

GALACTIC-HF:

Global Approach to Lowering Adverse Cardiac Outcomes Through Improving Contractility In Heart Failure

Purpose: Determine if treatment with omecamtiv mecarbil (OM) when added to standard of care is well tolerated and superior to placebo in reducing the risk of CV death or heart failure events in subjects with chronic HFrEF.

Trial Design: N = 8256, international, multicenter, parallel, randomized, double-blind, placebo-controlled; standard of care + omecamtiv mecarbil twice daily vs placebo; median 21.8 months follow-up.

Primary Endpoints: Time to CV death or first heart failure event. HF event defined as urgent clinic/office/ED visit, or hospitalization for worsening HF leading to intensification of treatment.

Secondary Endpoints: Time to CV death, change in KCCQ Total Symptom Score, time to first HF hospitalization, time to all-cause death.

Endpoints	OM	Placebo	HR (95% CI)	P value
CV death or first HF event	1523	1607	0.92 (0.86-0.99)	0.03
CV death	808	798	1.01 (0.92-1.11)	0.86
HF event	1177	1236	0.93 (0.86-1.00)	NA*
First HF Hospitalization	1142	1179	0.95 (0.87-1.03)	NA*

Results: In patients with HFrEF, omecamtiv mecarbil statistically, significantly reduced the risk of the primary composite outcome. Did not meet secondary endpoint of reduction in CV death. Pattern of adverse events were similar in OM and placebo groups.

*NA denotes not applicable.

