

PARADIGM

A Multicenter, Randomized, Double-blind, Parallel Group, Active-controlled Study to Evaluate the Efficacy and Safety of LCZ696 Compared to Enalapril on Morbidity and Mortality in Patient with Chronic Heart Failure and Reduced Ejection Fraction

Study Phase III

Purpose

The study will evaluate the efficacy and safety of LCZ696 compared to enalapril on morbidity and mortality in patients with chronic heart failure (NYHA Class II – IV and EF <40%).

The study population will include those who meet the following inclusion/exclusion criteria, some of which are:

Inclusion Criteria

- Men & Women \geq 18 years of age
- Patients with a diagnosis of CHF NYHA class II-IV and reduced EF <40% and elevated BNP
- Must be on an ACEI or an ARB at a stable dose of at least enalapril 10mg/d or equivalent for at least 4 weeks
- Must be treated with a B-Blocker, unless contraindicated or not tolerated, at a stable dose for at least 4 weeks.
- Signed & dated, written informed consent to participate in this study.

Exclusion Criteria

- Use of other investigational drugs at the time of enrollment, or within 30 days or 5 half-lives of enrollment, whichever is longer.
- Previous history of intolerance to recommended target doses of ACEIs or ARBs
- Known history of angioedema
- Current acute decompensated HF (exacerbation of chronic HF manifested by signs/symptoms that may require IV therapy).
- Symptomatic hypotension and/or a SBP < 100mmHg.
- Estimated GFR <30 mL/min/1.73m² as measured by the simplified MDRD formula.
- Serum potassium >5.2 mmol/L

To inquire if you are eligible for this study or hear more about it, please contact:

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