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News Release

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Data from Phase III study FIGARO-DKD and from FIDELITY, a prespecified meta-analysis of FIGARO-DKD and FIDELIO-DKD, presented at ESC Congress 2021

New Data on Finerenone for the protection of patients with chronic kidney disease and type 2 diabetes from cardiovascular events and kidney disease progression

- FIGARO-DKD detailed study results confirmed the cardiovascular benefits of finerenone as demonstrated in the FIDELIO-DKD study, focusing on chronic kidney disease (CKD) and type 2 diabetes (T2D) across a broad range of disease severity, including patients with stages 1-4 CKD and T2D
 - Results from the FIGARO-DKD study were simultaneously published in the [New England Journal of Medicine](#)
 - Results from FIDELITY, a prespecified meta-analysis of more than 13,000 patients from the Phase III studies FIGARO-DKD and FIDELIO-DKD demonstrated kidney and cardiovascular benefits of finerenone in patients with CKD and T2D
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Berlin, August 28, 2021 – Detailed results from the Phase III FIGARO-DKD study demonstrate that compared to placebo in addition to standard of care, the investigational drug finerenone, a non-steroidal, selective mineralocorticoid receptor (MR) antagonist, reduced the risk of cardiovascular (CV) outcomes in a broad population of patients with stages 1-4 chronic kidney disease (CKD) and type 2 diabetes (T2D).

Finerenone significantly reduced the risk of the composite primary endpoint of time to first occurrence of CV death or non-fatal myocardial infarction, non-fatal stroke, or heart failure hospitalization by 13% (relative risk reduction, HR 0.87 [95% CI: 0.76-0.98]; p=0.0264) over a median duration of follow-up of 3.4 years versus placebo when added to maximum tolerated dose of guideline-directed therapy. In the FIGARO-DKD study, finerenone was well-tolerated, which is consistent with the safety profile seen in previous studies. The FIGARO-DKD study adds significant evidence of the CV benefits of finerenone across a

broader patient population, building on the FIDELIO-DKD study which demonstrated that finerenone improved the primary composite kidney endpoint and the key secondary composite CV endpoint in patients with predominantly stages 3-4 CKD and severely elevated albuminuria.

The findings from the FIGARO-DKD study were presented today during a Hot Line session at ESC Congress 2021, and simultaneously published in the [*New England Journal of Medicine*](#).

“The unfortunate reality is that patients living with chronic kidney disease and type 2 diabetes are three times more likely to die from a cardiovascular event than those with type 2 diabetes alone, so early diagnosis and treatment is important to reduce the high cardiovascular and heart failure burden in these patients,” said Professor Bertram Pitt, Professor of Medicine Emeritus at the University of Michigan School of Medicine in Ann Arbor, and co-principal investigator of the FIGARO-DKD clinical trial. “The FIGARO-DKD study demonstrated cardiovascular benefits of finerenone across a wide range of patients, including those with earlier stages of chronic kidney disease.”

The study showed that the effects of finerenone on the primary outcome were generally consistent across pre-specified subgroups, including baseline estimated glomerular filtration rate (eGFR) and urine albumin-to-creatinine ratio (UACR) categories. Patients in both groups received standard of care, including blood glucose lowering therapies and a maximum tolerated dose of a renin-angiotensin system (RAS)-blocking therapy such as an angiotensin-converting enzyme (ACE) inhibitor or an angiotensin II receptor blocker (ARB).

Also presented during the Hotline session at ESC were data from FIDELITY, a prespecified meta-analysis of more than 13,000 patients from the Phase III studies FIGARO-DKD and FIDELIO-DKD. The results demonstrated cardiovascular and renal benefits of finerenone in patients with CKD and T2D. In the FIDELITY analysis, finerenone reduced the risk of the composite CV outcome of time to CV death, non-fatal myocardial infarction, non-fatal stroke or hospitalisation for heart failure by 14% compared to placebo (HR:0.86 [95% CI: 0.78–0.95]; p=0.0018). The risk of the composite kidney outcome of time to first onset of kidney failure, sustained $\geq 57\%$ decrease in eGFR from baseline over ≥ 4 weeks, or renal death was 23% lower with finerenone versus placebo

(HR: 0.77 [95% CI: 0.67–0.88]; p=0.0002). A kidney outcome event occurred in 360 (5.5%) patients receiving finerenone and 465 (7.1%) receiving placebo.

“Despite current treatment options, patients remain at high risk of progression to kidney failure and cardiovascular events,” said Professor 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. “The data from the meta-analysis also highlight the importance of detecting kidney damage early to slow CKD progression and prevent poor patient outcomes. This can only be achieved through regular monitoring of albuminuria to spot earliest signs of kidney damage.”

“The new data presented today provide further insights into the potential of finerenone to delay chronic kidney disease progression and reduce the risk of cardiovascular events in these vulnerable patients,” said Dr. Christian Rommel, Member of the Executive Committee of Bayer AG’s Pharmaceutical Division and Head of Research and Development.

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 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 programme with finerenone, FINEOVATE, currently comprises three Phase III studies, FIDELIO-DKD, FIGARO-DKD, and FINEARTS-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 studies, evaluating the

effect of finerenone versus placebo on top of standard of care on both renal and cardiovascular outcomes. FIDELIO-DKD (Finerenone in reducing kidney failure and disease progression in Diabetic Kidney Disease) 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 (Finerenone in reducing cardiovascular mortality and morbidity in Diabetic Kidney Disease) 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 48 countries including sites in Europe, Japan, China and the U.S. Finerenone 10 mg or 20 mg orally once daily when added to standard of care, including blood glucose lowering therapies and a maximum tolerated dose of a RAS-blocking therapy such as an angiotensin-converting enzyme (ACE) inhibitor or an angiotensin II receptor blocker (ARB), significantly reduced the combined risk of time to cardiovascular death, non-fatal myocardial infarction, non-fatal stroke or hospitalization for heart failure compared to placebo by 13% (relative risk reduction, HR 0.87 [95% CI: 0.76-0.98]; $p=0.0264$) over a median duration of follow-up of 3.4 years. At 42 months, the number needed to treat (NNT) to prevent a primary composite endpoint was 47. The incidences of the primary endpoint components of CV death (HR 0.90 [95% CI: 0.74-1.09]) and heart failure hospitalization (HR 0.71 [95% CI: 0.56-0.90]) were lower with finerenone than placebo, whereas non-fatal myocardial infarction (HR 0.99 [95% CI: 0.76-1.31]) and non-fatal stroke (HR 0.97 [95% CI: 0.74-1.26]) were balanced between groups.

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. Therefore, subsequent hierarchical outcomes are exploratory. The incidences of each of the first secondary outcome components were lower with finerenone than with placebo: kidney failure: HR 0.72 [95% CI: 0.49-1.05]; sustained decrease of eGFR $\geq 40\%$ from baseline over a period of at least four weeks: HR 0.87 [95% CI: 0.75-1.00]. End-stage kidney disease occurred in 32 (0.9%) and 49 (1.3%) patients in the finerenone and placebo groups, respectively (HR 0.64 [95% CI: 0.41-

0.995]). With respect to other secondary outcomes, the composite of kidney failure, sustained decrease in eGFR by 57% or more from baseline, or renal death occurred in 108 (2.9%) and 139 (3.8%) patients in the finerenone and placebo groups, respectively (HR 0.77 [95% CI: 0.60–0.99]).

In the FIGARO-DKD study, finerenone was well-tolerated, which is consistent with the safety profile seen in previous studies with finerenone. Overall treatment-emergent adverse events and serious adverse events were similar between groups. The majority of adverse events were mild or moderate. The frequency of serious adverse events was lower in patients treated with finerenone (31.4%) compared to placebo (33.2%). Overall, hyperkalemia-related adverse events occurred more often in patients receiving finerenone compared with placebo (10.8% and 5.3%, respectively). Hyperkalemia-related serious adverse events were low (0.7% and 0.1%, respectively), and there was no hyperkalemia-related death in either treatment group. Treatment was discontinued due to hyperkalemia in 1.2% of patients treated with finerenone compared to 0.4% in the placebo group.

FIDELITY (Finerenone in chronic kidney disease and type 2 diabetes: Combined FIDELIO-DKD and FIGARO-DKD Trial programme analysis), including the FIDELIO-DKD and FIGARO-DKD studies, comprises the largest Phase III cardiorenal outcomes clinical trial programme to evaluate the occurrence of progression of kidney disease as well as fatal and nonfatal CV events in >13,000 patients with CKD and T2D. The prespecified FIDELITY meta-analysis investigated the efficacy and safety of finerenone across the spectrum of patients with CKD in T2D and provide 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. Finerenone reduced the risk of experiencing the composite CV outcome of time to CV death, non-fatal myocardial infarction, non-fatal stroke or hospitalisation for heart failure by 14% compared with placebo (HR: 0.86 [95% CI: 0.78–0.95]; $p=0.0018$), with a number needed to treat of 46 at 36 months. Regarding the components of the composite CV outcome, lower incidences of cardiovascular death and hospitalization for heart failure were observed with finerenone versus placebo (HR: 0.88 [95% CI: 0.76–1.02]; and HR: 0.78 [95% CI: 0.66–0.92], respectively).

The risk of the composite kidney outcome of time to first onset of kidney failure, sustained $\geq 57\%$ decrease in eGFR from baseline over ≥ 4 weeks, or renal death was 23% lower with finerenone than placebo (HR: 0.77 [95% CI: 0.67–0.88]; $p=0.0002$). A kidney outcome

event occurred in 360 (5.5%) patients receiving finerenone and 465 (7.1%) receiving placebo. All components of the composite kidney outcome were significantly lower with finerenone than placebo, including end stage kidney disease, with the exception of renal death for which there were too few events.

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 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).

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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