PARAGON-HF: Angiotensin Receptor Neprilysin Inhibition in Heart Failure with Preserved Ejection Fraction

Purpose: Evaluate effect of sucabirtil/valsartan vs. valsartan alone in reducing CV death and heart failure (HF) hospitalizations in patients with HF with preserved ejection fraction.

Trial Design: N = 4,822. Phase 3, multicenter, randomized, double-blind, parallel group, active-controlled, 80 mg valsartan daily vs 100 mg. LCZ696 daily for 57 months.

Primary endpoints: Cumulative primary composite events of CV death and total (first and recurrent) HF hospitalizations (reported here).

Secondary endpoints: Change in clinical summary score from baseline to month 8 by Kansas City Cardiomyopathy Questionnaire (KCCQ); change from baseline to month 8 in New York Heart Association (NYHA) functional class; time to first occurrence of composite renal endpoint; time to all-cause mortality.

Primary Endpoint	Sucabitril / valsartan	Valsartan	Rate Ratio	P value
First and recurrent HF hospitalizations and CV death	N=2407 (894 events, 12.8 per 100 pt/yrs.	N=2389 (1009 events, 14.6 per 100/pt/yrs.	0.87, (95% CI = 0.753, 1.005)	P=0.0585

Results:

- Primary endpoint narrowly missed.
- But benefit observed in some secondary endpoints
- More benefit of treatment shown in HFpEF patients with lower ejection fraction (EF< = 57%) and in women

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