

company announcement

Novo Nordisk will stop the once-weekly injectable semaglutide kidney outcomes trial, FLOW, based on interim analysis

Bagsværd, Denmark, 10 October 2023 – Novo Nordisk today announced the decision to stop the kidney outcomes trial FLOW (Effect of semaglutide versus placebo on the progression of renal impairment in people with type 2 diabetes and chronic kidney disease).

The decision to stop the trial is based on a recommendation from the independent Data Monitoring Committee (DMC) concluding that the results from an interim analysis met certain pre-specified criteria for stopping the trial early for efficacy.

Based on the decision to stop the trial at interim, the process of closing the trial will be initiated. To protect the integrity of the trial, Novo Nordisk remains blinded to the results until trial completion. Novo Nordisk expects that FLOW will read out during the first half year of 2024.

About FLOW

FLOW is 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 renal impairment and risk of renal and cardiovascular mortality in people with type 2 diabetes and chronic kidney disease (CKD). 3,534 people are enrolled in the trial which has been conducted in 28 countries at more than 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 $\geq 50\%$ reduction in eGFR¹ according to the CKD-EPI² equation compared with baseline, onset of persistent eGFR¹ (CKD-EPI²) < 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 in people with type 2 diabetes and chronic kidney disease. Key secondary endpoints include annual rate of change in eGFR¹ (CKD-EPI²), major adverse cardiovascular events (non-fatal myocardial infarction, non-fatal stroke, cardiovascular death) and all-cause death. The trial protocol provides for an interim analysis when a prespecified number of primary endpoint events has occurred.

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Novo Nordisk Exhibit 2017
Mylan Pharms. Inc. v. Novo Nordisk A/S

About Ozempic®

Once-weekly subcutaneous semaglutide is approved in 0.5, 1.0 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 mellitus and to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus 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 59,000 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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1. eGFR: estimated glomerular filtration rate

2. CKD-EPI: Chronic Kidney Disease Epidemiology Collaboration

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