

Subject: Competitive intelligence update
Date: Tuesday, October 10, 2023 at 5:10:37 PM Eastern Daylight Time
From: Robert Stoekenbroek
To: Metsera
Attachments: image001.png, image002.png, image003.png, image004.png, image005.png, PHP_Logo_Primary_210826_01_1200x294_small_edb56208-d78e-4f54-ba89-2644d9621fe6.jpg



October 10, 2023

Clinical Trial Updates

Novo Nordisk announces premature discontinuation of FLOW trial for efficacy

Summary and Implications

- Novo Nordisk today announced that the FLOW trial (effect of semaglutide versus placebo on the progression of renal impairment in people with type 2 diabetes and chronic kidney disease) has been discontinued prematurely for efficacy.
- Novo Nordisk expects that FLOW results will become available during the first half year of 2024.

Context

Novo Nordisk and Eli Lilly are investigating GLP-1RAs for a variety of weight-related and T2DM-related diseases.

The FLOW trial was evaluating the efficacy of semaglutide 1 mg (T2DM dose) versus placebo on a composite of persistent eGFR decline (50%+ decline from trial start), end-stage renal disease, death from kidney disease, or death from cardiovascular disease in 3534 patients with T2DM and renal impairment. The trial was designed as an event-driven trial, and was expected to be completed in 2024.

Prior cardiovascular safety trials with GLP-1RAs in patients with T2DM, in which CKD outcomes were a secondary endpoint, have generally shown positive outcomes. These outcomes formed the basis for the evaluation of semaglutide in CKD patients in a dedicated outcomes trial.

Content

The FLOW trial was discontinued 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*.

Novo Nordisk expects that FLOW will read out during the first half year of 2024.

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