FLOW TRIAL

Effects of semaglutide on Chronic Kidney Disease in patients with type 2 diabetes

STUDY OBJECTIVE

Assessed the efficacy and safety of subcutaneous semaglutide at a dose of 1.0 mg once weekly for the prevention of kidney failure, substantial loss of kidney function, and death from kidney-related or cardiovascular causes in patients with type 2 diabetes and chronic kidney disease

STUDY DESIGN

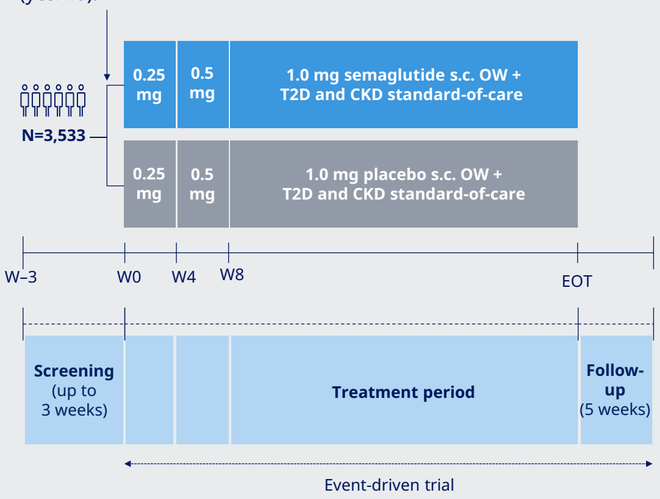
Randomized, double-blind, parallel-group, multinational phase 3b trial

387 trial locations and 28 countries

3533 participants

- Adults¥ with T2D and pre-existing CKD HbA_{1c} ≤10 %
- eGFR ≥ 50 to ≤75 ml/min/1.73 m^2 and UACR >300 to <5000 mg/g or eGFR ≥ 25 to ≤50 ml/min/1.73 m^2 and UACR >100 to <5000 mg/g

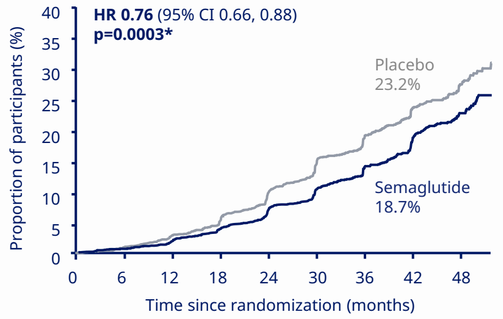
Randomization 1:1
(Stratified by sodium-glucose cotransporter-2 inhibitor use (yes/no).



RESULTS

01. First composite primary endpoint

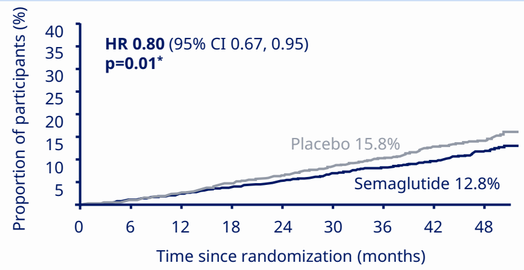
24% risk reduction of the primary composite kidney outcome vs. placebo



02. Confirmatory secondary endpoints

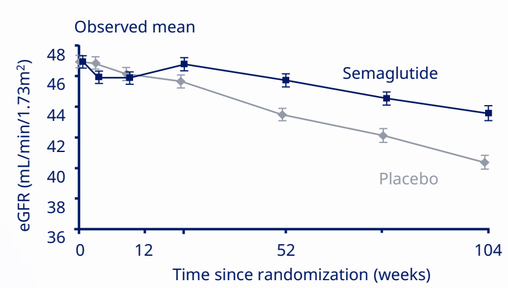
Time to all cause death

- 20% risk reduction in time to occurrence of all-cause death vs. placebo
- 29% risk reduction in time to occurrence of CV death vs. placebo



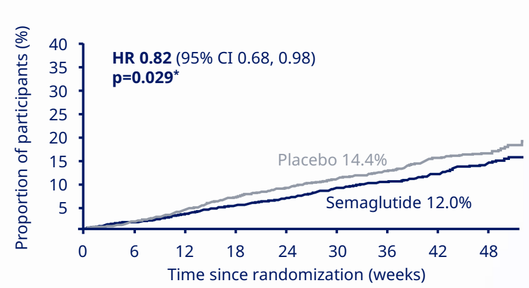
02. Confirmatory secondary endpoints

Total eGFR slope



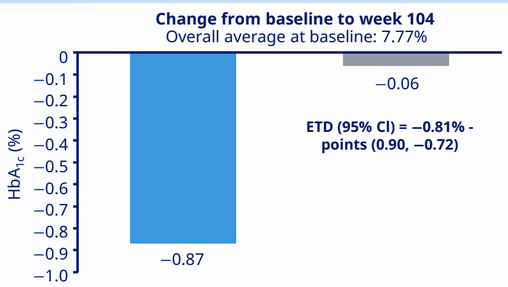
Time to first major cardiovascular event

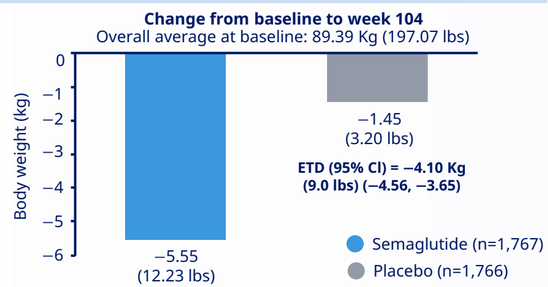
- 18% risk reduction in the time to first MACE vs. placebo‡



03. Supportive secondary endpoints

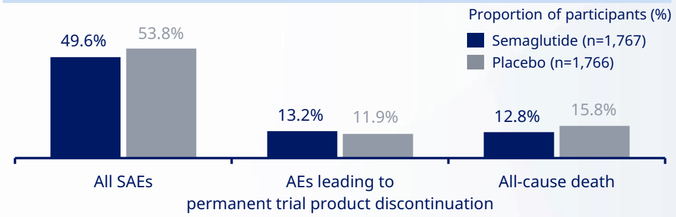
- Significant decrease in HbA_{1c} vs. placebo (-0.87% vs. -0.06%, respectively)
- Significant decrease in body weight vs. placebo (-5.55 kg vs. -1.45 kg, respectively)



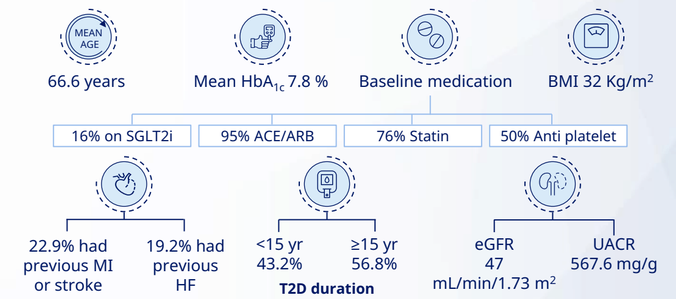


04. Overall safety profile

- SAEs were reported less in the semaglutide group (49.6%) vs the placebo group (53.8%)



BASELINE CHARACTERISTICS AND OUTCOMES



Composite primary endpoints

- Onset of persistent ≥50% reduction in eGFR (CKD-EPI) versus baseline
- Onset of kidney failure, defined as initiation of CKRT (dialysis or kidney transplantation) or persistent eGFR <15 ml/min/1.73 m^2 for at least 4 weeks
- Death from kidney failure
- CV death

CONCLUSION

- Semaglutide at a dose of 1.0 mg once weekly reduced the risk of primary endpoint, by 24%.
- Semaglutide reduced the risk of major cardiovascular events and death from any cause.
- Serious adverse events were reported in fewer participants in the semaglutide group than in the placebo group (49.6% vs. 53.8%)

¥>20 years in Japan; *Superiority if p value <0.032; †eGFR was calculated using the CKD-EPI formula. ‡MACE was defined as a composite of non-fatal myocardial infarction, non-fatal stroke, or cardiovascular death

AE, adverse events; CI, confidence interval; CKD, chronic kidney disease; CKRT, Continuous kidney replacement therapy; CV, cardiovascular; eGFR, estimated glomerular filtration rate; ETD, estimated treatment difference; HbA_{1c}, glycated hemoglobin; HF, heart failure; HR, hazard ratio; MI, myocardial infarction; SAE, serious adverse events

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Ozempic label