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News Release

Not intended for U.S. and UK Media

U.S. FDA grants Priority Review for new indication of finerenone for patients with common form of heart failure

- Finerenone is the first drug targeting the mineralocorticoid receptor (MR) pathway to demonstrate 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
- Regulatory submission is based on positive results from the Phase III FINEARTS-HF study, which is part of the ongoing Phase III clinical trial program MOONRAKER – one of the largest Phase III clinical trial programs to date in heart failure
- The FDA grants Priority Review designation for the evaluation of medicines that, if approved, would offer significant improvements in the efficacy or safety of the treatment, diagnosis, or prevention of serious conditions when compared to available therapies
- Approximately 6.7 million people in the U.S. have heart failure, and more than half of these patients suffer from HF with an LVEF of ≥40%

Berlin, March 17, 2025 – Bayer announced today that the U.S. Food and Drug Administration (FDA) has accepted its supplemental New Drug Application (sNDA) and granted Priority Review designation for finerenone for the treatment of adult patients with heart failure (HF) with a left ventricular ejection fraction (LVEF) of ≥40%, i.e. mildly reduced LVEF (HFmrEF) or preserved LVEF (HFpEF). The regulatory submission was based on the positive results from the Phase III FINEARTS-HF study, detailed results of which were presented at ESC Congress 2024, and simultaneously published in the *New England Journal of Medicine*.

The FDA grants Priority Review designation for the evaluation of medicines that, if approved, would offer significant improvements in the efficacy or safety of the treatment, diagnosis, or prevention of serious conditions when compared to available therapies.

Based on a priority review designation, the FDA’s goal is to take action on a New Drug Application within 6 months of submission, compared to 10 months under standard review. This would result in a PDUFA date and a potential approval of Kerendia in the U.S. in heart failure with an LVEF of ≥40% in the third quarter of 2025.

“The FDA’s Priority Review designation reinforces the potential of finerenone to emerge as a new pillar of therapy, advancing the treatment paradigm in heart failure with a left ventricular ejection fraction (LVEF) of ≥40%,” said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization and Member of the Pharmaceuticals Leadership Team at Bayer. “Currently, there are limited treatment options with proven efficacy available to physicians. We are excited about the Priority Review designation for finerenone, as this brings us an important step closer to bringing finerenone to patients as quickly as possible."

Finerenone is a non-steroidal, selective mineralocorticoid receptor antagonist (nsMRA) and the first drug targeting the mineralocorticoid receptor (MR) pathway that has demonstrated cardiovascular benefits in patients with HF and an LVEF of ≥40% in the Phase III study FINEARTS-HF. Finerenone is already marketed as Kerendia™ or, in some countries, as Firialta™, and approved for the treatment of adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D) in more than 90 countries worldwide, including in China, Europe, Japan, and the U.S.

By targeting MR and renin-angiotensin-aldosterone system (RAAS) overactivation, finerenone addresses key aspects of HF with an LVEF ≥40%, including hemodynamic factors and inflammatory and fibrotic processes. Results from the Phase III study FINEARTS-HF demonstrate that compared to placebo, finerenone 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%.

The supplemental New Drug Application submitted to the U.S. FDA is based on positive data from the FINEARTS-HF study, which is part of the ongoing MOONRAKER study program with finerenone. Finerenone has also been submitted for marketing authorization in HF with an LVEF of ≥40% in China, the EU, and Japan, and these applications are currently under review. Further regulatory applications to health authorities in other markets worldwide will follow.

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.

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. 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 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 aging 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 of 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 guideline-directed 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 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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de (2025-0042e)

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.