company announcement

Oral semaglutide demonstrates a 14% reduction in risk of major adverse cardiovascular events in adults with type 2 diabetes in the SOUL trial

Bagsværd, Denmark, 21 October 2024 — Novo Nordisk today announced the headline results from the SOUL cardiovascular outcomes trial. The double-blinded, randomised trial compared oral semaglutide to placebo as an adjunct to standard of care for the prevention of major adverse cardiovascular events (MACE). The trial enrolled 9,650 people with type 2 diabetes and established cardiovascular disease (CVD) and/or chronic kidney disease (CKD). As part of standard of care, 49% of patients received SGLT2i at some point during the trial.

The trial achieved its primary objective by demonstrating a statistically significant and superior reduction in MACE of 14% for people treated with oral semaglutide compared to placebo[1]. The primary endpoint of the study was defined as the composite outcome of the first occurrence of MACE defined as cardiovascular death, non-fatal myocardial infarction or non-fatal stroke. All three components of the primary endpoint contributed to the superior MACE reduction demonstrated by oral semaglutide.

In the trial, oral semaglutide appeared to have a safe and well-tolerated profile in line with previous oral semaglutide trials.

"We are pleased to see that the results from SOUL demonstrate that oral semaglutide reduces the risk of cardiovascular events and that the benefits of oral semaglutide come on top of standard of care," said Martin Holst Lange, executive vice president and head of Development at Novo Nordisk. "Approximately one in three adults with type 2 diabetes also have cardiovascular disease; therefore, it is crucial to have therapies that can address both conditions."

[1] Based on treatment policy estimand: treatment effect regardless of treatment adherence

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Novo Nordisk expects to file for regulatory approval of a label expansion for Rybelsus® in both the US and EU around the turn of the year. The detailed results from SOUL will be presented at a scientific conference in 2025.

About the SOUL trial
SOUL was a multicentre, international, randomised, double-blind, parallel-group, placebo-controlled, phase 3 cardiovascular outcomes trial with 9,650 people enrolled. It was conducted to assess the effect of oral semaglutide vs placebo on cardiovascular outcomes in people with type 2 diabetes and established CVD and/or CKD. The SOUL trial was initiated in 2019.

The key objective of SOUL was to demonstrate that oral semaglutide lowers the risk of major adverse cardiovascular events (a composite endpoint consisting of cardiovascular death, non-fatal myocardial infarction and non-fatal stroke) compared to placebo, both added to standard of care in patients with type 2 diabetes and established CVD and/or CKD.

About Rybelsus®
Oral semaglutide is administered once daily and is approved for use in three doses, 3 mg, 7 mg and 14 mg, under the brand name Rybelsus®. It is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise. In the EU, a new formulation of 1.5 mg, 4 mg and 9 mg doses of Rybelsus® are approved and are bioequivalent to the original formulation of Rybelsus®.

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 69,000 people in 80 countries and markets its products in around 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, Instagram, X, LinkedIn and YouTube.

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