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News Release

Not intended for U.S. and UK Media

Bayer receives positive CHMP opinion for finerenone as a new treatment for adult patients with chronic kidney disease associated with type 2 diabetes

- Finerenone, a non-steroidal, selective mineralocorticoid receptor (MR) antagonist, is recommended by CHMP for marketing authorization for the treatment of chronic kidney disease (CKD) associated with type 2 diabetes (T2D)
- CHMP opinion is based on the results of the Phase III FIDELIO-DKD study investigating the efficacy and safety of finerenone on kidney and cardiovascular outcomes in patients with CKD associated with T2D
- Final European Commission decision is expected in the coming months

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Berlin, December 17, 2021 – The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended finerenone, a non-steroidal, selective mineralocorticoid receptor (MR) antagonist, for marketing authorization in the European Union (EU). Finerenone (10 mg or 20 mg) is recommended for the treatment of chronic kidney disease (stage 3 and 4 with albuminuria) associated with type 2 diabetes in adults.

“Despite currently available treatment options, many patients with chronic kidney disease associated with type 2 diabetes progress to kidney failure or premature death. These patients have a critical need for treatment options that can delay kidney disease progression and reduce the risk of cardiovascular events,” said Professor Peter Rossing, Head of Complications Research at the Steno Diabetes Center Copenhagen. “Once approved, finerenone will be the first non-steroidal MR antagonist to offer adult patients living with chronic kidney disease associated with type 2 diabetes a new therapy to help improve kidney outcomes.”

“Chronic kidney disease often progresses silently and unpredictably, with many symptoms not apparent until the disease is advanced. Timely detection is vital to ensure the best outcomes for patients and kidney health needs to be carefully monitored in those at-risk,” said Dr. Christian Rommel, Member of the Executive Committee of Bayer AG’s Pharmaceutical Division and Head of Research and Development. “The positive CHMP opinion for finerenone brings us closer to providing this new treatment option to patients with chronic kidney disease associated with type 2 diabetes.”

The positive CHMP opinion is based on the results of the pivotal Phase III FIDELIO-DKD study, presented at the American Society of Nephrology’s (ASN) Kidney Week 2020 and simultaneously published in the *New England Journal of Medicine* (NEJM) in October 2020.

In July 2021, finerenone was approved under the brand name Kerendia® by the United States (U.S.) Food and Drug Administration (FDA) based on the positive results of the FIDELIO-DKD Phase III study for adult patients with CKD and T2D. Finerenone has also been submitted for marketing authorization in China and multiple other countries worldwide; these applications are currently under review.

About Finerenone

Finerenone (BAY 94-8862) is a non-steroidal, selective mineralocorticoid receptor (MR) antagonist that in preclinical studies has been shown to block harmful effects of MR overactivation. In T2D, MR overactivation is thought to contribute to CKD progression and cardiovascular damage which can be driven by metabolic, hemodynamic or inflammatory and fibrotic factors. The Phase III study programme with finerenone, FINEOVATE, currently comprises five Phase III studies, FIDELIO-DKD, FIGARO-DKD, FINEARTS-HF, FIND-CKD and FIONA.

Having randomized more than 13,000 patients with CKD and T2D around the world, the Phase III program with finerenone in CKD and T2D comprises two completed and published studies, evaluating the effect of finerenone versus placebo on top of standard of care on both renal and cardiovascular outcomes. FIDELIO-DKD (**FI**nerenone in reducing ki**D**n**E**y fai**L**ure and d**I**sease pr**O**gression in **D**iabetic **K**idney **D**isease) investigated the efficacy and safety of finerenone in comparison to placebo in addition to standard of care on the reduction of kidney failure and kidney disease progression in approximately 5,700

patients with CKD and T2D. FIGARO-DKD (**FI**nerenone in reducin**G** c**A**rdiovascular mo**R**tality and m**O**rbidity in **D**iabetic **K**idney **D**isease) investigated the efficacy and safety of finerenone versus placebo in addition to standard of care on the reduction of cardiovascular morbidity and mortality in approximately 7,400 patients with CKD and T2D.

FIDELITY (**FI**nerenone in chronic ki**D**ney diseas**E** and type 2 diabetes: Combined FIDE**L**IO-DKD and F**I**GARO-DKD **T**rial programme anal**Y**sis), including the FIDELIO-DKD and FIGARO-DKD studies, comprises the largest Phase III cardiorenal outcomes clinical trial program to evaluate the occurrence of progression of kidney disease as well as fatal and nonfatal CV events in >13,000 patients with CKD and T2D. The prespecified FIDELITY pooled analysis investigated the efficacy and safety of finerenone across the spectrum of patients with CKD in T2D and provided insights into the relationship between CKD stage (based on baseline Kidney Disease: Improving Global Outcomes risk categories) and the effects of finerenone on composite cardiovascular and kidney-specific endpoints.

In November 2021, Bayer announced the initiation of FIONA, a multicenter, randomized, double-blind, placebo-controlled Phase III study, to investigate the efficacy, safety and pharmacokinetics/pharmacodynamics (PK/PD) of finerenone, in addition to standard of care, in approximately 200 pediatric patients with chronic kidney disease (CKD) and severely increased proteinuria.

In September 2021, Bayer announced the initiation of the Phase III study FIND-CKD, a multicenter, randomized, double-blind, placebo-controlled Phase III study to investigate the efficacy and safety of finerenone in addition to guideline-directed therapy on the progression of chronic kidney disease (CKD) in more than 1,500 patients with non-diabetic chronic kidney disease etiologies, including hypertension and chronic glomerulonephritis (inflammation of the kidneys).

In June 2020, Bayer announced the initiation of the FINEARTS-HF study, a multicenter, randomized, double-blind, placebo-controlled Phase III study which will investigate finerenone compared to placebo in more than 5,500 patients with symptomatic heart failure (New York Heart Association class II-IV) with preserved ejection fraction, i.e. a left ventricular ejection fraction of ≥40%. The primary objective of the study is to demonstrate superiority of finerenone over placebo in reducing the rate of the composite endpoint of

cardiovascular death and total (first and recurrent) heart failure (HF) events (defined as hospitalizations for HF or urgent HF visits).

In July, finerenone was approved under the brand name Kerendia® by the United States (U.S.) Food and Drug Administration (FDA) based on the positive results of the FIDELIO-DKD Phase III study.

About Chronic Kidney Disease in Type 2 Diabetes

Chronic kidney disease (CKD) is a common and potentially deadly condition that is widely underrecognized. CKD progresses silently and unpredictably, with many symptoms not appearing until the disease is well-advanced. CKD is one of the most frequent complications arising from diabetes and is also an independent risk factor of cardiovascular disease. Up to 40% of all patients with type 2 diabetes develop chronic kidney disease. Despite guideline-directed therapies, patients with CKD and T2D remain at high risk of CKD progression and cardiovascular events. It is estimated that CKD affects more than 160 million people with T2D worldwide. Chronic kidney disease in type 2 diabetes is the main cause of end stage kidney disease, which requires dialysis or a kidney transplant to stay alive. Patients with chronic kidney disease and type 2 diabetes are three times more likely to die from a cardiovascular-related cause than those with type 2 diabetes alone.

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. Its products and services are designed to help people and planet thrive by supporting efforts to master the major challenges presented by a growing and aging

global population. Bayer is committed to drive sustainable development and generate 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 2020, the Group employed around 100,000 people and had sales of 41.4 billion euros. R&D expenses before special items amounted to 4.9 billion euros. For more information, go to www.bayer.com.

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