

Synopsis of the original article
***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***

Knop FK, et al. *Lancet* 2023. DOI: 10.1016/S0140-6736(23)01185-6

Synopsis created and reviewed by Novo Nordisk

Introduction



The efficacy and safety of once-daily oral semaglutide 50 mg, a GLP-1 analogue, were assessed vs placebo for the treatment of overweight or obesity in adults without type 2 diabetes

OASIS 1 trial design



Trial design

Double-blind, randomised, controlled, phase 3 superiority trial of once-daily oral semaglutide 50 mg vs placebo, plus lifestyle intervention



Adults with BMI $\geq 30 \text{ kg/m}^2$ (or $\geq 27 \text{ kg/m}^2$ with ≥ 1 weight-related complication/comorbidity)



No history of diabetes

N=667

R

1:1

Oral semaglutide escalated to 50 mg once daily + lifestyle intervention

Placebo once daily + lifestyle intervention

0 68-week treatment period 68



Coprimary endpoints

Percentage change in body weight at week 68
Achievement of $\geq 5\%$ body weight loss at week 68



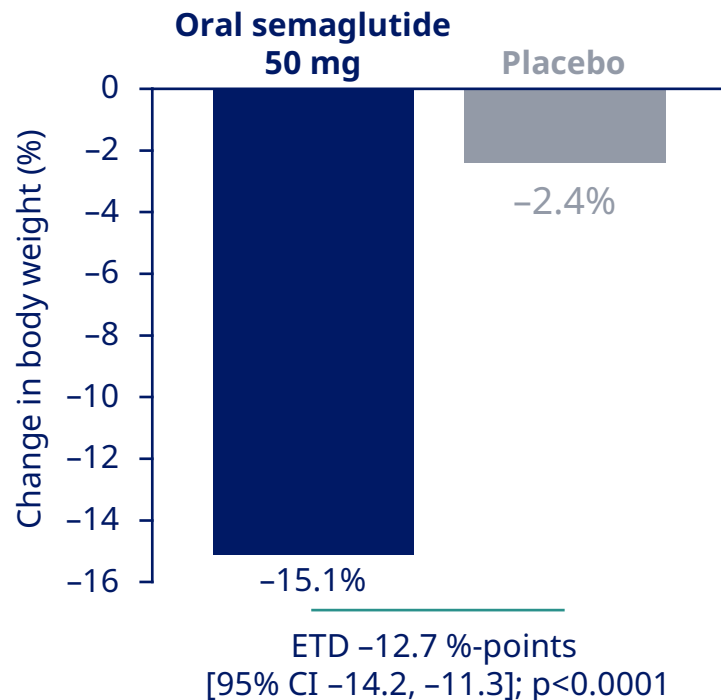
Confirmatory secondary endpoints

Achievement of $\geq 10\%$, $\geq 15\%$ and $\geq 20\%$ body weight loss at week 68

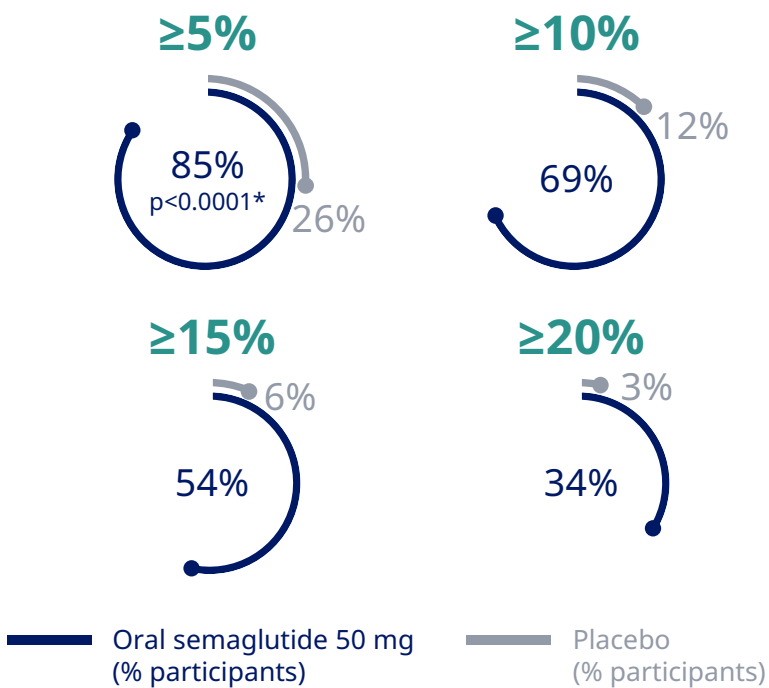
Oral semaglutide 50 mg led to superior and clinically meaningful weight loss vs placebo



Change in body weight from baseline to week 68



Proportions of participants achieving $\geq 5\%$, $\geq 10\%$, $\geq 15\%$ and $\geq 20\%$ body weight loss at week 68



Safety

Adverse events

More frequent with oral semaglutide 50 mg vs placebo:
92% vs 86%

Gastrointestinal adverse events

80% with oral semaglutide 50 mg
46% with placebo
Mostly **mild-to-moderate** in severity

*P value is based on the odds ratio and is only provided for the coprimary endpoint. CI, confidence interval; ETD, estimated treatment difference.

Conclusions

50 mg



In adults with overweight or obesity, without type 2 diabetes, **once-daily oral semaglutide 50 mg** achieved a **superior** and **clinically meaningful** decrease in body weight compared with placebo