STEP 1

SEMAGLUTIDE 2.4 versus Placebo (FPO)

STEP 1 was a **68-week**, phase 3, randomized, **placebo-controlled**, double-blind multicenter trial with a **52-week** off-treatment extension phase in **1961 patients** with obesity or overweight and at least 1 related comorbidity.

Select Eligibility Criteria

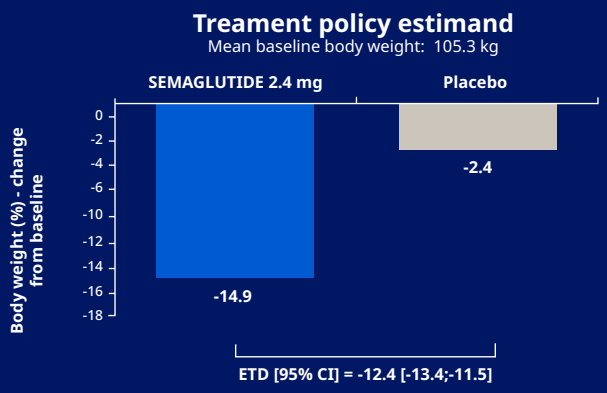
- BMI: ≥30.0 kg/m^2 or ≥27 kg/m^2 with at least 1 comorbidity
- Baseline glycosylated hemoglobin (HbA_{1c}) <6.5% (no diabetes)
- Stable body weight for at least 90 days

Study Design

Patients were randomized (**2:1**) to blinded treatment with either **SEMAGLUTIDE 2.4 mg** subcutaneous injection or **placebo**, each once weekly. ⊕

Key Results at 68 Weeks

Primary efficacy end point: Body weight % change from baseline to week 68



Analysis at Week 68	ETD	95% CI	*P*-value
SEMAGLUTIDE 2.4 mg vs placebo	-12.4	[-13.4;-11.5]	<.0001

Primary efficacy end point: Odds of achieving ≥5% weight loss at week 68

Confirmatory secondary efficacy end points: Odds of achieving ≥10% and ≥15% weight loss at week 68

SEMAGLUTIDE 2.4 mg vs placebo	OR	95% CI	*P*-value
≥5%*	11.22	[8.88;14.19]	<.0001
≥10%	14.68	[11.08;19.44]	<.0001
≥15%	19.26	[12.89;28.76]	<.0001
≥20%	26.89	[14.18;50.96]	<.0001

*Primary end point

Other confirmatory end points: (change at 68 weeks)

- WAIST CIRCUMFERENCE ⊕
- SYSTOLIC BLOOD PRESSURE ⊕
- SF-36 PHYSICAL FUNCTION SCALE SCORE ⊕
- IWQOL-LITE-CT PHYSICAL FUNCTION ⊕

Safety

- The most common adverse events (AEs) were gastrointestinal in nature, including nausea, diarrhea, and vomiting. ⊕
- Patients treated with SEMAGLUTIDE 2.4 mg discontinued treatment due to AEs at a higher rate than those treated with placebo (7.0% vs 3.1%), primarily due to gastrointestinal AEs (4.5%).

AE, adverse event; BMI, body mass index; ETD, estimated treatment difference; HbA_{1c}, glycosylated hemoglobin; IWQoL-Lite-CT, Impact of Weight on Quality of Life-Lite Clinical Trials Version; OR, odds ratio; SF-36, Short Form 36.