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News Release

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Late-Breaking Data from subgroup analysis of Phase III FIDELIO-DKD study presented at the American Heart Association (AHA) Scientific Sessions 2020

Finerenone showed consistent benefits on cardiovascular outcomes in patients with chronic kidney disease and type 2 diabetes with or without history of cardiovascular disease

- In the FIDELIO-DKD Phase III study among patients with chronic kidney disease and type 2 diabetes, overall finerenone significantly lowered the combined risk of cardiovascular events, with comparable treatment efficacy for patients with or without history of cardiovascular disease
- People 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
- Finerenone is a first-in-class investigational non-steroidal, selective mineralocorticoid receptor (MR) antagonist that specifically addresses MR overactivation, a key driver of disease progression

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Berlin, November 17, 2020 – Late-breaking data from the Phase III FIDELIO-DKD study indicate that compared to placebo, finerenone reduced the key secondary composite cardiovascular (CV) endpoint consistently in patients with chronic kidney disease (CKD) and type 2 diabetes (T2D), with or without history of cardiovascular disease. This new subgroup analysis underscores the potential role of finerenone in both primary and secondary CV prevention in these patients.

The prespecified subgroup analysis of FIDELIO-DKD, presented as a late-breaker at the American Heart Association's (AHA) Scientific Sessions 2020, and simultaneously published in *Circulation*, further adds to the recently published results of the FIDELIO-DKD trial, which demonstrated that compared to placebo, finerenone significantly reduced the risk of the key secondary CV endpoint, a composite CV outcome of time to CV death, non-fatal myocardial infarction MI, non-fatal stroke or hospitalization for heart failure by

14%. The overall significant and clinically meaningful effect of finerenone on the hazard ratio of the composite CV outcome was not modified by a history of cardiovascular disease (CVD), (p-value for interaction: 0.85).

- Of the patients with a history of CVD, the composite CV outcome occurred in 231 (17.7%) patients in the finerenone group and 263 (20.2%) patients in the placebo group (incidence rate per 100 patient-years 7.18 and 8.5, respectively; HR 0.85 [95% CI, 0.71–1.02]).

- Of the patients without a history of CVD, the composite CV outcome occurred in 136 (8.9%) patients in the finerenone group and 157 (10.2%) patients in the placebo group (incidence rate per 100 patient-years 3.43 and 3.92, respectively; HR 0.86 [95% CI, 0.68–1.08]).

“Patients with chronic kidney disease and type 2 diabetes are not only at high risk of progression to kidney failure, they are also exposed to a higher risk of cardiovascular events – and face substantial cardiovascular morbidity and mortality,” said Gerasimos Filippatos, M.D., Professor of cardiology at the National and Kapodistrian University of Athens, Greece, and co-principal investigator of FIDELIO-DKD. “These new findings from the FIDELIO-DKD study suggest the potential of finerenone as a new treatment option to reduce the risk of cardiovascular events in a broad range of patients with chronic kidney disease and type 2 diabetes, irrespective of whether patients had a history of cardiovascular disease.”

Results were consistent across subgroups of history of myocardial infarction, ischemic stroke, MI and/or ischemic stroke, coronary artery disease and peripheral artery disease. The overall incidence of treatment-emergent adverse events was similar between the finerenone and the placebo arm, irrespective of CVD history. Overall, finerenone was shown to be well-tolerated. The majority of adverse events were mild or moderate. The frequency of serious adverse events was lower in patients treated with finerenone (31.9%) compared to placebo (34.3%). Overall, hyperkalemia-related adverse events occurred more often in patients receiving finerenone compared with placebo (18.3% and 9%, respectively).

“Finerenone could potentially offer a streamlined approach to addressing cardiovascular risk across this vulnerable patient population,” said Dr. Joerg Moeller, Member of the

Executive Committee of Bayer AG's Pharmaceutical Division and Head of Research and Development. “We look forward to future milestones from the finerenone Phase III studies FIGARO-DKD, and FINEARTS-HF, which will deepen our understanding of the role of finerenone as a potential new disease-modifying strategy to help protect patients with earlier stages of chronic kidney disease and type 2 diabetes, or symptomatic heart failure with a left ventricular ejection fraction of ≥40%, by reducing the risk of cardiovascular events.”

The FIDELIO-DKD data were presented in October at the American Society of Nephrology’s (ASN) Kidney Week 2020, and simultaneously published in the *New England Journal of Medicine*. Based on these data, Bayer submitted finerenone for marketing authorization in the U.S. and the EU.

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 cardiovascular damage through inflammatory and fibrotic processes.

The Phase III program with finerenone in CKD and T2D enrolled over 13,000 patients across a broad range of disease severity including those with early kidney damage and more advanced stages of kidney disease. It is the largest Phase III clinical trial program to date in CKD and T2D and comprises two 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) is a randomized, double-blind, placebo-controlled, parallel-group, multicenter, event-driven Phase III study that 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 from more than 1,000 sites across 48 countries worldwide. Patients with a history of heart failure with reduced ejection fraction (NYHA II-IV) were excluded. 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 kidney failure, a sustained decrease of estimated glomerular filtration rate (eGFR) ≥ 40% from baseline over a period of at least four weeks, or renal death by 18% (relative risk reduction; HR 0.82 [95% CI, 0.73-0.93; p=0.0014]) over a median duration of follow-up of 2.6 years. Finerenone also significantly reduced the risk of 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 by 14% (relative risk reduction, HR 0.86 [95% CI, 0.75-0.99; p=0.0339]) over a median duration of follow-up of 2.6 years.

FIGARO-DKD (**FI**nerenone in reducin**G** c**A**rdiovascular mo**R**tality and m**O**rbidity in **D**iabetic **K**idney **D**isease) is still ongoing and is investigating 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.

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 symptomatic heart failure patients (New York Heart Association class II-IV) with 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).

About Chronic Kidney Disease in Type 2 Diabetes

Chronic kidney disease (CKD) is a deadly condition that is underrecognized. CKD is one of the most frequent complications arising from diabetes and is also an independent risk factor of cardiovascular disease. Approximately 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 benefit people by supporting efforts to overcome the major challenges presented by a growing and aging global population. At the same time, the Group aims to increase its earning power and create value through innovation and growth. Bayer is committed to the principles of sustainable development, and the Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2019, the Group employed around 104,000 people and had sales of 43.5 billion euros. Capital expenditures amounted to 2.9 billion euros, R&D expenses to 5.3 billion euros. For more information, go to www.bayer.com.

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