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 ≥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.

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.