DAPA-HF - Dapagliflozin in Patients with Heart Failure and Reduced Ejection Fraction

Purpose: Evaluate effect of dapagliflozin on the incidence of worsening heart failure (HF) or CV death in patients with chronic HF failure with reduced ejection fraction (≤40%).

Trial Design: N = 4,744. Phase 3; multicenter, parallel group, event-driven, randomized, double-blind, placebo-controlled; 10 mg vs. placebo.

Primary Endpoints: Time to first occurrence of any of components of the composite: CV death or hospitalization for HF or an urgent HF visit. Up to 3 years

Secondary Endpoints: Time to first occurrence of either component of the composite: CV death or hospitalization for HF; total number of (first and recurrent) HF hospitalizations and CV death; change from baseline measured at 8 months in the total symptom score of the Kansas City Cardiomyopathy Questionnaire (KCCQ), time to first occurrence of any components of the composite: ≥50% sustained decline in eGFR or reaching End Stage Renal Disease (ESRD) or renal death; time to death from any cause.

Time to composite adverse events	Dapagliflozin	placebo	Hazard ratio 95% CI	P value
CV death	n= 227 (9.6%)	n= 273 (11.5%)	HR = 0.82 CI = (0.69 – 0.98)	p = 0.03
HF hospitalization	n= 231 (9.7%)	n= 318 (13.4%)	HR = 0.70 CI = (0.59 – 0.83)	p=<0.001
HF hospitalization Urgent HF visit	n= 237 (10.0%)	n= 326 (13.7%)	HR = 0.70 CI = (0 .59 - 0.83)	p=<0.001

Results:

- **Dapagliflozin reduces death and hospitalization in patients with HF and reduced EF, including those with and without DM. Works very well with excellent HF standard therapy.**

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