

# EMPULSE: EMPagliflozin 10 mg compared to placebo, initiated in patients hospitalised for acUte heart faiLure (*de novo* or decompensated chronic HF) who have been StabilisEd (EMPULSE)

**Purpose:** To investigate the safety and efficacy of empagliflozin in patients hospitalized for acute HF (*de novo* or decompensated chronic HF), irrespective of type 2 diabetes (T2D) status, and with either HFrEF or HFpEF.

**Trial design:** N=530. Multi-center, randomized, double-blind, 90-day superiority trial.

**Primary endpoint:** Clinical benefit - composite of death, number of HF events (HFE; includes hospitalizations for HF, urgent HF visits, and unplanned outpatient visits), time to first HFE, and change from baseline in Kansas City Cardiomyopathy Questionnaire Total Symptom Score (KCCQ-TSS) after 90 days of treatment. Assessed by win ratio.

**Secondary endpoints:** Time to cardiovascular death or first HFE, change in KCCQ-TSS from baseline at after 90 days, and change in NT-proBNP concentration from baseline at Day 30.

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Primary endpoint	Empagliflozin vs placebo stratified win ratio (95% CI)	p-value
Clinical benefit	1.36 (1.09, 1.68)	0.0054
Secondary endpoint	Empagliflozin vs placebo HR (95% CI)	p-value
Time to cardiovascular death or first HFE	0.69 (0.45, 1.08)	0.1021
Secondary endpoint	Day 90 placebo-adjusted mean difference (95% CI)	p-value
Change in KCCQ-TSS from baseline	4.45 (0.32, 8.59)	0.0347
Secondary endpoint	Adjusted geometric mean ratio at Day 30 (95% CI)	
Change in NT-proBNP concentration from baseline (area under curve)	0.90, (0.82, 0.98)	
<b>Interpretation:</b> Initiation of empagliflozin versus placebo in patients hospitalized for acute HF resulted in a significant clinical benefit within 90 days, improvement in quality of life, greater reduction in NT-proBNP, and no safety concerns.		

*Results reflect the data available at the time of presentation.*