

Maria A. Pabon, Orly Vardeny, Muthiah Vaduganathan, Akshay S. Desai, Brian L. Claggett, Ian J Kulac, Pardeep S. Jhund, Carolyn SP Lam, Michele Senni, Sanjiv J Shah, Adriaan A. Voors, Faiez Zannad, Bertram Pitt, Clara I. Saldarriaga, Mark C Petrie, Béla Merkely, Maria Borentain, Katharina Mueller, Prabhakar Viswanathan, Flaviana Amarante, Alanna A. Morris, John JV McMurray, Scott D. Solomon

## Background

- With advancements in the management of heart failure with reduced ejection fraction (HFrEF), an increasing number of patients have an improvement in their ejection fraction, resulting in a growing population with heart failure with improved EF (HFimpEF).
- Despite this, patients with HFimpEF may still face residual risks

## Study Aim

- We assessed clinical profiles, risk, and treatment response to finerenone in participants with HFimpEF enrolled in FINEARTS-HF.

## Methods

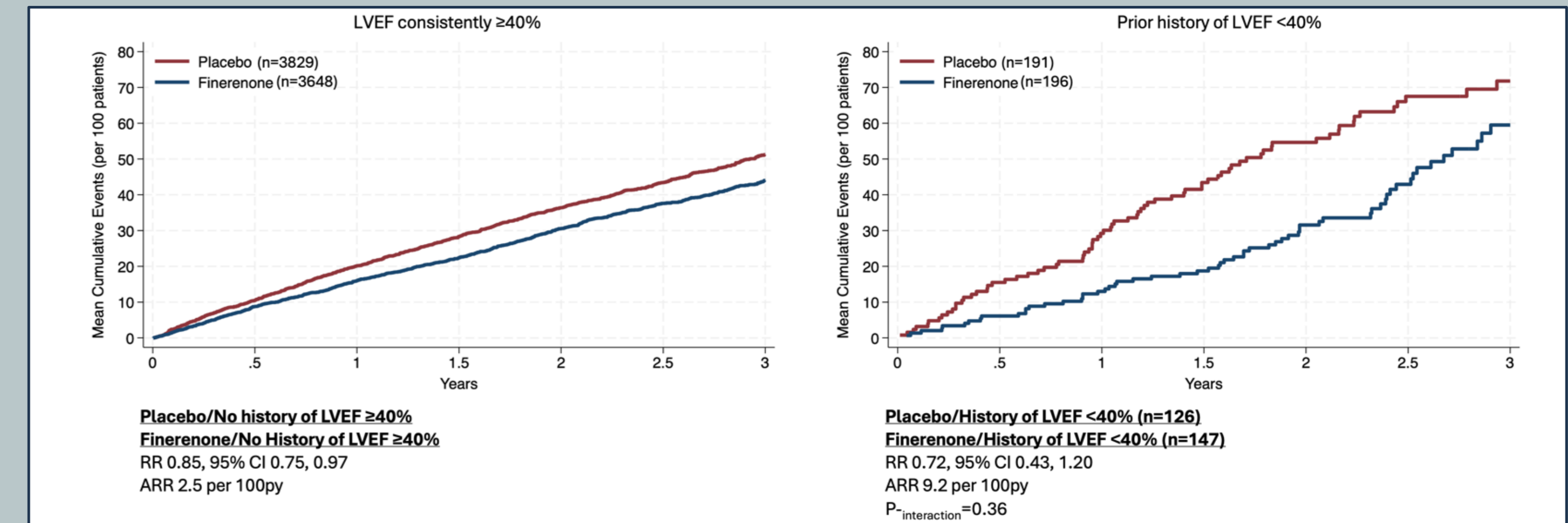
- FINEARTS-HF is the second large, randomized clinical trial that permitted enrollment of patients with HFimpEF.
- Symptomatic patients with HF with LVEF  $\geq 40\%$  were allocated to receive either the non-steroidal MRA finerenone or placebo
- Identification of HFimpEF status was collected in a case report form at the screening visit.
- The primary study outcome was a composite of cardiovascular (CV) death and total (first and recurrent) HF events.
- The primary outcome and total HF events by HFimpEF status were compared using a recurrent events model based on the Lin, Wei, Yang and Ying (LWYY) model, stratified by geographic region and baseline LVEF ( $< 60\%$ ,  $\geq 60\%$ ). All-cause mortality was analyzed using stratified Cox model.

**Disclosure information:** The FINEARTS-HF study was sponsored by Bayer.

## Baseline characteristics by HFimpEF status of participants of FINEARTS-HF

Characteristic	LVEF consistently $\geq 40\%$	HFimpEF	p-value
	n=5728	n=273	
Age — years.	72.1 $\pm$ 9.6	70.1 $\pm$ 10.4	< 0.001
Women	2664 (47%)	68 (25%)	< 0.001
Race or ethnic group — no. (%)			< 0.001
White	4555 (80%)	180 (66%)	
Asian	909 (16%)	87 (32%)	
Black	86 (2%)	2 (1%)	
Other	178 (3%)	4 (2%)	
Any prior HF hospitalization— no. (%)	3433 (60%)	186 (68%)	0.007
Clinical features — no. (%)			
Hypertension	5110 (89%)	215 (79%)	< 0.001
Atrial fibrillation	2218 (39%)	75 (28%)	< 0.001
Myocardial infarction	1445 (25%)	96 (35%)	< 0.001
Body mass index	30 $\pm$ 6	28 $\pm$ 6	< 0.001
LVEF — %	53 $\pm$ 8	46 $\pm$ 6	< 0.001
NYHA classification— no. (%)			0.042
II	3942 (69%)	204 (75%)	
III/IV	1785 (31%)	69 (25%)	
Median NT-proBNP (IQR)	1038 [444, 1937]	1075 [496, 2211]	0.10
Median eGFR	62 $\pm$ 20	61 $\pm$ 21	0.54
Heart Failure Therapies			
Beta-blocker	4849 (85%)	246 (90%)	0.014
ACE inhibitor	2071 (36%)	84 (31%)	0.07
ARB	2043 (36%)	59 (22%)	< 0.001
ARNI	418 (7%)	95 (35%)	< 0.001
Loop diuretic	4987 (87%)	252 (92%)	0.011
SGLT-2 inhibitor	744 (13%)	73 (27%)	< 0.001

## Primary outcome of total HF events and CV death by HFimpEF status



## Primary and secondary outcomes by HFimpEF status

	LVEF consistently $\geq 40\%$		HFimpEF		p-int
	Finerenone	Placebo	Finerenone	Placebo	
	n = 2856	n = 2872	n = 147	n = 126	
<b>Total worsening HF events and CV death</b>					
Events	1023	1205	60	78	
Rate (per 100 pt-yrs)	14.8	17.3	17.2	26.4	
RR (95% CI)	0.85 (0.75, 0.97)	REF	0.72 (0.43, 1.20)	REF	0.356
<b>Total worsening HF events</b>					
Events	793	959	49	65	
Rate (per 100 pt-yrs)	11.4	13.8	14.0	22.0	
RR (95% CI)	0.83 (0.71, 0.96)	REF	0.72 (0.41, 1.24)	REF	0.424
<b>CV death</b>					
Events (%)	231 (8.1%)	247 (8.6%)	11 (7.5%)	13 (10.3%)	
Rate (per 100 pt-yrs)	3.3	3.6	3.1	4.4	
HR (95% CI)	0.94 (0.79, 1.13)	REF	0.73 (0.32, 1.67)	REF	0.523
<b>Death from any cause</b>					
Events (%)	473 (16.6%)	499 (17.4%)	18 (12.2%)	23 (18.3%)	
Rate (per 100 pt-yrs)	6.8	7.2	5.2	7.7	
HR (95% CI)	0.95 (0.84, 1.08)	REF	0.70 (0.37, 1.32)	REF	0.273

*In this high-risk cohort of patients with HF, finerenone demonstrated consistent safety and efficacy in reducing adverse CV outcomes regardless of prior history of LVEF <40%. These findings robustly support the safety and efficacy of finerenone in patients with HFimpEF, reinforcing its role as a valuable therapeutic option in this at-risk population*