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News Release

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Late-breaking data presented at the European Association for the Study of Diabetes (EASD) Annual Meeting 2024

New subgroup analysis from FINEARTS-HF revealed patients with heart failure and a left ventricular ejection fraction of $\geq 40\%$ receiving finerenone had a reduced risk of new-onset diabetes

- Late-breaking data from a prespecified analysis showed that patients with heart failure and a left ventricular ejection fraction of $\geq 40\%$ receiving finerenone in FINEARTS-HF had a 24% reduced risk of new-onset diabetes compared to placebo
 - The reduction in new-onset diabetes seen with finerenone was consistent across subgroups and robust to different definitions of diabetes
 - The prespecified analysis of FINEARTS-HF also showed that finerenone reduced the combined risk of cardiovascular death and worsening heart failure events compared to placebo, irrespective of glycemic status at baseline
 - Patients with heart failure are at increased risk of developing diabetes, which is associated with worse symptoms, higher rates of hospitalization and higher mortality
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Berlin, September 10, 2024 – Bayer announced today new late-breaking data showing that patients with heart failure and a left ventricular ejection fraction of $\geq 40\%$ receiving finerenone (Kerendia™/ Firalta™) had a 24% reduced risk of new-onset diabetes, compared to placebo. The data is from a pre-specified analysis of the Phase III FINEARTS-HF trial, which randomized around 6,000 patients with heart failure (HF) and showed that finerenone reduced the combined risk of cardiovascular death and worsening HF events compared to placebo. The new prespecified analysis was presented today at the European Association for the Study of Diabetes (EASD) Annual Meeting 2024.

“There is a clearly detrimental relationship between heart failure and diabetes that has a huge and harmful impact on symptoms and outcomes in patients,” said Prof. John McMurray, MD, Professor of Medical Cardiology and honorary Consultant Cardiologist at the Queen Elizabeth University Hospital, Glasgow. “Hopefully, reducing the incidence of new-onset diabetes means that these heart failure patients might have a better quality of life and be at lower subsequent risk of hospitalization and death.”

Heart failure is a life-changing and debilitating disease, often resulting in distressing symptoms and a reduced ability to carry out everyday tasks. Patients with heart failure are at increased risk of developing diabetes. For patients with heart failure, developing diabetes increases their risk of worse symptoms and quality of life, more rapid decline in kidney function, hospitalization, and death when compared to HF patients without diabetes.

In FINEARTS-HF, 262 (8.1%) patients developed new-onset diabetes over a median follow-up of 32 months, of which 115 (7.2%) were in the finerenone group and 147 (9.1%) were in the placebo group. Compared with placebo, finerenone significantly reduced the risk of new-onset diabetes by 24% (HR 0.76 [95% CI, 0.59-0.97]). The effect of finerenone was robust to different definitions of diabetes regardless of whether based on HbA1c measurement or initiation of glucose-lowering therapy. The effect of finerenone was also consistent across key patient sub-groups. Moreover, new-onset diabetes was associated with a higher risk of cardiovascular death and total worsening HF events, and all-cause death and these associations persisted after adjustment for other recognized prognostic variables.

“The relationships between cardiovascular, kidney and metabolic health are becoming increasingly well understood, but there is more to discover,” said Dr. Christian Rommel, Member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Research and Development. “It is exciting to see additional benefits of finerenone with regard to new-onset diabetes, based on the data from the FINEARTS-HF study. These data provide important insights on finerenone in patients with this common but underserved form of heart failure.”

The pre-specified analysis of the FINEARTS-HF trial also investigated the efficacy and safety of finerenone on the combined primary endpoint of cardiovascular death and total worsening HF events, compared with placebo, according to history of diabetes, glycemic

status at baseline, HbA1c level at baseline, and HbA1c levels during follow-up. The new analysis showed that compared to placebo, finerenone reduced the risk of cardiovascular death and total worsening events consistently, regardless of history of diabetes, glycemic status or HbA1c level at baseline, and HbA1c levels during follow-up.

Late-breaking data from a prespecified analysis of the pooled analysis FINE-HEART were also presented today at EASD, showing that finerenone was effective in reducing morbidity and mortality in patients with type 2 diabetes and either chronic kidney disease (CKD) or heart failure (HF) with mildly reduced or preserved ejection fraction, regardless of patients' baseline HbA1c and glucose-lowering regimens, and irrespective of concomitant treatment with a sodium/glucose cotransporter 2-inhibitor (SGLT2is) or glucagon-like peptide-1 receptor agonists (GLP1RAs).

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.

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 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.

Finerenone once daily significantly reduced the combined risk of cardiovascular death and total (first and recurrent) HF events, defined as hospitalizations for HF or urgent HF visits, by 16 % (relative risk reduction, rate ratio (RR) 0.84 [95% CI, 0.74-0.95; $p=0.0072$]) over a median duration of 32 months.

Bayer plans to submit applications for marketing authorization for finerenone for an indication in heart failure with a LVEF of $\geq 40\%$ to health authorities in due course.

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.

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

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