

# company announcement

## **CagriSema demonstrated 23% weight loss in an open-label head-to-head REDEFINE 4 trial in people with obesity, the primary endpoint was not achieved**

- CagriSema achieved 23% weight loss after 84 weeks of treatment
- CagriSema 2.4/2.4 mg did not meet the primary endpoint of showing non-inferiority on weight loss compared to tirzepatide 15 mg at 84 weeks<sup>1</sup>
- Additional trials are exploring the full weight loss potential of CagriSema, including higher-dose combinations

**Bagsværd, Denmark, 23 February 2026** – Novo Nordisk today announced headline results from REDEFINE 4, an open-label phase 3 trial from the global REDEFINE clinical trial programme.

REDEFINE 4 was an 84-week trial investigating CagriSema (a fixed dose combination of cagrilintide 2.4 mg and semaglutide 2.4 mg) compared to tirzepatide 15 mg, both administered once-weekly and subcutaneously. The trial included 809 randomised people with obesity and one or more comorbidities and with a mean baseline body weight of 114.2 kg. The trial had an open-label design, meaning that all investigators and participants were aware of the specific drug administered throughout the trial.

When evaluating the effects of treatment, if all people adhered to treatment<sup>1</sup>, people treated with CagriSema 2.4 mg/2.4 mg achieved a weight loss of 23.0% after 84 weeks compared to 25.5% with tirzepatide 15 mg. When applying the treatment-regimen estimand<sup>2</sup>, people treated with CagriSema 2.4 mg/2.4 mg achieved a weight loss of 20.2% compared to 23.6% with tirzepatide at 84 weeks. The trial did not achieve its primary endpoint of demonstrating non-inferiority on weight loss for CagriSema compared to tirzepatide after 84 weeks.

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<sup>1</sup> Based on the efficacy estimand according to the trial protocol, regardless of dose modification

<sup>2</sup> Based on the treatment-regimen estimand: treatment effect regardless of treatment adherence

In the trial, CagriSema appeared to have a safe and well-tolerated profile. The most common adverse events with CagriSema were gastrointestinal, and the vast majority were mild to moderate and diminished over time, consistent with the GLP-1 receptor agonist class.

“We are pleased with the weight loss of 23% for CagriSema in this open-label trial. CagriSema has the potential to be the first GLP-1/amylin-combination product to reach the market for people living with obesity, documenting that cagrilintide adds to the existing benefits of semaglutide and offers clinically meaningful additive weight loss effects superior to what has been observed with GLP-1 biology alone. Based on the learnings from completed studies we look forward to the REDEFINE 11 readout, and the initiation of the higher-dose CagriSema trial, which are both designed to assess the full weight-loss potential of CagriSema”, said Martin Holst Lange, executive vice president, R&D and chief scientific officer at Novo Nordisk. “The results in the REDEFINE programme reinforce our commitment to transforming obesity care, through novel products such as CagriSema and zenaglutide with the potential to offer even greater health benefits for patients living with obesity.”

CagriSema for weight management was submitted to the US FDA in December 2025 based on the REDEFINE 1 and REDEFINE 2 pivotal trials, and an FDA decision is anticipated by late 2026. The REDEFINE 11 phase 3 trial exploring CagriSema 2.4/2.4 mg full weight-loss potential in obesity is expected to report data during the first half of 2027, while initiation of the phase 3 CagriSema higher-dose trial is planned for the second half of 2026.

### **Conference call**

Novo Nordisk will host a conference call for investors at 11.30 CEST on 23 February 2026, corresponding to 5:30 am EDT. A dial-in link to the conference call will be published on the investor section of [novonordisk.com](http://novonordisk.com).

### **About CagriSema**

Once-weekly subcutaneous CagriSema is being investigated by Novo Nordisk as a treatment for adults with overweight or obesity (REDEFINE programme) and as a treatment for adults with type 2 diabetes (REIMAGINE programme). CagriSema is a fixed-dose combination of a long-acting amylin analogue, cagrilintide 2.4 mg and semaglutide 2.4 mg. The two molecules induce weight loss by reducing hunger, increasing feelings of fullness and thereby help people eat less and reduce their calorie intake.

## **About the REDEFINE programme**

REDEFINE is a phase 3 clinical development programme with once-weekly subcutaneous CagriSema in obesity. The global clinical trial programme includes two pivotal phase 3 trials, which included approximately 4,600 adults with overweight or obesity. The phase 3 trial programme includes:

REDEFINE 1 – a 68-week efficacy and safety phase 3 trial of once-weekly CagriSema 2.4 mg/2.4 mg, cagrilintide 2.4 mg and semaglutide 2.4 mg versus placebo in 3,417 adults with obesity or overweight with one or more comorbidities and without type 2 diabetes.

REDEFINE 2 – a 68-week efficacy and safety phase 3 trial of once-weekly CagriSema 2.4 mg/2.4 mg versus placebo in 1,206 adults with type 2 diabetes and either obesity or overweight.

REDEFINE 3 – an event-driven cardiovascular outcomes phase 3 trial of once-weekly CagriSema 2.4 mg/2.4 mg versus placebo in 7,000 adults with established cardiovascular disease with or without type 2 diabetes.

REDEFINE 8 – a 104-week efficacy and safety phase 3 trial of once-weekly CagriSema 2.4 mg/2.4 mg versus placebo in 400 adults with obesity, including assessments on body composition. The trial includes a 52-week extension phase investigating maintenance of weight loss with CagriSema 2.4 mg/2.4 mg or a dose-tapering algorithm.

REDEFINE 9 – a 68-week efficacy and safety phase 3 trial of once-weekly CagriSema 1.7 mg/1.7 mg and CagriSema 1.0 mg/1.0 mg versus placebo in 300 adults with overweight or obesity.

REDEFINE 11 – an 80-week efficacy and safety phase 3 trial of once-weekly CagriSema 2.4 mg/2.4 mg versus placebo in 600 adults with obesity. The trial includes an 80-week extension phase investigating the maintenance of weight loss.

High-dose CagriSema 2.4 mg/7.2 mg, an efficacy and safety phase 3 trial, is planned to be initiated in the second half of 2026 in adults with obesity.

*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 68,800 people in 80 countries and markets its products in around 170 countries. For more information, visit [novonordisk.com](https://www.novonordisk.com), [Facebook](#), [Instagram](#), [X](#), [LinkedIn](#) and [YouTube](#).*

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

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