GALACTIC-HF

NCT02929329

Principal Investigator: Dr. John Collins (St. Mary's of Michigan)

Condition: Heart Failure

Drug: Omecamtiv Mecarbil vs. Placebo

Official Title: A Double-blind, Randomized, Placebo-controlled, Multicenter Study to Assess the Efficacy and Safety of Omecamtiv Mecarbil on Mortality and Morbidity in Subjects With Chronic Heart Failure With Reduced Ejection Fraction (GALACTIC-HF)

Sponsor: Amgen

Purpose: The purpose of this study is to determine if treatment with omecamtiv mecarbil/AMG 423 when added to standard of care is well tolerated and superior to placebo in reducing the risk of cardiovascular death or heart failure events in subjects with chronic HFrEF.

Key Inclusion Criteria:

- Male or female, ≥ 18 to ≤ 85 years
- History of chronic HF (defined as requiring treatment for HF for a minimum of 30 days before randomization)
- LVEF ≤ 35%, not in the setting of acute decompensation
- NYHA class II to IV
- Managed with HF SoC therapies consistent with regional clinical practice guidelines according to investigator judgment of subject's clinical status
- Current hospitalization with primary reason of HF or prior HF hospitalization, or urgent HF admission to emergency department (ED) within 1 year prior to screening
- Elevated BNP or NT-proBNP

Key Exclusion Criteria:

- Currently receiving treatment in another investigational device or drug study, or < 30 days since ending treatment on another investigational device or drug study(ies)
- Receiving mechanical hemodynamic support or mechanical ventilation ≤ 7 days prior to randomization
- Receiving IV inotropes or IV vasopressors ≤ 3 days prior to randomization
- Receiving IV diuretics or IV vasodilators, or supplemental oxygen therapy ≤ 12 hours prior to randomization
- Acute coronary syndrome, stroke, or transient ischemic attack, major cardiac surgery, percutaneous coronary intervention, or valvuloplasty within the 3 months prior to randomization
- Severe uncorrected valvular heart disease, or hypertrophic obstructive cardiomyopathy, active myocarditis, constrictive pericarditis, or clinically significant congenital heart disease
- Untreated severe ventricular arrhythmia
- Systolic BP > 140 mmHg or < 85 mmHg, or diastolic BP > 90 mmHg
- TBL ≥ 2x ULN; AST or ALT ≥ 3x ULN
- eGFR < 20 ml/min/1.73m2

Source: **https://clinicaltrials.gov/ct2/show/NCT02929329**
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