk employs about 78,400 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, Instagram, X, LinkedIn and YouTube.

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