

## press release

# Health Canada approves Wegovy® (semaglutide injection) to reduce the risk of non-fatal myocardial infarction

- Wegovy<sup>®</sup> is the first-and-only medication indicated for both chronic weight management and to reduce the risk of non-fatal myocardial infarction (MI) in Canada.<sup>1</sup>
- Close to one in three Canadian adults are living with obesity, which is a risk factor for heart disease.<sup>2,3</sup>

**Mississauga, ON, November 27, 2024** – Novo Nordisk announced today that Wegovy<sup>®</sup> (semaglutide injection) is now approved to reduce the risk of non-fatal myocardial infarction in adults with established cardiovascular disease and BMI equal to or greater than 27 kg/m<sup>2</sup>.<sup>1</sup> It is the first Health Canada approved treatment to support both chronic weight management and to reduce the risk of non-fatal MI.<sup>1</sup>



The prevalence of obesity, which increases the risk of serious chronic illness including heart disease, has grown over the last two decades.<sup>2,3</sup> According to self-reported data from the 2022 Canadian Community Health survey, close to one in three Canadian adults are living with obesity.<sup>2</sup> Canadians living with obesity are more than twice as likely to have heart disease than those with a healthy weight.<sup>4</sup>

Myocardial infarction, commonly referred to as a heart attack, is the most common manifestation of ischemic heart disease.<sup>5</sup> In Canada, heart disease is the second leading

cause of death and a leading cause of hospitalization.<sup>5</sup> It's estimated that 9 in 10 Canadians have at least one risk factor for stroke, heart disease, or vascular cognitive impairment including: sex, age, diabetes, family history and Indigenous, South Asian and African family heritage.<sup>6</sup> On average, men are two-times more likely than women to suffer a first acute myocardial infarction, and the incidence is steadily increasing across Canada.<sup>5</sup>

Health Canada's non-fatal MI indication for Wegovy® is based on results of the Semaglutide Effects on Cardiovascular Outcomes in People with Overweight or Obesity (SELECT) trial.<sup>7</sup>

#### **Statements**

- "As a national lead investigator for the SELECT trial in Canada, and a Cardiac Surgeon, I can attest to the ongoing recalcitrant risk of myocardial infarctions in individuals living with overweight or obesity. This burden not only impacts their prognosis but also places a significant cost on healthcare systems," said Dr. Subodh Verma, internationally renowned cardiac surgeon-scientist and Professor at the University of Toronto. "The introduction of semaglutide 2.4 mg as the only therapy proven to reduce non-fatal myocardial infarctions in patients living with overweight or obesity without diabetes is a remarkable breakthrough. These data mark a new era in the treatment of obesity, shifting the focus from viewing it merely as a risk factor to recognizing it as a critical therapeutic target. This is a great advance and a pivotal moment for patients, representing a crucial step toward reducing the risk of first or recurrent heart attacks in this population."
- "Canadians living with obesity are at increased risk of heart attacks. We welcome
  expanded treatment options to support Canadians living with obesity and related
  complications. People deserve evidence-based care to proactively manage this
  disease, including medical nutrition therapy, psychological interventions, physical
  activity, pharmacotherapy and surgery," said Dr. Sanjeev Sockalingam, Scientific
  Director of Obesity Canada.
- "We are very pleased that Wegovy® is now approved in Canada to help people who are at risk of non-fatal myocardial infarction. Heart attacks have a profound impact on many families across our country. Wegovy® is a clinically evaluated therapy that offers new hope for Canadians living with cardiovascular disease and obesity. We are dedicated to providing Canadians with innovative treatment options to support unmet needs," said Vince Lamanna, President of Novo Nordisk Canada Inc.

#### About the SELECT Trial7

SELECT was a randomized, double-blind, parallel-group, placebo-controlled trial designed to evaluate the efficacy of semaglutide 2.4 mg versus placebo as an adjunct to standard of care for prevention of major adverse cardiovascular outcomes (MACE) in people with established cardiovascular disease with overweight or obesity with no prior history of diabetes. People included in the trial were aged  $\geq$ 45 years with a BMI  $\geq$ 27 kg/m².

The primary objective of the SELECT trial was to demonstrate superiority of semaglutide 2.4 mg compared to placebo with respect to reducing the incidence of three-point MACE consisting of cardiovascular death, non-fatal myocardial infarction or non-fatal stroke. Secondary objectives included comparing the effects of semaglutide 2.4 mg to placebo with regards to mortality, cardiovascular risk factors, glucose metabolism, body weight and renal function. The trial enrolled 17,604 adults and has been conducted in 41 countries at more than 800 investigator sites. The SELECT trial was initiated in 2018.

#### About Wegovy® 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 the largest phase 3a trial, STEP 1, results showed that patients taking Wegovy® achieved a mean weight loss of 15 per cent (15 kg) sustained over 68 weeks. In addition, 83.5 per cent of patients achieved 5 per cent or more body weight reduction in the Wegovy® arm vs. 31.1 per cent for placebo.

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

#### **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 63,400 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.ca, Facebook, Instagram, LinkedIn and YouTube.

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<sup>&</sup>lt;sup>1</sup> Novo Nordisk Canada Inc. (2024, November 25). Wegovy® Product Monograph.

<sup>&</sup>lt;sup>2</sup> Statistics Canada. An overview of weight and height measurements on World Obesity Day. https://www.statcan.gc.ca/o1/en/plus/5742-overview-weight-and-height-measurements-world-obesity-day

<sup>&</sup>lt;sup>3</sup> Twells LK, Janssen I, Kuk JL. Canadian Adult Obesity Clinical Practice Guidelines: Epidemiology of Adult Obesity. https://obesitycanada.ca/guidelines/epidemiology

<sup>&</sup>lt;sup>5</sup> Heart disease in Canada: Highlights from the Canadian Chronic Disease Surveillance System. The Burden at a Glance. Government of Canada. <a href="https://www.canada.ca/en/public-health/services/publications/diseases-conditions/heart-disease-canada-fact-sheet.html">https://www.canada.ca/en/public-health/services/publications/diseases-conditions/heart-disease-canada-fact-sheet.html</a>

<sup>&</sup>lt;sup>6</sup> Heart and Stroke Foundation. Working with your doctor. <u>https://www.heartandstroke.ca/heart-disease/recovery-and-support/working-with-your-doctor</u>

<sup>&</sup>lt;sup>7</sup> Semaglutide and Cardiovascular Outcomes in Obesity without Diabetes: A. Michael Lincoff, M.D., Kirstine Brown-Frandsen, M.D., Helen M. Colhoun, M.D., John Deanfield, M.D., et al. Published November 11, 2023. N Engl J Med 2023;389:2221-2232. DOI: 10.1056/NEJMoa2307563 VOL. 389 NO. 24