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News Release

Not intended for U.S. and UK Media

Heart Failure Society of America (HFSA) Annual Meeting 2024

Bayer to present seven new analyses from FINEARTS-HF examining the benefits of finerenone across a broad spectrum of high-risk heart failure patients

- At HFSA, new subgroup analyses of the FINEARTS-HF trial will be presented, across a broad spectrum of patients with heart failure (HF) with a left ventricular ejection fraction (LVEF) of $\geq 40\%$, presenting data on efficacy and safety of finerenone according to a variety of subgroups, such as age and health status
 - Late-breaking presentations include data on the effect of finerenone in patients with HF with a LVEF of $\geq 40\%$ across the ejection fraction spectrum, in relation to the recency of a heart failure (HF) event and in combination with a sodium-glucose cotransporter-2 inhibitor (SGLT2i)
 - Analyses presented will also include data on time to clinical benefit of finerenone and its long-term treatment effects, as well as patient-reported outcomes following treatment
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Berlin, September 27, 2024 – Bayer announced today that new subgroup analyses from the Phase III FINEARTS-HF trial evaluating finerenone (Kerendia™) in patients with heart failure (HF) with a left ventricular ejection fraction (LVEF) of $\geq 40\%$ will be presented at the Heart Failure Society of America (HFSA) Annual Meeting 2024.

Data being presented at HFSA include:

Finerenone in HF with LVEF of $\geq 40\%$ in combination with an SGLT2i

SGLT2 inhibitors and the non-steroidal mineralocorticoid receptor (MR) antagonist finerenone have been shown to reduce the risk of cardiovascular events in HF with LVEF of $\geq 40\%$, but the effects of their combined use are not known. The analysis examined the treatment effects of finerenone in combination with an SGLT2i:

- [Finerenone in patients with heart failure and mildly reduced or preserved ejection fraction treated with a SGLT2i: the FINEARTS-HF trial](#)
 - o September 28, 2024, 04:00 pm (ET) / 10:00 pm (CEST)

Time to clinical benefit of finerenone in HF with LVEF of $\geq 40\%$

The analysis evaluated the time until first statistical significance for the primary endpoint in FINEARTS-HF was observed for finerenone in patients with HF and a LVEF of $\geq 40\%$.

- Time to First Statistical Significance of Finerenone in Patients with Heart Failure
 - o ePoster, September 27-29

Long-term benefit of finerenone in HF with LVEF of $\geq 40\%$

The analysis evaluated the estimated long-term effects of treatment with finerenone in this patient population, based on the FINEARTS-HF trial.

- Estimated Long-Term Benefits of Finerenone in Heart Failure: A Prespecified Secondary Analysis of a Phase 3 Randomized Clinical Trial
 - o ePoster, September 27-29

Impact of finerenone on KCCQ-TSS in HF with LVEF of $\geq 40\%$

Patients with HF are limited by symptoms and have impaired quality of life. The Kansas City Cardiomyopathy Questionnaire (KCCQ) is a patient-reported outcome measure that enables evaluation of the impact of HF and the effect of new therapies on health status in patients with HF. This pre-specified analysis of FINEARTS-HF assessed the efficacy and safety of finerenone according to baseline KCCQ Total Symptom Score (KCCQ-TSS) and the effect of finerenone on KCCQ-TSS.

- [Effect Of Finerenone On Kansas City Cardiomyopathy Questionnaire \(KCCQ\) Score In Heart Failure With Mildly Reduced And Preserved Ejection Fraction: The FINEARTS-HF Trial](#)
 - o September 28, 2024, 04:53 pm (ET) / 10:53 pm (CEST), C101

Finerenone in HF with LVEF of $\geq 40\%$ in relation to a recent HF event

Patients with HF and a recent HF event are known to be at high risk of recurrent hospitalization and death, regardless of ejection fraction. Accepted as a late-breaker, this latest analysis assessed the effect of finerenone according to the time since their most recent heart failure event.

- [Efficacy And Safety Of Finerenone In Patients With Heart Failure And Mildly Reduced Or Preserved Ejection Fraction And A Recent Worsening Heart Failure Event: The FINEARTS-HF Trial](#)
 - o September 29, 2024, 09:35 am (ET) / 03:35 pm (CEST), Georgia Ballroom 2

Finerenone in HF with LVEF of $\geq 40\%$ across the ejection fraction spectrum

The effect of treatments for HF may vary among patients according to LVEF. In the FINEARTS-HF Phase III trial, finerenone reduced the risk of cardiovascular death and total worsening heart failure events in patients with LVEF of $\geq 40\%$. Accepted as a late-breaker, this analysis examined the effect of finerenone according to LVEF in FINEARTS-HF.

- [Efficacy And Safety Of Finerenone Across The Ejection Fraction Spectrum In Heart Failure With Mildly Reduced And Preserved Ejection Fraction: The FINEARTS-HF Trial](#)
 - o September 29, 2024, 09:43 am (ET) / 03:43 pm (CEST), Georgia Ballroom 2

Finerenone in HF with LVEF of $\geq 40\%$ according to age

The FINEARTS-HF Phase III trial showed finerenone improves outcomes in patients with LVEF of $\geq 40\%$, however, it is important to also understand the efficacy and safety of finerenone in these patients according to age. As such, this analysis aimed to evaluate the interaction between age and the efficacy and safety of finerenone in the FINEARTS-HF trial.

- [Efficacy And Safety Of Finerenone According To Age In Heart Failure With Mildly Reduced And Preserved Ejection Fraction: The FINEARTS-HF Trial](#)
 - o September 29, 2024, 05:15 pm (ET) / 11:15 pm (CEST), C101

About Kerendia™ (finerenone) / Firalta™ (finerenone)

Kerendia™ and Firalta™ are globally protected trademarks for finerenone. Finerenone is a non-steroidal, selective mineralocorticoid receptor (MR) antagonist that has been shown to block harmful effects of MR overactivation. MR overactivation contributes to chronic kidney disease (CKD) progression and cardiovascular damage which can be driven by metabolic, hemodynamic, or inflammatory and fibrotic factors.

Finerenone is marketed as Kerendia™ or, in some countries, as Firalta™, and approved for the treatment of adult patients with CKD associated with type 2 diabetes (T2D) in more than 90 countries worldwide, including in China, Europe, Japan, and the U.S.

The study program with finerenone, FINEOVATE, currently comprises ten Phase III studies with dedicated programs in HF and CKD, respectively. The MOONRAKER program includes FINEARTS-HF, as well as the ongoing collaborative, investigator-sponsored studies REDEFINE-HF, CONFIRMATION-HF, and FINALITY-HF. The THUNDERBALL CKD program consists of the completed studies FIDELIO-DKD and FIGARO-DKD, as well as the ongoing studies FIND-CKD, FIONA, FIONA-OLE, FINE-ONE, and the Phase II study CONFIDENCE.

About Bayer's Commitment in Cardiovascular and Kidney Diseases

Bayer is an innovation leader in the area of cardiovascular diseases, with a long-standing commitment to delivering science for a better life by advancing a portfolio of innovative treatments. The heart and the kidneys are closely linked in health and disease, and Bayer is working in a wide range of therapeutic areas on new treatment approaches for cardiovascular and kidney diseases with high unmet medical needs. The cardiology franchise at Bayer already includes a number of products and several other compounds in various stages of preclinical and clinical development. Together, these products reflect the company's approach to research, which prioritizes targets and pathways with the potential to impact the way that cardiovascular diseases are treated.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. In line with its mission, "Health for all, Hunger for none," the company's products and services are designed to help people and the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2023, the Group employed around 100,000 people and had sales of 47.6 billion euros. R&D expenses before special items amounted to 5.8 billion euros. For more information, go to www.bayer.com.

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de (2024-0163E)

Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.