PARAGON-HF

NCT01920711

Principal Investigator: Dr. Peter Fattal, MD (S. Washington Office)

Condition: Heart Failure With Preserved Ejection Fraction

Drug: LCZ696 vs. Valsartan

Official Title: Efficacy and Safety of LCZ696 Compared to Valsartan, on Morbidity and Mortality in Heart Failure Patients With Preserved Ejection Fraction (PARAGON-HF)

Sponsor: Novartis Pharmaceuticals

Purpose: The purpose of this study is to evaluate the effect of LCZ696 compared to valsartan in the reduction of cardiovascular death and heart failure (HF) hospitalizations in patients with HF with preserved ejection fraction.

Inclusion Criteria:

- Left ventricular ejection fraction (LVEF) ≥45% by echo during screening epoch or within 6 months prior to study entry.
- Symptom(s) of heart failure (HF) and requiring treatment with diuretic(s) for HF at least 30 days prior to study entry.
- Current symptom(s) of HF
- Structural heart disease (left atrial enlargement or left ventricular hypertrophy) documented by echocardiogram.
- Elevated NT-proBNP

Exclusion Criteria:

- Any prior measurement of LVEF < 40%.
- Acute coronary syndrome (including MI), cardiac surgery, other major CV surgery within 3 months , or urgent percutaneous coronary intervention within 3 months or and elective PCI within 30 days prior to entry.
- Any clinical event within the 6 months prior to entry could have reduced the LVEF (e.g., MI, CABG), unless an echo measurement performed after the event confirms a LVEF ≥45%.
- Current acute decompensated HF requiring therapy.
- Patients who require treatment with 2 or more of the following: an angiotensin converting enzyme inhibitor (ACEI), an angiotensin receptor blocker (ARB) or a renin inhibitor.
- Alternative reason for shortness of breath such as: significant pulmonary disease or severe COPD, hemoglobin (Hgb) <10 g/dl, or body mass index (BMI) > 40 kg/m2.
- Systolic blood pressure (SBP) ≥ 180 mmHg at entry, or SBP >150 mmHg and <180 mmHg at entry unless the patient is receiving 3 or more antihypertensive drugs, or SBP < 110 mmHg at entry.

Other protocol-defined inclusion/exclusion criteria may apply.

Source: https://clinicaltrials.gov/ct2/show/NCT01920711
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