company announcement

CagriSema demonstrates superior weight loss in adults with obesity or overweight in the REDEFINE 1 trial

Bagsværd, Denmark, 20 December 2024 – Novo Nordisk today announced headline results from REDEFINE 1, a phase 3 trial in the global REDEFINE programme. REDEFINE 1 is a 68-week efficacy and safety trial investigating subcutaneous CagriSema (a fixed dose combination of cagrilintide 2.4 mg and semaglutide 2.4 mg) compared to the individual components cagrilintide 2.4 mg, semaglutide 2.4 mg and placebo, all administered once-weekly. The trial included 3,417 randomised people with obesity or overweight with one or more comorbidities and a mean baseline body weight of 106.9 kg.

The trial achieved its primary endpoint by demonstrating a statistically significant and superior weight loss at week 68 with CagriSema versus placebo.

The REDEFINE 1 trial was based on a flexible protocol, allowing patients to modify their dosing throughout the trial. After 68 weeks, 57.3% of patients treated with CagriSema were on the highest dose compared to 82.5% with cagrilintide 2.4 mg and 70.2% with semaglutide 2.4 mg.

When evaluating the effects of treatment if all people adhered to treatment[1], people treated with CagriSema achieved a superior weight loss of 22.7% after 68 weeks compared to a reduction of 11.8% with cagrilintide 2.4 mg, 16.1% with semaglutide 2.4 mg and 2.3% with placebo alone. In addition, 40.4% of patients who received CagriSema reached a weight loss of 25% or more after 68 weeks, compared to 6.0% with cagrilintide 2.4 mg, 16.2% with semaglutide 2.4 mg, and 0.9% with placebo.

When applying the treatment policy estimand[2], people treated with CagriSema achieved a superior weight loss of 20.4% compared to a reduction of 11.5% with cagrilintide 2.4 mg, 14.9% with semaglutide 2.4 mg and 3.0% with placebo.

[1] Based on the trial product estimand according to the trial protocol, regardless of dose strength
[2] Based on the treatment policy estimand: treatment effect regardless of treatment adherence

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In the trial, CagriSema, cagrilintide 2.4 mg and semaglutide 2.4 mg 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 encouraged by the weight loss profile of CagriSema demonstrating superiority over both semaglutide and cagrilintide in monotherapy in the REDEFINE 1 trial. This was achieved even though only 57% of patients reached the highest CagriSema dose," said Martin Holst Lange, executive vice president for Development at Novo Nordisk. "With the insights obtained from the REDEFINE 1 trial, we plan to further explore the additional weight loss potential of CagriSema."

The results from the second pivotal phase 3 trial, REDEFINE 2, in adults with type 2 diabetes and either obesity or overweight are expected during the first half of 2025.

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 clinical trial programme
REDEFINE is a phase 3 clinical development programme with once-weekly subcutaneous CagriSema in obesity. The global clinical trial programme consists of two pivotal phase 3 trials, which have enrolled approximately 4,600 adults with overweight or obesity. Additional phase 3 trials are ongoing.

REDEFINE 1 – a 68-week efficacy and safety phase 3 trial of once-weekly CagriSema, cagrilintide 2.4 mg and semaglutide 2.4 mg versus placebo in 3,400 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 versus placebo in 1,200 adults with type 2 diabetes and either obesity or overweight.

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

REDEFINE 4 – a 72-week efficacy and safety phase 3 trial of once-weekly CagriSema versus once-weekly tirzepatide 15 mg in 800 adults with obesity.

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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