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## News Release

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### **Bayer extends clinical development program for finerenone with Phase III study in patients with non-diabetic chronic kidney disease**

- There are limited treatment options available for chronic kidney disease (CKD), and patients often still progress to kidney failure or premature death
  - The Phase III study FIND-CKD will investigate the effect of finerenone on kidney and cardiovascular outcomes in patients with non-diabetic chronic kidney disease
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**Berlin, September 20, 2021** – Bayer announced today the initiation of the FIND-CKD study, a multicenter, randomized, double-blind, placebo-controlled Phase III study to investigate the efficacy and safety of finerenone in addition to guideline-directed therapy, on the progression of chronic kidney disease (CKD) in patients with non-diabetic CKD. The primary objective of the study is to demonstrate superiority of finerenone over placebo in delaying the progression of kidney disease in these patients. 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 2017, an alarming 1.2 million people died from chronic kidney disease worldwide. Although diabetes is well-recognized as a leading cause of chronic kidney disease globally, a substantial proportion of the global burden is non-diabetic in origin and attributable to other causes, such as hypertension. To improve outcomes, new treatments that can target kidney-specific disease mechanisms are highly desired,” said Hiddo L. Heerspink, Professor of Clinical Trials and Personalized Medicine and a clinical pharmacologist/trialist at the Department of Clinical Pharmacy and Pharmacology at the University Medical Center Groningen, Netherlands, and Co-Chair of the study’s Executive Committee. “If successful, this study could be of great significance to those living with chronic kidney disease globally.”

Finerenone is an investigational, non-steroidal, selective mineralocorticoid (MR) antagonist that has been shown in preclinical studies to block harmful effects of MR overactivation. MR overactivation is thought to contribute to CKD progression and cardiovascular damage which can be driven by metabolic, hemodynamic or inflammatory and fibrotic factors. Finerenone has already demonstrated benefits on kidney and cardiovascular outcomes in patients with chronic kidney disease and type 2 diabetes in two completed Phase III studies, FIDELIO-DKD and FIGARO-DKD.

“Finerenone has been studied so far in more than 13,000 patients through the comprehensive Phase III clinical trial program in chronic kidney disease and type 2 diabetes, which demonstrated positive kidney and cardiovascular outcomes for finerenone versus placebo on top of standard of care,” said Dr. Christian Rommel, Member of the Executive Committee of Bayer AG’s Pharmaceutical Division and Head of Research and Development. “The new FIND-CKD study extends our clinical research for finerenone to a non-diabetic population where the unmet need is high for new treatments to delay disease progression.”

The planned Phase III FIND-CKD study will investigate finerenone compared to placebo in addition to standard of care in more than 1,500 patients with non-diabetic chronic kidney disease etiologies, including hypertension and chronic glomerulonephritis (inflammation of the kidneys). Patients will be randomized to receive either finerenone 10mg or 20mg or placebo on top of individually tolerated maximum labeled doses of a renin-angiotensin system (RAS)-blocking therapy such as an angiotensin-converting enzyme (ACE) inhibitor or an angiotensin II receptor blocker (ARB).

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 for patients with CKD and T2D. 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. 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.

The initiation of the Phase III FIND-CKD study (**F**inerenone, in addition to standard of care, on the progression of kidney disease in patients with **N**on-**D**iabetic **C**hronic **K**idney **D**isease) builds upon the robust Phase III results from the FIDELIO-DKD and FIGARO-DKD studies which evaluated the effects of finerenone versus placebo on top of standard of care on both renal and cardiovascular outcomes in patients with CKD and T2D. Based on these findings, and since the beneficial kidney effect of finerenone observed in previous studies was independent of the glycemic state and was shown in a related population, FIND-CKD will investigate the effect of finerenone in patients with non-diabetic etiologies, including hypertension and chronic glomerulonephritis (inflammation of the kidneys).

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).

### **About Chronic Kidney Disease**

CKD is a common and potentially deadly condition that is widely underrecognized. CKD progresses silently and unpredictably, with many symptoms not appearing until the disease is well-advanced. CKD affects 840 million people worldwide. In the U.S., 1 in 3 adults is at risk for the disease. At advanced stages of CKD, patients may need dialysis or a kidney transplant to stay alive. Healthy kidneys act as the body's filter, removing waste products from the blood. They also control how much water and electrolytes are in the body, regulating blood pressure. As kidney function goes down, patients may experience a range of symptoms including leg swelling, tiredness in the day, nausea, muscle cramps, joint pain and confusion, trouble focusing, memory problems. Major risk factors of CKD include diabetes and hypertension.

## **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](http://www.bayer.com).

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**Forward-Looking Statements**

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