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News Release

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Cardiovascular Clinical Trials Forum (CVCT) 2024:

Bayer to present new analyses from FINEARTS-HF with finerenone

- A new analysis of FINEARTS-HF evaluated the effects of finerenone on systolic blood pressure in patients with heart failure and mildly reduced or preserved ejection fraction
 - Additional analyses assessed the impact of finerenone across specific patient subgroups, including those with outpatient worsening heart failure events, as well as patients categorized by varying ejection fraction levels and body mass index ranges
 - Another analysis evaluated the effects of finerenone in patients with heart failure and mildly reduced or preserved ejection fraction across three Phase III clinical trials
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Berlin, December 9th, 2024 – Bayer announced today that new 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 Cardiovascular Clinical Trials (CVCT) Forum, taking place in Washington, D.C. from December 9-11, 2024.

Data being presented at CVCT 2024 include the following. All posters will be presented at the poster session on Tuesday, December 10th from 7:30 - 9:00 pm EST:

Blood Pressure Effects of Finerenone in HFmrEF/HFpEF

Blood pressure optimization is a guideline-recommended priority of heart failure (HF) care. A new prespecified analysis of the FINEARTS-HF trial in patients with HF and mildly reduced or preserved ejection fraction (HFmrEF/HFpEF) evaluated the effect of finerenone, a non-steroidal MRA, on systolic blood pressure overall and in individuals with apparent treatment-resistant hypertension, as well as the relationship between the effects of finerenone on blood pressure and clinical outcomes.

- [Blood pressure effects of finerenone in heart failure with mildly reduced or preserved ejection fraction: A prespecified analysis of the FINEARTS-HF trial](#)

Effect of Finerenone on Outpatient Worsening Heart Failure Events

Outpatient worsening HF events are common and associated with poor subsequent prognosis. This analysis investigated the effect of finerenone on outpatient worsening HF events in patients with HF and mildly reduced or preserved ejection fraction.

- [Effect of Finerenone on Outpatient Worsening Heart Failure Events in Patients with Mildly Reduced or Preserved Ejection Fraction](#)

Effect of Finerenone and Number of Hospitalizations

Recency of a heart failure hospitalization is associated with readmission and death in patients with heart failure. Number of prior hospitalizations due to heart failure may be an additional predictor of outcomes.

- [Number of hospitalizations and effect of Finerenone in FINEARTS-HF](#)

Impact of Body Mass Index on Finerenone's Efficacy

Obesity is associated with increased aldosterone secretion, making mineralocorticoid receptor antagonists (MRAs) potentially more effective in obese heart failure patients. This study compared the effects of finerenone versus placebo across different BMI categories in the FINEARTS-HF trial.

- [Effect of Finerenone in Patients With HFmrEF/HFpEF According to Body Mass Index: A Prespecified Analysis of the FINEARTS-HF Trial](#)

Initial eGFR Decline with Finerenone

An initial decline in estimated glomerular filtration rate (eGFR) often leads to reluctance to continue the life-saving therapy in patients with HF. However, this early dip in eGFR has been shown to predict a favorable response to several HF therapies. This study analyzed early change in eGFR and outcomes in patients treated with finerenone versus placebo.

- [Initial decline \(dip\) in estimated glomerular filtration rate with initiation of finerenone in patients with mildly reduced or preserved ejection fraction: A prespecified analysis of FINEARTS-HF Trial](#)

Finerenone and Frailty in Heart Failure

Patients with frailty are often perceived to have a less favorable benefit-risk profile, and therefore may be less likely to receive new treatments. This study investigated the efficacy and tolerability of finerenone according to frailty status in patients with HF with mildly reduced or preserved ejection fraction in the FINEARTS-HF trial.

- [Finerenone and frailty in heart failure with mildly reduced or preserved ejection fraction: An analysis from FINEARTS-HF](#)

Participant-level Pooled Analysis of Finerenone in Heart Failure Across Three Phase III trials (FINE-HEART)

In this prespecified participant-level pooled analysis, efficacy and safety of finerenone in patients with heart failure and mildly reduced or preserved ejection fraction was evaluated across three Phase III studies, using Cox proportional hazards models stratified by trial.

- [Efficacy and Safety of Finerenone in Heart Failure with Mildly Reduced or Preserved Ejection Fraction: A Prespecified Participant-Level Pooled Analysis of Three Randomized Clinical Trials](#)

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. Finerenone is not approved for the treatment of heart failure.

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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Forward-Looking Statements

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