Sumitomo Pharma

Press Release

June 19, 2026

Sumitomo Pharma Co., Ltd.

Wegovy® Subcutaneous Injection, Co-Promoted with Novo Nordisk Pharma, Approved in Japan for Metabolic Dysfunction-Associated Steatohepatitis (MASH)

Sumitomo Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Toru Kimura; the "Company") announced today that Novo Nordisk Pharma Ltd. (Head Office: Tokyo, Japan; President and Representative Director: Keisuke Kotani; "Novo Nordisk Pharma") has received a partial change approval of the manufacturing and marketing authorization from the Ministry of Health, Labour and Welfare in Japan for Wegovy® Subcutaneous Injection SD and MD (generic name: semaglutide (genetical recombination); the "Product"), a once-weekly GLP-1 receptor agonist co-promoted with Sumitomo Pharma in Japan. This approval covers an additional indication for metabolic dysfunction-associated steatohepatitis ("MASH") without cirrhosis in patients with moderate to advanced fibrosis.
With this approval, the Product becomes the first approved treatment for MASH in Japan. Building on the collaborative relationship established with Novo Nordisk Pharma through promotional activities for obesity disease, the Company will continue to work closely with Novo Nordisk Pharma to provide information to healthcare professionals regarding MASH.

This approval is based on Part 1 of the Phase 3 ESSENCE study, which enrolled adult patients with MASH and moderate to advanced fibrosis (stage F2 or F3)*. The Product (semaglutide 2.4 mg) demonstrated superiority to placebo with statistically significant results compared to placebo in both improvement in liver fibrosis without worsening of MASH and resolution of MASH without worsening of liver fibrosis. In Part 1 of the ESSENCE study, at week 72, improvement in liver fibrosis without worsening of MASH was observed in 36.8% of patients in the Product (semaglutide 2.4 mg) group compared with 22.4% in the placebo group. In addition, resolution of MASH without worsening of liver fibrosis was observed in 62.9% of patients in the Product (semaglutide 2.4 mg) group compared with 34.3% in the placebo group. The safety profile was consistent with previous data, and no new safety concerns were identified.

MASH is a progressive disease that often presents with few symptoms in its early stages but may lead to irreversible liver fibrosis, liver failure, and liver cancer over time, posing significant health risks to patients. This serious liver disease is also frequently associated with other metabolic conditions such as obesity and type 2 diabetes.

The Company is also jointly engaged with Novo Nordisk Pharma in providing information to healthcare professionals regarding Ozempic® Subcutaneous Injection 2 mg, a once-weekly GLP-1 receptor agonist indicated for the treatment of type 2 diabetes. By leveraging the expertise and networks of both companies, the Company will continue to work closely with Novo Nordisk Pharma

to provide information so that more patients can benefit from these treatments.

*: Fibrosis stage (0–1: no fibrosis or mild fibrosis; 2: moderate fibrosis; 3–4: advanced/ progressed fibrosis)

(Reference)

Novo Nordisk

Novo Nordisk is a leading global healthcare company founded in 1923 and headquartered in Denmark. Its purpose is to drive change to defeat serious chronic diseases built upon its heritage in diabetes. Novo Nordisk does so by pioneering scientific breakthroughs, expanding access to its medicines and working to prevent and ultimately cure disease. Novo Nordisk currently employs about 67,900 people in 80 countries and markets its products in around 170 countries. The Japanese subsidiary, Novo Nordisk Pharma Ltd., was established in 1980. For more information, please see the website: www.novonordisk.co.jp (in Japanese only).

Metabolic dysfunction-associated steatohepatitis (MASH)

Metabolic dysfunction-associated steatohepatitis (MASH) is a chronic, progressive disease characterized by liver inflammation and fibrosis associated with metabolic dysfunction. In recent years, the number of patients has been increasing, with the prevalence in Japan estimated to be approximately 3.0%. MASH often progresses with few or no noticeable symptoms and may lead to serious conditions such as liver cirrhosis and liver cancer. The five-year relative survival rate for patients who progress to liver cancer is low, at 35.8%, making it one of the diseases associated with poor prognosis.

In addition, MASH has been associated not only with an increased risk of cardiovascular diseases but also with malignancies other than liver cancer, including colorectal and breast cancers. Therefore, it is considered to have a significant impact on healthy life expectancy.

ESSENCE study

The ESSENCE study is a Phase 3 study evaluating the efficacy of once-weekly subcutaneous administration of the Product (semaglutide 2.4 mg) in adult patients with MASH and moderate to advanced liver fibrosis (stage F2 or F3). The study consists of two parts and is designed to randomize 1,200 patients in a 2:1 ratio to receive the Product (semaglutide 2.4 mg) or placebo, administered on top of standard of care for 240 weeks.

The primary objective of Part 1 was to evaluate whether the Product (semaglutide 2.4 mg) improves liver histology at week 72 compared with placebo. An application for regulatory approval was submitted based on the results of an interim analysis of the first 800 randomized patients. In the ongoing Part 2, the primary objective is to assess whether treatment with the Product (semaglutide 2.4 mg) reduces the risk of liver-related clinical events at week 240 compared with placebo in adult patients with MASH and moderate to advanced liver fibrosis. Part 2 of the ESSENCE study is ongoing, with study completion expected in 2029.

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