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

News Release

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Finerenone recommended for the treatment of patients with heart failure with LVEF ≥40% in the EU

- CHMP adopts positive opinion for the marketing authorization of finerenone for patients with heart failure (HF) with left ventricular ejection fraction (LVEF) ≥40%, i.e. mildly reduced or preserved LVEF, in the European Union
- The positive opinion is based on the results from the Phase III FINEARTS-HF study, which included around 6,000 patients with HF with LVEF ≥40% across a broad range of patient characteristics
- 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 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%, where currently only limited approved and guideline-directed treatment options are available and the risk for cardiovascular events remains high

Berlin, January 30, 2026 – Bayer today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending finerenone (Kerendia™), a non-steroidal, selective mineralocorticoid receptor antagonist (nsMRA), for the treatment of adults with heart failure (HF) with left ventricular ejection fraction (LVEF) ≥40%, i.e. mildly reduced LVEF (HFmrEF) or preserved LVEF (HFpEF). The final decision by the European Commission is expected over the course of the next few weeks.

“The positive CHMP opinion for finerenone in heart failure with mildly reduced or preserved LVEF marks a significant step forward in addressing the high cardiovascular risks of this large and growing group of patients,” said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization and Member of the

Pharmaceuticals Leadership Team at Bayer. “Based on the pivotal FINEARTS-HF study where finerenone showed early, consistent and sustained efficacy across a range of patient profiles and in addition to usual care, we are confident about the potential of finerenone to become a relevant therapy for these patients."

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.

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 with left ventricular ejection fraction (LVEF) ≥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 95 countries worldwide, including in China, Europe, Japan, and the U.S. In the U.S. and in Japan, finerenone is also approved for the treatment of heart failure with LVEF ≥ 40%. Applications in HF with LVEF ≥ 40% in additional markets, including China, are under review.

The CHMP recommendation 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 SGLT2is. 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.

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.

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

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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.