CLOSER LOOK

MEMORANDUM

EU's CHMP issues positive opinion for oral Wegovy (semaglutide 25 mg) for weight loss – May 22, 2026

Follows December 2025 FDA approval of oral Wegovy for weight loss in the US and positions the therapy to become Europe's first oral GLP-1 RA for weight management

Novo Nordisk announced early this morning that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion for the Wegovy pill (oral semaglutide 25 mg), positioning it to become the first oral GLP-1 RA therapy approved for weight management in the EU. The opinion is supported by results from the OASIS-4 trial (n=307) and the SELECT cardiovascular outcomes trial (n=17,604), which together demonstrate strong oral weight loss efficacy and cardiometabolic benefit. Novo Nordisk expects to launch the therapy in select markets outside the US in the second half of this year, which would build on the therapy's rapid US uptake and join over one million Americans who began treatment within four months of its launch in December 2025.

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OASIS-4 trial demonstrated 17% mean body weight loss with oral semaglutide 25 mg and demonstrated comparable side effects to injectable formulations

In the OASIS 4 trial (n=307) that University of Alabama's Dr. Tim Garvey presented at ObesityWeek in 2024 in San Antonio, delivery of once-daily oral semaglutide 25 mg resulted in a record near-17% mean body weight loss among adults with obesity or overweight and one or more comorbidities. Remarkably, one in three participants achieved ≥20% weight loss, a milestone for an oral drug. Weight loss efficacy was similar to injectable Wegovy 2.4 mg despite the oral formulation, which comes with challenges to absorption among other clinical issues.

The safety profile of oral semaglutide 25 mg was also consistent with that of injectable semaglutide and other incretin-based therapies. Nearly three quarters (74%) of participants taking semaglutide experienced a GI-related adverse event (e.g., nausea, vomiting, or constipation) compared to under half (42%) in the placebo group (still a high percentage).

SELECT trial data extended oral Wegovy label for MACE risk reduction

The phase 3 SELECT cardiovascular outcomes trial (n=17,604) also demonstrated that semaglutide 2.4 mg (injectable Wegovy) reduces the risk of major adverse cardiovascular events (MACE), a benefit that will be included in the Wegovy pill label in the EU. Furthermore, secondary endpoints from the OASIS-4 trial showed that C-reactive protein – a biomarker for inflammation strongly linked to lower risk of heart attacks and strokes – also dropped significantly by 46% versus 4% in placebo from a baseline of 3.7 mg/L. While this was not mentioned in today's press release, we are very impressed by the difference here, particularly given the degree of cardiovascular concerns for the average person with obesity or who is overweight.

The OASIS-4 trial continues the work of the broader OASIS program with an emphasis on a diverse patient base

The OASIS-4 findings build on the broader OASIS program,, a 1,300-person set of four trials initiated in 2022 designed to investigate oral semaglutide in people with overweight or obesity. The program includes:

- **The OASIS-1 trial** (n= 667), which investigated oral semaglutide as an adjunct to lifestyle intervention in people with obesity or overweight and one weight-related comorbidity without T2D. Full results were reported at ADA 2023. It was published in The Lancet in August, 2023: "Oral semaglutide 50 mg taken once per day in adults with overweight or obesity (OASIS 1): a randomised, double-blind, placebo-controlled, phase 3 trial," by Professor Filip Knop and Dr. Tim Garvey, et al. In this study, semaglutide 50 mg conferred 16% weight loss at 68 weeks from a baseline of 104 kg (230 lbs) versus just 2% weight loss with placebo from a baseline of 106 kg (234 lbs) in the trial product estimand. In addition, 80% of the oral semaglutide group experienced GI-related events compared to 46% in the placebo group.
- **The OASIS-2 trial** (n=2o1) assessed oral semaglutide in East Asian individuals with overweight or obesity with and without diabetes. It was published in JAMA Internal Medicine in August, 2025: "Oral Semaglutide in an East Asian Population With Overweight or Obesity, With or Without Type 2 Diabetes" by Prof. Takashi Kadowaki and Professor Leonard (Kyoung-Kon) Kim, et al. Participants on semaglutide achieved an average of 14% weight loss compared to 1% with placebo at 68 weeks.
- **The OASIS-3 trial** (n=200) evaluated oral semaglutide in Chinese adults who are above the healthy weight range (BMI 28 kg/m^2 or BMI 24 kg/m^2 with one or more weight-related comorbidities). This trial has not yet been published.

Multiple oral GLP-1 RAs are also in late-stage development with the potential for international approval

The momentum behind oral incretin therapies continues to accelerate with multiple companies advancing GLP-1 RAs and multi-agonist programs.

- Lilly's Foundayo (orforglipron) was approved by the FDA in April 2026 for chronic weight management and has performed well in the US. The therapy is differentiated by having no restrictions on food, water, or timing. During its 1Q26 call, Lilly stated that regulatory reviews for Foundayo in obesity and T2D are underway in over 40 countries.
- Viking's VK2735 (a dual GLP-1/GIP RA) demonstrated up to 12.2% weight loss at Week 13 in the phase 2a VENTURE-Oraltrial (n=280) with a favorable tolerability profile. Phase 3 initiation is expected in 4Q26.
- AstraZeneca's elecoglipron (AZD5004, a small molecule GLP-1 RA) also met primary endpoints in the phase 2b VISTA(obesity) and SOLSTICE (T2D) trials with phase 3 development planned for this year.

Beyond Foundayo, VK2735, and elecoglipron, other oral incretin candidates remain in earlier-stage clinical development from Pfizer, Roche, and Structure Therapeutics. We imagine there are dozens more in pre-clinical development.

US pricing context for the Wegovy pill

As the Wegovy pill moves toward EU review, a key open question is how it will be priced. With US pricing now publicly established at $149/month, we are particularly interested in how EU list prices will compare. Oral GLP-1 RAs were included in the November 2025expansion of GLP-1 RAs to MFN pricing, with Wegovy pills priced at $150 per on TrumpRx direct-to-consumer platform.

Close Concerns' Questions

1. How is it expected that oral Wegovy's early launch in the EU will compare to its impressive uptake in the US?
2. Which non-US markets will Novo Nordisk prioritize for the primary launch of oral Wegovy, and what criteria will drive that sequencing?

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