press release

Novo Nordisk files for FDA approval of CagriSema, the first once-weekly combination of GLP-1 and amylin analogues for weight management

- CagriSema 2.4 mg/2.4 mg is an investigational fixed-dose injectable medicine that combines the novel amylin analogue, cagrilintide, with semaglutide to target complementary obesity-related pathways[1,2]

- In the REDEFINE 1 phase 3 trial, adults with obesity, or overweight with at least one obesity-related complication, taking CagriSema lost an average of 23% body weight when evaluating the treatment effect if all patients stayed on treatment*[2]

- Novo Nordisk continues to build on its 100-year-plus legacy of science and innovation, with potential new treatments in obesity

Plainsboro, NJ, US and Bagsværd, Denmark, December 18, 2025 – Today, Novo Nordisk announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for once-weekly CagriSema (cagrilintide 2.4 mg and semaglutide 2.4 mg) injection, to be used with a reduced-calorie diet and increased physical activity, to reduce excess body weight and maintain weight reduction long term in adults with obesity or overweight in the presence of at least one weight-related comorbid condition.[1] CagriSema is a fixed-dose combination of a long-acting amylin analogue, cagrilintide 2.4 mg, and the GLP-1 receptor agonist, semaglutide 2.4 mg.[2] If approved, CagriSema would become the first injectable GLP-1 receptor agonist and amylin analogue combination treatment.

“The FDA submission of CagriSema marks an important milestone and signals a new era in weight management, reinforcing Novo Nordisk’s long-standing commitment to serving people living with obesity through innovation and science. Building on the well-established profile of semaglutide and combining it with a novel mechanism of action, CagriSema has the potential to represent a meaningful step forward in the holistic treatment of obesity. With our leadership in metabolic disease, we are encouraged by the promise of this first-in-class combination to expand treatment options and address the evolving needs of patients,” said Mike Doustdar, president and CEO of Novo Nordisk.

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“This submission reflects the continued advancement of Novo Nordisk’s obesity pipeline and our focus on translating scientific innovation into patient-relevant outcomes. If approved, CagriSema would provide patients and healthcare professionals with an additional treatment option supported by results from the REDEFINE clinical program, including powerful efficacy, high treatment completion rates, and a tolerability profile consistent with its underlying pharmacology. We believe these data underscore the potential of CagriSema to address unmet medical needs in obesity and support long-term disease management,” added Mike Doustdar.

The NDA is based on results from REDEFINE 1, a 68-week, phase 3, randomized, double-blind, placebo-and active-controlled trial that evaluated the efficacy and safety of once-weekly, CagriSema compared to semaglutide 2.4 mg alone, cagrilintide 2.4 mg alone, or placebo, all as an adjunct to lifestyle intervention in 3,417 adults with obesity (BMI ≥30 kg/m^2) or overweight (BMI ≥27 kg/m^2) with one or more obesity-related complications and without diabetes, and REDEFINE 2, a double-blind, randomized, placebo-controlled, 68-week, phase 3 trial that evaluated the efficacy and safety of once-weekly CagriSema versus placebo, as an adjunct to lifestyle intervention in 1,206 adults with type 2 diabetes and either obesity (BMI ≥30 kg/m^2) or overweight (BMI ≥27 kg/m^2).[2,3]

The REDEFINE 1 trial found that when evaluating the treatment effect regardless of whether patients stayed on treatment, those treated with CagriSema achieved weight loss of 20.4% (from an average baseline body weight of 236 lb) at 68 weeks versus 3.0% (from an average baseline body weight of 235 lb) for the placebo group which was statistically significant.[2**] CagriSema resulted in greater weight loss of 22.7% at 68 weeks versus 2.3% in the placebo group when evaluating the treatment effect if all patients stayed on treatment.[2*] 91.9% of participants taking CagriSema achieved a body weight reduction of greater than or equal to 5%, compared to 31.5% for the placebo group.[2**] In addition, a supportive secondary analysis showed that about half (54%) of trial participants with obesity at baseline treated with CagriSema reached the threshold for non-obesity (BMI <30 kg/m^2) at week 68. In the placebo group, 11.1% reached that threshold at 68 weeks.[2**]

Safety data generated in the REDEFINE 1 and 2 trials was comparable with the GLP-1 RA class. Overall, discontinuation rates due to adverse events were low, with 5.9% for CagriSema versus 3.5% for placebo in REDEFINE 1 and 8.4% with CagriSema versus 3% with placebo in REDEFINE 2.[2,3] In REDEFINE 1, adverse events were mainly gastrointestinal (79.6% in the CagriSema group vs 39.9% with placebo) including nausea (55% vs 12.6%), constipation (30.7% vs 11.6%), and vomiting (26.1% vs 4.1%).[2]

The FDA is expected to review the CagriSema application in 2026.

* Based on the trial product estimand: estimated efficacy in an idealized scenario in which all patients stayed on treatment and took no other weight loss therapies
** Based on the treatment policy estimand: estimated efficacy regardless of whether patients stayed on treatment or took other weight loss therapies

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About CagriSema
CagriSema is being investigated by Novo Nordisk as a once-weekly subcutaneous injectable treatment for adults with overweight or obesity (REDEFINE program) and as a treatment for adults with type 2 diabetes (REIMAGINE program). CagriSema is a fixed-dose combination of a long-acting amylin analogue, cagrilintide 2.4 mg, and the GLP-1 receptor agonist, semaglutide 2.4 mg.[2]

CagriSema is not approved in the US or EU.

About the REDEFINE clinical trial program
REDEFINE is a phase 3 clinical development program of once-weekly subcutaneous CagriSema in obesity and overweight. REDEFINE 1 and REDEFINE 2 have enrolled approximately 4,600 adults with overweight or obesity.[2,3] REDEFINE 1 was a 68-week, double-blind, randomized, placebo and active-controlled phase 3 trial that evaluated the efficacy and safety of once-weekly CagriSema versus cagrilintide 2.4 mg monotherapy, semaglutide 2.4 mg monotherapy, and placebo, all in combination with lifestyle intervention in 3,417 adults with obesity or overweight with one or more obesity-related complications and without type 2 diabetes.[2] REDEFINE 2 was a double-blind, randomized, placebo-controlled 68-week phase 3 trial that evaluated the efficacy and safety of once-weekly CagriSema versus placebo, both along with lifestyle intervention in 1,206 adults with type 2 diabetes and either obesity or overweight.[3]

Multiple REDEFINE clinical trials are currently underway including: REDEFINE 3, an event-driven cardiovascular outcomes phase 3 trial; and REDEFINE 11, a phase 3 trial with longer duration and patients with BMI ≥30 kg/m^2.[4,5]

About obesity
Obesity is a serious, chronic, progressive, and complex disease that requires long-term management.[6-8] One key misunderstanding is that this is a disease of just lack of willpower, when in fact there is underlying biology that may impede people with obesity from losing weight and keeping it off.[6,8] Obesity is influenced by a variety of factors, including genetics, social determinants of health, and the environment.[9,10]

Novo Nordisk is a leading global healthcare company with a heritage of more than 100 years in diabetes care. Building on this foundation, our purpose is to drive change to defeat serious chronic diseases — from diabetes and obesity to rare blood and endocrine disorders — by pioneering scientific breakthroughs, expanding access to medicines, and working to prevent and ultimately cure disease. We are committed to long-term, responsible business practices that deliver financial, social and environmental value. Headquartered in Denmark and operating in around 80 countries, Novo Nordisk employs approximately 78,500 people and markets products in roughly 170 countries. In the United States, Novo Nordisk has a 40-year presence, is headquartered in New Jersey and employs over 10,000 people across more than 10 manufacturing, R&D and corporate locations in eight states plus Washington, D.C. For more information, visit novonordisk.com and novonordisk-us.com, and follow us on Facebook, Instagram, X, LinkedIn and YouTube.

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