company announcement

Ozempic® approved in the US for CV risk reduction in people with type 2 diabetes and established CVD

Rybelsus® label updated with additional information from the PIONEER 6 CV outcomes trial

Bagsværd, Denmark, 16 January 2020 – Novo Nordisk today announced that the US Food and Drug Administration (FDA) has approved a label expansion based on a supplemental New Drug Application (sNDA) for Ozempic® (once-weekly semaglutide) for the indication of reducing the risk of major adverse cardiovascular events (MACE) including cardiovascular death, non-fatal heart attack, or non-fatal stroke in adults with type 2 diabetes and established cardiovascular disease (CVD).

The approval is based on the SUSTAIN 6 cardiovascular outcomes trial (CVOT), which demonstrated that Ozempic® statistically significantly reduced the risk of CV death, non-fatal heart attack or non-fatal stroke by 26% versus placebo, when added to standard of care in people with type 2 diabetes with increased CV risk.

The FDA also updated the Rybelsus® label to include additional information from the PIONEER 6 CVOT demonstrating CV safety. Rybelsus® demonstrated CV safety by meeting the primary endpoint of non-inferiority for the composite MACE endpoint. The proportion of patients who experienced at least one MACE was 3.8% with Rybelsus® and 4.8% with placebo.

"We strongly believe in the benefits of semaglutide and this approval marks an important milestone. Ozempic® now offers people in the US with type 2 diabetes and established cardiovascular disease an effective treatment option to both lower their blood glucose and reduce their cardiovascular risk," said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "We also appreciate that the results from the PIONEER 6 study are reflected in the label for Rybelsus® and to further evaluate the cardiovascular risk reduction profile we are currently conducting the cardiovascular outcomes trial, SOUL."

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About Ozempic®
Ozempic® (once-weekly semaglutide) is an analogue of the naturally occurring hormone glucagon-like peptide-1 (GLP-1). It is administered in a once-weekly injection of 0.5 mg or 1 mg and indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes as well as to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular disease. Ozempic® was first approved by the US FDA in 2017 and is now launched in 25 countries.

About Rybelsus®
Rybelsus® (oral semaglutide) is an analogue of the naturally occurring hormone GLP-1, and it is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes. Rybelsus® is the world's first and only GLP-1 in a tablet. It is administered once daily and is approved for use in two therapeutic dosages, 7 mg and 14 mg.

Rybelsus® was approved by the US FDA in September 2019 and is currently under review by several regulatory agencies, including the European Medicines Agency and the Japanese Pharmaceuticals and Medical Devices Agency.

About SUSTAIN 6 and PIONEER 6
SUSTAIN 6 was an event and time-driven CVOT for Ozempic®. It was a randomised, double-blinded, placebo-controlled trial evaluating the CV safety of Ozempic® versus placebo when added to standard of care in 3,297 adults with type 2 diabetes with established CVD or high risk of CV events.

PIONEER 6 was a purely event-driven, pre-approval CVOT for oral semaglutide. It was a randomised, double-blinded, placebo-controlled trial evaluating the CV safety of Rybelsus® versus placebo when added to standard of care in 3,183 adults with type 2 diabetes with established CVD or high risk of CV events.

About the SOUL trial
Novo Nordisk is conducting SOUL, a CVOT for Rybelsus® in 9,642 people with type 2 diabetes and established cardiovascular disease, investigating the effects of oral semaglutide on the incidence of MACE, compared to placebo, both on top of standard of care.

Novo Nordisk is a global healthcare company with more than 95 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 42,200 people in 80 countries and markets its products in more than 170 countries. Novo Nordisk's B shares are listed on Nasdaq Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube.

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