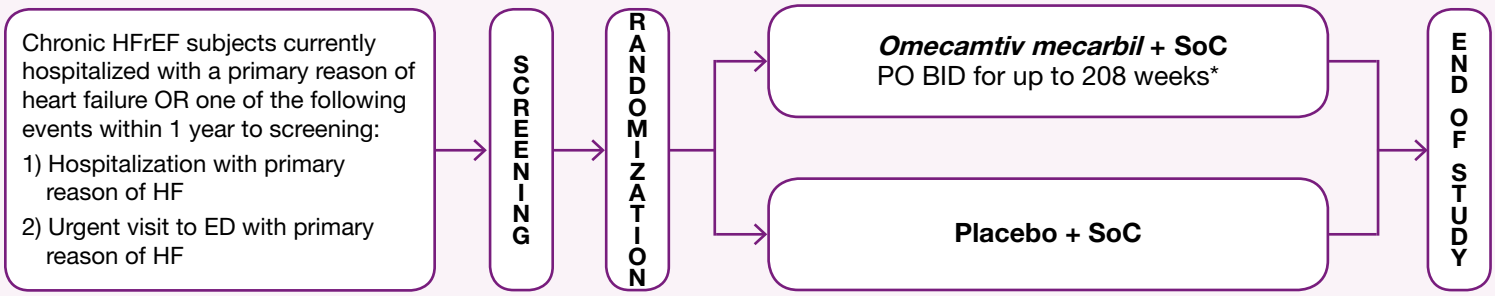
GALACTIC-HF

Global **A**pproach to **L**owering **A**dverse **C**ardiac Outcomes **T**hrough **I**mproving **C**ontractility in **H**eart **F**ailure

NCT Clinical Study: 02929329

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

PHASE 3 STUDY DESIGN:



STUDY PURPOSE:

To determine if treatment with *omecamtiv mecarbil* when added to standard of care (SoC) is well tolerated and superior to placebo and SoC in reducing the risk of cardiovascular (CV) death or heart failure (HF) events in subjects with chronic HF with reduced ejection fraction

PRIMARY ENDPOINT:

Time to CV death or first HF event

SECONDARY ENDPOINTS:

- Time to CV death
- Changes in Kansas City Cardiomyopathy Questionnaire Total Symptom Score from baseline to week 24
- Time to first HF hospitalization
- Time to all-cause death

OTHER OUTCOME MEASURES:

- Incidence of reported adverse events
- Incidence of reported serious adverse events of ventricular arrhythmias requiring treatment
- Incidence of positively adjudicated major cardiac ischemic events

KEY INCLUSION CRITERIA:

- Men or women aged ≥ 18 to ≤ 85 years, with informed consent
- History of chronic HF (defined as requiring treatment for HF for a minimum of 30 days before randomization)
- Left ventricular ejection fraction ≤ 35% per subject's most recent medical record, within 12 months prior to screening
- New York Heart Association class II–IV at the most recent screening assessment
- Managed with HF SoC therapies consistent with regional clinical practice guidelines according to the investigator's judgment of subject's clinical status
- Current hospitalization with a primary reason of heart failure OR one of the following events within 1 year to screening:
  1. Hospitalization with primary reason of HF
  2. Urgent visit to emergency department with primary reason of HF
- Elevated B-type natriuretic peptide (BNP) or N-terminal pro-BNP

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). Participation in other investigational procedures while participating in this study is not allowed
- Malignancy within 5 years prior to randomization with the following exceptions: localized basal or squamous cell carcinoma of the skin, cervical intraepithelial neoplasia, stage 1 prostate carcinoma, or breast ductal carcinoma in situ
- Known sensitivity to any of the products or components to be administered during testing
- Other exclusion criteria may apply

ADDITIONAL INFORMATION:

www.clinicaltrials.gov (Identifier: 02929329)

*Dose level determined by periodic blood testing.

BID = twice a day; ED = emergency department; HF = heart failure; HFrEF = heart failure with reduced ejection fraction; PO = orally; SoC = standard of care.

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Cytokinetics

Omecamtiv mecarbil is an investigational cardiac myosin activator. Efficacy and safety have not been established.