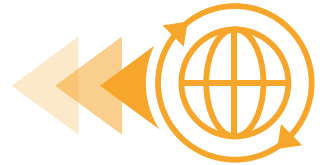


# PARAGON-HF: The Largest Clinical Trial in HFpEF to Date

**Heart failure with preserved ejection fraction, or HFpEF, is a distinct type of heart failure in which the heart muscle is stiff, so the chamber can't expand to fill with and pump out enough blood to meet the body's needs<sup>1,2</sup>.**

**HFpEF**, which affects **~13 million people**, is associated with high hospitalization rates and consequently poor survival<sup>3,4,5</sup>.

There is currently no approved treatment beyond symptomatic relief<sup>2,6</sup>.



## A Look at PARAGON-HF

**Developing a treatment for HFpEF is challenging**, and outcomes trials in HFpEF over the last decades have not been successful<sup>7</sup>.

**PARAGON-HF follows the only positive phase II HFpEF trial, PARAMOUNT-HF<sup>8</sup>.**

### Design

- **PARAGON-HF was designed to evaluate the effect of sacubitril/valsartan** on the total burden of HFpEF, including the effect on repeated hospitalizations, a critical endpoint for HFpEF patients<sup>7</sup>.
- In the Phase III double-blind, parallel group, active-controlled, 2-arm, event-driven trial, patients were randomized to receive 97/103mg of Entresto twice daily or 160mg of valsartan twice daily. There was follow-up through 57 months<sup>7,9</sup>.
- **PARAGON-HF included an active comparator, valsartan, designed to show real-world benefit** and chosen because RAAS inhibitors are widely used in HFpEF patients, predominantly to treat comorbidities<sup>7</sup>.



## Population



The PARAGON-HF patient population reflects everyday clinical practice<sup>7</sup>.

### THE TRIAL ENROLLED

**4,822 HFpEF patients in 43 countries** being treated for symptoms and comorbidities, half of whom have a **history of hospitalizations**<sup>9</sup>

## Primary Endpoint

- **Patients with HFpEF experience recurrent hospitalizations**, with each event worsening prognosis and requiring resources<sup>3</sup>.
- Because of this, PARAGON-HF evaluated the **combined reduction in the rate of cardiovascular death and total heart failure hospitalizations**—important long-term critical outcomes—as the primary endpoint<sup>7</sup>, for which statistical significance was narrowly missed<sup>10</sup>.

## The Need For A HFpEF-Specific Treatment



**Heart failure is a specific, chronic and progressive condition<sup>11</sup> that requires a safe and effective treatment that focuses on treating the heart to keep patients out of the hospital.**

Potential treatments are being evaluated in clinical trials<sup>26,7</sup>.

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