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News Release

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Late-Breaking Data from exploratory analysis of Phase III FIDELIO-DKD study presented at the American College of Cardiology's (ACC) 70th Annual Scientific Session (ACC.21)

Finerenone has potential to reduce the risk of new onset atrial fibrillation or flutter in patients with chronic kidney disease and type 2 diabetes

- A prespecified exploratory analysis of the FIDELIO-DKD study demonstrates that finerenone may significantly reduce the risk of new onset atrial fibrillation or flutter (AFF) in patients with CKD and T2D versus placebo when added to standard of care
 - This analysis also concluded that finerenone reduced the risk of kidney or cardiovascular events with no significant difference in the effect of finerenone between patients with and without history of AFF at baseline
 - Based on the comprehensive finerenone clinical trial program, finerenone is the first investigational non-steroidal, selective mineralocorticoid receptor (MR) antagonist to demonstrate cardiovascular and renal benefits in patients with chronic kidney disease and type 2 diabetes
 - Results from the exploratory analysis were simultaneously published in the *Journal of the American College of Cardiology*
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Berlin, May 17, 2021 – Late-breaking data from a prespecified exploratory analysis of the Phase III FIDELIO-DKD study indicate that compared to placebo when added to standard of care, finerenone may significantly reduce the risk of new onset atrial fibrillation or flutter (AFF) in patients with chronic kidney disease (CKD) and type 2 diabetes (T2D). The analysis also showed that finerenone reduced the risk of the combined primary and the combined key secondary endpoint in the study compared to placebo with no significant difference between patients with and without history of AFF at baseline.

The exploratory analysis was today presented as a late-breaker at the American College of Cardiology's (ACC) 70th Annual Scientific Session and simultaneously published in the *Journal of the American College of Cardiology (JACC)*.

The results indicated that the prevalence of AFF was lower with finerenone compared with placebo (120 [4.2%] patients vs. 153 [5.4%] patients, respectively). The incidence for adjudicated new-onset AFF in patients without a history of AFF was significantly lower with finerenone than with placebo (82/2,593 [3.2%] vs. 117/2,620 [4.5%] patients, respectively; incidence per 100 patient-years: 1.20 and 1.72, respectively; HR: 0.71; 95% CI: 0.53 to 0.94; $p = 0.0164$).

For the effect of finerenone on the overall incidence of the primary kidney outcome (composite of time to kidney failure, a sustained $\geq 40\%$ decrease in eGFR from baseline, or renal death), there was no significant difference in the effect of finerenone between patients with and without a history of AFF (HR: 1.13; 95% CI: 0.71 to 1.79 and HR: 0.81; 95% CI: 0.71 to 0.91, respectively; p value for interaction: 0.16). For the key secondary endpoint, a composite of time to cardiovascular death, non-fatal myocardial infarction, non-fatal stroke or hospitalization for heart failure compared to placebo, the effect of finerenone was found to be consistent for patients with and without a history of AFF (HR: 0.88; 95% CI: 0.62 to 1.24 and HR: 0.85; 95% CI: 0.73 to 0.99, respectively; p value for interaction: 0.85).

"Patients with chronic kidney disease and type 2 diabetes are at a significantly increased risk of atrial fibrillation, which is a major growing health problem, putting patients at a higher risk of heart failure and a 5-fold greater risk of stroke," said Gerasimos Filippatos, M.D., Professor of Cardiology at the National and Kapodistrian University of Athens, Greece, and co-principal investigator of FIDELIO-DKD. "This exploratory analysis deepens our understanding of the potential ability of finerenone to address cardiovascular outcomes by indicating a reduction in the risk of new onset atrial fibrillation or flutter in patients with chronic kidney disease and type 2 diabetes."

"The unfortunate reality is that patients with chronic kidney disease and type 2 diabetes are often characterised by a complex risk profile and are at a three times higher risk of cardiovascular events than those with type 2 diabetes alone. We are delighted to see the potential benefits finerenone is showing in reducing the risk of cardiovascular events in this underserved patient population," said Dr. Christian Rommel, Member of the Executive

Committee of Bayer AG's Pharmaceutical Division and Head of Research and Development. "These results add to the existing body of evidence for finerenone as they shed light on how this potential new treatment option may address unmet needs in cardiovascular and kidney care whilst improving patient outcomes."

The marketing authorization application (MAA) submitted to the EMA, and the new drug application (NDA) accepted by U.S. FDA for Priority Review were based on positive data from the Phase III FIDELIO-DKD study and are currently under review.

About Finerenone

Finerenone (BAY 94-8862) is an investigational novel, non-steroidal, selective mineralocorticoid receptor antagonist (MRA) that has been shown to block many of the harmful effects of mineralocorticoid receptor (MR) overactivation. MR overactivation is a major driver of kidney and heart damage.

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. FIGARO-DKD (**F**inerenone in reducing **C**ardiovascular 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 across 47 countries including sites in Europe, Japan, China and the U.S. The study met its primary endpoint. The clinical data from FIGARO-DKD will be presented at an upcoming scientific meeting. FIDELIO-DKD (**F**inerenone in reducing ki**D**ne**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. Based on the positive data from FIDELIO-DKD, finerenone has been submitted for marketing authorization in the U.S. and the EU and other countries worldwide.

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 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. MR over-activation is known to trigger detrimental processes (e.g. inflammation and fibrosis) in kidneys and heart in patients with CKD and type 2 diabetes (T2D).

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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