

SCORED:

Effect of Sotagliflozin on Cardiovascular and Renal Events in Patients With Type 2 Diabetes and Moderate Renal Impairment Who Are at Cardiovascular Risk

Purpose: Compare the effect of sotagliflozin to placebo on total occurrences of cardiovascular (CV) death, hospitalizations for heart failure (HHF), and urgent visits for HF in patients with type 2 diabetes (A1c $\geq 7\%$), cardiovascular risk factors, and chronic kidney disease.

Trial Design: N = 10,584, multicenter, randomized, double-blind, placebo-controlled, parallel group; sotagliflozin daily vs placebo; median 16 month follow up.

Primary Endpoints: Composite of CV death, hospitalizations for HF, urgent visits for HF.

Secondary: HHF + urgent HF visits, CV death + non-fatal MI/stroke, CV death, CV death + HHF + urgent HF visits, HF events while hospitalized, composite renal event.

Endpoints	Sotagliflozin*	Placebo*	Hazard Ratio (95% CI)	P value
Total CV deaths, HHF, urgent HF visits	5.6 (400)	7.5 (530)	0.74 (0.63-0.88)	0.0004
Total HHF and urgent HF visits	3.5 (245)	5.1 (360)	0.67 (0.55-0.82)	0.0001
Total CV death, non-fatal MI or non-fatal stroke	4.8 (343)	6.3 (442)	0.77 (0.65-0.91)	0.002
CV death	2.2 (155)	2.4 (170)	0.90 (0.73-1.12)	0.35

*Events/100 patient-years (number of events)

Results: In patients with diabetes and chronic kidney disease, sotagliflozin significantly reduced the composite of total CV deaths, hospitalizations for HF, and urgent HF visits by 26%. Total HHF and urgent HF visits were reduced by 33%. There was no significance difference in all-cause mortality.

