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News Release

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Finerenone receives positive CHMP opinion for EU-label extension for broad range of patients with chronic kidney disease and type 2 diabetes

- CHMP opinion is based on the results from the Phase III FIGARO-DKD cardiovascular (CV) outcomes study in patients with chronic kidney disease (CKD) and type 2 diabetes (T2D), which included approximately 7,400 patients across a broad range of disease severity, including stages 1-4 CKD associated with T2D
- The positive data from FIGARO-DKD demonstrated that finerenone significantly reduced the risk of cardiovascular events in adult patients with CKD and T2D
- In a newly published update to the Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease, Kerendia is suggested as currently the only nonsteroidal mineralocorticoid receptor antagonist (MRA) with proven kidney and cardiovascular benefit as part of a comprehensive treatment plan for patients with CKD associated with T2D

Berlin, December 16, 2022 – Bayer announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion, recommending a label extension for Kerendia™ (finerenone, 10 mg or 20 mg) to include results on cardiovascular outcomes from the Phase III FIGARO-DKD study. The study demonstrated that finerenone reduced the risk of cardiovascular events in a broad population of patients with stages 1-4 CKD and T2D. The CHMP recommended the approval of the extension of the indication of Kerendia™ (10 mg or 20 mg) to early stages[i] of CKD associated with T2D: “Kerendia is indicated for the treatment of chronic kidney disease (with albuminuria) associated with type 2 diabetes in adults. For study results with respect to renal and cardiovascular events, see section 5.1.” The final decision by the European Commission, authorizing marketing approval in the European Union, is expected early in 2023.

Results from the pivotal Phase III FIGARO-DKD study were presented at the European Society of Cardiology (ESC) Congress 2021 and simultaneously published in the *New England Journal of Medicine*. FIGARO-DKD investigated the efficacy and safety of finerenone versus placebo in addition to standard of care on the reduction of CV morbidity and mortality in approximately 7,400 patients with CKD and T2D. The positive data from FIGARO-DKD demonstrated that finerenone significantly reduced the risk of cardiovascular events in adult patients with CKD and T2D.

“As patients are faced with an increased risk of cardiovascular events already in early stages of chronic kidney disease and type 2 diabetes, and as this risk is growing with kidney health decline, timely diagnosis and treatment is crucial to limit disease progression and to potentially prevent cardiovascular complications and mortality,” said Professor Peter Rossing, Head of Complications Research at the Steno Diabetes Center Copenhagen. “FIGARO-DKD is the first contemporary Phase III cardiovascular outcomes trial to show cardiovascular benefit in patients with chronic kidney disease and type 2 diabetes where the majority of the population were in earlier stages* with albuminuria.”

Mineralocorticoid receptor (MR) overactivation contributes to CKD progression and CV damage which can be driven by metabolic, hemodynamic, or inflammatory and fibrotic factors. Addressing an alternative pathway, Kerendia offers protection as it selectively binds to the MR receptor, blocking harmful effects of MR overactivation.

“Patients with chronic kidney disease and type 2 diabetes are three times more likely to die from a cardiovascular event than those with type 2 diabetes alone. These patients are in need of treatment options that can both delay kidney disease progression and reduce the risk of cardiovascular events,” said Dr. Christian Rommel, member of the Executive Committee of Bayer AG’s Pharmaceutical Division and Global Head of Research and Development. “At Bayer, we are committed to providing treatment options that offer clinically meaningful benefits for patients. The recommendation from the CHMP to extend the label underlines Kerendia as a distinctive treatment option that has demonstrated kidney and cardiovascular benefits in a broad patient population with chronic kidney disease and type 2 diabetes.”

In October, there was an update to the Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease of KDIGO (Kidney Disease: Improving Global

Outcomes), published in *Kidney International,* which suggests Kerendia as a nonsteroidal MRA with proven kidney and cardiovascular benefit as part of a comprehensive treatment plan for patients with CKD associated with T2D: “We suggest a nonsteroidal mineralocorticoid receptor antagonist with proven kidney or cardiovascular benefit for patients with T2D, an eGFR ≥25 ml/min per 1.73 m^2 , normal serum potassium concentration, and albuminuria (≥30 mg/g [≥3 mg/mmol]) despite maximum tolerated dose of RAS inhibitor (RASi) (2A).”

Based on the positive results of the FIDELIO-DKD Phase III study, Kerendia was granted the initial marketing authorization by the European Commission in February 2022 for the treatment of CKD (stage 3 and 4 with albuminuria) associated with T2D in adults. Once approved by the European Commission, the extended EU label for Kerendia will reflect data from more than 13,000 patients with CKD and T2D, based on the Phase III FIDELIO-DKD and FIGARO-DKD studies.

About Kerendia™ (finerenone)
Kerendia is a non-steroidal, selective mineralocorticoid receptor (MR) antagonist that has been shown to block harmful effects of MR overactivation. MR overactivation contributes to CKD progression and cardiovascular damage which can be driven by metabolic, hemodynamic, or inflammatory and fibrotic factors.

In March 2022, Bayer submitted a Type II Variation application based on the data from FIGARO-DKD to the European Medicines Agency (EMA) to seek an extension of the marketing authorization for Kerendia™ to include early stages of CKD associated with T2D. Based on the positive results of the FIDELIO-DKD Phase III study, Kerendia™ was granted marketing authorization by the U.S. Food and Drug Administration (FDA) in July 2021, the European Commission in February 2022, and the Chinese National Medical Products Administration (NMPA) in June 2022. In September 2022, Bayer announced that it received approval from the U.S. FDA for a label update for Kerendia™ to include findings from the Phase III FIGARO-DKD CV outcomes study. Based on the positive results of both pivotal Phase III studies, FIDELIO-DKD and FIGARO-DKD, Kerendia™ was approved in March 2022 by the Japanese Ministry of Health, Labour, and Welfare (MHLW). Further regulatory approvals by other health authorities in multiple other countries have been granted or are currently pending following submissions for marketing authorization.

The Phase III study programme with finerenone, FINEOVATE, currently comprises five Phase III studies, FIDELIO-DKD, FIGARO-DKD, FINEARTS-HF, FIND-CKD, and FIONA, as well as the Phase II study CONFIDENCE.

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, FIDELIO-DKD and FIGARO-DKD, evaluating the effect of finerenone versus placebo on top of standard of care on both renal and cardiovascular outcomes.

The prespecified FIDELITY pooled analysis, including the FIDELIO-DKD and FIGARO-DKD studies, investigated the efficacy and safety of finerenone across the spectrum of patients with CKD in T2D in reducing the risk of chronic kidney disease progression as well as fatal and nonfatal CV events and provided insights into the relationship between CKD stage (based on baseline Kidney Disease: Improving Global Outcomes – KDIGO – risk categories) and the effects of finerenone on composite cardiovascular and kidney-specific endpoints.

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 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 2021, the Group employed around 100,000 people and had sales of 44.1 billion euros. R&D expenses before special items amounted to 5.3 billion euros. For more information, go to www.bayer.com.

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[i] Stages 1-2 of CKD according to an estimated glomerular filtration rate [eGFR] of ≥60 ml/min/1.73m^2, following KDIGO classification.