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News Release

Not intended for U.S. and UK Media

Bayer submits application to U.S. FDA and to China's CDE for new indication of finerenone for patients with common form of heart failure with high unmet medical need

- 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 $\geq 40\%$, i.e. mildly reduced or preserved LVEF
 - Regulatory submissions are based on positive data from the Phase III FINEARTS-HF study recently presented at ESC Congress 2024, and simultaneously published in the [New England Journal of Medicine](#)
 - Approximately 32 million people worldwide are living with HF with a LVEF of $\geq 40\%$, which is associated with substantial morbidity and mortality; however, limited approved and guideline-directed treatments are currently available
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Berlin, January 10, 2025 – Bayer today announced the submission of marketing authorization applications to the U.S. Food and Drug Administration (FDA) and to the Center of Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA), seeking approval of finerenone in the U.S. and in China for adult patients with HF with a left ventricular ejection fraction (LVEF) of $\geq 40\%$, i.e. mildly reduced LVEF (HFmrEF) or preserved LVEF (HFpEF).

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 this common form of HF in the Phase III study FINEARTS-HF. Finerenone is already marketed as Kerendia™ or, in some 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 90 countries worldwide, including in China, Europe, Japan, and the U.S.

“Heart failure represents a serious global health challenge, particularly for patients with a left ventricular ejection fraction of $\geq 40\%$, who are difficult to treat”, said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization and Member of the Pharmaceuticals Leadership Team at Bayer. “If approved, finerenone could emerge as a new pillar of treatment for this common form of heart failure, offering the potential to improve cardiovascular outcomes for patients who currently have limited treatment options with proven efficacy.”

Heart failure (HF) affects over 60 million people worldwide and is a rapidly growing public health issue. Approximately half of these patients suffer from HF with a LVEF of $\geq 40\%$. HF with a LVEF $\geq 40\%$ is associated with multiple comorbidities, making the condition complex to manage. Time trends suggest this growing population will soon account for the majority of patients hospitalized with HF.

By targeting MR and renin-angiotensin-aldosterone system (RAAS) overactivation, finerenone addresses key aspects of HF with an LVEF $\geq 40\%$, 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 New Drug Applications submitted to the U.S. FDA and to the CDE of China’s National Medical Products Administration are based on positive data from the FINEARTS-HF study, which is part of one of the largest Phase III clinical trial programs to date in HF with more than 15,000 patients in total, aiming to establish a comprehensive understanding of finerenone in HF across a broad spectrum of patients and clinical settings.

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.

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™ / Firalta™ (finerenone)

Kerendia™ and Firalta™ 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 Firalta™, 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 not approved for the treatment of heart failure.

The 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 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 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 2023, the Group employed around 100,000 people and had sales of 47.6 billion euros. R&D expenses before special items amounted to 5.8 billion euros. For more information, go to www.bayer.com.

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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.