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News Release

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Finerenone approved in Japan for treatment of patients with chronic heart failure

- MHLW approves finerenone in Japan for chronic heart failure, introducing a new therapeutic option for patients with chronic heart failure (HF) with a left ventricular ejection fraction (LVEF) of ≥40%, i.e. mildly reduced or preserved LVEF
- 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 of ≥40%
- New indication is based on positive data from the Phase III FINEARTS-HF study presented at ESC Congress 2024, and simultaneously published in the *New England Journal of Medicine*
- In the new joint 2025 Guidelines of the Japanese Circulation Society (JCS) and the Japanese Heart Failure Society (JHFS) on Diagnosis and Treatment of Heart Failure, finerenone is the only MRA with a Class IIa recommendation for the treatment of HF with LVEF ≥ 40%
- In Japan, approximately 1.2 million patients are living with heart failure. About 60% of these patients suffer from HF with LVEF ≥40%, and up to now there were only limited approved and guideline-directed therapies for these patients, who have a high risk for cardiovascular events

Berlin, December 22, 2025 – Bayer today announced that Japan's Ministry of Health, Labour and Welfare (MHLW) has approved finerenone (Kerendia™), a non-steroidal, selective mineralocorticoid receptor antagonist (nsMRA), for the treatment of adult patients with chronic heart failure (HF) with left ventricular ejection fraction (LVEF) of ≥40%, i.e. mildly reduced LVEF (HFmrEF) or preserved LVEF (HFpEF).

Heart failure is a rapidly growing public health issue, affecting over 64 million people worldwide. It also is a growing burden in Japan's aging society. An estimated 1.2 million

people are living with HF nationwide, and about six in ten have LVEF ≥40%. These patients frequently have multiple comorbidities such as hypertension and atrial fibrillation, contributing to hospitalizations and mortality.

“The approval of finerenone in Japan helps to address a major gap in heart failure care: the high rates of cardiovascular events such as hospitalization for heart failure or cardiovascular death in the large and growing group of patients with heart failure with left ventricular ejection fraction of ≥40%,” 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 showed early, consistent and sustained efficacy across a range of patient profiles and in addition to existing treatments. We are enthusiastic about the potential of finerenone to emerge as a foundational therapy addressing the substantial needs of these patients in Japan.”

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 a left ventricular ejection fraction (LVEF) of ≥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. Finerenone is also approved for the treatment of heart failure with left ventricular ejection fraction (LVEF) ≥ 40% in the U.S.

In Japan, in the new joint 2025 Guidelines of the Japanese Circulation Society (JCS) and the Japanese Heart Failure Society (JHFS) on Diagnosis and Treatment of Heart Failure, finerenone is the only MRA with a Class IIa recommendation for the treatment of HF with LVEF ≥ 40%. In this Guideline, finerenone also has Class I recommendation and Level A evidence for prevention of HF in patients with type 2 diabetes (T2D) and chronic kidney disease (CKD), based on the positive data on finerenone from the pivotal Phase III clinical studies FIDELIO-DKD and FIGARO-DKD in patients with CKD and T2D. The updated recommendation on prevention of HF in CKD associated with T2D is in line with the Guidelines of the European Society of Cardiology (ESC).

The approval of finerenone by the MHLW is based on the positive results from the Phase III FINEARTS-HF study, presented at ESC Congress 2024 and 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, versus placebo in addition to usual therapy. 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.

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

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.

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 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 ≤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.

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