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News Release

Not intended for U.S. and UK Media

Kerendia™ approved in China for new indication in adult patients with heart failure with LVEF $\geq 40\%$

- The Chinese National Medical Products Administration granted approval for a label update to extend the indication of Kerendia™ to adult patients with heart failure (HF) with left ventricular ejection fraction (LVEF) $\geq 40\%$, i.e. HF with mildly reduced (HFmrEF) or preserved LVEF (HFpEF)
 - The approval of Kerendia™ in China 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) $\geq 40\%$ 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 $\geq 40\%$
 - More than 64 million people globally, and over 13 million patients in China are living with HF – about 60% of these patients suffer from HF with LVEF $\geq 40\%$
 - Approved and guideline-directed treatment options for HF with LVEF $\geq 40\%$ have been limited so far, and HF hospitalization and mortality remain high
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Berlin, May 22, 2026 – Bayer today announced that the Chinese National Medical Products Administration (NMPA) granted marketing authorization for a label extension for Kerendia™ (finerenone), a non-steroidal, selective mineralocorticoid receptor antagonist (nsMRA), to include the treatment of adults with heart failure (HF) with left ventricular ejection fraction (LVEF) $\geq 40\%$, i.e. HF with mildly reduced (HFmrEF) or preserved LVEF (HFpEF). In China, Kerendia (10mg, 20mg, 40mg) is now indicated for the treatment of symptomatic chronic heart failure with LVEF $\geq 40\%$ in adults, expanding its use beyond the existing indication in patients with chronic kidney disease associated with type 2 diabetes (10mg, 20mg).

“Patients with heart failure and LVEF of 40% or greater have a poor prognosis: Most are balancing multiple comorbidities, such as diabetes, hypertension, obesity, and CKD, and they face high rates of cardiovascular events such as hospitalization for heart failure or cardiovascular death,” said Professor Ma Changsheng, Chairman of the Society of Cardiology, Chinese Medical Association, Director of Cardiology Department, Beijing Anzhen Hospital; and the principal investigator of the FINEARTS-HF study in China. “Finerenone addresses mineralocorticoid receptor overactivation, a key disease driver in heart failure, and based on its proven efficacy in the FINEARTS-HF trial can fill an important gap in improving outcomes in this vulnerable population.”

“The approval of Kerendia in China marks a significant milestone in our commitment to improving care for millions of patients with heart failure and left ventricular ejection fraction of $\geq 40\%$. In the FINEARTS-HF study, Kerendia has demonstrated robust efficacy in reducing the combined risk of heart failure events and cardiovascular death versus placebo in addition to usual therapy, irrespective of background therapy and clinical setting,” said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization and Member of the Pharmaceuticals Leadership Team at Bayer. “Given the breadth and consistency of findings generated so far in five Phase III studies involving over 20,000 patients across multiple patient populations with chronic kidney disease and/or heart failure, we are excited about the potential of Kerendia to become an essential treatment option for both heart failure with LVEF $\geq 40\%$ and chronic kidney disease.”

Heart failure is a rapidly growing public health issue affecting over 64 million people worldwide. Approximately half of these patients suffer from HF with LVEF of $\geq 40\%$, 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.

The new drug application approval by the Chinese NMPA 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 $\geq 40\%$, 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 $\geq 40\%$ in the U.S. since July 2025. In the EU, Japan, several other markets, and now in China, finerenone is also approved in heart failure with LVEF $\geq 40\%$. Applications in HF with LVEF $\geq 40\%$ in additional markets are under review. Since 2021, finerenone is already marketed as Kerendia™ or, in selected countries, as Firalta™, 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™ / Firalta™ (finerenone)

Kerendia™ and Firalta™ 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 twelve Phase III studies with dedicated programs in HF and CKD respectively. The MOONRAKER program includes the completed pivotal Phase III study FINEARTS-HF, the ongoing investigator-sponsored, collaborative studies REDEFINE-HF, CONFIRMATION-HF, and FINALITY-HF, as well as the ongoing Phase III studies in

paediatric patient populations, FIORE and FIORELLO. 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 $\geq 40\%$, 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.

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 $\leq 40\%$
- 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 $\geq 50\%$

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

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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Forward-Looking Statements

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