

company announcement

European regulatory authority adopts positive opinion for an update of the Ozempic® label to reflect risk reduction of kidney disease-related events

Bagsværd, Denmark, 12 December 2024 – Novo Nordisk today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for an update of the Ozempic® (once-weekly subcutaneous semaglutide) label to reflect data from the FLOW kidney outcomes trial. The FLOW trial assessed the risk reduction from Ozempic® therapy in chronic kidney disease-related events, including persistent $\geq 50\%$ decline in estimated glomerular filtration rate (eGFR), onset of persistent eGFR < 15 ml/min/1.73 m², initiation of chronic kidney replacement therapy, kidney death or cardiovascular death in adults with type 2 diabetes and chronic kidney disease (CKD).

In the FLOW trial, semaglutide 1.0 mg demonstrated a statistically significant and superior 24% risk reduction in kidney disease progression as well as cardiovascular and kidney death compared to placebo. In addition, the secondary endpoints in the trial showed that the risk of major cardiovascular events was reduced by 18%, and the risk of all-cause mortality was reduced by 20%.

"Approximately 40% of people with type 2 diabetes develop chronic kidney disease, and there is a need for treatments that can help to reduce kidney disease progression," said Martin Holst Lange, executive vice president for Development at Novo Nordisk. "With this positive opinion, Ozempic® will become the first and only GLP-1 receptor agonist to show lowering of risk of kidney disease progression in adults with type 2 diabetes and chronic kidney disease."

Novo Nordisk has also filed for a label expansion in the US, and a decision is expected in the first half of 2025.

About FLOW

FLOW was a randomised, double-blinded, parallel-grouped, placebo-controlled, superiority trial comparing injectable semaglutide 1.0 mg with placebo as an adjunct to standard of care. The

trial assessed the effect of the treatments on kidney outcomes for prevention of progression of kidney disease and risk of kidney and cardiovascular mortality in people with type 2 diabetes and CKD (defined as eGFR ≥ 50 and ≤ 75 mL/min/1.73 m² with urine albumin-to-creatinine ratio [UACR] >300 and $<5,000$ mg/g or eGFR ≥ 25 and <50 mL/min/1.73 m² with UACR >100 and $<5,000$ mg/g). A total of 3,533 people were enrolled in the trial, which was conducted in 28 countries at around 400 investigator sites. The FLOW trial was initiated in 2019.

The key objective of the FLOW trial was to demonstrate delay in progression of CKD and to lower the risk of kidney and cardiovascular mortality through a composite primary endpoint consisting of the following five components: onset of persistent $\geq 50\%$ reduction in eGFR according to the CKD-Epidemiology Collaboration (EPI) 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 included annual rate of change in eGFR (CKD-EPI), major adverse cardiovascular events (non-fatal myocardial infarction, non-fatal stroke, cardiovascular death) and all-cause death.

The FLOW data were presented at the European Renal Association Congress (ERA) in May 2024 and published in the New England Journal of Medicine (NEJM).

About Ozempic®

Once-weekly subcutaneous semaglutide is approved in 0.25 mg, 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.

About Novo Nordisk

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 72,000 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](https://www.novonordisk.com), [Facebook](#), [Instagram](#), [X](#), [LinkedIn](#) and [YouTube](#).

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