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News Release

Not intended for U.S. and UK Media

Kerendia™ approved in EU for new indication in adult patients with heart failure with LVEF ≥40%

- The approval of Kerendia™ in the EU is based on the positive results from the Phase III FINEARTS-HF study, which included around 6,000 patients with heart failure (HF) with left ventricular ejection fraction (LVEF) ≥40% across a broad range of patient characteristics
- Kerendia™ (finerenone) 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 patients with HF with LVEF ≥40%
- More than 15 million people in Europe are living with HF, and about 50% of these patients suffer from HF with LVEF ≥40%
- Approved and guideline-directed treatment options for HF with LVEF ≥40% have been limited so far, and HF hospitalization and mortality remain high

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Berlin, March 30, 2026 – Bayer today announced that the European Commission has granted approval in the European Union (EU) for Kerendia™ (finerenone), a selective, non-steroidal mineralocorticoid receptor antagonist (nsMRA), for the treatment of adults with heart failure (HF) with left ventricular ejection fraction (LVEF) ≥40%, i.e. HF with mildly reduced (HFmrEF) or preserved LVEF (HFpEF). In the EU, Kerendia (10mg, 20mg, 40mg) is now indicated for the treatment of symptomatic chronic heart failure with LVEF ≥40% in adults, expanding its use beyond the existing indication in patients with chronic kidney disease associated with type 2 diabetes.

“Patients with heart failure with left ventricular ejection fraction of 40% or greater represent a large and growing group of patients with a poor prognosis who face substantial clinical challenges including repeat hospitalizations for worsening heart failure, and high mortality risk,” 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. “Finerenone addresses mineralocorticoid receptor overactivation, a key disease driver in heart failure, and based on its proven efficacy in the FINEARTS-HF trial can become a new pillar of comprehensive care to improve outcomes in this vulnerable population with persistent high unmet medical need.”

"The approval of the new indication for Kerendia in the EU is excellent news for millions of patients in Europe with heart failure and left ventricular ejection fraction of ≥40%. We are committed to ensuring that eligible patients have access to this important new treatment option to improve their outcomes," said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization and Member of the Pharmaceuticals Leadership Team at Bayer. "Kerendia has proven efficacy in reducing the combined risk of heart failure events and cardiovascular death, irrespective of background therapy and clinical setting as demonstrated in the FINEARTS-HF study. The robust evidence from five Phase III studies involving over 20,000 patients across multiple patient populations with chronic kidney disease and/or heart failure underscores the potential of Kerendia to become an essential treatment pillar for both heart failure with LVEF ≥40% and kidney disease. "

Heart failure is a rapidly growing public health issue affecting over 64 million people worldwide and at least 15 million people in Europe alone. Approximately half of these patients suffer from HF with LVEF of ≥40%, which is frequently associated with multiple comorbidities such as chronic kidney disease, hypertension and atrial fibrillation, contributing to hospitalizations and mortality. Currently, these patients have only limited approved and guideline-directed therapy options, while facing a high risk for cardiovascular events. Time trends suggest this growing population will soon account for the majority of patients hospitalized with HF. Repeated hospitalizations are a major contributor to heart failure-related costs, which in the EU are estimated at 29 billion Euros annually.

The approval by the European Commission is based on the positive results from the pivotal Phase III FINEARTS-HF study, which showed that finerenone significantly reduced the composite primary endpoint of cardiovascular death and total (first and recurrent) heart failure events, defined as hospitalizations for HF or urgent HF visits, versus placebo in addition to usual therapy. The benefits of finerenone shown in the primary endpoint were consistent regardless of background therapy, comorbidities, or hospitalization status, including patient subgroups based on ejection fraction or baseline use of SGLT-2-inhibitors. The FINEARTS-HF results were presented at ESC Congress 2024, and

simultaneously published in the *New England Journal of Medicine*. 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.

Finerenone is a non-steroidal, selective mineralocorticoid receptor antagonist (nsMRA) and the first drug targeting the MR pathway that in five pivotal Phase III studies has demonstrated cardiovascular and/or kidney benefits, respectively, in patients with HF with LVEF ≥40%, patients with CKD associated with type 2 diabetes, patients with CKD associated with type 1 diabetes, and patients with non-diabetic CKD. Following priority review designation, finerenone has been approved for the treatment of heart failure with LVEF ≥ 40% in the U.S. since July 2025. In Japan, several other markets, and now in the EU, finerenone is also approved in heart failure with LVEF ≥ 40%. Applications in HF with LVEF ≥ 40% in additional markets, including in China, are under review. Since 2021, finerenone is already marketed as Kerendia™ or, in selected 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 100 countries worldwide, including in China, Europe, Japan, and the U.S.

About Kerendia™ / Firialta™ (finerenone)
Kerendia™ and Firialta™ are globally protected trademarks for finerenone. Finerenone is a non-steroidal, selective mineralocorticoid receptor antagonist (nsMRA) 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.

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 the completed pivotal Phase III study FINEARTS-HF, as well as the ongoing investigator-sponsored, collaborative studies REDEFINE-HF, CONFIRMATION-HF, and FINALITY-HF. The THUNDERBALL CKD program consists of the completed Phase III studies FIDELIO-DKD, FIGARO-DKD, FIND-CKD, and FINE-ONE, and the Phase II study CONFIDENCE; as well as the ongoing Phase III studies in paediatric patient populations FIONA, and FIONA-OLE.

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.

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 64 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 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 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 cardiovascular 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 and kidney 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 2025, the Group employed around 88,000 people and had sales of 45.6 billion euros. R&D expenses amounted to 5.8 billion euros. For more information, go to www.bayer.com.

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