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News Release

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Late-breaking data from the prespecified pooled analysis FIDELITY presented at the European Society of Cardiology (ESC) Congress 2022

New data indicate positive effects of Kerendia™ (finerenone) on mortality in patients with chronic kidney disease and type 2 diabetes

- Data from FIDELITY, a prespecified pooled analysis of the Phase III FIDELIO-DKD and FIGARO-DKD studies, highlight the potential of Kerendia™ (finerenone) to reduce the incidence of sudden cardiac death
- While in the overall FIDELITY population, the effect of finerenone on all-cause and CV mortality narrowly missed statistical significance, new data from a prespecified on-treatment analysis from FIDELITY indicate that both of these outcomes were reduced with finerenone versus placebo in this population
- Patients with chronic kidney disease (CKD) and type 2 diabetes (T2D) are approximately three times more likely to die from a cardiovascular-related cause than those with T2D alone

Berlin, August 29, 2022 – Late-breaking data presented today at the European Society of Cardiology Congress 2022 highlight the potential of Kerendia™ (finerenone), compared to placebo, to significantly reduce the incidence of sudden cardiac death across a broad range of patients with early to late-stage chronic kidney disease (CKD) and type 2 diabetes (T2D).

While in the overall population of FIDELITY the effect of finerenone on all-cause and CV mortality narrowly missed statistical significance, new data from a prespecified exploratory on-treatment analysis from FIDELITY indicate that both of these outcomes were reduced with finerenone versus placebo in this population. The positive effect of finerenone on all mortality outcomes was consistent across a broad range of patients with early to late-stage chronic kidney disease and type 2 diabetes, regardless of baseline eGFR or UACR

values, and appeared to be more pronounced in patients with a higher baseline eGFR. CV mortality was the most common cause of mortality in the study.

“Chronic kidney disease is a common yet widely underrecognized and potentially deadly condition. Chronic kidney disease can shorten life expectancy of patients with diabetes by up to 16 years, relative to the general population living without either disease,” said Gerasimos Filippatos, M.D., Professor of Cardiology at the National and Kapodistrian University of Athens, Greece, and co-principal investigator of the FIDELIO-DKD and FIGARO-DKD Phase III clinical trials. “Building on the growing body of clinical evidence for finerenone, which demonstrated the benefit of this treatment on renal and cardiovascular outcomes, these new data highlight the positive effects of finerenone on morbidity and mortality across a broad range of disease severities in patients with chronic kidney disease and type 2 diabetes.”

The mean age of the FIDELITY population was 64.8 years, and 69.8% of patients were male. At baseline, patients had a mean eGFR of 57.6 ml/min/1.73 m^2 and the median UACR was 515 mg/g. CV medications were used by most patients (99.8% on a renin-angiotensin system (RAS)-blocking therapy, 72.2% on statins and 49.9% on beta-blockers). In the overall population, the incidence of all-cause mortality was 8.5% with finerenone vs 9.4% with placebo (HR 0.89 [95% CI: 0.79- >1.00]; p=0.051). CV mortality was reported as the most common cause of death (4.9% with finerenone vs 5.6% with placebo), followed by mortality caused by infection (1.5% with finerenone vs 1.4% with placebo) and malignancy (1.2% with finerenone vs 1.6% with placebo).

Finerenone was found to significantly reduce sudden cardiac death vs placebo (HR 0.75 [95% CI: 0.57- <1.00]; p=0.046). Prespecified on-treatment analyses revealed significant reductions in the incidence of all-cause mortality with finerenone vs placebo (HR 0.82 [95% CI 0.70-0.96]; p=0.014) and the incidence of CV mortality with finerenone vs placebo (HR 0.82 [95% CI 0.67-0.99]; p=0.040). Event probability analyses for time to CV mortality at year 4 showed that the benefit of finerenone was consistent irrespective of baseline eGFR and UACR, and a more pronounced effect was observed with finerenone vs placebo in patients with an eGFR of ≥60 ml/min/1.73m^2.

“Despite optimized blood glucose and blood pressure control, many patients with chronic kidney disease and type 2 diabetes continue to progress to kidney failure and are at a significantly increased risk of cardiovascular death,” said Dr. Christian Rommel, Member

of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Research and Development. “The exploratory analysis presented demonstrates the potential of finerenone to reduce the risk of mortality amongst this vulnerable patient population, and keep them healthier for longer.”

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. 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.

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 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 approximately 6000 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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