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News Release

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Late-breaking data presented at the American Society of Nephrology (ASN) Kidney Week 2023

New Kerendia™ (finerenone) data show impact of early albuminuria reduction in patients with chronic kidney disease and type 2 diabetes

- Late-breaking data from an analysis of FIDELITY show early albuminuria reduction after four months of finerenone treatment has an impact on long-term kidney outcomes
- Based on a patient cohort of more than 12,500 individuals, this comprehensive analysis demonstrates that the treatment effect of finerenone on kidney outcomes is primarily mediated by early urine albumin-to-creatinine ratio (UACR) reduction in patients with chronic kidney disease (CKD) and type 2 diabetes (T2D)
- FIDELITY, a prespecified pooled analysis including the FIDELIO-DKD and FIGARO-DKD studies, comprises the largest Phase III cardiorenal outcomes clinical trial program to investigate the efficacy of finerenone in delaying the progression of kidney disease as well as in reducing the risk for fatal and nonfatal cardiovascular (CV) events in >13,000 patients with CKD and T2D

Berlin, November 2, 2023 – Bayer announced today new late-breaking Kerendia™ (finerenone) data from FIDELITY, a prespecified pooled analysis of the Phase III FIDELIO-DKD and FIGARO-DKD trials, confirming that early albuminuria reduction in patients with chronic kidney disease (CKD) in type 2 diabetes (T2D) mediated a large proportion of the treatment effect against CKD progression. Findings also demonstrate a notable, albeit modest, correlation between early albuminuria reduction and improved cardiovascular (CV) outcomes. The analyses, based on pooled data from more than 12,500 patients, were presented today at the American Society of Nephrology's (ASN) Kidney Week 2023.

“The latest analyses from FIDELITY are of great reassurance to the clinical community, confirming the impact of early UACR reduction with finerenone treatment on long-term outcomes of patients with chronic kidney disease and type 2 diabetes,” said Rajiv Agarwal, MD, Professor of Medicine, Indiana University School of Medicine and VA Medical Centre, Indianapolis, USA and Co-Chair of the FIDELIO-DKD and FIGARO-DKD Steering Committee. “Chronic kidney disease is a progressive condition, significantly impacting patients’ lives as the disease advances. Reducing the urine albumin-to-creatinine ratio as early as possible to reduce the risk of kidney and cardiovascular outcomes is vital.”

The post hoc mediation analysis used data from the pooled analysis FIDELITY to quantify finerenone-induced kidney and CV risk reductions over a 4-year period, compared to placebo, mediated by change in urine albumin-to-creatinine ratio after 4 months of treatment. To measure the mediated effect of UACR reduction, causal mediation analyses were conducted, separating composite kidney (kidney failure, sustained ≥57% decrease in estimated glomerular filtration rate from baseline, or kidney death) and CV outcomes (CV death, nonfatal myocardial infarction, nonfatal stroke, or hospitalization for heart failure).

The analysis showed that UACR reduction, analyzed as a continuous variable, mediated 83% and 36% of the treatment effect of finerenone on the kidney and CV outcomes, respectively.

“It is good news to see that early UACR reduction with finerenone translates especially into a reduction of kidney complications,” said Dr. Christian Rommel, Member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Research and Development. “At Bayer, our commitment to improve the long-term outcomes of patients in need of innovative treatments is unwavering. The new findings help underscore the important role finerenone can play in improving the lives of people living with chronic kidney disease associated with type 2 diabetes.”

About Kerendia™ / Firialta™ (finerenone)

Kerendia™ and Firialta™ are globally protected trademarks for finerenone. Finerenone 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.

Finerenone is marketed as Kerendia™ or, in some countries, as Firialta™, and approved for the treatment of adult patients with chronic kidney disease associated with type 2 diabetes (T2D) in more than 80 countries worldwide, including in China, Europe, Japan, and the U.S.

The study program with finerenone, FINEOVATE, currently comprises ten Phase III studies with dedicated programs in heart failure and chronic kidney disease, respectively. The THUNDERBALL chronic kidney disease program consists of FIDELIO-DKD, FIGARO-DKD, FIND-CKD, FIONA, FIONA-OLE, FINE-ONE, as well as the Phase II study CONFIDENCE. The MOONRAKER program includes FINEARTS-HF, REDEFINE-HF, CONFIRMATION-HF, and FINALITY-HF.

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 kidney and CV-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 (T2D) 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

190 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. Patients with CKD and T2D are three times more likely to die from a cardiovascular-related cause than those with T2D 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 2022, the Group employed around 101,000 people and had sales of 50.7 billion euros. R&D expenses before special items amounted to 6.2 billion euros. For more information, go to www.bayer.com.

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Forward-Looking Statements
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