Bayer AG
Communications
51368 Leverkusen
Germany
Phone +49 214 30-1
www.bayer.com/en/media

News Release

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Late-Breaking data from pivotal Phase III FINEARTS-HF study presented at ESC Congress 2024

Finerenone showed statistically significant improvement in cardiovascular outcomes in adults with common form of heart failure with high unmet medical need

- Finerenone is the first mineralocorticoid receptor (MR) antagonist to demonstrate definitive cardiovascular benefits in a Phase III study in patients with heart failure (HF) with a left ventricular ejection fraction (LVEF) of ≥40%, i.e. mildly reduced or preserved LVEF
- Finerenone showed a 16% relative risk reduction of the composite primary endpoint of cardiovascular death and total (first and recurrent) heart failure events compared to placebo
- The primary endpoint results were consistent across all prespecified subgroups including those based on comorbidities, hospitalization status, ejection fraction or baseline use of SGLT2-inhibitors
- Results from FINEARTS-HF were simultaneously published in the *New England Journal of Medicine*
- Unmet medical need is high for patients with heart failure (HF) and a LVEF of ≥40%: Hospitalization and mortality rates are comparable to those in patients with HF with reduced ejection fraction (LVEF≤40%), however, only limited approved and guideline-directed treatment options are currently available

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Berlin, September 1, 2024 – Detailed results from the Phase III study FINEARTS-HF demonstrate that compared to placebo, finerenone (Kerendia™/ Firialta™) showed a statistically significant improvement in cardiovascular outcomes in patients with heart failure (HF) and a left ventricular ejection fraction (LVEF) of greater than or equal to 40%. Finerenone significantly reduced the risk of the composite primary endpoint of

cardiovascular death and total (first and recurrent) HF events, defined as hospitalizations for HF or urgent HF visits, by 16 % (relative risk reduction, rate ratio (RR) 0.84 [95% CI, 0.74-0.95; p=0,0072]) over a median duration of 32 months. Based on the results of FINEARTS-HF, finerenone is the first MR antagonist to demonstrate definitive cardiovascular benefits in a Phase III study in patients with this common form of heart failure. The FINEARTS-HF findings were presented today during a Hot Line session at ESC Congress 2024 and simultaneously published in the *New England Journal of Medicine*.

“Treating heart failure patients with LVEF ≥ 40% has provided a significant challenge for many physicians, and there is a high unmet medical need as these patients have a substantial risk for serious cardiovascular events. Unlike heart failure with reduced ejection fraction, where many treatments are now available, for heart failure with LVEF ≥ 40%, we currently have limited treatment options with proven efficacy,” said Scott D. Solomon, MD, The Edward D. Frohlich Distinguished Chair, Professor of Medicine at Harvard Medical School, Director of Non-invasive Cardiology and Senior Physician at Brigham and Women’s Hospital and Chair of the study’s Executive Committee. “With FINEARTS-HF as the first large-scale study of a non-steroidal, selective mineralocorticoid receptor antagonist in these underserved heart failure patients, finerenone, if approved, has the potential to help these vulnerable patients.”

The benefits shown in the primary endpoint were consistent across all prespecified subgroups, regardless of background therapy, comorbidities, or hospitalization status, including those based on disease state (ejection fraction) or baseline use of SGLT2-inhibitors. Finerenone also significantly reduced the secondary endpoints of total HF events (RR 0.82 [95% CI, 0.71-0.94; p=0.0062]) and improved patient-reported health status as measured by the change from baseline in Total Symptom Score of Kansas City Cardiomyopathy Questionnaire (KCCQ-TSS), (between-group difference 1.6 points [95% CI, 0.8-2.3; p<0.0001]).

Heart failure (HF) affects over 60 million people worldwide; approximately half of these patients suffer from HF with a LVEF of ≥40%. HF with a LVEF ≥40% is associated with multimorbidity, making the condition complex to manage. Time trends suggest this growing population will soon account for the majority of patients hospitalized with HF. Patients with HF LVEF ≥40% have similar hospitalization and mortality rates as those with HF LVEF ≤40% (HF with reduced ejection fraction, HFrEF). More than half of patients

with HF LVEF ≥40% will die within 5 years. The high residual risk of CV events and mortality remains high despite available treatments in patients with HF LVEF ≥40%.

“Bayer has a strong heritage in cardiology, and heart failure is a key focus area for us, with these promising results underpinning our ongoing commitment to patients with this devastating condition. In FINEARTS-HF, finerenone reduced cardiovascular outcomes in a complex to treat patient population. This confirms the potential of finerenone, if approved, as a valuable treatment option in heart failure with mildly reduced or preserved ejection fraction irrespective of background therapy and disease state,” said Dr. Christian Rommel, Head of Research and Development at Bayer’s Pharmaceuticals Division. “FINEARTS-HF included a high percentage of hospitalized or recently hospitalized patients, which means the results are highly relevant for improving cardiovascular outcomes for patients who do not have enough options.”

Finerenone is a non-steroidal, selective mineralocorticoid receptor (MR) antagonist. By targeting MR and renin-angiotensin-aldosterone system (RAAS) overactivation, finerenone addresses hallmarks of HF with a LVEF ≥40%, such as fibrotic drivers.

Finerenone was well-tolerated in the FINEARTS-HF study, which is consistent with the well-established safety profile of finerenone. The overall incidence of treatment-emergent serious adverse events was comparable between finerenone and placebo groups. Hyperkalemia-related adverse events occurred more frequently with finerenone than placebo (9.7 % and 4.2%, respectively). There were no fatal adverse events of hyperkalemia in either treatment group, and hospitalization or discontinuation due to hyperkalemia was rare. The occurrence of increased potassium and creatinine levels was also more frequent in the finerenone group, but the incidence of potassium above 6.0 mmol/L was generally low.

Bayer plans to submit applications for marketing authorization for finerenone for an indication in heart failure with a LVEF of ≥40% to health authorities in due course.

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 ≥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. Finerenone once daily significantly reduced the combined risk of cardiovascular death and total (first and recurrent) HF events, defined as hospitalizations for HF or urgent HF visits, by 16 % (relative risk reduction, rate ratio (RR) 0.84 [95% CI, 0.74-0.95; p=0,0072]) over a median duration of 32 months. The results for the individual components of the primary endpoint are: cardiovascular death: hazard ratio (HR) 0.93 [95% CI, 0.78-1.11]; total (first and recurrent) HF events, defined as hospitalizations for HF or urgent HF visits: RR 0.82 [95% CI, 0.71-0.94; p=0.0062]). Finerenone also significantly reduced the secondary endpoint of improved patient-reported health status as measured by the change from baseline in Total Symptom Score of Kansas City Cardiomyopathy Questionnaire (KCCQ-TSS) (between-group difference 1.6 points [95% CI, 0.8-2.3; p<0.0001]). There was no difference in the finerenone and placebo groups for NYHA class (odds ratio (OR) 1.01 [95% CI, 0.88-1.15]; the composite kidney outcome (HR 1.33; [95% CI, 0.94–1.89]), or all-cause mortality (HR 0.93; [95% CI, 0.83–1.06]).

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™ / Firialta™ (finerenone)

Kerendia™ and Firialta™ 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 Firialta™, 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 Heart Failure

Heart failure is a complex clinical syndrome, characterized by a progressive decline in the heart's ability to fill with and pump enough blood to meet the body's needs for blood and oxygen. HF affects more than 60 million people worldwide and is the leading cause of hospitalization in people over 65. Prevalence of HF is projected to increase drastically over the next decade, partly as a consequence of the ageing population. Patients with HF face a poor prognosis, with mortality rates similar to or worse than the most common cancers. HF can be complicated by several comorbidities, with more than half of patients living with conditions such as obesity, chronic kidney disease, diabetes mellitus, hypertension, and/or atrial fibrillation. Symptoms of HF may include dizziness, shortness of breath, fatigue, sleep disturbance, chest discomfort, edema (swelling of feet and legs), and chronic coughing or wheezing.

Risk factors include hypertension, diabetes mellitus, smoking, a past myocardial infarction, and coronary artery disease. Despite advances in treatment, around 30% of people diagnosed with HF die within one year, increasing to around 40% after five years.

When categorized by left ventricular ejection fraction (LVEF), which is a measure of cardiac function indicating how much blood the left ventricle pumps out with each contraction, HF is divided into three different categories:

- Heart failure with reduced ejection fraction (HFrEF) is characterized by the compromised ability of the heart to eject oxygen-rich blood sufficiently during its contraction phase, where LVEF is ≤40%

- Heart failure with mildly reduced ejection fraction (HFmrEF) is a category for patients whose LVEF is between 41 to 49% and who have some impairment in the heart's ability to pump
- Heart failure with preserved ejection fraction (HFpEF) is a condition characterized by stiffness of the heart, leading to filling abnormalities as the left ventricle is unable to relax sufficiently to fill with blood, where LVEF is ≥50%

While LVEF ≤40% and LVEF ≥40% each account for approximately half of all HF cases, the burden of CV and non-CV comorbidities is higher in patients with LVEF ≥40%. Time trends also suggest that LVEF ≥40% will soon account for the majority of patients hospitalized with HF. While advances in therapy have been achieved in HF with LVEF ≤40%, there are limited treatment options for HF with LVEF ≥40%.

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.

Contact for media inquiries:
Dr. Daniela Esser, phone +49 30 2215-41588
Email: daniela.esser@bayer.com

Contact for investor inquiries:
Bayer Investor Relations Team, phone +49 214 30-72704
Email: ir@bayer.com
www.bayer.com/en/investors/ir-team

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