company announcement

Novo Nordisk phase 2 trial with amycretin reports significant weight loss and HbA_{1c} reduction in type 2 diabetes

- Amycretin showed statistically significant weight loss of up to 14.5% at 36 weeks
- Amycretin demonstrated statistically significant reductions in HbA_{1c} with up to 89.1% achieving HbA_{1c} levels below 7%
- Amycretin appeared to have a safe and well-tolerated profile consistent with incretin and amylin-based therapies

Bagsværd, Denmark, 25 November 2025 – Novo Nordisk today announced positive headline results from a phase 2 clinical trial with amycretin in people with type 2 diabetes. This marks the first evaluation of amycretin in people with type 2 diabetes, further demonstrating Novo Nordisk's commitment to advancing innovation in the treatment of type 2 diabetes. Amycretin is a unimolecular agonist of the glucagon-like peptide 1 (GLP-1) and amylin receptors, intended for once-weekly subcutaneous administration and once-daily oral administration.

The trial investigated the efficacy, safety and pharmacokinetics of once-weekly subcutaneous amycretin and once-daily oral amycretin compared to placebo in 448 people with type 2 diabetes inadequately controlled on metformin with or without an SGLT2 inhibitor as standard of care. Approximately 40% of all participants were using an SGLT2 inhibitor before initiating the trial. The trial was a combined multiple ascending dose study, investigating six subcutaneous doses from 0.4 mg to 40 mg administered weekly, and three daily oral doses of 6 mg, 25 mg and 50 mg, with a total treatment duration of up to 36 weeks.

When evaluating the effects of treatment, if all people adhered to treatment[1] from a mean baseline HbA_{1c} of 7.8%, once-weekly subcutaneous amycretin achieved dose-dependent reductions in HbA_{1c} of up to -1.8% by week 36. The proportion of people achieving HbA_{1c} <7% and ≤6.5% was up to 89.1% and 76.2% respectively.

[1]I.e. if all people followed the planned dosing schedule for the full trial period without initiation of rescue medication

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From a mean baseline HbA_{1c} of 8.0%, people treated with once-daily oral amycretin achieved dose-dependent improvements in HbA_{1c} of up to -1.5% by week 36. The proportion of people achieving an HbA_{1c} level of <7% and ≤6.5% with once-daily oral amycretin was 77.6% and 62.6% respectively.

By comparison, people treated with placebo achieved HbA_{1c} improvement of -0.2% and -0.4% with subcutaneous and oral amycretin, respectively. The estimated improvements in HbA_{1c} were all statistically significant versus placebo, confirming the primary endpoints of the trial.

From a mean baseline body weight of 99.2 kg, subcutaneous amycretin achieved statistically significant weight loss of up to -14.5% compared to -2.6% in people treated with placebo. People treated with the highest dose of subcutaneous amycretin were on the final maintenance dose for a duration of 4 weeks. Similarly, from a mean baseline body weight of 101.1 kg, people treated with oral amycretin also achieved statistically significant weight loss of up to -10.1% compared to -2.5% in people treated with placebo. For the higher doses of amycretin, irrespective of administration route, no weight loss plateau was observed at week 36.

In the trial, subcutaneous and oral amycretin appeared to have a safe and well-tolerated profile, consistent with other incretin and amylin-based therapies. The most common adverse events with amycretin were gastrointestinal, and the vast majority were mild to moderate in severity.

“We are very encouraged by the phase 2 data with amycretin in people with type 2 diabetes - the first time amycretin has been evaluated in this population. The data further validate the potential best-in-class profile of amycretin” said Martin Holst Lange, chief scientific officer and executive vice president of Research and Development at Novo Nordisk. “Amycretin is built on the complementary biology of GLP-1 and amylin, and we are looking forward to bringing amycretin into an extensive phase 3 development programme across multiple indications in 2026”.

Based on the results, Novo Nordisk is now planning to initiate a phase 3 development programme with amycretin for adults with type 2 diabetes in 2026.

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 2 trial in T2D

This trial is an interventional, multinational, multi-centre, randomised, parallel, double-blind (within arms), placebo-controlled, dose-finding study. The phase 2 trial investigated the safety, efficacy and PK properties of once-weekly subcutaneous and once-daily oral amycretin in participants with type 2 diabetes inadequately controlled (HbA_{1c} 7.0-10.0 %) on a stable dose of metformin with or without an SGLT2 inhibitor. In the trial, close to two-thirds of the participants were male across both routes of administration. The trial consisted of nine active treatment arms. Participants received increasing doses of once-weekly subcutaneous amycretin (0.4 mg, 1.5 mg, 5 mg, 10 mg, 20 mg, and 40 mg) in six groups, and oral amycretin (6 mg, 25 mg, and 50 mg) in three groups for up to 36 weeks. The primary objective is to determine and characterise the dose-response relationship of subcutaneous and oral amycretin on change in HbA_{1c} from baseline to week 36 in participants with type 2 diabetes. Secondary endpoints included changes in body weight (%) from baseline to week 36.

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 78,500 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.

Publication of inside information pursuant to Market Abuse Regulation, Article 17.

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