

press release

Ozempic® approved in Canada for the treatment of adults with type 2 diabetes

Ozempic® demonstrated clinically meaningful improvements in blood sugar and body weight vs comparators¹

Mississauga, January 9, 2018 — Novo Nordisk announced today that Health Canada has approved Ozempic® (semaglutide injection) as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, when metformin is not tolerated or contraindicated.¹ Ozempic®, a once-weekly glucagon-like peptide 1 (GLP-1) receptor agonist, can also be used together with other antidiabetic drugs, when diet and exercise do not achieve adequate glycemic control.¹

"Many of our patients with type 2 diabetes are overweight and have elevated blood sugar levels despite lifestyle changes and current therapies," explains Dr. Lawrence Leiter, Professor of Medicine at the University of Toronto. "The availability of a once-weekly injectable associated with effective glucose lowering and weight loss is a welcome addition to our treatment options."

In type 2 diabetes, the body becomes resistant to insulin which leads to heightened blood sugar levels.^{2,3} To cope, cells in the pancreas produce more insulin but they eventually fail to keep up.^{2,3} Although the exact causes of insulin resistance is not completely understood, scientists think the major contributors to insulin resistance are excess weight and physical inactivity.³ Some experts believe obesity, especially excess fat around the waist, is a primary cause of insulin resistance.³

"Factors contributing to the increased global prevalence of type 2 diabetes include an aging population, lifestyle and environmental changes leading to increases in obesity and improved survival for those living with diabetes," explains Dr. Jan Hux, President and Chief Science Officer, Diabetes Canada. "It is critically important that both population health and clinical approaches are applied to help prevent the onset and consequences of diabetes, including solutions designed to manage weight."

Ozempic® was extensively studied in the SUSTAIN clinical trial program, which involved more than 8,000 adults with type 2 diabetes.¹ In the SUSTAIN program, Ozempic® was studied in combination with oral-antidiabetic agents and basal insulin.¹

In pivotal trials, Ozempic® demonstrated statistically significant and sustained blood glucose control compared to sitagliptin, exenatide extended-release, once-daily insulin

glargine U100 and placebo.¹ These trials also evaluated the effect of Ozempic[®] on weight loss compared with such treatments.¹

Across the SUSTAIN clinical trial program, Ozempic[®] had a safe and well-tolerated profile.¹ The most frequently reported adverse reactions in clinical trials were gastrointestinal disorders, including nausea, diarrhea and vomiting.¹ In general, these reactions were mild or moderate in severity.¹

About Ozempic[®]

Ozempic[®] is a new once-weekly analog of human glucagon-like peptide 1 (GLP-1) that stimulates insulin and suppresses glucagon secretion in a glucose-dependent manner.¹ Ozempic[®] will be available in a prefilled pen, based on the latest generation of Novo Nordisk prefilled devices.

Ozempic[®] (semaglutide injection) was approved by the US Food and Drug Administration on December 5, 2017.⁴ European regulatory authorities adopted a positive opinion, recommending marketing authorization for Ozempic[®] (semaglutide) on December 15, 2017.⁵

For information about Ozempic[®], including important safety information, please visit <http://www.novonordisk.ca/content/dam/Canada/AFFILIATE/www-novonordisk-ca/OurProducts/PDF/ozempic-product-monograph.pdf>.

About the SUSTAIN phase 3a clinical trial program

SUSTAIN is a global clinical trial program for Ozempic[®] that is comprised of phase 3a clinical trials and a cardiovascular outcomes trial, involving more than 8,000 adults with type 2 diabetes.¹ Summary results of key trials are described below.

The SUSTAIN 2 trial showed that from a mean baseline HbA_{1c} of 8.0-8.2 per cent, 1,225 adults with type 2 diabetes treated with Ozempic[®] 0.5 mg and 1.0 mg achieved statistically significantly greater HbA_{1c} reductions of 1.3 per cent and 1.5 per cent, respectively, vs 0.7 per cent with sitagliptin 100 mg at 56 weeks (both p<0.0001), as add-on to metformin and/or thiazolidinediones.¹ In addition, adults treated with Ozempic[®] 0.5 mg and 1.0 mg achieved reductions in mean body weight of 4.2 kg and 5.5 kg, respectively, vs 1.7 kg with sitagliptin 100 mg.¹

The SUSTAIN 3 trial with 809 adults with type 2 diabetes and a mean baseline HbA_{1c} of 8.3-8.4 per cent achieved a statistically significantly greater HbA_{1c} reduction of 1.4 per cent when treated with Ozempic[®] 1.0 mg vs 0.9 per cent with exenatide ER 2.0 mg (p<0.0001), as add-on to one or two oral antidiabetics (metformin, sulfonylurea or thiazolidinediones).¹ Furthermore, adults with type 2 diabetes achieved reductions in mean body weight of 4.8 kg when treated with Ozempic[®] 1.0 mg vs 2.0 kg exenatide ER 2.0 mg.¹

The SUSTAIN 4 trial showed that from a mean baseline HbA_{1c} of 8.1-8.2 per cent, 1,082 adults with type 2 diabetes receiving metformin with or without sulfonylurea, achieved statistically significantly greater improvements in HbA_{1c} reductions of 1.2 per cent and 1.5 per cent when treated with Ozempic[®] 0.5 mg and 1.0 mg, respectively, vs a 0.9 per cent reduction with insulin glargine U100 (both p<0.005).¹ End of trial mean dose of insulin glargine U100 was 29 IU/day.² Additionally, adults treated with Ozempic[®] 0.5 mg and 1.0 mg achieved reductions in mean body weight of 3.2 kg and 4.7 kg compared to an increase of 0.9 kg with insulin glargine U100.¹

The SUSTAIN 5 trial showed that, from a mean baseline HbA_{1c} of 8.3-8.4 per cent, 396 adults treated with Ozempic[®] 0.5 mg and 1.0 mg achieved statistically significantly greater HbA_{1c} reductions of 1.3 per cent and 1.7 per cent, respectively, vs 0.2 per cent reduction with placebo, when added on to basal insulin with or without metformin (both $p < 0.0001$).¹ In addition, adults with type 2 diabetes treated with Ozempic[®] 0.5 mg and 1.0 mg achieved weight losses of 3.5 kg and 6.0 kg, respectively, compared to 1.2 kg with placebo.¹

The SUSTAIN 6 trial showed that Ozempic[®] did not increase the risk of major adverse cardiovascular (CV) events (MACE), defined as the composite endpoint of time to first occurrence of either CV death, non-fatal myocardial infarction (heart attack) or non-fatal stroke. The estimated hazard ratio of MACE associated with Ozempic[®] relative to placebo was 0.74 with a 95 per cent confidence interval of (0.58, 0.95).¹

About Novo Nordisk

Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat obesity, haemophilia, growth disorders and other serious chronic diseases. Headquartered in Denmark, Novo Nordisk employs approximately 41,700 people in 77 countries and markets its products in more than 165 countries. For more information, visit novonordisk.com, [Facebook](#), [Twitter](#), [LinkedIn](#), [YouTube](#).

Further information

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References

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