

## press release

### **Novo Nordisk's oral semaglutide 25 mg (Wegovy® in a pill\*) delivered 16.6% weight loss in people with obesity in a newly published study**

- Oral semaglutide 25 mg (the once-daily pill formulation of Wegovy®) achieved significant weight loss, with one in three study participants losing 20% or more body weight<sup>1\*\*</sup>
- Oral semaglutide 25 mg also demonstrated improvements in the ability to perform everyday physical activities such as bending, standing, walking, being physically active, and improvements in cardiovascular risk factors<sup>1</sup>
- Oral semaglutide 25 mg is the first oral GLP-1 therapy submitted to the US Food and Drug Administration (FDA) for chronic weight management,<sup>2</sup> and Novo Nordisk has already begun production at its US sites

**Bagsværd, Denmark, Plainsboro, NJ, 17 September 2025** – Today, *The New England Journal of Medicine* published the results from the OASIS 4 phase 3 trial that studied the efficacy and safety of the investigational once-daily oral semaglutide 25 mg (Wegovy® in a pill\*), marking a significant milestone in the company's ambition to advance obesity care. In the 64-week trial, oral semaglutide 25 mg, alongside lifestyle modifications, was compared to placebo in 307 adults with obesity or overweight with one or more weight-related comorbidities, without diabetes.<sup>1</sup>

Results showed that if all participants adhered to treatment, average weight loss of 16.6% was achieved by people taking oral semaglutide 25 mg compared to 2.7% for placebo at 64 weeks, with over a third (34.4%) experiencing a weight loss of 20% or more, versus 2.9% for placebo.<sup>1\*\*</sup> This was comparable with previous trial results of injectable Wegovy®.<sup>3</sup>

When looking at the effect regardless of whether the participants took the medicine exactly as they should, people taking oral semaglutide 25 mg still achieved an average weight loss of 13.6% versus 2.2% with the placebo.<sup>1\*\*\*</sup> Close to a third (29.7%) had a weight loss of 20% or more versus 3.3% for placebo.<sup>1\*\*\*</sup> Additionally, the study also found that oral semaglutide 25 mg improved cardiovascular risk factors, as well as the ability to be more active in daily life, compared to placebo. This was consistent with previous trial results of injectable Wegovy®.<sup>1,3</sup>

“The oral semaglutide 25 mg data show compelling efficacy for an oral weight management medication with 16.6% weight loss and a safety and tolerability profile consistent with injectable Wegovy<sup>®</sup>,” said Martin Holst Lange, chief scientific officer and executive vice president of Research & Development at Novo Nordisk. “Currently, less than 2% of individuals with obesity in the US receive obesity medication and Wegovy<sup>®</sup> in a pill may also address patient preference for oral treatment. Pending FDA approval, ample supply will be available to meet the expected US demand as we hope to set a new treatment benchmark for oral weight loss medications for people with overweight or obesity.”

The safety and tolerability profile of oral semaglutide was consistent with that for injectable Wegovy<sup>®</sup>.<sup>1,3</sup> In the OASIS 4 trial, gastrointestinal adverse events with oral semaglutide 25 mg were generally mild to moderate in severity and transient; the most common of which were nausea (46.6% versus 18.6% for placebo) and vomiting (30.9% versus 5.9% for placebo).<sup>1</sup> Adverse events leading to permanent treatment discontinuation were 6.9% (oral semaglutide 25 mg) and 5.9% (placebo). The incidence of serious adverse events was 3.9% (oral semaglutide 25 mg) and 8.8% (placebo).<sup>1</sup> This reinforces the safety and tolerability profile of semaglutide, as also demonstrated in more than 37 million patient-years of exposure.<sup>1,4</sup>

“The OASIS 4 trial results further underscore the significant impact that semaglutide can have in achieving sustainable weight loss and broader health benefits,” said Sean Wharton, lead study author and medical director of the Wharton Medical Clinic. “Oral semaglutide 25 mg builds on the proven efficacy and established safety and tolerability profile of semaglutide and represents a significant advancement in obesity treatment. People with overweight or obesity have individual preferences, and with oral semaglutide as a potential new treatment option, more of those who are not on treatment today may consider starting GLP-1 treatment.”

In February, Novo Nordisk submitted a New Drug Application (NDA) for the once-daily pill formulation of Wegovy<sup>®</sup>.<sup>2\*</sup> The FDA review of this NDA is anticipated to be completed by the end of this year.<sup>5</sup> Currently, there are no approved oral formulations of a GLP-1 medicine for weight loss.

If approved by the FDA, the pill for weight management will be fully made in the US, with production already underway at Novo Nordisk’s significantly expanded manufacturing facility.

\* Tradename of ‘Wegovy<sup>®</sup> pill’ submitted to the FDA and is pending approval.

\*\* Based on the trial product estimand: estimated treatment effect if all participants adhered to treatment.

\*\*\* Based on the treatment policy estimand: treatment effect regardless of treatment adherence.

### **About OASIS 4**

OASIS 4 was a 64-week phase 3 randomised, double-blind, placebo-controlled trial evaluating the efficacy and safety of once-daily oral semaglutide 25 mg versus placebo in 307 adults with obesity (BMI  $\geq 30$  kg/m<sup>2</sup>) or overweight (BMI  $\geq 27$  kg/m<sup>2</sup>) with one or more weight-related comorbidities.<sup>1</sup> People with diabetes were excluded.<sup>1</sup> OASIS 4 included a 64-week treatment period, including a 12-week dose escalation, and a 7-week off-treatment follow-up period.<sup>1</sup>

In total, 307 participants were randomised in a 2:1 ratio to once-daily oral semaglutide 25 mg or placebo, alongside lifestyle intervention for 64 weeks.<sup>1</sup>

### **About obesity**

Obesity is a serious, chronic, progressive, and complex disease that requires long-term management.<sup>6-8</sup> 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.<sup>6,8</sup> Obesity is influenced by a variety of factors, including genetics, social determinants of health, and the environment.<sup>9,10</sup>

### **About Wegovy®**

Injectable semaglutide 2.4 mg is marketed under the brand name Wegovy®. In the EU, Wegovy® is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adults with a BMI of 30 kg/m<sup>2</sup> or greater (obesity) or adults with a BMI of 27 kg/m<sup>2</sup> or greater (overweight) in the presence of at least one weight-related comorbid condition. In the EU, Wegovy® is also indicated for paediatric patients aged 12 years and older with an initial BMI at the 95<sup>th</sup> percentile or greater for age and gender (obesity) and body weight above 60 kg. The clinical section of the label also includes data on Wegovy® major adverse cardiovascular events (MACE) risk reduction, improvements in HFpEF-related symptoms and physical function, as well as pain reduction related to knee osteoarthritis.<sup>10</sup>

In the US, Wegovy® (semaglutide) injection 2.4 mg is currently approved along with a reduced calorie diet and increased physical activity, for adults and children aged 12 years and older with obesity, or some adults with overweight who also have weight-related medical problems, to help them lose excess body weight and keep the weight off and to reduce the risk of major cardiovascular events such as death, heart attack, or stroke in adults with known heart disease and either obesity or overweight.<sup>11</sup> It is important to note that semaglutide injection 2.4 mg contains a Boxed Warning for possible thyroid tumors, including cancer and should not be used in those with a personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

Oral semaglutide 25 mg (Wegovy® in a pill\*) is not approved in the US or in Europe.

*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 78,400 people in 80 countries and markets its products in around 170 countries. For more information, visit [novonordisk.com](https://www.novonordisk.com), [Facebook](#), [Instagram](#), [X](#), [LinkedIn](#) and [YouTube](#).*

## **Contacts for further information**

### **Media:**

**Ambre James-Brown**

+45 3079 9289

[abmo@novonordisk.com](mailto:abmo@novonordisk.com)

**Liz Skrbkova (US)**

+1 609 917 0632

[lzsk@novonordisk.com](mailto:lzsk@novonordisk.com)

### **Investors:**

**Jacob Martin Wiborg Rode**

+45 3075 5956

[jrde@novonordisk.com](mailto:jrde@novonordisk.com)

**Sina Meyer**

+45 3079 6656

[azey@novonordisk.com](mailto:azey@novonordisk.com)

**Max Ung**

+45 3077 6414

[mxun@novonordisk.com](mailto:mxun@novonordisk.com)

**Christoffer Sho Togo Tullin**

+45 3079 1471

[cftu@novonordisk.com](mailto:cftu@novonordisk.com)

**Alex Bruce**

+45 3444 2613

[axeu@novonordisk.com](mailto:axeu@novonordisk.com)

**Frederik Taylor Pitter**

+1 609 613 0568

[fptr@novonordisk.com](mailto:fptr@novonordisk.com)

## References

1. Wharton S, Lingvay I, Bogdanski P, *et al.* Oral Semaglutide 25 mg in Adults with Overweight or Obesity. *N Engl J Med.* 2025; 393:1077-1087. DOI: 10.1056/NEJMoa2500969
2. Oral Semaglutide 25 mg FDA NDA filing; Novo Nordisk data on file.
3. Wilding, JPH, Batterham RL, Calanna S, *et al.* Once-Weekly Semaglutide in Adults with Overweight or Obesity. *N Engl J Med.* 2021;384:989–1002.
4. Novo Nordisk A/S. Data on file.
5. Novo Nordisk Press Release. FDA accepts filing application for oral semaglutide 25 mg, which if approved, would be the first oral GLP-1 treatment for obesity. Available at: <https://www.novonordisk-us.com/media/news-archive/news-details.html?id=915988>. Accessed September 2025.
6. Kaplan LM, Golden A, Jinnett K, *et al.* Perceptions of barriers to effective obesity care: results from the national action study. *Obesity.* 2018;26(1):61–69.
7. Bray GA, Kim KK, Wilding JPH; World Obesity Federation. Obesity: a chronic relapsing progressive disease process. A position statement of the World Obesity Federation. *Obes Rev.* 2017;18(7):715–723.
8. Garvey WT, Mechanick JI, Brett EM, *et al.* American association of clinical endocrinologists and American College of Endocrinology comprehensive clinical practice guidelines for medical care of patients with obesity. *Endocr Pract.* 2016;22 (Suppl 3):1–203.
9. Centers for Disease Control and Prevention. Adult obesity facts. Available at: <https://www.cdc.gov/obesity/adult-obesity-facts/index.html>. Last accessed: September 2025.
10. World Obesity Federation. World Obesity Atlas 2024. Available at: <https://data.worldobesity.org/publications/WOF-Obesity-Atlas-v7.pdf>. Last accessed: September 2025.
11. Wegovy® Summary of Product Characteristics. Available at: [https://www.ema.europa.eu/en/documents/product-information/wegovy-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/wegovy-epar-product-information_en.pdf). Last accessed: September 2025.
12. Wegovy® Prescribing information. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2024/215256s015lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/215256s015lbl.pdf). Last accessed: September 2025.