company announcement

Semaglutide 1.0 mg demonstrates 24% reduction in the risk of kidney disease-related events in people with type 2 diabetes and chronic kidney disease in the FLOW trial

Bagsværd, Denmark, 5 March 2024 – Novo Nordisk today announced the headline results from the kidney outcomes trial FLOW. The announcement today follows the decision to stop the trial early due to efficacy, which was announced on 10 October 2023, based on a recommendation from an Independent Data Monitoring Committee. The double-blind trial compared injectable semaglutide 1.0 mg with placebo as an adjunct to standard of care for prevention of progression of kidney impairment and risk of kidney and cardiovascular mortality in people with type 2 diabetes and chronic kidney disease (CKD). The trial enrolled 3,533 people with type 2 diabetes and CKD.

The trial achieved its primary endpoint by demonstrating a statistically significant and superior reduction *in kidney disease progression, major adverse cardiovascular events (MACE) and death of 24% for people treated with semaglutide 1.0 mg compared to placebo[1]. The combined primary endpoint included five components measuring the progression of CKD and the risk of kidney and cardiovascular mortality. Both CKD and cardiovascular components of the primary endpoint contributed to the risk reduction. Further, superiority of semaglutide 1 mg vs placebo was confirmed for the confirmatory secondary endpoints.

In the trial, semaglutide 1.0 mg appeared to have a safe and well-tolerated profile in line with previous semaglutide 1.0 mg trials.

"We are very excited about the results from FLOW showing that semaglutide 1.0 mg reduces the risk of kidney disease progression," said Martin Holst Lange, executive vice president for Development at Novo Nordisk. "Approximately 40% of people with type 2 diabetes have chronic kidney disease, so the positive results from FLOW demonstrate the potential for semaglutide to become the first GLP-1 treatment option for people living with type 2 diabetes and chronic kidney disease."

Correction in the second paragraph: "... in kidney disease progression, major adverse cardiovascular events (MACE) and death ..." **should have read** "... in kidney disease progression as well as cardiovascular and kidney death ..."

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Novo Nordisk expects to file for regulatory approvals of a label expansion for Ozempic® in the US and EU in 2024. The detailed results from FLOW will be presented at a scientific conference in 2024.

About FLOW
FLOW was a randomised, double-blind, parallel-group, placebo-controlled, superiority trial comparing injectable semaglutide 1.0 mg with placebo as an adjunct to standard of care on kidney outcomes for prevention of progression of kidney impairment and risk of kidney and cardiovascular mortality in people with type 2 diabetes and CKD (defined as eGFR[2] ≥50 and ≤75mL/min/1.73 m2 and UACR >300 and <5000 mg/g or eGFR ≥25 and <50 mL/min/1.73 m2 and UACR >100 and <5000 mg/g). 3,533 people were enrolled in the trial conducted in 28 countries at around 400 investigator sites. The FLOW trial was initiated in 2019.

The key objective of the FLOW trial is to demonstrate delay in progression of CKD and to lower the risk of kidney and cardiovascular mortality through the composite primary endpoint consisting of the following five components: onset of persistent ≥ 50% reduction in eGFR according to the CKD-EPI[3] equation compared with baseline, onset of persistent eGFR (CKD-EPI) < 15 mL/min/1.73 m2, initiation of chronic kidney replacement therapy (dialysis or kidney transplantation), death from kidney disease or death from cardiovascular disease. Confirmatory secondary endpoints include annual rate of change in eGFR[1] (CKD-EPI), MACE (non-fatal myocardial infarction, non-fatal stroke, cardiovascular death) and all-cause death.

About Ozempic®
Once-weekly subcutaneous semaglutide is approved in 0.5 mg, 1.0 mg and 2.0 mg doses under the brand name Ozempic® and indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes and to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular disease.

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 63,400 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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1. Based on treatment policy estimand: treatment effect regardless of treatment adherence
2. eGFR: estimated glomerular filtration rate
3. CKD-EPI: Chronic Kidney Disease Epidemiology Collaboration