press release

Novo Nordisk's subcutaneous and oral amycretin data published in *The Lancet* and presented at ADA 2025

- Subcutaneous amycretin phase 1b/2a data on the safety, tolerability and weight loss potential in people with overweight or obesity was published in *The Lancet* and presented at the American Diabetes Association (ADA) Scientific Sessions.[1,2]
- Oral amycretin phase 1 data on the safety, tolerability and weight loss potential in people with overweight or obesity was also published in *The Lancet.*[3]
- Findings from the clinical trials indicate amycretin appeared tolerable with a safety profile consistent with other GLP-1 and amylin receptor agonists.[1,2,3]

Bagsværd, Denmark, 20 June 2025 – Novo Nordisk announces subcutaneous amycretin data being presented at the American Diabetes Association (ADA) 85th Scientific Sessions in Chicago, US.[1] Full results of two clinical trials evaluating the safety, tolerability and weight loss potential of subcutaneous and oral amycretin in people with overweight or obesity were published today in *The Lancet* medical journal.[1,3] Amycretin is the first treatment that combines GLP-1 and amylin receptor agonism biology in a single molecule.

The published and presented results from the once-weekly subcutaneous amycretin phase 1b/2a clinical trial showed that participants who received the treatment demonstrated significantly greater weight loss across the full range of doses investigated compared to placebo. Data being presented at ADA were collected from two parts of the trial; dose escalation (amycretin 60 mg), and dose escalation and maintenance (amycretin 20 mg, 5 mg and 1.25 mg).[1,2] No plateauing in weight reduction was observed at the end of treatment (ranging from 20 to 36 weeks) with all tested doses, suggesting that a longer treatment duration may potentially contribute to additional weight loss.[1,2]

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Estimated mean change in body weight from baseline with once-weekly subcutaneous (SC) amycretin: [1,2] *****

Dose	Treatment duration	% Weight change (SC amycretin)	% Weight change (placebo)
60 mg	36 weeks	-24.3%	-1.1%
20 mg**	36 weeks	-22.0%	1.9%
5 mg**	28 weeks	-16.2%	2.3%
1.25 mg**	20 weeks	-9.7%	2.0%

** 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.*

*** Administered during a 12-week maintenance period.*

Once-weekly subcutaneous amycretin treatment escalated up to 60 mg appeared tolerable with a safety profile consistent with other GLP-1 and amylin receptor agonists.[1,2] The number of treatment-emergent adverse events (TEAEs) increased in a dose-dependent manner, were mostly gastrointestinal, and were comparable to the rate and profile of TEAEs reported in early-phase studies of GLP-1 receptor, GLP-1 receptor/gastric inhibitory polypeptide (GIP) receptor, and amylin receptor agonists.[1,2] The majority of TEAEs were mild to moderate in severity and resolved by the end of the study period.[1,2] Of the participants who discontinued the trial, the majority were due to non-TEAE reasons.[1,2]

“As pioneers in obesity innovation, we are exploring multiple biological pathways to develop potentially transformative medicines that support the individual needs and preferences of people with obesity on their weight loss journey towards overall improved health,” said Martin Holst Lange, executive vice president for Development at Novo Nordisk. “Amycretin is the first investigational treatment that combines GLP-1 and amylin receptor agonism biology in one molecule, working on distinct pathways and offering complementary effects on appetite control. The findings published and presented today are encouraging. We are excited to advance the clinical development of subcutaneous and oral amycretin into phase 3 to assess its potential as a therapeutic option for weight management.”

The published once-daily oral amycretin phase 1 clinical trial data showed that participants receiving amycretin achieved greater weight loss compared to placebo.[3] After 12 weeks of treatment with amycretin up to 50 mg and up to 2 times 50 mg, participants achieved a mean change in body weight of -10.4% and -13.1% respectively, compared to -1.2% with placebo.[3]

There were no apparent signs of weight loss plateauing within the 12 weeks of treatment in either of these amycretin-treated groups.[3]

Once-daily oral amycretin appeared to have an acceptable safety profile and was tolerable in all tested doses, with TEAEs in line with what was expected from targeting GLP-1 and amylin receptors.[3] All reported TEAEs occurred in a dose-proportional manner, were mild to moderate in severity, and mostly gastrointestinal. No new safety signals appeared during the study.[3]

Based on the findings from the oral and subcutaneous amycretin trials, Novo Nordisk recently announced it will advance amycretin into phase 3 trials to further investigate the treatment as a potential new therapeutic option for weight management.[4]

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 for adults with type 2 diabetes. Amycretin is developed for subcutaneous and oral administration.

Oral amycretin Phase 1 trial - The trial evaluated the single-ascending dose and multiple ascending doses for oral amycretin, up to 2 times 50 mg, in 144 people with overweight or obesity, with a total treatment duration of up to 12 weeks.

Subcutaneous amycretin Phase 1b/2a trial - The trial investigated the safety, tolerability, pharmacokinetics, and proof-of-concept of once-weekly subcutaneous 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.

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 77,400 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.com, Facebook, Instagram, X, LinkedIn and YouTube.

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3. The Lancet: Gasiorek A, Heydorn A, Gabery S, et al. Safety, tolerability, pharmacokinetics, and pharmacodynamics of the first-in-class GLP-1 and amylin receptor agonist, amycretin: a first-in-human, phase 1, randomised, placebo-controlled study.
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