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News Release

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Kerendia™ (finerenone) approved in China for the treatment of adults with chronic kidney disease associated with type 2 diabetes

- Despite available treatment options, many patients with chronic kidney disease (CKD) and type 2 diabetes (T2D) are progressing to kidney failure and premature death
- Kerendia™ (finerenone) is the first non-steroidal, selective mineralocorticoid receptor (MR) antagonist to demonstrate positive kidney and cardiovascular (CV) outcomes in patients with CKD associated with T2D
- The approval in China is based on the results of the Phase III FIDELIO-DKD study investigating the efficacy and safety of Kerendia on kidney and CV outcomes in patients with CKD associated with T2D

Berlin, June 30, 2022 – Bayer announced today that the Chinese National Medical Products Administration (NMPA) has granted marketing authorization for finerenone under the brand name Kerendia™. Kerendia™ (10 mg or 20 mg), a non-steroidal, selective mineralocorticoid receptor (MR) antagonist, is indicated for the treatment of chronic kidney disease (CKD) (eGFR of ≥ 25 to 75 mL/min/1.73 m^2 with albuminuria) associated with type 2 diabetes (T2D) in adults, to reduce the risk of sustained eGFR decline and end-stage kidney disease. The approval of Kerendia in China is based on the results of the pivotal Phase III study FIDELIO-DKD, presented at the American Society of Nephrology's (ASN) Kidney Week 2020 and simultaneously published in the *New England Journal of Medicine* in October 2020.

Worldwide, T2D is the second leading cause of CKD and CKD-related deaths, with up to 40% of people with T2D developing CKD. China is the country with the largest number of adults with diabetes, with an estimated 140 million people living with diabetes and a further estimated 73 million people with undiagnosed diabetes. The prevalence of T2D has been increasing dramatically in China. As China also carries the highest burden of

diabetes-related CKD worldwide, CKD associated with type 2 diabetes has become one of the most important health crises in China.

“With the approval of Kerendia, we have reached a critical milestone to change the treatment paradigm for the millions of people living with chronic kidney disease associated with type 2 diabetes in China,” said Dr. Michael Devoy, Chief Medical Officer and Head of Medical Affairs and Pharmacovigilance at Bayer’s Pharmaceuticals Division. “We are proud soon to be able to offer physicians a new, disease-modifying intervention improving patients’ outcomes, by delaying their chronic kidney disease progression.”

Finerenone offers an alternative pathway to treating chronic kidney disease by blocking mineralocorticoid receptor (MR) overactivation, which contributes to CKD progression and cardiovascular damage.

In Japan, Kerendia obtained approval by the Japanese Ministry of Health, Labour, and Welfare (MHLW) based on the results of both pivotal Phase III studies with finerenone in CKD and T2D in March 2022. Based on the results of the FIDELIO-DKD Phase III study, Kerendia was granted marketing authorization in the European Union in February 2022 and was approved by the U.S. Food and Drug Administration (FDA) in July 2021. Further regulatory approvals by other health authorities in multiple other countries have been granted or are currently pending following submissions for marketing authorization.

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.

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, 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 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 in reducing the risk of chronic kidney disease progression as well as fatal and nonfatal CV events and insights into the relationship between CKD stage (based on baseline KDIGO [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 February 2022, Bayer announced the initiation of the CONFIDENCE study, a Phase II, three-arm study that will investigate simultaneous initial combination therapy with finerenone and the SGLT2 inhibitor empagliflozin, compared with finerenone alone and empagliflozin alone respectively in patients with chronic kidney disease (CKD) and type 2 diabetes (T2D). The primary objective of the study is to demonstrate that the simultaneous initiation and combined use of finerenone and empagliflozin is superior to either empagliflozin alone, or finerenone alone, in reducing urine albumin-to-creatinine ratio (UACR).

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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