press release

STUDY FINDS VICTOZA® SIGNIFICANTLY REDUCED THE RISK OF HEART ATTACK AND STROKE IN PEOPLE WITH TYPE 2 DIABETES

Diabetes community welcomes news that Victoza® reduces the risk of cardiovascular deaths by 22 per cent

Mississauga, ON – June 13, 2016 – Novo Nordisk Canada Inc. today announced that Victoza® (liraglutide) significantly reduced the risk of the composite primary endpoint of cardiovascular (CV) death, non-fatal myocardial infarction (heart attack) or non-fatal stroke by 13 per cent vs placebo (95% confidence interval [CI]: 0.78; 0.97, p=0.01), when added to standard of care in 9,340 adults with type 2 diabetes at high CV risk. The main results of the LEADER trial were presented today at the American Diabetes Association's 76th Scientific Sessions (ADA 2016) and also published in the *New England Journal of Medicine*.[1,2] Victoza® is the only approved GLP-1 receptor agonist to demonstrate a superior reduction of major CV events vs placebo, both on top of standard of care, in a cardiovascular outcomes trial.

There was a significant 22 per cent reduction in cardiovascular death with Victoza® treatment vs placebo (95% CI: 0.66; 0.93, p=0.007) and reductions in non-fatal myocardial infarction (HR=0.88, 95% CI: 0.75; 1.03, p=0.11) and non-fatal stroke (HR=0.89, 95% CI: 0.72; 1.11, p=0.30).[1,2]

“The results of this trial are extremely encouraging,” said Dr. Lawrence Leiter, endocrinologist at St. Michael's Hospital in Toronto and LEADER investigator. “The potential to prevent heart attacks, strokes and cardiovascular deaths in patients with type 2 diabetes who are most at risk is an exciting advance, and central to successful diabetes care.”

All-cause death was significantly reduced by 15 per cent with Victoza® compared to placebo (95% CI: 0.74; 0.97, p=0.02). The expanded CV endpoint was significantly reduced by 12 per cent with Victoza® compared to placebo (95% CI: 0.81; 0.96, p=0.005). The expanded CV endpoint included the three components of the primary endpoint in addition to unstable angina leading to hospitalization, coronary revascularization and hospitalization for heart failure.[1,2]

From a mean baseline of 8.7 per cent (both groups), there was a greater reduction in HbA_{1c} with Victoza® vs placebo, both on top of standard of care, at three years (estimated treatment difference [ETD]: -0.40%, 95% CI: -0.45; -0.34). Weight loss was also sustained over three years with Victoza® treatment vs placebo (ETD: -2.3 kg, 95% CI: -2.5; -2.0). Mean baseline weight was 91.9 kg and 91.6 kg, respectively.[1,2]

"Novo Nordisk is pleased to share these exciting results from LEADER with the healthcare and broader diabetes community," said Brian Hilberdink, president, Novo Nordisk Canada Inc. "This is a tremendous advancement in the treatment of diabetes as reducing CVD risk has been an ongoing challenge for physicians. To ensure this important treatment option is available to more Canadians living with type 2 diabetes, we will be working closely with provinces across Canada to demonstrate the value of Victoza®. We've seen positive support from private insurers and the province of Quebec and we look forward to securing increased coverage for Victoza® as an option to help improve the long-term health outcomes for people living with diabetes, no matter where they live in Canada."

The proportion of adults experiencing adverse events was similar between the Victoza® and the placebo groups (62.3% vs 60.8%, respectively). The most common adverse events leading to the discontinuation of Victoza® were gastrointestinal events. The incidence of pancreatitis was non-significantly lower in the Victoza® group than in the placebo group.[1,2]

About LEADER
LEADER was a multicentre, international, randomized, double-blind, placebo-controlled trial investigating the long-term effects of Victoza® (liraglutide up to 1.8 mg) compared to placebo, both in addition to standard of care, in people with type 2 diabetes at high risk of major cardiovascular events. Standard of care was comprised of lifestyle modifications, glucose-lowering treatments and cardiovascular medications.

LEADER was initiated in September 2010 and randomized 9,340 people with type 2 diabetes from 32 countries that were followed for 3.5–5 years. The primary endpoint was the first occurrence of a composite cardiovascular outcome comprising cardiovascular death, non-fatal myocardial infarction or non-fatal stroke.[2]

About Victoza®[3]:
Victoza® is a human glucagon-like peptide-1 (GLP-1) analog that was approved by Health Canada for once-daily administration for the treatment of adults with type 2 diabetes to improve glycemic control in combination with:

- Metformin, when diet and exercise plus maximal tolerated dose of metformin do not achieve adequate glycemic control.
- Metformin and a sulfonylurea, when diet and exercise plus dual therapy with metformin and a sulfonylurea do not achieve adequate glycemic control.
- Metformin and basal insulin, when diet and exercise plus dual therapy with Victoza® and metformin do not achieve adequate glycemic control.

Victoza® was launched in the EU in 2009 and is commercially available in more than 85 countries, including Canada, treating more than 1 million people with type 2 diabetes globally.[4,5]
For information about Victoza®, including important safety information, please visit http://novonordisk.ca/PDF_Files/our_products/Victoza/Victoza_PM_EN.pdf.

About Novo Nordisk Canada Inc.

Novo Nordisk Canada Inc. is an affiliate of Novo Nordisk A/S, 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 other serious chronic conditions: hemophilia, growth disorders and obesity. Headquartered in Denmark, Novo Nordisk employs approximately 40,300 employees in 75 countries, and markets its products in more than 180 countries.

Novo Nordisk's company history has deep Canadian roots, with company founders Marie and August Krogh traveling to Toronto in 1922 to meet with Banting, Best, Collip and MacLeod to discuss the insulin preparation. Novo Nordisk would become the first company in Europe to produce insulin in 1923.

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For more information, or to arrange an interview with a Canadian LEADER trial investigator, please contact:

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