

company announcement

Novo Nordisk to enter phase 3 development in Alzheimer's disease with oral semaglutide

Bagsværd, Denmark, 16 December 2020 – Novo Nordisk today announced the decision to enter phase 3 development in Alzheimer's disease with 14 mg oral semaglutide, a once-daily oral formulation of the long-acting GLP-1 analogue semaglutide. The decision follows evaluation of GLP-1 data from preclinical models, real-world evidence studies, post-hoc analysis of data from large cardiovascular outcomes trials, as well as discussions with regulatory authorities.

Novo Nordisk intends to initiate a pivotal phase 3a programme with approximately 3,700 people with early Alzheimer's disease. The programme is planned for initiation in the first half of 2021 and will investigate the efficacy and safety of once-daily oral semaglutide, compared to placebo. The expected main treatment period in the trials is around two years.

"As a company we aspire to address high unmet medical needs within serious chronic diseases, and we are therefore pleased to initiate phase 3 development of semaglutide within Alzheimer's disease," said Mads Krosgaard Thomsen, executive vice president and chief scientific officer at Novo Nordisk. "Alzheimer's disease has been an area of extensive research in the past decades, unfortunately without any major medical breakthroughs. Due to the growing unmet medical need and the increasing evidence of a potential therapeutic role for GLP-1, we will investigate the benefits of oral semaglutide in early Alzheimer's disease."

Conference call

On 16 December at 4 pm CET, corresponding to 10 am EST, a conference call for investors will be held where members of management will elaborate on the decision and provide a brief update on the GLP-1 R&D strategy. Investors will be able to listen in via a link on the investor section of novonordisk.com.

About Alzheimer's disease

Alzheimer's disease represents a rapidly growing public health concern causing significant detrimental consequences to the affected people and their families and has led to substantial and increasing global socioeconomic impact. Worldwide, 70-100 million people are estimated to have early Alzheimer's disease (mild cognitive impairment and mild dementia stages).

About data from preclinical models, real-world evidence studies and the post-hoc analysis

Animal studies highlight the key effects of GLP-1 relevant for Alzheimer's disease including improved memory function and reduced phospho-tau accumulation. Semaglutide has specifically been shown to reduce measures of neuro-inflammation which may affect cognition and function.

Further, real-world evidence from two Danish nationwide registries, the US Truven claims database and the US FDA FAERS database support a potential association between lower risk of dementia following treatment with GLP-1.

Finally, in a post-hoc analysis of data from three large cardiovascular outcomes trials conducted by Novo Nordisk (LEADER, SUSTAIN 6 and PIONEER 6), which included 15,820 patients with type 2 diabetes with median follow-up of 3.6 years, a total number of 47 people were identified with development of dementia, of which 32 were on placebo and 15 on GLP-1 (liraglutide or semaglutide). The rate of developing dementia was statistically significantly reduced by 53% in favour of GLP-1.

About oral semaglutide

Oral semaglutide (7 mg and 14 mg) is approved as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes in the US, EU and Japan. The approval of Rybelsus® is based on the results from 10 clinical trials which included 9,543 adults with type 2 diabetes. Rybelsus® demonstrated a safe and well-tolerated profile across the clinical trials, with the most common adverse event being mild to moderate nausea which diminished over time.

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat diabetes and other serious chronic diseases such as obesity and rare blood and endocrine disorders. We do so by pioneering scientific breakthroughs, expanding access to our medicines and working to prevent and ultimately cure disease. Novo Nordisk employs about 44,000 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](#), [Twitter](#), [LinkedIn](#), [YouTube](#).

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