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News Release

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Bayer submits marketing authorization applications for finerenone in the U.S. and the EU for patients with chronic kidney disease and type 2 diabetes

Regulatory submissions based on positive data from Phase III FIDELIO-DKD study recently published in the *New England Journal of Medicine*

Berlin, November 9, 2020 – Bayer today announced the submission of regulatory applications to the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) seeking approval of finerenone for patients with chronic kidney disease (CKD) and type 2 diabetes (T2D). Finerenone is a first-in-class investigational non-steroidal, selective mineralocorticoid receptor antagonist (MRA) that demonstrated renal and cardiovascular benefits in patients with CKD and T2D in the Phase III FIDELIO-DKD study.

“Despite recent advances in treatment, many patients with chronic kidney disease and type 2 diabetes are still progressing to end-stage kidney failure or premature death,” said Professor George L. Bakris, MD, Department of Medicine, American Heart Association Comprehensive Hypertension Center, University of Chicago Medicine, USA and principal investigator of FIDELIO-DKD. “Finerenone works differently than current therapies and, if approved, provides a potential new treatment option to slow disease progression by directly targeting inflammation and fibrosis, major drivers of CKD progression.”

“With more than 160 million patients living with CKD and T2D, and the prevalence of T2D continuing to rise, CKD is a serious global health challenge that needs to be addressed,” said Dr. Joerg Moeller, Member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Research and Development. “These submissions are an important step towards our aim to providing finerenone to patients soon. The findings from the FIDELIO-DKD study demonstrated the effects of finerenone in improving outcomes in these patients by delaying CKD progression and reducing the risk for

cardiovascular events, and we look forward to working with the regulatory bodies to hopefully make this treatment available to patients as soon as possible."

The marketing authorization application (MAA) submitted to the EMA and the new drug application (NDA) submitted to the U.S. FDA were based on positive data from the FIDELIO-DKD study, which is part of the largest Phase III clinical trial program to date in CKD and T2D. Results from the trial were presented at the American Society of Nephrology's (ASN) Kidney Week Reimagined 2020, and simultaneously published in the *New England Journal of Medicine* in October 2020.

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 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.
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. Finerenone was well-tolerated, which is consistent with the safety profile seen in previous studies with finerenone.

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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Forward-Looking Statements
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