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

News Release

Not intended for U.S. and UK Media

U.S. FDA Approves Finerenone for New Indication in Patients with Heart Failure with Left Ventricular Ejection Fraction of ≥ 40%

- Finerenone (Kerendia™) is the first drug targeting the mineralocorticoid receptor (MR) pathway to demonstrate statistically significant and clinically meaningful cardiovascular benefits in a Phase III study in adult patients with heart failure (HF) with a left ventricular ejection fraction (LVEF) of ≥40%, i.e. mildly reduced or preserved LVEF
- Approximately 3.7 million people in the U.S. live with heart failure with an LVEF of ≥40%, which accounts for more than 500,000 hospitalizations per year
- Approved and guideline-directed treatment options for HF with an LVEF of ≥40% have been limited so far, and HF hospitalization and mortality remain high
- New indication approval follows the U.S. Food and Drug Administration (FDA)'s Priority Review designation and is based on positive results from the Phase III FINEARTS-HF study, which is part of the ongoing MOONRAKER program – one of the largest Phase III clinical trial programs to date in heart failure

---

Berlin, July 14, 2025 – Bayer announced today that the U.S. Food and Drug Administration (FDA) has approved finerenone (Kerendia™), a non-steroidal, selective mineralocorticoid receptor antagonist, for the treatment of adult patients with heart failure (HF) and a left ventricular ejection fraction (LVEF) of ≥40%. Finerenone (10mg, 20mg, 40mg) is now indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adult patients with heart failure with LVEF of ≥40%.

In March, the FDA granted Priority Review designation for the supplemental New Drug Application for finerenone for the treatment of adult patients with HF with an LVEF of ≥40%. The approval of finerenone by the FDA is based on the positive results of the pivotal Phase III FINEARTS-HF study, the results of which were presented at ESC

Congress 2024, and simultaneously published in the *New England Journal of Medicine*. In FINEARTS-HF, finerenone achieved a statistically significant and clinically meaningful reduction of the composite of cardiovascular death and total (first and recurrent) HF events, defined as hospitalizations for HF or urgent HF visits. These benefits were demonstrated regardless of background therapy, comorbidities, or hospitalization status. The study is part of the ongoing MOONRAKER program, one of the largest Phase III clinical trial programs to date in heart failure, including over 15,000 patients, which aims to establish a comprehensive understanding of finerenone in HF across a broad spectrum of patients and clinical settings.

“The FDA’s approval of finerenone expands treatment options for patients with heart failure with a left ventricular ejection fraction of ≥40% – a large and growing group of patients with a poor prognosis,” said Scott D. Solomon, MD, Professor of Medicine, Harvard Medical School, Director, Clinical Trials Outcomes Center, Mass General Brigham, and Chair of the study’s Executive Committee. “Based on the clinical efficacy we saw in the FINEARTS-HF study, finerenone can become a new pillar of comprehensive care, improve clinical outcomes and offer new hope to these patients in the U.S. with persistent high unmet medical needs.”

With this FDA approval, Kerendia is the only non-steroidal mineralocorticoid receptor (MR) antagonist approved in the U.S. for chronic kidney disease (CKD) associated with T2D and for HF with LVEF of ≥40%. Finerenone is a non-steroidal, selective MRA (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 a Phase III study (FINEARTS-HF). 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.

“Building on our longstanding expertise in bringing innovative science to the cardiovascular space, today’s approval of finerenone in heart failure with a left ventricular ejection fraction of ≥40% marks an important milestone in Bayer’s commitment to improving the lives of patients with this condition. While often balancing multiple comorbidities such as hypertension and atrial fibrillation, physicians have faced limited proven treatment options for these complex patients,” said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization and Member of the Pharmaceuticals Leadership Team at Bayer. “In the FINEARTS-HF study, finerenone

reduced the occurrence of cardiovascular events in patients with this common form of heart failure, and we are excited about the potential of finerenone to emerge as a foundational therapy that can contribute to addressing patients' tremendous needs."

Approximately 3.7 million Americans live with HF LVEF ≥40%, which accounts for more than 500,000 hospitalizations per year. Most are balancing multiple comorbidities, such as diabetes, hypertension, obesity, and CKD, and they face high rates of hospitalization, leading to considerable mortality risk and significant strain on healthcare systems. In patients with HF LVEF ≥40%, 25% are rehospitalized due to HF within 1 year of discharge, and the 5-year mortality rate is 75%.

Finerenone is not currently approved in HF with an LVEF of ≥40% outside of the U.S. Finerenone has 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 have been filed or will follow.

Since 2021, Kerendia™ (finerenone, 10 mg or 20 mg) is approved in the U.S. for the treatment of adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D) to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure. Based on the data from the FIDELIO-DKD and FIGARO-DKD trials, finerenone is approved for the treatment of adult patients with CKD associated with T2D in more than 95 countries worldwide, including in China, Europe, Japan, and the U.S., and recommended across multiple international guidelines as a pillar of therapy for improved kidney and cardiovascular outcomes in patients with CKD associated with T2D.

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 95 countries worldwide, including in China, Europe, Japan, and the U.S. In the U.S., finerenone is now approved under the brand name Kerendia for the treatment of heart failure and an LVEF of ≥40%.

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 Phase III studies FIDELIO-DKD and FIGARO-DKD, and the completed Phase II study CONFIDENCE, as well as the ongoing Phase III studies FIND-CKD, FIONA, FIONA-OLE, and FINE-ONE.

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 a leader in the area of cardiology and is advancing a portfolio of innovative treatments. The heart and the kidneys are closely linked in health and disease, and Bayer

is working on new treatment approaches for cardiovascular and kidney diseases with high unmet medical needs. The strategy is to unlock the strong potential of the future CV market by transforming Bayer's portfolio into precision cardiology, addressing the high disease burden, and driving long-term growth. Bayer's portfolio already includes several innovative products and 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.

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

Find more information at https://pharma.bayer.com
Follow us on Facebook: http://www.facebook.com/bayer
Follow us on Twitter: @BayerPharma

de (2025-0129e)

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.