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News Release

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The American Society of Nephrology (ASN)'s Kidney Week 2021:

New data from finerenone clinical trial program reinforces renal and cardiovascular benefits in patients with CKD and T2D independent of baseline therapy

- Exploratory analysis of the FIGARO-DKD study with finerenone, a non-steroidal, selective mineralocorticoid receptor antagonist, indicated a reduction in renal outcomes in patients with chronic kidney disease (CKD) and type 2 diabetes (T2D), as seen in the FIDELIO-DKD study
 - Analysis of the FIDELIO-DKD study highlighted that early reduction of urine albumin-to-creatinine ratio (UACR) with finerenone reduced the risk of cardiovascular events and of disease progression of CKD, underpinning the importance of timely intervention in patients with CKD and T2D
 - Data from prespecified pooled analysis FIDELITY of more than 13,000 patients from the Phase III studies FIGARO-DKD and FIDELIO-DKD underscore the potential benefit of finerenone across the disease spectrum, and irrespective of concomitant treatment with SGLT2 inhibitors in patients with CKD and T2D
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Berlin, November 8, 2021 – New data analyses of the comprehensive finerenone clinical trial program, including the pivotal Phase III studies FIGARO-DKD and FIDELIO-DKD and the pre-specified pooled analysis FIDELITY reinforce the renal and cardiovascular (CV) benefits of finerenone, the first non-steroidal, selective mineralocorticoid receptor (MR) antagonist, in patients with chronic kidney disease (CKD) and type 2 diabetes (T2D). Data from the analyses were presented at the American Society of Nephrology (ASN)'s Kidney Week 2021 in two oral presentations and two late-breaking posters.

In the FIGARO-DKD study, presented at ESC Congress 2021 and published in the *New England Journal of Medicine*, the incidence of the first secondary endpoint, a composite of time to kidney failure, a sustained decrease of estimated glomerular filtration rate (eGFR) $\geq 40\%$ from baseline over a period of at least four weeks, or renal death occurred in 350 (9.5%) patients in the finerenone arm and 395 (10.8%) patients in the placebo arm; this narrowly missed statistical significance (HR 0.87 [95% CI: 0.76-1.01]; $p=0.0689$) over a median duration of follow-up of 3.4 years. In the oral session presented at ASN's Kidney week on an exploratory analysis of the FIGARO-DKD study data in patients with CKD stages 1–4 with moderate-to-severely elevated albuminuria, it was seen that finerenone reduced the risk for the $\geq 40\%$ and $\geq 57\%$ estimated glomerular filtration rate (eGFR) kidney composite outcomes, which was generally consistent with the benefit seen in FIDELIO-DKD. The effect of finerenone on the composite kidney outcomes was reflected by a 36% relative risk reduction of end-stage kidney disease (ESKD). ESKD occurred in 0.9% of finerenone versus 1.3% placebo recipients (HR=0.64; 95% CI 0.41-0.995; $p=0.046$).

An analysis of the FIDELIO-DKD study, presented as a late-breaking poster, evaluated the association between urine albumin-to-creatinine ratio (UACR) change and CV and renal protection in patients with CKD and T2D. Compared to FIGARO-DKD, FIDELIO-DKD included more patients with advanced chronic kidney disease. The data demonstrate that finerenone reduced the risk of the CV composite outcome (time to CV death, non-fatal MI, nonfatal stroke or heart failure hospitalization) and the kidney composite outcome (time to kidney failure, sustained $\geq 40\%$ decrease in eGFR ≥ 4 weeks from baseline, or renal death), early but also irrespective of a change in UACR from baseline to month four.

“More needs to be done to slow the progression of chronic kidney disease (CKD) secondary to type 2 diabetes (T2D). It is the most common cause of end-stage kidney disease (ESKD) worldwide,” 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 results presented at ASN from FIDELIO-DKD and FIGARO-DKD, and specifically from the FIDELITY pooled analysis of these trials, clearly demonstrate the potential to improve outcomes in patients through timely detection and monitoring of the earliest signs of chronic kidney disease. Moreover, they underscore finerenone as a potential effective treatment option to improve cardiovascular and kidney outcomes across a broad range of

patients, including those with early kidney damage and more advanced stages of CKD and T2D.”

Results from FIDELITY, a prespecified pooled analysis of more than 13,000 patients from the Phase III studies FIGARO-DKD and FIDELIO-DKD, were presented as a late-breaking poster at Kidney Week 2021, further demonstrating the renal and CV benefits of finerenone across the spectrum of CKD severity in patients with T2D. The results show that finerenone consistently reduced the risk of the kidney composite outcome (time to kidney failure, sustained $\geq 57\%$ decrease in eGFR from baseline, or renal death) by 23% (HR=0.77; 95% CI 0.67–0.88; $p=0.0002$), and the risk of ESKD by 20% (HR=0.80; 95% CI 0.64–0.99; $p=0.040$). Safety was also shown to be similar between finerenone and placebo groups, with renal adverse events (AEs) balanced between treatment groups and low discontinuation in the finerenone group as a result of hyperkalemia AEs.

Additional data from the pre-specified pooled analysis FIDELITY were provided in an oral presentation, showing that irrespective of SGLT2i use at baseline, finerenone demonstrated consistent kidney and CV benefits versus placebo, and reduced UACR in patients with CKD and T2D (32% vs 37%, respectively).

Preclinical data indicate that combination therapy with finerenone and an SGLT2i has benefits over respective monotherapy. In the prespecified pooled analysis FIDELITY, patients treated with an SGLT2i at baseline had higher mean eGFR, lower UACR and higher statin and GLP-1RA use. The new analysis shows consistent kidney and CV benefits of finerenone versus placebo, and an improvement of UACR in patients with CKD and T2D, irrespective of baseline treatment with an SGLT-2i.

“Sadly, despite existing treatments, many patients with chronic kidney disease and type 2 diabetes are often still progressing to kidney failure or premature death. There is an urgent need for new treatments that can help to slow down the progression of disease in these vulnerable patients,” said Professor Peter Rossing, Head of Complications Research at Steno Diabetes Center Copenhagen. “Finerenone is different to existing treatments as it blocks mineralocorticoid receptor overactivation, a key driver of kidney disease progression. The analysis of FIDELITY underscores the potential role of finerenone alongside current treatment options to help ease patients’ disease burden.”

About Finerenone

Finerenone (BAY 94-8862) is a non-steroidal, selective mineralocorticoid receptor (MR)

antagonist that in preclinical studies has been shown to block harmful effects of MR overactivation. In T2D, MR overactivation is thought to contribute to CKD progression and cardiovascular damage which can be driven by metabolic, hemodynamic or inflammatory and fibrotic factors. The Phase III study program with finerenone, FINEOVATE, currently comprises four Phase III studies: FIDELIO-DKD, FIGARO-DKD, FINEARTS-HF and FIND-CKD.

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 studies, evaluating the effect of finerenone versus placebo on top of standard of care on both renal and cardiovascular outcomes. FIDELIO-DKD (**F**inerenone in reducing **kiDnEy** fai**L**ure and **d**isease **prO**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 (**F**inerenone 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.

In September 2021, Bayer announced the initiation of the FIND-CKD study, a multicenter, randomized, double-blind, placebo-controlled Phase III study which will investigate finerenone in patients with non-diabetic chronic kidney disease. FIND-CKD will 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). The primary outcome measure is the mean rate of change in kidney function over time (estimated glomerular filtration rate, eGFR slope) from baseline to month 32.

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 $\geq 40\%$. 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 July, finerenone was approved under the brand name Kerendia® by the United States (U.S.) Food and Drug Administration (FDA) based on the positive results of the FIDELIO-DKD Phase III study. Finerenone has also been submitted for marketing authorization in the European Union (EU) and China, as well as multiple other countries worldwide and these applications are currently under review.

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 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 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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