company announcement

CagriSema demonstrates superior weight loss in adults with obesity or overweight and type 2 diabetes in the REDEFINE 2 trial

Bagsværd, Denmark, 10 March 2025 – Today, Novo Nordisk announced headline results from REDEFINE 2, a phase 3 trial in the global REDEFINE programme. REDEFINE 2 is a 68-week efficacy and safety trial investigating once-weekly subcutaneous CagriSema (a fixed dose combination of cagrilintide 2.4 mg and semaglutide 2.4 mg) compared to placebo. The trial included 1,206 randomised people with obesity or overweight and type 2 diabetes and a mean baseline body weight of 102 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 2 trial was based on a flexible protocol, allowing patients to modify their dosing throughout the trial. After 68 weeks, 61.9% of patients treated with CagriSema were on the highest dose.

When evaluating the effects of treatment, if all people adhered to treatment[1], people treated with CagriSema achieved a superior weight loss of 15.7% after 68 weeks compared to 3.1% with placebo. Weight loss of 5% or more after 68 weeks was a co-primary endpoint and was achieved by 89.7% of patients on CagriSema, compared to 30.3% by placebo.

When applying the treatment policy estimand[2], people treated with CagriSema achieved a superior weight loss of 13.7% compared to 3.4% with placebo.

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.

[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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“The REDEFINE 2 results confirmed the superior efficacy of CagriSema in people with overweight or obesity and type 2 diabetes”, said Martin Holst Lange, executive vice president for Development at Novo Nordisk. “We look forward to bringing this second pivotal trial to regulatory authorities with the aim of making this next-generation therapy available to the millions of patients in need.”

Novo Nordisk expects to file for the first regulatory approval of CagriSema in the first quarter of 2026. The detailed results from REDEFINE 1 and REDEFINE 2 will be presented at a scientific conference in 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 helping 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. The phase 3 trial programme includes:

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 3,417 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 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 – an 84-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 76,300 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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