

# FDA Approves Ozempic (semaglutide) for Cardiovascular Risk Reduction in Adults with Type 2 Diabetes and Known Heart Disease

PLAINSBORO, N.J., Jan. 16, 2020 /PRNewswire/ -- Novo Nordisk today announced that the U.S. Food and Drug Administration (FDA) has approved a new indication for Ozempic (semaglutide) injection 0.5 mg or 1 mg to reduce the risk of major adverse cardiovascular events (MACE) such as heart attack, stroke, or death in adults with type 2 diabetes and known heart disease.<sup>1</sup> Additional details were added to the Rybelsus (semaglutide) tablets 7 mg or 14 mg Prescribing Information about the primary analysis for PIONEER 6.

Cardiovascular disease (CVD) is the main cause of death and disability among people with type 2 diabetes.<sup>2</sup> Adults with type 2 diabetes are two to four times more likely to develop CVD than adults without diabetes.<sup>3</sup>

The FDA's decision on Ozempic is based on results from the SUSTAIN 6 cardiovascular outcomes trial (CVOT) which examined the cardiovascular safety of adding Ozempic or placebo to standard of care in adults with type 2 diabetes and established cardiovascular disease. In the 2-year SUSTAIN 6 trial, Ozempic significantly reduced the risk of the occurrence of a three-component MACE endpoint consisting of cardiovascular death, non-fatal heart attack or non-fatal stroke. The estimated relative risk reduction of MACE was 26% vs placebo (HR 0.74 [95% CI: 0.58, 0.95],  $p < 0.001$  for noninferiority, median observation time 2.1 years) with the primary composite outcome occurring in 6.6% of patients treated with Ozempic® vs 8.9% with placebo.<sup>1,4</sup> During the trial, gastrointestinal adverse events were more frequent in the Ozempic® group than in the placebo group. The majority of gastrointestinal adverse events occurred during the first 30 weeks.<sup>4</sup>

"There is a well-established link between cardiovascular disease and type 2 diabetes. It's one of our biggest concerns with type 2 diabetes because even when patients reach their blood sugar targets, the risk of a major adverse CV event remains," said Todd Hobbs, vice president and U.S. chief medical officer of Novo Nordisk. "Today's milestone establishes Ozempic® as an option for patients to help address two critical aspects of managing type 2 diabetes, blood sugar control and cardiovascular risk reduction, in those with known heart disease."

The Rybelsus prescribing information has been updated in section 14 (clinical studies) to include an analysis from the primary endpoint of the PIONEER 6 CVOT showing the hazard ratio for time to first

In June 2019, Novo Nordisk initiated the SOUL CVOT in 9,642 adults with type 2 diabetes and established cardiovascular disease to further evaluate the cardiovascular effect of Rybelsus. The trial is investigating the effects of Rybelsus on the incidence of MACE vs placebo in addition to standard of care.

## About the SUSTAIN 6 Trial

SUSTAIN 6 was an event- and time-driven, pre-approval CVOT for Ozempic®. It was a randomized, double-blinded, noninferiority placebo-controlled trial evaluating the cardiovascular safety of Ozempic® vs placebo when added to standard of care in 3,297 adults with type 2 diabetes with established CVD for a minimum observation period of two years.

## About Ozempic

Ozempic (semaglutide) injection 0.5 mg or 1 mg is a once-weekly glucagon-like peptide-1 (GLP-1) receptor agonist indicated along with diet and exercise to improve blood sugar (glucose) in adults with type 2 diabetes mellitus and to reduce the risk of major cardiovascular events such as heart attack, stroke or death in adults with type 2 diabetes mellitus with known heart disease. Ozempic was approved by the U.S. Food and Drug Administration on December 5, 2017, by Health Canada on January 4, 2018, by the European Commission on February 9, 2018, by the Japanese Ministry of Health, Labour and Welfare on March 23, 2018, by Swissmedic on July 2, 2018, and by the Brazilian National Health Surveillance Agency on August 6, 2018.

## About Novo Nordisk

Novo Nordisk is a global healthcare company that's been making innovative medicines to help people with diabetes lead longer, healthier lives for 95 years. This heritage has given us experience and capabilities that also enable us to help people defeat other serious diseases including obesity, hemophilia and growth disorders. We remain steadfast in our conviction that the formula for lasting success is to stay focused, think long-term and do business in a financially, socially and environmentally responsible way. With U.S. headquarters in New Jersey and production and research facilities in six states, Novo Nordisk employs nearly 6,000 people throughout the country. For more information, visit [novonordisk.us](http://novonordisk.us), Facebook, Instagram and Twitter.

## References

1. Ozempic® [package insert]. Plainsboro, NJ: Novo Nordisk Inc; January 2020.
2. Low Wang CC, Hess CN, Hiatt WR, Goldfine AB. Clinical Update: Cardiovascular disease in diabetes mellitus: Atherosclerotic cardiovascular disease and heart failure in type 2 diabetes mellitus mechanisms, Management, and Clinical Considerations. *Circulation*. 2016;133(24):2450-2502.

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4. Marso SP, Bain SC, Consoli A, et al; SUSTAIN-6 Investigators. Semaglutide and cardiovascular outcomes in patients with type 2 diabetes. *N Engl J Med*. 2016;375:1834-1844.
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