

company announcement

Oral semaglutide 50 mg achieved 15.1% weight loss (17.4% if all people adhered to treatment) in adults with obesity or overweight in the OASIS 1 trial

Bagsværd, Denmark, 22 May 2023 – Novo Nordisk today announced headline results from OASIS 1, a phase 3a trial in the global OASIS programme. OASIS 1 is a 68-week, efficacy and safety trial comparing once-daily oral semaglutide 50 mg for weight management to placebo in 667 adults with obesity or overweight with one or more comorbidities. Both treatment arms were in conjunction with lifestyle intervention. The trial achieved its primary endpoint by demonstrating a statistically significant and superior weight loss at week 68 with oral semaglutide 50 mg versus placebo.

When evaluating the effects of treatment if all people adhered to treatment¹ from a mean baseline body weight of 105.4 kg, people treated with oral semaglutide 50 mg achieved a statistically significant weight loss of 17.4% after 68 weeks compared to a 1.8% reduction with placebo. In addition, 89.2% of those who received oral semaglutide 50 mg, reached a weight loss of 5% or more after 68 weeks, compared to 24.5% with placebo.

When applying the treatment policy estimand², people treated with oral semaglutide 50 mg achieved a superior weight loss of 15.1% compared to a reduction of 2.4% with placebo and 84.9% achieved a weight loss of 5% or more, compared to 25.8% with placebo.

“We are very pleased with the weight loss demonstrated by the once-daily oral formulation of semaglutide in obesity. The results show comparable weight loss as in the STEP 1 trial with injectable semaglutide 2.4 mg in obesity branded as Wegovy[®]”, said Martin Holst Lange, executive vice president for Development at Novo Nordisk. “The choice between a daily tablet or weekly injection for obesity has the potential to offer patients and healthcare providers the opportunity to choose what best suits individual treatment preferences”.

¹ Based on the trial product estimand: treatment effect if all people adhered to treatment

² Based on the treatment policy estimand: treatment effect regardless of treatment adherence

In the trial, oral semaglutide 50 mg appeared to have a safe and well-tolerated profile. The most common adverse events were gastrointestinal, and the vast majority were mild to moderate and diminished over time and were consistent with the GLP-1 receptor agonist class. Gastrointestinal adverse events were most prominent during dose escalation.

Novo Nordisk expects to file for regulatory approval in the US and the EU in 2023. The global launch of oral semaglutide 50 mg is contingent on portfolio prioritisations and manufacturing capacity.

About the OASIS clinical trial programme

OASIS is a phase 3 clinical development programme with once-daily oral semaglutide 25 mg and 50 mg in obesity. The global clinical phase 3 programme currently consists of four trials, having enrolled approximately 1,300 adults with obesity or overweight with one or more comorbidities.

OASIS 1 – a 68-week efficacy and safety phase 3a trial of once-daily oral semaglutide 50 mg versus placebo in 667 adults with obesity or overweight with one or more comorbidities.

OASIS 2 – a 68-week efficacy and safety phase 3a trial of once-daily oral semaglutide 50 mg versus placebo in 198 East Asian (including Japan) adults with obesity or overweight with one or more comorbidities.

OASIS 3 – a 44-week efficacy and safety phase 3a trial of once-daily oral semaglutide 50 mg versus placebo in 200 Chinese adults with obesity or overweight with one or more comorbidities.

OASIS 4 – a 64-week efficacy and safety phase 3b trial of once-daily oral semaglutide 25 mg versus placebo in 300 adults with obesity or overweight with one or more comorbidities.

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat diabetes and other serious chronic diseases such as obesity and rare blood and endocrine disorders. We do so by pioneering scientific breakthroughs, expanding access to our medicines, and working to prevent and ultimately cure disease. Novo Nordisk employs about 57,100 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](https://www.novonordisk.com), [Facebook](#), [Twitter](#), [LinkedIn](#) and [YouTube](#).

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