

## press release

### Health Canada approves Ozempic® to reduce the risk of sustained eGFR decline, end-stage kidney disease, and cardiovascular death in adults with type 2 diabetes and chronic kidney disease

- *Ozempic® is the first-and-only medication indicated for both the once-weekly treatment of adult patients with type 2 diabetes mellitus to improve glycemic control and to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease, and cardiovascular death in adults with type 2 diabetes and chronic kidney disease.<sup>1</sup>*
- *Chronic kidney disease in patients with type 2 diabetes is associated with an elevated risk of end-stage kidney disease, cardiovascular disease, and death.<sup>2</sup>*

**MISSISSAUGA, ON, August 19, 2025** – Novo Nordisk announced today that Ozempic® (semaglutide injection) is now approved as the first-and-only medication indicated for both the once-weekly treatment of adult patients with type 2 diabetes mellitus to improve glycemic control and to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease, and cardiovascular death in adults with type 2 diabetes (T2D) and chronic kidney disease (CKD).<sup>1</sup>



Dr. David Cherney, Senior Scientist, Toronto General Hospital Research Institute, and Primary Investigator on FLOW, says: "Chronic kidney disease, or CKD, affects 30-50% of people living with type 2 diabetes (T2D), and is associated with a dramatically higher risk of cardiovascular disease and mortality. Fortunately, we have witnessed a significant evolution in the management of CKD in T2D over the last 5 years with the identification of newer therapies that reduce both heart and kidney risk in T2D. The results of the FLOW trial are of major importance for people living with type 2 diabetes and chronic kidney disease because this trial demonstrated that the addition of semaglutide to standard of care medicines reduced the risk of kidney disease progression, and death due to cardiovascular disease or loss of kidney function over time. Based on the FLOW results, we now can offer our patients a better chance of avoiding kidney failure or cardiovascular complications."

Dr. Alice Cheng, Endocrinologist at Trillium Health Partners and Unity Health Toronto, and Associate Professor at University of Toronto, says: "Many people living with type 2 diabetes may not be aware that they have chronic kidney disease (CKD) which is why it is so important to ensure that a urine test is done at least annually. The FLOW study provides evidence that there is another tool in the toolbox to not only slow the progression of kidney disease but also reduce cardiovascular risk in people living with type 2 diabetes and CKD - a tool that is already familiar to us. The more tools, the better."

Health Canada's CKD indication for Ozempic® is based on the results of the FLOW trial. The dedicated kidney outcomes trial was designed to determine the kidney-protective effects of semaglutide in participants with CKD and T2D, as well as assessing the effect of CVD mortality. The FLOW trial achieved its primary endpoint, with semaglutide 1 mg demonstrating a 24% reduction in the risk of kidney disease progression and cardiovascular and kidney mortality compared to placebo (331 vs. 410 events; hazard ratio: 0.76 [0.66; 0.88];  $P=0.0003$ ).<sup>3</sup>

### **About the FLOW Trial**

FLOW was an international, randomized, double-blind, parallel-group, placebo-controlled, event-driven superiority trial comparing injectable semaglutide 1 mg with placebo as an adjunct to standard of care on kidney outcomes for reducing the risk of progression of kidney impairment and risk of kidney and cardiovascular mortality in people with type 2 diabetes and CKD (defined as  $eGFR^2 \geq 50$  and  $\leq 75$  mL/min/1.73 m<sup>2</sup> and  $UACR > 300$  and  $< 5000$  mg/g or  $eGFR \geq 25$  and  $< 50$  mL/min/1.73 m<sup>2</sup> and  $UACR > 100$  and  $< 5000$  mg/g). 3,533 people (1,767 in the semaglutide group and 1,766 in the placebo group) were enrolled in the trial conducted in 28 countries, including Canada, at around 400 investigator sites. The FLOW trial

was initiated in 2019,<sup>1</sup> and was stopped early due to efficacy, based on a recommendation from an Independent Data Monitoring Committee.

The key objective of the FLOW trial was to demonstrate delay in the progression of CKD and a lower risk of kidney and cardiovascular mortality through the composite primary endpoint consisting of the following five components: onset of persistent  $\geq 50\%$  reduction in eGFR according to the CKD-EPI<sup>3</sup> equation compared with baseline, onset of persistent eGFR (CKD-EPI)  $< 15$  mL/min/1.73 m<sup>2</sup>, initiation of chronic kidney replacement therapy (dialysis or kidney transplantation), death from kidney disease or death from cardiovascular disease. Confirmatory secondary endpoints included annual rate of change in eGFR (CKD-EPI), MACE (non-fatal myocardial infarction, non-fatal stroke, cardiovascular death) and all-cause death.<sup>1</sup>

### **About CKD and T2D**

CKD is a major health problem affecting approximately 4 million Canadians.<sup>4</sup> It is defined as the presence of kidney damage, or a decreased level of kidney function, for a period of three months or more. It can often start slow and develop without symptoms over a number of years and may not be detected until it has progressed to the point where kidney function is low. Kidney disease can be a devastating complication, as it is associated with significant reductions in both length and quality of life.<sup>5</sup> Around 40% of people with type 2 diabetes (T2D) will develop chronic kidney disease (CKD),<sup>6</sup> however, CKD is asymptomatic in its early stages and is under-diagnosed in people with T2D.<sup>7</sup> Renal function decline increases the probability of multi-morbidity as well as excess mortality.<sup>8</sup> T2D, CKD and cardiovascular disease (CVD) are interconnected.<sup>9</sup>

### **About Ozempic**

Ozempic® is indicated for the once-weekly treatment of adult patients with type 2 diabetes mellitus to improve glycemic control. It was approved by Health Canada in 2018.

Ozempic® can be used with metformin, sulfonylurea and a sodium-glucose cotransporter 2 inhibitor (SGLT2i) and basal insulin with metformin. Ozempic® is also indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, and cardiovascular death in adults with type 2 diabetes and chronic kidney disease.<sup>10</sup> For information about Ozempic®, including important safety information, please view the product monograph [here](#).

### **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](#).*

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- <sup>10</sup> Novo Nordisk Canada Inc. (August 13, 2025). Ozempic® Product Monograph. <https://www.novonordisk.ca/content/dam/nncorp/ca/en/products/ozempic-product-monograph.pdf>