HEALTH FOR ALL, HUNGER FOR NONE

ESC Congress 2024: RESULTS FROM FINERENONE IN HEART FAILURE

INVESTOR WEBINAR

September 2, 2024

Agenda

01 Welcome

Thomas Kornek

Vice President Investor Relations

02 Prepared Remarks

Christoph Koenen

Head of
Clinical Development &
Operations,
Bayer Pharmaceuticals

Maria Borentain

Head of
Cardiovascular and Renal
Clinical Development,
Bayer Pharmaceuticals

Bernardo Kanahuati

Product Team Lead
Kerendia,
Bayer Pharmaceuticals

03 Q&A

Cautionary Statements Regarding Forward-Looking Information

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http://www.bayer.com/

The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

HEALTH FOR ALL, HUNGER FOR NONE

Finerenone: POTENTIAL TO MAKE A DIFFERENCE IN HEART FAILURE

INVESTOR WEBINAR
Christoph Koenen

September 2, 2024

Heart Failure Is a Huge Burden for Patients as Well as Healthcare Systems

Characteristics
of Heart Failure (HF)

64 million
people worldwide
live with HF[1]

#1 reason for hospitalization in patients aged >65 years worldwide[2]

~50% of patients die
within 5 years of diagnosis[3] **– worse** survival than some common cancers[4]

Implications for
Healthcare Systems

~$346 billion
total expenditure associated to HF worldwide[5]

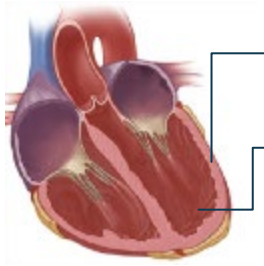
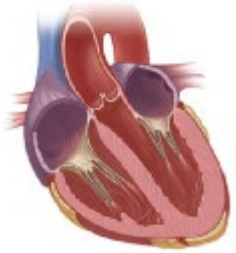
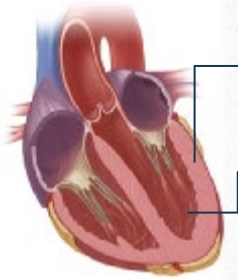
87% of overall HF costs driven by hospitalization for HF[6]

comprises the largest component of direct medical costs associated with HF[7]

1. Vos D et al. Lancet. 2017;390:1211–1259; 2. Mozaffarian D et al. Circulation. 2016;133:e38–e360; 3. Virani SS et al. Circulation. 2020;141:e139–e596; 4. Mamas MA et al. Eur J Heart Fail. 2017;19:1095–1104; 5. Lippi G, Sanchis-Gomar F. AME Med J. 2020;5:15
6. World Heart Federation. Accelerate change together: heart failure gap review, 2023. Available at: https://world-heart-federation.org/resource/accelerate-change-together-heart-failure-gap-review/ Last accessed: May 2024; 7. Lam CSP et al. Clin Cardiol. 2021;44(5):646-655.

HF Is a Complex Disease With Major Differences in Each Subtype Requiring Different Treatment Approaches

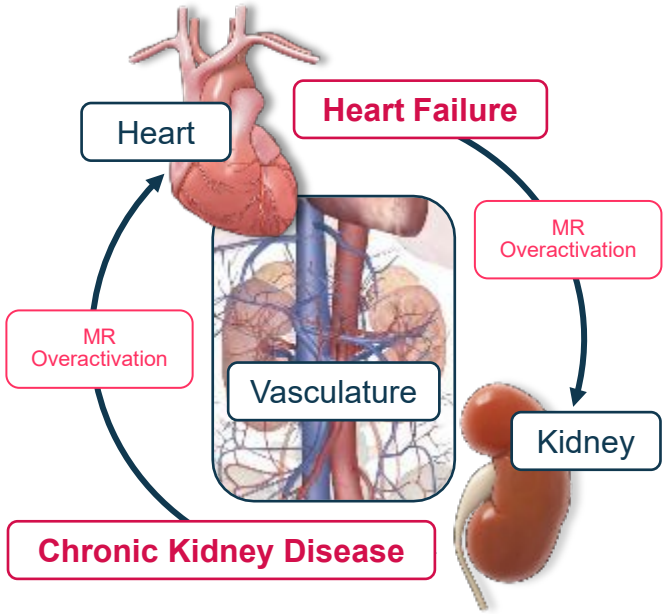
Scope of FINEARTS-HF

HFrEF (LVEF ≤40%)	HFmrEF (LVEF 41%-49%)	HFpEF (LVEF ≥50%)
Impaired ventricular contraction	Mildly impaired ventricular contraction and/or ventricular filling	Impaired ventricular filling
 Thin ventricular walls; Dilation of chamber	 // Pathophysiology not yet well understood; // Intermediate biomarker profile — Enhanced expression of both markers of cardiac stretch and of inflammation	 Thick, stiff ventricular walls; Reduced chamber dimension
~35-45% of HF patients		**~55-65%** of HF patients
4 treatments with class I guideline recommendation	vs	**1** treatment with class I guideline recommendation (SGLT2i)

HF: Heart failure; HFmrEF: Heart failure with mildly reduced ejection fraction; HFpEF: Heart failure with preserved ejection fraction; HFrEF: Heart failure with reduced ejection fraction; LVEF: Left ventricular ejection fraction

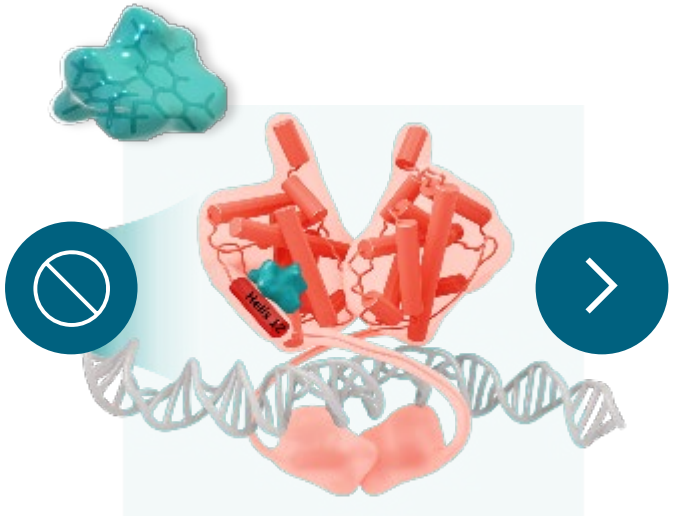
Highly Selective Inhibition of MR Overactivation With Finerenone to Address Fundamental Drivers of Disease Progression

Vicious Cycle of Worsening Disease



Pathophysiologic Heart-kidney Interplay

Finerenone



- Reduces Fibrosis
- Reduces inflammation
- Reduces Oxidative Stress
- Improves Endothelial Function

Halting the Vicious Cycle by Blocking MR Overactivation

- Highly selective inhibition of the MR receptor – reducing MR overactivation[1]
- Improved heart and kidney health[2]
- Improved patient outcomes[2]
- Breaking the MR-induced spiral of pathogenic heart-kidney damage [2,3]
- Address fundamental drivers of end-organ damage in HF and LVEF ≥40% [2,3]

HF: Heart failure; LVEF: Left ventricular ejection fraction; MR: Mineralocorticoid receptor
[1] Kolkhof P, et al. Handb Exp Parmacol 2017;243:271–305 [2] Kolkhof P, et al. Int J Mol Sci 2022, 23(16):9243 [3] Epstein M, et al. Am J Kidney Dis 2022;80(5):658-666

Due to Its Distinct Structural and Pharmacological Properties, Finerenone's Clinical Profile Significantly Differs from Other MRAs

Structural and pharmacological properties of MRAs[2]

	Spironolactone	Eplerenone	Finerenone
MRA Class	Steroidal	Steroidal	Non-steroidal
Potency	High	Low	High
Selectivity	Low	Medium	High
Metabolites	Multiple, active	No active	No active
Tissue distribution[3]	Kidney>>heart (>6-fold)	Kidney>heart (~3-fold)	Balanced (1:1)
Indication and key studies	HF with LVEF ≥40%: TOPCAT study failed[4] HF with LVEF <40%: class 1 recommendation[1-3] (RALES study)	HF with LVEF ≥40%: not tested HF with LVEF <40%: class 1 recommendation[1-3] (EPHESUS study)	Significant risk reduction in HF with LVEF ≥40% and patients with CKM
First launch	**1960**	**2002**	**2021** in CKD/T2D

Characteristics of Finerenone

- Significant molecular and pharmacological differences that explain cardiorenal clinical effects[4]
- High selectivity for the MR over other steroid hormone receptors, which prevents antiandrogenic and progestational side effects[4]
- **Balanced** cardiac and kidney distribution
- **Low incidence** of hyperkalaemia-related adverse events with clinical impact and permanent treatment discontinuation[5]

CKM: Cardiovascular-kidney-metabolic; HFpEF: Heart Failure with preserved ejection fraction; HFrEF: Heart Failure with reduced ejection fraction; LVEF: Left ventricular ejection fraction; MRA: Mineralocorticoid receptor antagonist

[1] Kolkhof P, Nowack C, Eitner F. Curr Opin Nephrol Hypertens. 2015;24:417-424. [2] Modified from: Kolkhof B, Borden SA. Mol Cell Endocrinol. 2012;350:310-317. [3] Determined in rodents. [4] Kintscher U, Bakris GL, Kolkhof P. Novel non-steroidal mineralocorticoid receptor antagonists in cardiorenal disease. Br J Pharmacol. 2022 Jul;179(13):3220-3234. [5] Agarwal R, Filippatos G, Pitt B, Anker SD, Rossing P, Joseph A, Kolkhof P, Nowack C, Gebel M, Ruilope LM, Bakris GL; FIDELIO-DKD and FIGARO-DKD investigators. Cardiovascular and kidney outcomes with finerenone in patients with type 2 diabetes and chronic kidney disease: the FIDELITY pooled analysis. Eur Heart J. 2022 Feb 10; 43(6):474-484. doi: 10.1093/eurheartj/ehab777. Erratum in: Eur Heart J. 2022 May 21;43(20):1989.

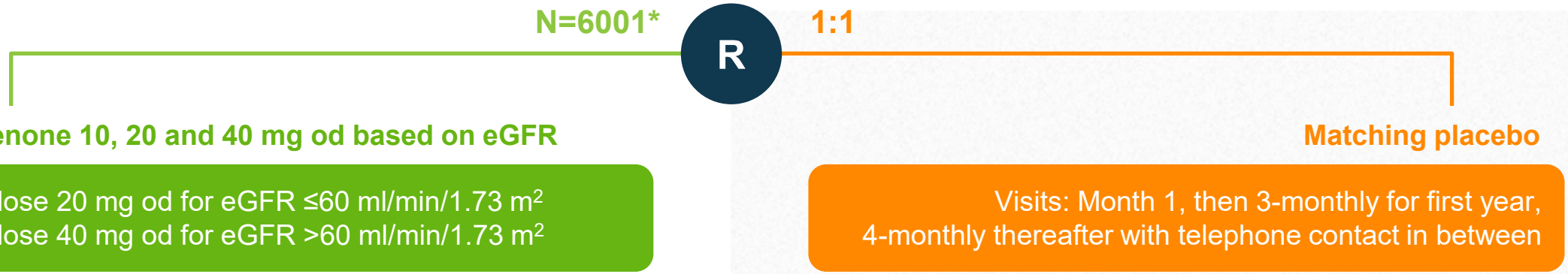
HEALTH FOR ALL, HUNGER FOR NONE

Finerenone:
KEY STUDY RESULTS OF FINEARTS-HF AND FINE-HEART

INVESTOR WEBINAR
Maria Borentain

September 2, 2024

FINEARTS-HF Evaluates the Efficacy and Safety of Finerenone in Patients With HF and LVEF ≥40%



Primary endpoints

Composite of **CV Death** and **total HF events**

Secondary endpoints

Total HF events

Change in **KCCQ-TSS** to Months 6, 9 and 12

Improvement in **NYHA class** to Month 12

Composite renal endpoint (sustained decrease in eGFR ≥50% relative to baseline, sustained eGFR decline <15 ml/min/1.73 m², initiation of dialysis or renal transplantation)

All-cause mortality

CV: Cardiovascular; eGFR: estimated glomerular filtration rate; HF: Heart Failure; LVEF: Left ventricular ejection fraction; KCCQ-TSS: Total symptom score of Kansas City Cardiomyopathy Questionnaire; NYHA: New York Heart Association; Od: once daily; R: Randomization
* 6016 randomized, 6001 included in efficacy analysis

FINEARTS-HF Achieved Its Objective

Finerenone reached primary composite endpoint

Significantly reduced the composite of CV death and total HF events

Demonstrated consistency across all pre-specified subgroups

Finerenone demonstrated significant benefits in secondary efficacy endpoints

Reduced total HF events

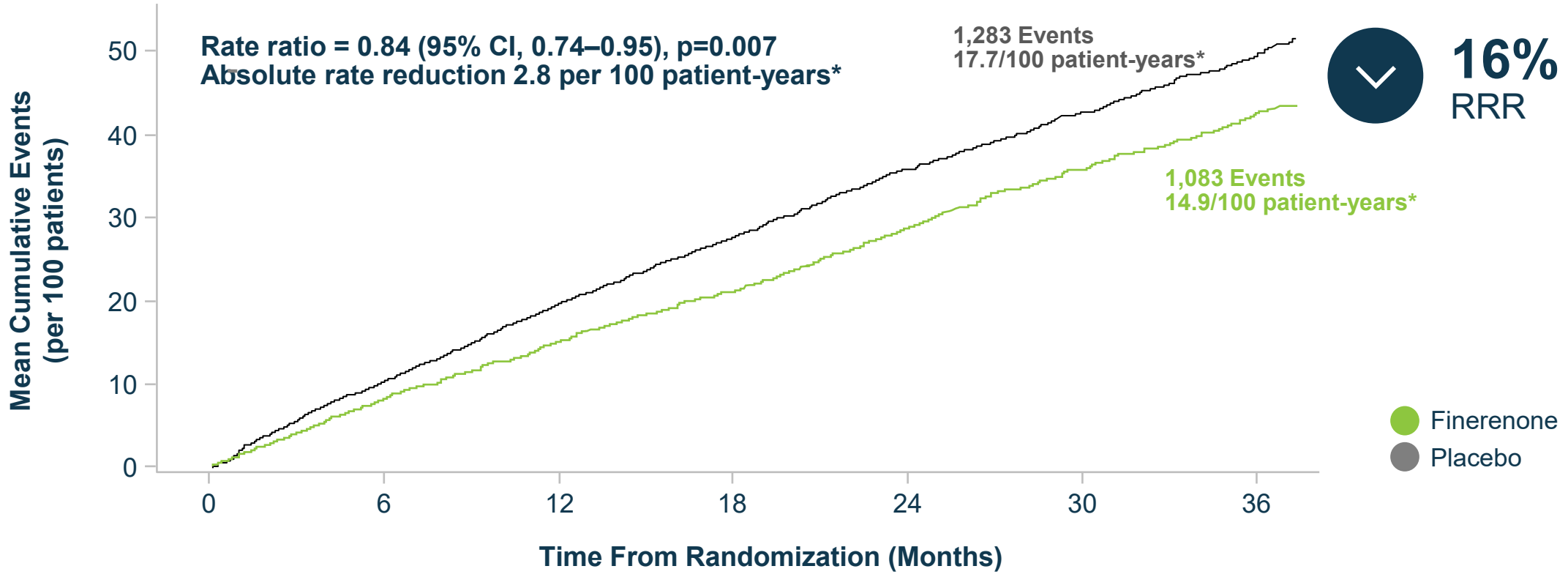
Improved patient-reported health status in patients with HF and LVEF ≥40%

Safety profile was in line with previous studies

CV: Cardiovascular; HF: Heart Failure; HFmr/pEF: Heart Failure with mildly reduced / preserved ejection fraction

Finerenone Demonstrated Clinically Meaningful 16% Relative Risk Reduction in Composite of CV Death and Total HF Events

Primary Endpoint: Composite of CV Death and Total HF Events

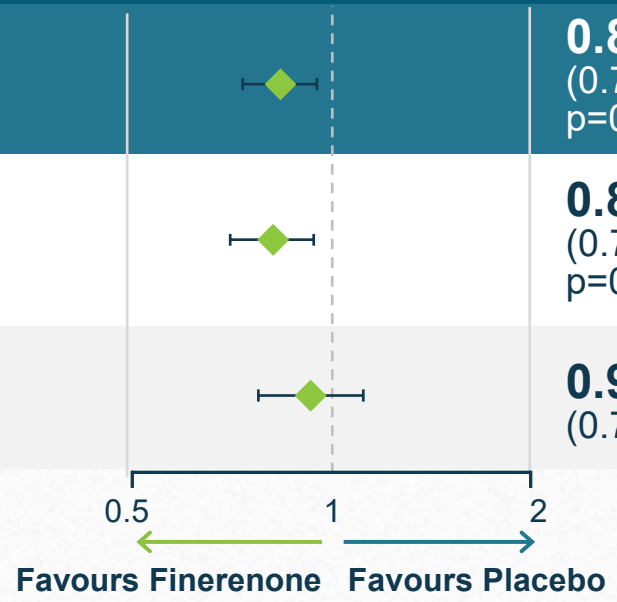


ARR: Absolute risk reduction; CI: Confidence interval; CV: Cardiovascular; HF: Heart Failure; RR: Risk ratio; RRR: Relative Risk Reduction; Pt-yrs: Patient years
* Note: in a previous version, 17.6/100 patient-years were shown for placebo and 14.3/100 patient-years for finerenone, equivalent to an absolute rate reduction of 3.3 per 100 patient-years. This has been corrected.

The Statistically Significant Reduction in Composite CV Outcome Was Driven by a Reduction in HF Events

Primary Endpoint | Components Of Composite CV Outcome

Outcome	Finerenone (N=3003) n	Placebo (N=2998) n	RR (95% CI)
Composite CV Outcome	**1083**	**1283**	**0.84** (0.74–0.95) p=0.007
Total HF Events*	**842**	**1024**	**0.82** (0.71–0.94) p=0.006
CV Death	**242**	**260**	**0.93** (0.78–1.11)

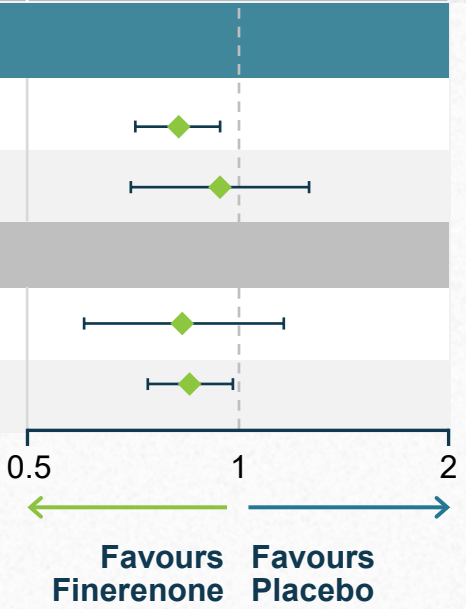


*One patient in each group was reported as having a HF event on the same day as a CV death and was counted as only one composite event in the primary analysis.
CI: Confidence interval; CV: Cardiovascular; HF: Heart failure; RR: Rate ratio
Source: Solomon S, et al. NEJM 2024 [in press].

Finerenone's Effects On Primary Outcome Were Consistent Regardless of LVEF and Background Therapy, Including SGLT2i

Primary Endpoint | Key sub-groups

Category	Finerenone			Placebo			RR (95% CI)
	Events	n/N	E/100 p-yrs	Events	n/N	E/100 p-yrs	
LVEF							
< 60%	877	512/2427	15.17	1061	594/2425	18.47	
≥ 60%	206	112/576	13.76	222	125/573	14.73	
SGLT2i							
Yes	176	95/393	21.77	234	122/424	26.50	
No	907	529/2610	14.02	1049	597/2574	16.48	



Rate ratios for the primary endpoint across all 17 pre-specified subgroups were in favour of finerenone

CI; Confidence interval; LVEF: Left ventricular ejection fraction; RR: Rate ratios; SGLT2i: Sodium-glucose cotransporter-2 inhibitors.
Source; Solomon S, et al. NEJM 2024 [in press].

FINEARTS-HF Also Reached Key Secondary Endpoints

Secondary Endpoints, hierarchical testing

	Finerenone (N=3003)	**Placebo** (N=2998)	**Difference** [1] (95% CI)
Total HF Events	**842**	**1024**	**RR: 0.82** (0.71, 0.94) p=0.0062 ✓
Change in KCCQ-TSS to Months 6, 9 and 12, LS mean (SE)	**7.99** (0.32)	**6.43** (0.32)	**Diff: 1.56** (0.79, 2.34) p<0.0001 ✓
Improvement in NYHA Class to Month 12, n/N (%)	**557/3002** (18.5%)	**553/2998** (18.4%)	**OR: 1.01** (0.88, 1.15)
Composite renal endpoint, n (%)	**75** (2.5%)	**55** (1.8%)	**HR: 1.33** (0.94, 1.89)
All-cause mortality, n (%)	**491** (16.4%)	**522** (17.4%)	**HR: 0.93** (0.83, 1.06)

[1] Treatment difference for Finerenone vs Placebo: HR: Hazard ratio; RR: Rate ratio; OR: Odds ratio; Diff: Difference in least squared means; CI: Confidence interval; CV: Cardiovascular; HF: Heart failure; KCCQ-TSS: Total symptom score of Kansas City Cardiomyopathy Questionnaire; LS: Least squared; NYHA: New York Heart Association; SE: Standard error; Composite renal endpoint: Time to sustained decrease in estimated glomerular filtration rate (eGFR) ≥50% relative to baseline over at least 4 weeks, or sustained eGFR decline <15ml/min/1.73m2 or initiation of dialysis or renal transplantation

Similar to Previous Clinical Trials, Finerenone Was Well Tolerated

Type of treatment-emergent safety outcome	**Finerenone** (N=2993)	**Placebo** (N=2993)
Any SAE	38.7%	40.5%
Serum creatinine ≥3.0 Mg/Dl	2.0%	2.1%
Serum potassium		
>5.5 Mmol/L	14.3%	6.9 %
>6.0 Mmol/L	3.0 %	1.4 %
<3.5 Mmol/L	4.4 %	9.7 %
Investigator-reported hyperkalemia	9.7%	4.2%
Leading to hospitalization	0.5%	0.2%
Leading to death	0%	0%
Systolic blood pressure <100 mmHg	18.5%	12.4%

Treatment emergent defined as all safety events that occurred in patients who received at least one dose of study drug and up until 3 days following permanent discontinuation
AE: Adverse event; SAE: Serious adverse event

FINEARTS-HF: Conclusions

- Among patients with HF with LVEF ≥40%, **finerenone reduced the risk of the primary composite outcome of cardiovascular death and total HF events,** reduced total HF events, and improved HF health status.
- **The benefit appears to be early and the curves continue to separate over time.**
- **Findings were consistent across prespecified subgroups,** including across LVEF and in those on SGLT2i's.
- **Hyperkalemia was more common, and hypokalemia less common,** in those receiving finerenone. Hyperkalemia leading to hospitalization was low, and there was no fatal hyperkalemia
- Subject to regulatory approval, **these data support the use of finerenone in patients with HF and LVEF ≥40%** (HFmr/pEF)

LVEF: Left ventricular ejection fraction; SGLT2i: Sodium-glucose cotransporter-2 inhibitors

FINE-HEART Represents The Largest Analysis of Efficacy and Safety of Finerenone Across the CKM Spectrum

FINEARTS-HF | FIGARO-DKD | FIDELIO-DKD

FINEHEART

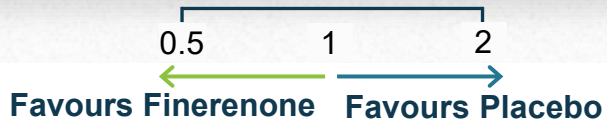
~19,000
Patients

FINE-HEART is designed to assess the safety and efficacy of finerenone on CV death and other heart and kidney outcomes, and is enriched for participants with a high burden of CKM multimorbidity. **Individual studies were not powered to evaluate treatment effects on CV mortality or efficacy in key subgroups.**

CKM: Cardiovascular-kidney-metabolic; CV: Cardiovascular

In FINE-HEART, Finerenone Demonstrated Benefits Across Cardio-Kidney Secondary Endpoints

Outcomes	Finerenone (N=9,501) No. of patients with event (%)	Finerenone (N=9,501) IR per 100py	Placebo (N=9,490) No. of patients with event (%)	Placebo (N=9,490) IR per 100py	HR (95% CI)	p-value
Primary Endpoint						
CV Death (excluding undetermined death)	421 (4.4)	1.5	471 (5.0)	1.7	0.89 (0.78-1.01)	0.076
Prespecified Sensitivity Analysis: CV Death (including Undetermined death)	627 (6.6)	2.3	703 (7.4)	2.6	0.88 (0.79-0.98)	0.025
Secondary Endpoints						
Kidney Composite Endpoint	557 (5.9)	2.3	685 (7.2)	2.8	0.80 (0.72-0.90)	<0.001
HF Hospitalization	705 (7.4)	2.7	839 (8.8)	3.2	0.83 (0.75-0.92)	<0.001
CV Death or HF Hospitalization	1009 (10.6)	3.9	1168 (12.3)	4.5	0.85 (0.78-0.93)	<0.001
New-onset Atrial Fibrillation	286 (3.0)	1.3	345 (3.6)	1.6	0.83 (0.71-0.97)	0.018
Major adverse CV events	1428 (15.0)	5.6	1554 (16.4)	6.2	0.91 (0.85-0.98)	0.010
All-Cause Death	1042 (11.0)	3.8	1136 (12.0)	4.2	0.91 (0.84-0.99)	0.027
All-Cause Hospitalization	4261 (44.8)	21.1	4401 (46.4)	22.2	0.95 (0.91 – 0.99)	0.025
All-Cause Death or All-Cause Hospitalization	4467 (47.0)	22.2	4653 (49.0)	23.5	0.94 (0.91 – 0.98)	0.007



Finerenone was well tolerated in the studies.

CI: Confidence Interval, CV: Cardiovascular; HF: Heart Failure; HR: Hazard Ratio, IR: Incidence Rate, py: patient years

FINE-HEART: Conclusions

- **FINE-HEART with ~19,000 patients** represents the largest analysis of efficacy and safety of the non-steroidal MRA finerenone across the CKM spectrum.
- **Finerenone consistently shows benefits** across a range of highly patient-relevant cardio-kidney outcomes incl. all-cause mortality.
- The incidence for the **primary endpoint of CV death** was numerically lower in patients treated with finerenone versus placebo, but narrowly missed statistical significance.
- **Finerenone was well** tolerated across diseases.

CKM: Cardiovascular-kidney-metabolic; CV: Cardiovascular

MOONRAKER To Further Strengthen the Profile for Finerenone in >15k Patients Across HF

FINEARTS-HF[1,2]

Efficacy and safety profile of finerenone in **patients with symptomatic HF vs placebo** (N=6001)

Population

Patients with HF (NYHA class II–IV) and LVEF ≥40%)

Primary outcome:

Total number of CV deaths and HF events

REDEFINE-HF[3]

Efficacy and safety profile of finerenone when **initiated early in patients hospitalised with HF vs placebo** (N=5200)

Population

Patients hospitalised due to HF with LVEF ≥40%

Primary outcome:

Total number of CV deaths and HF events

CONFIRMATION-HF[4]

Efficacy and safety profile of early **combination Rx in patients with HF independent of LVEF** (finerenone + SGLT2i vs usual care; N=1500)

Population*

Patients hospitalised due to HF independent of LVEF

Primary outcome:

All-cause mortality, total HF events, time to first HF events and KCCQ-TSS (win ratio)

FINALITY-HF[5]

Efficacy and safety profile of finerenone in patients with **symptomatic HF and LVEF ≤40 intolerant of or not eligible for sMRA** (vs placebo; N=2600)

Population#

Patients with HF and LVEF ≤40%, enriched with those hospitalised due to HF

Primary outcome:

Time to first CV death or HF event

Finerenone is indicated for the treatment of chronic kidney disease (with albuminuria) associated with type 2 diabetes in adults. For prescribing information please refer to the SmPC of the product applicable in your country. Finerenone is not indicated for the treatment of heart failure.

*Not on SGLT-2i, sMRA or nsMRA, or not suitable for sMRA; #not on or not suitable for sMRA.

CV: Cardiovascular; HF: Heart Failure; HFrEF: Heart failure with reduced ejection fraction; LVEF: Left ventricular ejection fraction; KCCQ-TSS: Kansas City Cardiomyopathy Questionnaire Total Symptom Score; NYHA: New York Heart Association; sMRA: steroidal mineralocorticoid receptor antagonist; nsMRA, nonsteroidal mineralocorticoid receptor antagonist; Rx: Prescription; SGLT2i: Sodium-glucose cotransporter-2 inhibitors

[1] Bayer. https://clinicaltrials.gov/ct2/show/NCT04435626; [2] Solomon SD, et al. Eur Heart J 2024;doi:10.1002/ejhf.3266; Bayer AG. https://clinicaltrials.gov/ct2/show/NCT06008197; [3] Bayer AG. https://clinicaltrials.gov/ct2/show/NCT06024746;
[4] Bayer AG. https://clinicaltrials.gov/ct2/show/NCT06033950; [5] Bayer AG. KERENDIA® (finerenone) Summary of Product Characteristics. 2023. https://www.ema.europa.eu/documents/product-information/kerendia-epar-product-information_en.pdf
[All URLs accessed 11 Mayl 2024]

HEALTH FOR ALL, HUNGER FOR NONE

Kerendia:

BUILDING A TRUE CARDIORENAL BRAND

INVESTOR WEBINAR

Bernardo Kanahuati

September 2, 2024

FINEARTS-HF Marks a Key Moment for Patients with HF and LVEF ≥40% and Their Caregivers

Kerendia® finerenone

Summary of FINEARTS-HF and FINE-HEART

01

First MRA to demonstrate proven clinical **benefit in all patients with HF and LVEF ≥40%**

02

Offers a new potential treatment option for >50% of HF patients, **in a highly underserved space**

03

Potential to become a primary pillar of a multi-treatment strategy to improve highly **patient-relevant health outcomes**

HF: Heart failure; LVEF: Left ventricular ejection fraction; MRA: Mineralocorticoidreceptor antagonist

Getting Ready to Accelerate Kerendia's Growth

CKD/T2D

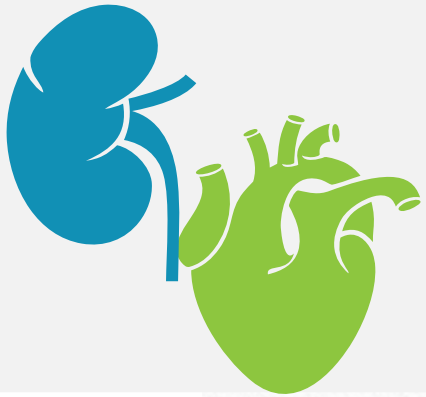
- Launched in **75 countries since 2021**
- Included in most key **international guideline recommendations**
- **>250k treated patients** in US, JP & DE alone
- **THUNDERBALL** study program ongoing to broaden the use across CKD subtypes

HEART FAILURE

- **First dossier** to be submitted soon
- **Fast speed** to launch readiness
- **MOONRAKER** study program ongoing to accelerate clinical adoption and uptake

FINEARTS-HF

Inflection point to unlock the full cardiorenal opportunity



HF indication offers significant standalone potential

CKD: Chronic kidney diesease; T2D: Type 2 diabetes mellitus

[1] Kolkhof P, et al. Curr Opin Nephrol Hypertens 2015;24:417–424; [2] Grune J, et al. Hypertension 2018;71:599–608; [3] Kolkhof P, et al. J Cardiovasc Pharmacol 2014;64:69–78

FINEOVATE to Further Support Finerenone's Ambition as a Foundational Treatment Across the Spectrum of CKD and HF

THUNDERBALL | **FINEOVATE** | MOONRAKER

Paediatric CKD

FIONA OLE — September 2028*

FIONA — March 2027*

Nondiabetic CKD

FIND-CKD — February 2026*

CKD and T1D

FINE-ONE — October 2025*

CKD and T2D

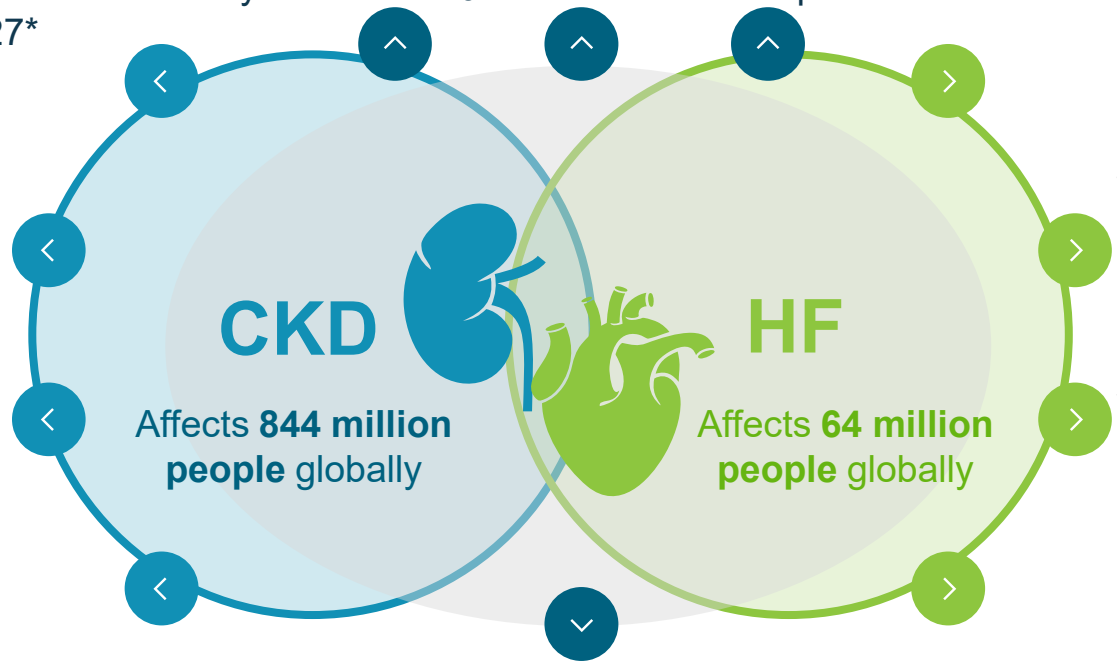
CONFIDENCE — February 2025*

Real-world evidence

FINE-REAL — January 2028*

FOUNTAIN — 2024#

WATERFALL-HF — Completion date tbc



HF (LVEF ≤40) not on or not eligible to steroidal MRAs

FINALITY-HF — January 2028*

Hospitalised for HF (LVEF ≥40%)

REDEFINE-HF — April 2026*

Hospitalised for HF independent of LVEF

CONFIRMATION-HF — SGLT2i combination therapy August 2025*

FIDELITY ✓ | FIDELIO-DKD ✓ | FIGARO-DKD ✓ | FINEHEART ✓

Symptomatic HF (LVEF ≥40%)

✓ FINEARTS-HF

CKD: Chronic kidney disease; HF: Heart failure; HFrEF: Heart failure with reduced ejection fraction; LVEF: Left ventricular ejection fraction; MRA: Mineralocorticoid receptor antagonist; SGLT2I: Sodium-glucose cotransporter-2 inhibitors; T1D: Type 1 diabetes mellitus; T2D: Type 2 diabetes mellitus
*Estimated study completion date; #estimated study completion dates for the FIRST-2 and FINEGUST studies are June 2024 and June 2025, respectively. All dates based on CT.gov – last accessed Aug 2024

Bayer is Committed to Improving the Lives of People Living With Heart and Kidney diseases

- FINEARTS-HF and FINE-HEART are milestones towards a potential **new foundational treatment option,** bringing a new treatment option for **>50%** of patients with HF, in a highly underserved space.
- **The next level evidence of cardiorenal protection,** confirming proven safety profile.
- Evidence program with **MOONRAKER and THUNDERBALL** already in place, showcasing Bayer's commitment to improving the lives of people living with heart and kidney disease
- Drive organizational readiness to enter the HF space and accelerating growth trajectory

HF: Heart failure

Q&A Session

Christoph Koenen

Head of
Clinical Development &
Operations,
Bayer Pharmaceuticals

Maria Borentain

Head of
Cardiovascular and Renal
Clinical Development,
Bayer Pharmaceuticals

Bernardo Kanahuati

Product Team Lead
Kerendia,
Bayer Pharmaceuticals

HEALTH FOR ALL, HUNGER FOR NONE

ESC Congress 2024: RESULTS FROM FINERENONE IN HEART FAILURE

INVESTOR WEBINAR
BACKUP

September 2, 2024

FINEARTS-HF: Key Inclusion and Exclusion Criteria

Key inclusion criteria

- **Aged** ≥40 years
- **HF diagnosis; NYHA class II–IV** (ambulatory or hospitalised primarily for HF)
- **LVEF ≥40%** measured within last 12 months
- **Structural heart** abnormalities within last 12 months
- **Diuretics in 30 days** prior to randomization
- NT-proBNP ≥**300 pg/mL** or BNP ≥**100 pg/mL** (sinus rhythm)
- NT-proBNP ≥**900 pg/mL** or BNP ≥**300 pg/mL** (atrial fibrillation)

Key exclusion criteria

- **eGFR** <25 ml/min/1.73 m²
- **Serum plasma** potassium >5.0 mmol/l
- **MI or any event** that could have reduced the EF
- **Acute inflammatory heart disease,** CABG, stroke or TIA within last 90 days or PCI in the last 30 days
- **Alternative causes** of HF symptoms[#]
- **SBP** ≥160 mmHg[‡]

CABG: Coronary artery bypass graft surgery; EF: Ejection fraction; eGFR: estimated glomerular filtration rate; HF: Heart failure; LVEF: Left ventricular ejection fraction; MI: Myocardial infarction; NT-proBNP: N-terminal pro–B-type natriuretic peptide; NYHA: New York Heart Association; PCI: Percutaneous coronary intervention; SBP: Systolic blood pressure; TIA: Transient ischemic attack

FINEARTS-HF: Baseline Characteristics

Well-balanced Between Treatment Groups and Similar to Other Contemporary HFmr/pEF Trials[1]

	Finerenone (n=3003), n (%)	Placebo (n=2998), n (%)
Age, years, mean ± SD	72±10	72±10
Sex, female	45%	46%
BMI, mean ± SD	30±6.1	30±6.1
Race and ethnicity		
Asian	17%	17%
Black	2%	1%
Other	3%	3%
White	79%	79%
Asia	16%	16%
Eastern Europe	44%	44%
Latin America	11%	11%
North America	8%	8%
Western Europe, Oceania, others	21%	21%
NYHA class		
II	69%	69%
III	30%	30%
IV	1%	1%
KCCQ-TSS ± SD	68±24	67±24
LVEF, %, mean ± SD	53±8	53±8
LVEF <50%	36%	36%
LVEF ≥50% and <60%	44%	49%
LVEF ≥60%	19%	19%
SBP, mmHg, mean ± SD	130±15	129±15
Recency of HF event		
≤7 days from randomization	20%	20%
>7 days – ≤ 3 months	34%	33%
>3 months or no index HF event	45%	46%

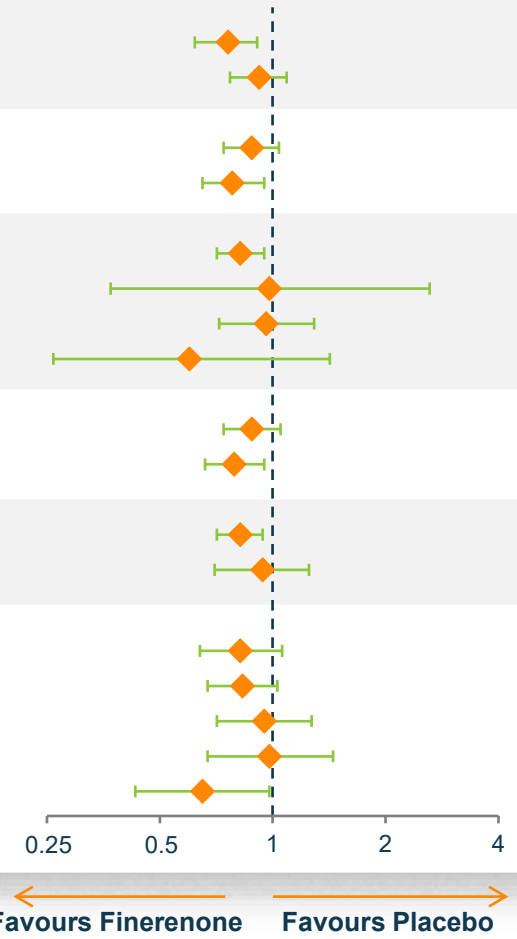
	Finerenone (n=3003), n (%)	Placebo (n=2998), n (%)
NT-proBNP, ng/mL, median	1052 [467,1937]	1028 [433,1963]
Creatinine, mean ± SD	1.1±0.3	1.1±0.4
eGFR, ml/min/1.73 m^2, mean ± SD	62±19	62±20
eGFR ≥60 ml/min/1.73 m^2	48%	48%
UACR, median, IQR	18 [7, 67]	19 [7,66]
Potassium, mean ± SD	4.4±0.5	4.4±0.5
Prior HHF	60%	61%
History of LVEF ≤40	5%	4%
History of diabetes	41%	41%
History of atrial fibrillation on ECG	38%	38%
History of stroke	12%	12%
History of hypertension	88%	90%
History of MI	26%	25%
Loop diuretic	87%	87%
Beta blocker	85%	85%
ACEi	36%	36%
ARB	35%	35%
ARNI	9%	9%
Calcium channel blockers	32%	34%
SGLT-2i	13%	14%
Thiazide diuretic	14.3%	13.4%
Potassium supplementation	11.6%	12.2%
GLP-1 agonists	2.6%	2.9%

ACEi: Angiotensin-converting enzyme inhibitors; ARB: Angiotensin receptor blockers; ARNI: Angiotensin receptor-neprilysin inhibitors; ECG: Electrocardiogram; eGFR: Estimated glomerular function rate; GLP-1: Glucagon-like peptide 1; HF: Heart failure; HHF: Hospitalization for heart failure; IQR: Interquartile range; KCCQ-TSS: Kansas City Cardiomyopathy Questionnaire total symptom score; LVEF: Left ventricular ejection fraction; MI: Myocardial infarction; NT-proBNP: N-terminal pro–B-type natriuretic peptide; NYHA: New York Heart Association; SBP: Systolic blood pressure; SD: Standard deviation; SGLT-2i: Sodium-glucose cotransporter-2 inhibitors; UACR: Urine albumin to creatinine ratio

FINEARTS-HF: The Effects of Finerenone on the Primary Outcome Were Consistent Across All Pre-specified Subgroups (1/3)

Including sex, region, LVEF and background medical therapy

Category	Finerenone Events	Finerenone n/N	Finerenone E/100 p-yrs	Placebo Events	Placebo n/N	Placebo E/100 p-yrs	RR (95% CI)
Age (years)							
≤ median (73.0)	468	278/1589	11.87	623	338/1579	15.84	0.76 (0.63–0.92)
> median (73.0)	615	346/1414	18.45	660	381/1419	19.89	0.92 (0.77–1.09)
Gender							
Male	632	358/1648	15.77	691	392/1621	17.80	0.88 (0.74–1.04)
Female	451	266/1355	13.80	592	327/1377	17.57	0.78 (0.65–0.95)
Race							
White	809	478/2366	14.10	986	560/2369	17.16	0.82 (0.71–0.95)
Black	29	13/49	24.97	22	12/39	24.07	0.98 (0.37–2.62)
Asian	211	117/497	17.26	218	122/499	17.95	0.96 (0.72–1.29)
Other	34	16/91	16.94	57	25/91	28.91	0.60 (0.26–1.42)
BMI							
< 30 kg/m^2	586	338/1658	14.76	648	379/1638	16.61	0.88 (0.74–1.05)
≥ 30 kg/m^2	486	282/1338	14.77	632	338/1354	18.93	0.79 (0.66–0.95)
LVEF							
< 60%	877	512/2427	15.17	1061	594/2425	18.47	0.82 (0.71–0.94)
≥ 60%	206	112/576	13.76	222	125/573	14.73	0.94 (0.70–1.26)
Pooled Region							
W Eur, Oce & Others	322	171/624	21.92	395	195/632	26.66	0.82 (0.64–1.06)
Eastern Europe	322	213/1329	9.53	389	244/1321	11.51	0.83 (0.67–1.03)
Asia	211	117/493	17.43	218	123/490	18.25	0.95 (0.71–1.27)
North America	122	63/235	23.18	118	69/236	23.58	0.98 (0.67–1.45)
Latin America	106	60/322	15.32	163	88/319	23.51	0.65 (0.43–0.98)

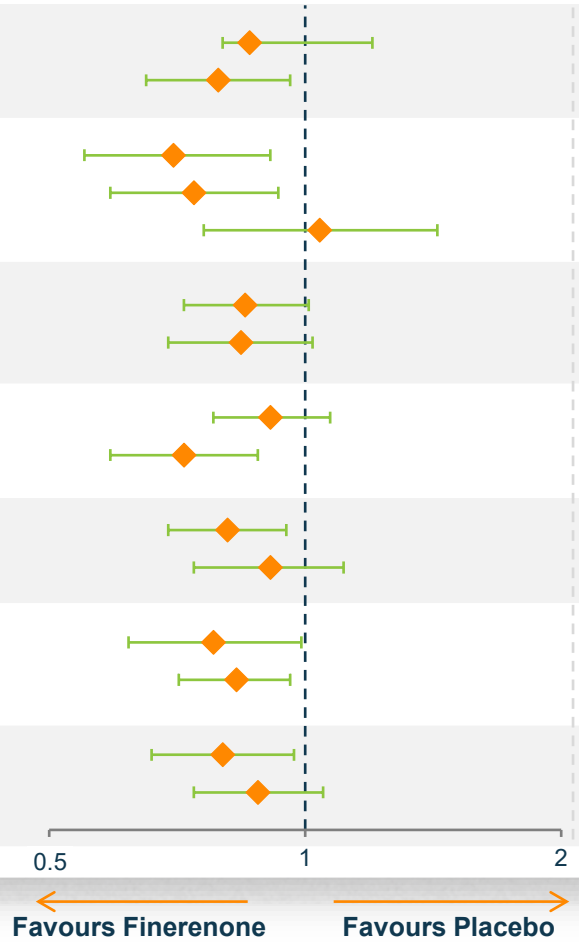


BMI: Body mass index; CI: Confidence interval; CV: Cardiovascular; LVEF: Left ventricular ejection fraction; RR: Rate ratios

FINEARTS-HF: The Effects of Finerenone on the Primary Outcome Were Consistent Across All Pre-specified Subgroups (2/3)

Including sex, region, LVEF and background medical therapy

Category	Finerenone Events	Finerenone n/N	Finerenone E/100 p-yrs	Placebo Events	Placebo n/N	Placebo E/100 p-yrs	RR (95% CI)
NYHA Class							
II	646	375/2081	12.58	741	437/2065	14.57	0.86 (0.73–1.02)
III/IV	437	249/921	20.46	542	282/933	27.62	0.79 (0.65–0.96)
Index HF Events							
≤ 7 days	270	158/609	20.47	372	183/610	28.25	0.74 (0.57–0.95)
> 7 days to ≤ 3 months	404	219/1030	17.53	492	268/998	22.10	0.79 (0.64–0.97)
> 3 months or no prior HFE	409	247/1364	11.20	419	268/1390	11.30	0.99 (0.81–1.21)
SBP (mmHg)							
≤ median (130.0)	608	348/1549	16.44	740	403/1597	19.38	0.85 (0.72–1.01)
> median (130.0)	475	276/1453	13.28	543	316/1400	15.83	0.84 (0.69–1.02)
eGFR							
< 60 mL/min/1.73m^2	727	394/1451	21.45	796	426/1437	23.70	0.91 (0.78–1.07)
≥ 60 mL/min/1.73m^2	356	230/1552	9.16	487	293/1561	12.51	0.72 (0.59–0.88)
Potassium							
≤ 4.5 mmol/L	714	397/1969	14.96	875	480/1958	18.55	0.81 (0.69–0.95)
> 4.5 mmol/L	369	227/1034	14.73	408	239/1040	16.10	0.91 (0.74–1.11)
NT-proBNP (pg/mL)							
≤ median (1041.4)	266	182/1458	7.22	342	215/1475	9.14	0.78 (0.62–0.99)
≤ median (1041.4)	782	422/1472	22.84	918	488/1438	27.62	0.83 (0.71–0.96)
UACR							
< 30 mg/g	429	268/1765	9.74	518	318/1746	12.02	0.81 (0.67–0.97)
≥ 30 mg/g	601	324/1136	22.75	705	370/1150	26.11	0.88 (0.74–1.05)

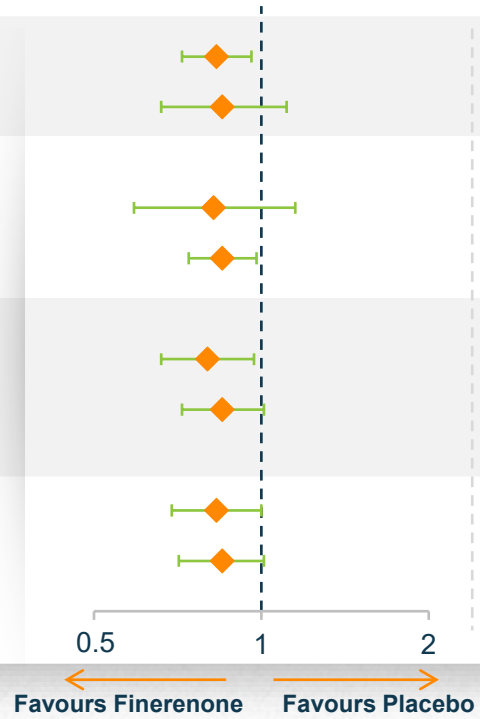


CI: Confidence interval; CV: Cardiovascular; eGFR: Estimated glomerular filtration rate; HF: Heart failure; HFE: Heart failure event; NT-proBNP: N-terminal pro–B-type natriuretic peptide; NYHA: New York Heart Association; RR: Rate ratios; SBP: Systolic blood pressure; UACR: Urine albumin to creatinine ratio.

FINEARTS-HF: The Effects of Finerenone on the Primary Outcome Were Consistent Across All Pre-specified Subgroups (3/3)

Including sex, region, LVEF and background medical therapy

Category	Finerenone Events	Finerenone n/N	Finerenone E/100 p-yrs	Placebo Events	Placebo n/N	Placebo E/100 p-yrs	RR (95% CI)
ACEi, ARB or ARNI							
Yes	795	470/2379	13.70	951	548/2380	16.29	0.83 (0.72–0.96)
No	288	154/624	19.57	332	171/618	23.49	0.85 (0.66–1.11)
SGLT2i							
Yes	176	95/393	21.77	234	122/424	26.50	0.83 (0.60–1.16)
No	907	529/2610	14.02	1049	597/2574	16.48	0.85 (0.74–0.98)
Atrial Fibrillation per ECG							
Yes	521	287/1165	18.83	621	330/1128	23.11	0.80 (0.66–0.97)
No	562	337/1838	12.46	662	389/1870	14.51	0.85 (0.72–1.01)
Diabetes Mellitus							
Yes	524	291/1217	18.28	638	344/1222	22.09	0.83 (0.69–1.00)
No	559	333/1786	12.67	645	375/1776	14.79	0.85 (0.71–1.01)



Rate ratios for the primary endpoint across all 17 pre-specified subgroups were in favour of finerenone

ACEi: Angiotensin-converting enzyme inhibitors; ARB: Angiotensin receptor blockers; ARNI: Angiotensin receptor-neprilysin inhibitors; CI: Confidence interval; CV: Cardiovascular; ECG: Electrocardiogram; RR: Rate ratios; SGLT2i: Sodium-glucose cotransporter-2 inhibitors