DECLARE-TIMI 58 Trial: The Dapagliflozin Effect on Cardiovascular Events

Purpose: safety and efficacy of dapagliflozin, a selective SGLT-2 inhibitor, in reducing CV events in patients with T2DM.

Trial Design: phase 3b, randomized 1:1, double-blinded, placebo-controlled. 17,160 patients ≥40 years of age with T2DM and either CVD or multiple CVD risk factors. Dapagliflozin 10 mg/d or placebo. Median follow-up 4.5 years.

Primary Efficacy Endpoints: MACE; composite of HF hospitalization (HHF) or CV death.

Results: Dapagliflozin compared to placebo in patients with T2DM was safe, reduced the composite of CV death or hospitalization for heart failure, but did not impact MACE.

Rate/1000 patient-yr	dapagliflozin	placebo	HR, p value
MACE efficacy	22.6	24.2	HR=0.93; p=0.17
CVD/HHF	12.2	14.7	HR=0.83; p=0.005
Secondary Composite Renal	10.86	14.1	HR=0.76
All-cause mortality	15.1	16.4	HR=0.93

Presented by: Stephen D Wiviott, AHA Scientific Sessions 2018 Chicago, Illinois