

## press release

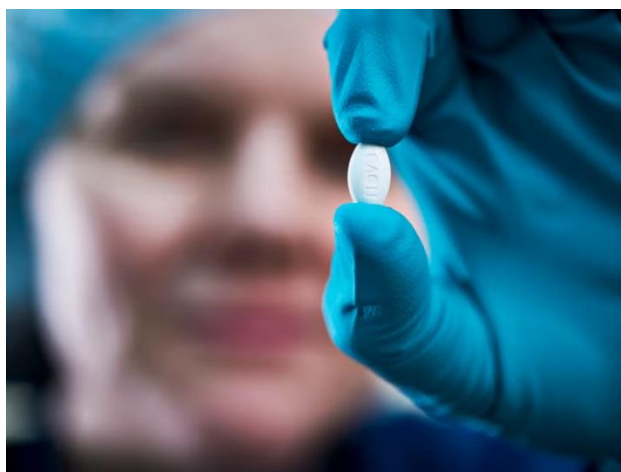
### **Health Canada approves RYBELSUS® (semaglutide tablets) to reduce the risk of major adverse cardiovascular events (MACE) in adults with type 2 diabetes**

- *RYBELSUS® (semaglutide tablets) is the first glucagon-like peptide-1 (GLP-1) approved in Canada to reduce the risk of major adverse cardiovascular events (MACE).<sup>1</sup>*
- *RYBELSUS® (semaglutide tablets) is approved to reduce the risk of major adverse cardiovascular (CV) events (CV death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or are at high risk for these events.<sup>1,2</sup>*
- *The indication expansion is based on positive outcomes observed in the cardiovascular outcomes (SOUL) trial data, which demonstrated that RYBELSUS® decreased the risk of major adverse cardiovascular events.<sup>1</sup>*
- *Cardiovascular disease is the second-leading cause of death in Canada.<sup>3</sup>*

**MISSISSAUGA, ON, January 12, 2026** - Novo Nordisk announced today that Health Canada has approved RYBELSUS® (semaglutide tablets) to reduce the risk of major adverse cardiovascular (CV) events (CV death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or are at high risk for these events.<sup>1,2</sup>

In Canada, cardiovascular disease remains a public health challenge, with heart disease as the second leading cause of death and a leading cause of hospitalization.<sup>4</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>5</sup>

Health Canada's approval of this indication is based on the results of the SOUL trial.<sup>2</sup> Trial results confirmed that the risk of a major adverse cardiovascular event (MACE) decreased with the use of RYBELSUS® as compared to a placebo, when used concomitantly with standard of care treatments for diabetes and cardiovascular disease.<sup>1</sup>



"This approval marks an important milestone for type 2 diabetes patients in Canada, who are at higher risk of cardiovascular events due to the chronic disease," says Vince Lamanna, President, Novo Nordisk Canada Inc. "RYBELSUS is the first and only approved GLP-1 in pill form in Canada that improves glycemic control and offers cardiovascular protection."

### **About the SOUL Trial<sup>2</sup>**

SOUL was a randomized, double-blind, parallel-group, placebo-controlled trial evaluating the effect of RYBELSUS<sup>®</sup> on patients who were 50 years of age or older with type 2 diabetes mellitus and established cardiovascular disease (CVD) and/or chronic kidney disease (CKD). In total, 9650 patients were randomised to receive either RYBELSUS<sup>®</sup> 14 mg or the placebo daily. The primary endpoint, MACE, was the time to first occurrence of a three-part composite outcome which included cardiovascular death, non-fatal myocardial infarction and non-fatal stroke.

### **About RYBELSUS<sup>®</sup> (semaglutide tablets)<sup>1</sup>**

RYBELSUS<sup>®</sup> is the first and only glucagon-like peptide-1 (GLP-1) analogue available in a tablet in Canada to treat type 2 diabetes mellitus and is indicated as a monotherapy when metformin is considered inappropriate due to intolerance or contraindications. Health Canada approved RYBELSUS<sup>®</sup> in April 2020 as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

## **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](https://www.novonordisk.ca), [Facebook](#), [Instagram](#), [X](#), [LinkedIn](#) and [YouTube](#).*

## **Contact for further information**

### **Novo Nordisk Canada**

**Jaclyn Crawford**

647-201-6817

[jlCW@novonordisk.com](mailto:jlCW@novonordisk.com)

## References

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- <sup>2</sup> Oral Semaglutide and Cardiovascular Outcomes in High-Risk Type 2 Diabetes. McGuire DK, Marx N, Mulvagh SL, *et al.*; SOUL Study Group. *N Engl J Med*. Published online March 29, 2025
- <sup>3</sup> Increasing Prevalence and Incidence of Atherosclerotic Cardiovascular Disease in Adult Patients in Ontario, Canada From 2002 to 2018 Mackinnon, Erin S. *et al.* *CJC Open*, Volume 4, Issue 2, 206 – 213.  
[https://www.cjopen.ca/article/S2589-790X\(21\)00272-9/fulltext](https://www.cjopen.ca/article/S2589-790X(21)00272-9/fulltext)
- <sup>4</sup> Heart disease in Canada: Highlights from the Canadian Chronic Disease Surveillance System. The Burden at a Glance. Government of Canada. <https://www.canada.ca/en/public-health/services/publications/diseases-conditions/heart-disease-canada-fact-sheet.html>
- <sup>5</sup> Heart and Stroke Foundation. Working with your doctor. <https://www.heartandstroke.ca/heart-disease/recovery-and-support/working-with-your-doctor>