company announcement

Novo Nordisk successfully completes phase 1b/2a trial with subcutaneous amycretin in people with overweight or obesity

Bagsværd, Denmark, 24 January 2025 – Novo Nordisk today announced topline results from a phase 1b/2a clinical trial with amycretin, a unimolecular GLP-1 and amylin receptor agonist intended for once weekly subcutaneous administration.

The trial investigated the safety, tolerability, pharmacokinetics, and proof-of-concept after once-weekly subcutaneous administrations of amycretin in 125 people with overweight or obesity. The trial was a combined single ascending dose, multiple ascending dose and dose-response trial investigating three different maintenance doses with a total treatment duration of up to 36 weeks.

The primary endpoint was treatment emergent adverse events. The safety profile of amycretin was consistent with incretin-based therapies. The most common adverse events with amycretin were gastrointestinal and the vast majority were mild to moderate in severity.

When evaluating the effects of treatment if all people adhered to treatment[1] from a mean baseline body weight of 92.7 kg, people treated with amycretin achieved an estimated body weight loss of 9.7% on 1.25mg (20 weeks), 16.2% on 5mg (28 weeks) and 22.0% on 20mg (36 weeks). People treated with placebo experienced an estimated 1.9%, 2.3% and 2.0% body weight gain, respectively.

“We are very encouraged by the subcutaneous phase 1b/2a results for amycretin in people living with overweight or obesity,” said Martin Lange, executive vice president for Development at Novo Nordisk. “The results seen in the trial support the weight lowering potential of this novel unimolecular GLP-1 and amylin receptor agonist, amycretin, that we have previously seen with the oral formulation.”

[1] If all people adhered to treatment i.e. if all people followed the planned dosing schedule for the full trial period without any treatment discontinuations.

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Based on the results, Novo Nordisk is now planning further clinical development of amycretin in adults with overweight or obesity.

About amycretin

Amycretin is a unimolecular long-acting GLP-1 and amylin receptor agonist under development by Novo Nordisk, to provide an efficacious and convenient treatment for adults with overweight or obesity and as a treatment for adults with type 2 diabetes. Amycretin is developed for oral and subcutaneous administration.

About the Phase 1b/2a subcutaneous amycretin trial

The trial was a randomised, placebo-controlled and double-blinded study assessing the safety, tolerability, pharmacokinetics, and proof-of-concept after subcutaneous administration of amycretin in people with overweight or obesity. The trial was conducted in 5 parts: A single ascending dose (Part A) for determination of pharmacokinetics and starting dose for the first multiple dose cohort in which the safety and tolerability were explored using dose escalation until 36 weeks of total treatment duration (Part B). Lastly, in the proof-of-concept part, body weight loss was explored for up to 36 weeks of dosing by escalating to dose levels of 1.25 mg, 5 mg, and 20 mg, respectively, dosed for 12 weeks (Part E, D and C).

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, Facebook, Instagram, X, LinkedIn and YouTube.

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