Bayer AG
Communications
51368 Leverkusen
Germany
Phone +49 214 30-1
media.bayer.com

News Release

Not intended for U.S. and UK Media

Bayer receives approval in Japan for Kerendia™ (finerenone), a new treatment for adults with chronic kidney disease and type 2 diabetes

- Despite available treatment options, many patients with chronic kidney disease (CKD) and type 2 diabetes (T2D) are progressing to kidney failure or 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 and T2D
- The approval is based on the results of the Phase III studies FIDELIO-DKD and FIGARO-DKD, investigating the efficacy and safety of finerenone on both kidney and cardiovascular outcomes in patients with CKD and T2D

Berlin, March 28, 2022 – Bayer announced today that the Japanese Ministry of Health, Labour, and Welfare (MHLW) 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 approved for the treatment of chronic kidney disease and type 2 diabetes, excluding patients with end-stage renal disease or on dialysis. The approval is based on the results of the pivotal Phase III studies, FIDELIO-DKD and FIGARO-DKD. The FIDELIO-DKD study was presented at the American Society of Nephrology's (ASN) Kidney Week 2020; the FIGARO-DKD study was presented at ESC Congress 2021. Both studies were published in the *New England Journal of Medicine* simultaneously with the congress presentations in October 2020 and August 2021, respectively.

In Japan, an estimated 13.3 million people have chronic kidney disease (CKD), a common and potentially deadly condition that is widely underrecognized. Type 2 diabetes and high blood pressure are the most common causes of CKD. Up to 40% of people with

T2D will develop CKD. Finerenone is different to existing CKD in T2D treatments. It acts by blocking mineralocorticoid receptor (MR) overactivation, which contributes to CKD progression and cardiovascular damage.

“There is a high burden of type 2 diabetes in Japan, and a large proportion of people with type 2 diabetes develop chronic kidney disease. Despite well-controlled blood glucose levels and blood pressure, patients with chronic kidney disease and type 2 diabetes remain at risk of chronic kidney disease progression and cardiovascular death,” said Dr. Michael Devoy, Chief Medical Officer and Head of Medical Affairs and Pharmacovigilance at Bayer’s Pharmaceuticals Division. “We look forward to providing patients and physicians in Japan with a new treatment option to delay kidney disease progression and reduce the risk of cardiovascular events. The approval of finerenone offers a new path to protect patients from further kidney and cardiovascular damage through addressing MR overactivation, a key driver of CKD progression, which is unaddressed by currently available therapies.”

Based on the positive 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. Finerenone has also been submitted for marketing authorization in multiple other countries worldwide and these applications are currently under review.

About Kerendia® (finerenone)
Kerendia is a non-steroidal, selective mineralocorticoid receptor (MR) antagonist that has been shown to block harmful effects of MR overactivation. In T2D, 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 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 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 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 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.

Contact for media inquiries:
Dr. Daniela Esser, phone +49 30 468-15805
Email: daniela.esser@bayer.com

Contact for investor inquiries:
Bayer Investor Relations Team, phone +49 214 30-72704
Email: ir@bayer.com
www.bayer.com/en/investors/ir-team

Find more information at https://pharma.bayer.com/
Follow us on Facebook: http://www.facebook.com/bayer
Follow us on Twitter: @BayerPharma

de (2022-0050E)