



CagriSema: Phase 3 Results & Clinical Overview

Evidence-informed review of the REDEFINE trial program, mechanism of action, weight loss efficacy, and development status.

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Content reviewed against published clinical literature

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Executive Summary

KEY TAKEAWAYS

- ✓ Combines semaglutide (GLP-1 agonist) + cagrilintide (amylin analogue) in one weekly injection
- ✓ Phase 3 REDEFINE 1: ~22.7% average body weight loss at 68 weeks
- ✓ Approximately 31% of participants achieved ≥25% body weight loss
- ✓ Meaningfully more effective than semaglutide alone (~15%) in published trials
- ✓ No dedicated cardiovascular outcomes trial published as of mid-2026
- ✓ NDA submission expected 2025–2026; est. approval 2026–2027

MECHANISM

Dual Pathway

GLP-1 agonist + Amylin analogue

PHASE 3 WEIGHT LOSS

~22.7%

REDEFINE 1 at 68 weeks

ADMINISTRATION

Weekly Injection

Fixed-dose combination

DEVELOPMENT STATUS

Phase 3

REDEFINE program complete

APPROVAL ESTIMATE

2026-2027

NDA submission expected

CV OUTCOMES DATA

None Published

No dedicated CVOT

What Is CagriSema?

CagriSema is a fixed-dose combination of semaglutide 2.4 mg and cagrilintide 2.4 mg, developed by Novo Nordisk. The combination targets two distinct satiety pathways simultaneously.

REDEFINE Trial Results

Key REDEFINE 1 results at 68 weeks: Mean weight loss ~22.7%; responders $\geq 20\%$: ~54%; responders $\geq 25\%$: ~31%. Semaglutide alone at same timepoint: ~15%.

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Sources & References

Enebo LB et al. Safety, tolerability, pharmacokinetics, and pharmacodynamics of cagrilintide with semaglutide 2.4 mg. *Lancet* 2021; 397(10290):2160–2172.

Novo Nordisk. REDEFINE Phase 3 Program. [ClinicalTrials.gov](https://clinicaltrials.gov). Accessed 2026.