press release

Wegovy® (semaglutide injection) Receives Conditional Marketing Authorization from Health Canada as the First and Only Treatment for Adults with Non-Cirrhotic MASH, a Serious Liver Disease

- *Wegovy® (semaglutide injection) granted conditional marketing authorization for the treatment of non-cirrhotic metabolic dysfunction-associated steatohepatitis (MASH) in adults with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).[1]*
- *It is estimated that by 2030 the prevalence of MASH in the Canadian general population will increase from 5.2% to 6.5%.[2] In Canada, the number of deaths is expected to double in people living with MASH by 2030.[2]*
- *Left untreated, MASH can progress to serious and even fatal outcomes, such as cirrhosis, liver cancer, and the need for liver transplant.[3]*

MISSISSAUGA, ON, December 15, 2025 – Novo Nordisk announced today that Health Canada has issued marketing authorization with conditions [Notice of Compliance with Conditions (NOC/c)] for Wegovy® (semaglutide injection) for the treatment of non-cirrhotic metabolic dysfunction-associated steatohepatitis (MASH) in adults with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).[1]

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Authorization in Canada under the NOC/c guidance was granted based on the acceptable safety profile, high quality and promising efficacy of Wegovy® (semaglutide injection) observed in Part 1 of the phase 3 ESSENCE trial.[4] The results from ESSENCE confirmed a statistically significant improvement in the resolution of steatohepatitis (liver injury), with no worsening of liver fibrosis, as the first primary endpoint, and a reduction in liver fibrosis (liver scarring), with no worsening of steatohepatitis as the second primary endpoint compared to placebo.[4] The conditional authorization was accelerated, under Health Canada's Priority Review policy.

MASH is a chronic, progressive metabolic disease affecting the liver, which can be potentially life-threatening if not properly managed.[5,6] Among people who are living with overweight or obesity, approximately one in three also have MASH.[7]

Excess fat can build up in the liver, which, over time, can lead to inflammation and severe scarring of the liver.[8] People living with MASH often experience few or no specific symptoms in the early stages of the disease, which often results in a delayed diagnosis.[9]

This year, two major Canadian clinical practice guidelines, both for obesity (Canadian Adult Obesity Clinical Practice Guidelines) and diabetes (Diabetes Canada Clinical Practice Guidelines), have been updated to include semaglutide for patients who have MASH.[10,11]

Statements:

- **Dr. Giada Sebastiani, Clinician Scientist, Hepatologist, and Investigator at Research Institute of the McGill University Health Centre:** "This approval represents a new treatment era. It not only addresses a significant unmet need, but up until now we've had no pharmacological options in Canada for this often-debilitating disease. What's more, in clinical trials semaglutide 2.4 mg showed to not only stop liver fibrosis from worsening but was shown to reverse fibrosis in a significant proportion of people living with MASH. I could not be more excited for my patients, their families, and the MASH community."
- **Michael Betel, President and Founder of the Fatty Liver Alliance:** "Our community has long awaited an approved treatment option for MASH. This approval brings renewed hope to people living with this serious condition and reflects a significant step forward in improving care and outcomes for Canadians living with MASH and their families."
- **Dr. Mark Swain, Hepatologist, Professor of Medicine, University of Calgary: "**Having treatment options in this patient population is extremely needed because the

disease affects a large population, has a high risk of severe complications like liver cirrhosis and cancer, and lacks effective treatments. Furthermore, it is often diagnosed late due to a lack of early symptoms. More awareness of both MASH and its complications is essential."

- **Dr. James Kim, Clinical Assistant Professor, Department of Family Medicine, University of Calgary:** "We know MASH can lead to poor and even fatal outcomes when left untreated, but studies show very few people, including healthcare professionals, are even aware of the disease, making it difficult to diagnose. I am thrilled that we now not only have an evidence-based pharmacological treatment option, but that we are also bringing such important awareness to the condition."
- **Vince Lamanna, President, Novo Nordisk Canada Inc.:** "This approval is a major milestone, marking the only Health Canada approved treatment option for eligible Canadians living with MASH. It further builds on the growing evidence demonstrating the benefits of semaglutide across a range of chronic conditions and has the potential to help even more Canadian patients and their families."

About ESSENCE[4]

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). It is a two-part trial where 1,197 participants were randomized 2:1 to receive semaglutide 2.4 mg or placebo, on top of standard of care for 240 weeks. Lifestyle counseling and management of coexisting diseases were recommended in alignment with guidelines. In Part 1, the primary objective was to demonstrate that treatment with semaglutide 2.4 mg improves liver histology compared with placebo in patients with MASH and fibrosis stage 2 or 3. In Part 2, which is ongoing, the primary 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.

About Wegovy® (semaglutide injection)[1]

Health Canada approved Wegovy® in 2021 as a once-weekly treatment for Canadians living with obesity, supported by the efficacy and safety data from the STEP (Semaglutide Treatment Effect in People with Obesity) clinical trial program. In 2024, Health Canada approved Wegovy® to reduce the risk of non-fatal myocardial infarction in adults with established cardiovascular disease and BMI equal to or greater than 27 kg/m2. The non-fatal MI indication for Wegovy® is based on results of the Semaglutide Effects on Cardiovascular Outcomes in People with Overweight or Obesity (SELECT) clinical trial.[12] It is the first Health Canada approved treatment to support chronic weight management and to reduce the risk

of non-fatal MI, and now, for the treatment of non-cirrhotic metabolic dysfunction-associated steatohepatitis (MASH) in adults with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).

Wegovy® is available in more than 10 countries. The most frequently reported adverse events were nausea, diarrhea, vomiting, constipation, abdominal pain, headache and fatigue.

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 76,300 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.ca, Facebook, Instagram, X, LinkedIn and YouTube.

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