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News Release

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American College of Cardiology's 74th Annual Scientific Session (ACC.25):

Bayer to present multiple new analyses of finerenone trials investigating cardiovascular outcomes and health markers

- New analyses to be presented at the [American College of Cardiology's 74th Annual Scientific Sessions \(ACC.25\)](#) include data from the pivotal FINEARTS-HF trial which demonstrated the efficacy and safety of finerenone in the treatment of adult patients with heart failure (HF) with a left ventricular ejection fraction (LVEF) of $\geq 40\%$ (mildly reduced or preserved LVEF)
 - Key analyses include evaluation of the effect of finerenone among relevant subgroups including people with comorbidities such as chronic obstructive pulmonary disease (COPD) status, atrial fibrillation (AF), left atrial (LA) enlargement and anemia
 - Additional analyses include pooled data from the FINE-HEART study, a causal mediation analysis of the FIDELITY trial and real-world research on patients with worsening HF
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Berlin, March 25, 2025 – Bayer announced today that 13 new sub-group analyses from across the finerenone (Kerendia™) Phase III clinical trial program will be presented at [the American College of Cardiology's \(ACC\) 74th Annual Scientific Sessions \(ACC.25\)](#), taking place in Chicago, IL, USA from March 29–31.

Ten presentations will feature new analyses from the FINEARTS-HF trial, investigating whether the therapeutic benefit of finerenone (Kerendia™) in reducing the risk of cardiovascular death and heart failure (HF) events in patients with symptomatic heart failure is consistent across patient characteristics such as KDIGO risk category, New York Heart Association (NYHA) classification, liver function, chronic obstructive pulmonary disease (COPD) status, atrial fibrillation (AF), left atrial (LA) enlargement, and anemia. The trial was the basis for a supplemental new drug application (sNDA) for Kerendia for

the treatment of adult patients with HF with a left ventricular ejection fraction (LVEF) of $\geq 40\%$, which the U.S. Food and Drug Administration (FDA) granted Priority Review designation to last week.

Additional ACC.25 presentations include:

- An analysis of the FINE-HEART study, an integrated, pooled, exploratory, participant-level analysis across three pivotal Phase III clinical trials with finerenone—FINEARTS-HF, FIDELIO-DKD and FIGARO-DKD—, to evaluate the effect of finerenone in reducing new onset AF across the cardio-kidney-metabolic (CKM) spectrum.
- A post-hoc analysis of FIDELITY, a pooled analysis of the Phase III FIDELIO-DKD and FIGARO-DKD trials that evaluated the long-term effects of finerenone on cardiovascular benefits in patients with chronic kidney disease (CKD) in type 2 diabetes (T2D).
- Real-world research on patients with worsening heart failure within a large healthcare delivery system from 2012-2021.

Data being presented at [ACC.25](#) include:

- [Efficacy and safety of finerenone across the spectrum of kidney risk in heart failure with mildly reduced or preserved ejection fraction](#)

This secondary analysis of the FINEARTS-HF trial evaluates the effect of finerenone on the primary endpoint (cardiovascular death or total [first and recurrent] HF events) and key secondary endpoints according to baseline KDIGO risk category.

- *Session: Innovations and Insights in Heart Failure With Preserved Ejection Fraction: Emerging Therapies, Biomarkers and Mechanistic Studies*
- March 29, 10:06 - 10:13 CT / 16:06 - 16:13 CET

- [Efficacy and safety of finerenone according to New York Heart Association functional class in heart failure with mildly reduced or preserved ejection fraction](#)

This prespecified analysis of the FINEARTS-HF trial evaluates the effect of finerenone according to baseline New York Heart Association (NYHA) classification on the primary endpoint (cardiovascular death or total [first and recurrent] HF events) and key secondary endpoints, including change in NYHA class at 12 months.

- *Session: Innovations and Insights in Heart Failure With Preserved Ejection Fraction: Emerging Therapies, Biomarkers and Mechanistic Studies*

- March 29, 10:18 - 10:25 CT / 16:18 - 16:25 CET
- **Finerenone, bilirubin, and heart failure with mildly reduced or preserved ejection fraction: an analysis from FINEARTS-HF**
This analysis of the FINEARTS-HF trial evaluates the effect of finerenone on clinical outcomes according to baseline bilirubin and the change in bilirubin during follow-up.
 - *Session: Innovations and Insights in Heart Failure With Preserved Ejection Fraction: Emerging Therapies, Biomarkers and Mechanistic Studies*
 - March 29, 11:18 - 11:25 CT / 17:18 - 17:25 CET
 - **Finerenone in patients with HFmrEF/HFpEF with and without atrial fibrillation: a prespecified analysis of FINEARTS-HF**
This prespecified analysis of the FINEARTS-HF trial evaluates the efficacy and safety of finerenone in subgroups of patients with paroxysmal, persistent, or permanent AF, as well as new onset AF or flutter (AF/AFL).
 - *Session: Finerenone: A Promising Addition to the Armamentarium or Merely an Academic Exercise?*
 - March 29, 12:36 - 12:43 CT / 18:36 - 18:48 CET
 - **Finerenone, chronic obstructive pulmonary disease, and heart failure with mildly reduced or preserved ejection fraction: An analysis of FINEARTS-HF**
This prespecified analysis of the FINEARTS-HF trial evaluates the effectiveness of finerenone on clinical outcomes according to investigator-reported COPD status.
 - *Session: Finerenone: A Promising Addition to the Armamentarium or Merely an Academic Exercise?*
 - March 29, 13:12 - 13:19 CT / 19:12 - 19:19 CET
 - **Efficacy of finerenone according to left atrial size in patients with heart failure and mildly reduced or preserved ejection fraction: An analysis of the FINEARTS-HF trial**
This post-hoc analysis of the FINEARTS-HF trial evaluates the efficacy and safety of finerenone based on investigator-reported LA enlargement, a sign of elevated LA pressure, to understand if LA enlargement is associated with worse outcomes in heart failure and mildly reduced or preserved ejection fraction (HFmrEF/HFpEF).
 - *Session: Finerenone: A Promising Addition to the Armamentarium or Merely an Academic Exercise?*
 - March 29, 12:12 - 12:19 CT / 18:12 - 18:19 CET

- [Efficacy and safety of finerenone in patients with heart failure and mildly reduced or preserved ejection fraction: A prespecified anemia-specific analysis of the FINEARTS-HF trial](#)

This prespecified analysis of the FINEARTS-HF trial evaluates the efficacy and safety of finerenone according to anemia status, defined as hemoglobin <12 g/dL in women and <13 g/dL in men at baseline.

- *Session: Finerenone: A Promising Addition to the Armamentarium or Merely an Academic Exercise?*
- *March 29, 13:36 - 13:43 CT / 19:36 - 19:43 CET*

- [Effect of finerenone on n-terminal pro-B-type natriuretic peptide in heart failure with mildly reduced or preserved ejection fraction: The FINEARTS-HF trial](#)

This analysis of the FINEARTS-HF trial evaluates the association between log-transformed N-terminal pro-B-type natriuretic peptide (NT-proBNP), a marker of prognosis and therapeutic response in HF, and the primary outcome (cardiovascular death or total [first and recurrent] HF events), specifically, whether baseline NT-proBNP modified the effect of finerenone on this outcome, and the effect of finerenone on NT-proBNP level.

- *Session: Finerenone: A Promising Addition to the Armamentarium or Merely an Academic Exercise?*
- *March 29, 13:48 - 13:55 CT / 19:48 - 19:55 CET*

- [Temporal changes in biomarkers and quality of life prior to adverse clinical outcomes in heart failure with mildly reduced or preserved ejection fraction](#)

This analysis of the FINEARTS-HF trial evaluates key variables in patients with HF and an LVEF $\geq 40\%$, including potassium, eGFR, NT-proBNP, and the KCCQ-Total Symptom Score (TSS) on the primary endpoint (cardiovascular death or total [first and recurrent] HF events). Patients who had an event were compared to controls who remained free of hospitalization and death during follow-up.

- *Session: Heart Failure and Cardiomyopathies 04*
- *March 29, 14:00 - 15:00 CT / 20:00 - 21:00 CET*

- [Finerenone reduces new-onset atrial fibrillation across the spectrum of cardio-kidney-metabolism: The FINE-HEART pooled analysis](#)

This prespecified analysis pools participants from two trials of chronic kidney disease and type 2 diabetes (FIDELIO-DKD and FIGARO-DKD) and a trial of HF with mildly reduced or preserved ejection fraction (FINEARTS-HF) to evaluate the effect of finerenone on incidence of AF across the cardio-kidney-metabolic (CKM) spectrum.

- *Session: Heart Failure and Cardiomyopathies 09*
- March 30, 13:30 - 14:30 CT / 20:30 - 22:30 CET

- [Mode of death in patients with heart failure with mildly reduced or preserved ejection fraction: The FINEARTS-HF trial](#)

This analysis of the FINEARTS-HF trial evaluates mode of death in relation to ejection fraction (EF) categories and assessed effect of randomized treatment on cause-specific death.

- *Session: Heart Failure With Preserved Ejection Fraction: Utility of Hemodynamic Data, Treatment Options and Mode of Death*
- March 30, 09:12 - 09:19 CT / 16:12 -16:19 CET

- [Worsening heart failure events in adults with mild-to-moderate chronic kidney disease](#)

This real-world study evaluates patients with worsening heart failure (WHF) within a large healthcare delivery system from 2012 to 2021, focusing on the burden of WHF events and the distribution of new heart failure cases by ejection fraction among those with mild-to-moderate CKD.

- *Session: Heart Failure and Cardiomyopathies 10*
- Abstract 1215-174; March 30, 15:00 - 16:00 CT / 22:00 - 23:00 CET

- [Mechanisms of cardiovascular benefit with finerenone – a causal mediation analysis of the joint effects of systolic blood pressure and albuminuria reduction](#)

This mediation analysis of FIDELITY (pooled data from the FIDELIO-DKD and FIGARO-DKD trials) explores the pathways of CV protection with finerenone by evaluating the single and joint influence of early changes in hemodynamic markers, markers of kidney injury and tubular mineralocorticoid effect on cardiovascular outcomes.

- *Session: Optimizing Cardiovascular Risk Across the Diabetes/Cardio-Kidney-Metabolic Spectrum*

- Abstract 991-21; March 31, 10:48 - 10:55 CT / 17:48 - 17:55 CET

About FINEARTS-HF

FINEARTS-HF is a randomized, double-blind, placebo-controlled, multicenter, event-driven Phase III study investigating the efficacy and safety of finerenone (Kerendia™) for the prevention of cardiovascular death and heart failure (HF) events in patients with a diagnosis of symptomatic heart failure (New York Heart Association class II-IV) with a left ventricular ejection fraction (LVEF) of $\geq 40\%$, measured by any modality within the last 12 months as well as receiving diuretic treatment for at least 30 days prior to randomization. The primary endpoint of FINEARTS-HF was the composite of cardiovascular death and total (first and recurrent) HF events, defined as hospitalizations for HF or urgent HF visits.

Around 6,000 patients were randomized from more than 630 sites across 37 countries worldwide to receive either finerenone or placebo once daily. In addition, patients in the study received usual therapy to treat symptoms and comorbidities.

With overall more than 15,000 patients, the ongoing MOONRAKER clinical trial program with finerenone, including FINEARTS-HF, is one of the largest HF study programs to date, and aims to establish a comprehensive understanding of finerenone in HF across a broad spectrum of patients and clinical settings.

About Kerendia™ / 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, as well as 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 currently not approved for the treatment of heart failure.

The clinical 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 2024, the Group employed around 93,000 people and had sales of 46.6 billion euros. R&D expenses amounted to 6.2 billion euros. For more information, go to www.bayer.com.

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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.