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News Release

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U.S. FDA approves finerenone for the treatment of patients with chronic kidney disease associated with type 2 diabetes

- Finerenone is the first non-steroidal, selective mineralocorticoid receptor (MR) antagonist to demonstrate positive kidney and cardiovascular outcomes in patients with chronic kidney disease associated with type 2 diabetes
- Despite guideline-directed therapies, many patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D) still progress to loss of kidney function and are at high risk for cardiovascular events
- By blocking MR overactivation, a key driver of CKD progression, finerenone works on a pathway largely unaddressed by existing treatments for CKD in T2D

Berlin, July 9th, 2021 – Bayer announced today that the U.S. Food and Drug Administration (FDA) has approved finerenone, the first non-steroidal, selective mineralocorticoid receptor (MR) antagonist, under the brand name Kerendia®. Finerenone 10 mg or 20 mg is indicated to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D).

The approval of finerenone by the FDA is based on the positive results of the pivotal Phase III FIDELIO-DKD study, presented at the American Society of Nephrology's (ASN) Kidney Week Reimagined 2020 and simultaneously published in the *New England Journal of Medicine* in October 2020, and follows Priority Review designation granted by the FDA in January 2021.

"There are more than 160 million patients living with CKD and T2D worldwide. Even when blood glucose levels and blood pressure are well-controlled, patients still remain at risk of

CKD progression. This means there is a high unmet medical need for early intervention to prevent further end-organ damage and premature death by slowing patients' rate of decline in kidney function as well as reducing cardiovascular risk," said Professor George L. Bakris, MD, Department of Medicine, American Heart Association Comprehensive Hypertension Center, University of Chicago Medicine, USA and principal investigator of the FIDELIO-DKD trial. "The approval of finerenone offers a new path to protect patients from further kidney damage through addressing MR overactivation, a key driver of CKD progression, which is unaddressed by currently available therapies."

Chronic kidney disease (CKD) is a common and potentially deadly condition that is generally underrecognized. CKD can shorten life expectancy of patients with type 2 diabetes by up to 16 years, relative to the general population living without either disease. Up to 40% of all patients with type 2 diabetes develop chronic kidney disease. In T2D, mineralocorticoid receptor (MR) overactivation is thought to contribute to CKD progression which can be driven by metabolic, haemodynamic or inflammation and fibrosis factors.

"The Phase III FIDELIO-DKD trial is the first large contemporary positive outcomes study in patients with chronic kidney disease (CKD) and type 2 diabetes (T2D) with a primary composite endpoint consisting exclusively of kidney-specific outcomes. It is also part of the largest global Phase III clinical trial program to date in CKD and T2D," said Dr. Michael Devoy, Chief Medical Officer and Head of Medical Affairs and Pharmacovigilance at Bayer's Pharmaceuticals Division. "With our longstanding expertise in innovative science in the cardiovascular space, today's approval of finerenone marks an important milestone in Bayer's commitment to improving the lives of patients with kidney and cardiovascular diseases."

Finerenone has also been submitted for marketing authorization in the European Union (EU) and in China, as well as multiple other countries worldwide and these applications are currently under review.

About Finerenone

Finerenone (BAY 94-8862) is a novel, non-steroidal, selective antagonist of the mineralocorticoid receptor (MR) that has been shown to block harmful effects of mineralocorticoid receptor (MR) overactivation. In T2D, MR overactivation is thought to contribute to CKD progression and cardiovascular damage which can be driven by

metabolic, haemodynamic or inflammation and fibrosis factors.

Having randomized more than 13,000 patients with CKD and T2D around the world, the Phase III programme with finerenone in CKD and T2D comprises two 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. Based on the positive data from FIDELIO-DKD, the U.S. FDA has approved finerenone for marketing authorization in the U.S. Finerenone has been submitted for marketing authorization in the EU and other countries worldwide based on the positive data from FIDELIO-DKD.

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 across 47 countries including sites in Europe, Japan, China and the U.S. The study met its primary endpoint. The clinical data from FIGARO-DKD are scheduled for presentation at the European Society of Cardiology (ESC) Congress 2021 on August 28th.

Bayer also recently 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 symptomatic heart failure patients (New York Heart Association class II-IV) with 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).

About Chronic Kidney Disease in Type 2 Diabetes

Chronic kidney disease (CKD) is a potentially deadly condition that is generally underrecognized. 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 CKD. 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. CKD in T2D is the main cause of end stage kidney disease, which requires dialysis or a kidney transplant to stay alive.

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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Forward-Looking Statements
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