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News Release

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Bayer extends clinical development program for finerenone with Phase III study in children and adolescents with chronic kidney disease

- For children and adolescents with chronic kidney disease (CKD), as for adults, the unmet need is high for new treatments to delay disease progression and preserve kidney function
- The Phase III study FIONA will investigate the effect of finerenone in pediatric patients with CKD and severely increased proteinuria

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Berlin, November 15, 2021 – Bayer announced today the initiation of the FIONA study, a multicenter, randomized, double-blind, placebo-controlled Phase III study, to investigate the efficacy, safety and pharmacokinetics/pharmacodynamics (PK/PD) of finerenone, in addition to standard of care, for the treatment of pediatric patients with chronic kidney disease (CKD) and severely increased proteinuria. The primary objective of the study is to demonstrate superiority of finerenone in addition to an angiotensin-converting enzyme (ACE) inhibitor or an angiotensin II receptor blocker (ARB) over placebo in reducing urine protein excretion in these patients. The primary outcome measure is the change in urine protein creatinine ratio (UPCR) from baseline to 6 months.

“Chronic kidney disease is a rare but devastating condition affecting children across the age spectrum. Despite some progress achieved through previous research efforts, children with this condition continue to experience disease progression and proteinuria – an important, modifiable risk factor for kidney function decline. New treatments are needed to target this risk factor whilst working synergistically with current therapies,” said Dr. Franz Schaefer, Professor of Pediatrics and Chief of the Pediatric Nephrology Division at Heidelberg University Hospital. “If successful, insights from this study could be of great significance to children living with chronic kidney disease and their families.”

Proteinuria is an important modifiable risk factor for CKD progression in children. Aldosterone-mediated activation of mineralocorticoid receptors (MR) in the kidney drive the downward spiral by promoting tissue inflammation and injury. Finerenone is an investigational, non-steroidal, selective MR antagonist that in preclinical studies has been shown to block harmful effects of MR overactivation, which is thought to contribute to CKD progression and cardiovascular damage.

Finerenone has been investigated in a broad population of adult patients with stages 1-4 CKD and type 2 diabetes (T2D) across two completed Phase III studies: FIDELIO-DKD and FIGARO-DKD. In these studies, finerenone demonstrated benefits on kidney and cardiovascular outcomes in patients with CKD and T2D. Finerenone demonstrated a consistent safety profile across studies. FIDELITY, a pre-specified pooled analysis of the FIDELIO-DKD and FIGARO-DKD studies to evaluate the occurrence of progression of kidney disease as well as fatal and nonfatal CV events in more than 13,000 patients with CKD and T2D, evaluated the potential benefit of finerenone across the disease spectrum.

“In the largest Phase III clinical trial program to date in chronic kidney disease and type 2 diabetes, which included more than 13,000 adult patients, finerenone has demonstrated the potential to improve kidney and cardiovascular outcomes,” said Dr. Christian Rommel, Member of the Executive Committee of Bayer AG’s Pharmaceutical Division and Head of Research and Development. “The new FIONA study extends our clinical research for finerenone to children and adolescents with chronic kidney disease, where the unmet need is high for new treatments to delay disease progression and preserve kidney function as much and for as long as possible.”

The planned Phase III FIONA study will investigate finerenone compared to placebo in addition to standard of care in approximately 200 patients with CKD. Patients will be randomized in a 2:1 ratio to receive either a body-weight adjusted dose of finerenone or placebo on top of individually optimized labeled doses of either ACE inhibitors or an ARB. The FIONA study will contribute to the IMI2 conect4children (c4c) project, by utilising the c4c network and its clinical sites across Europe. c4c aims to provide better medicines for babies, children and young people by improving the way clinical trials are planned and conducted across Europe. In addition, the study will be conducted in collaboration with two pediatric CKD-specific clinical research networks, ESCAPE (European Study

Consortium for Chronic Kidney Disorders affecting Pediatric Patients) and NAPRTCS (North-American Pediatric Renal Trials and Collaborative Studies).

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 adult 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; 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 five Phase III studies: FIDELIO-DKD, FIGARO-DKD, FINEARTS-HF, FIND-CKD and FIONA.

The initiation of the Phase III FIONA study (**FI**nerenone for the treatment of children with chr**O**nic kid**N**ey disease and proteinuri**A**) 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 across a broad range of disease severity, on both renal and cardiovascular outcomes in patients with CKD and T2D. Based on these findings, FIONA will investigate the effect of finerenone in pediatric participants with CKD and severely increased proteinuria.

The initiation of the Phase III FIND-CKD study (**FI**nerenone, in addition to standard of care, on the progression of kidney disease in patients with **N**on-**D**iabetic **C**hronic **K**idney Disease) builds upon the robust Phase III results from the FIDELIO-DKD and FIGARO-**D**KD 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).

About Chronic Kidney Disease in Pediatric Patients

Globally, between 30 and 90 children per million have CKD stage 2 or higher. The annual incidence in European countries ranges from 8.7 to 17.5 cases per million children. As in adults, secondary treatment strategies for CKD in children aim to prevent disease progression by focusing on control of blood pressure and proteinuria through RAAS blockade with an angiotensin converting enzyme inhibitor (ACEI) or an angiotensin receptor blocker (ARB). However, despite treatment with available standard ACEI or ARB therapy, pediatric patients with CKD, like adults, continue to have proteinuria and progression of renal disease. Therefore, novel treatment options are needed which target modifiable risk factors, and act synergistically with the established therapies to overcome their limitations and improve the outcome in children with CKD.

IMI2 conect4children

The Collaborative Network for European Clinical Trials for Children (conect4children or c4c) is an action under the Innovative Medicines Initiative 2 (IMI2) Joint Undertaking (https://www.imi.europa.eu/), Grant Agreement 777389.

IMI2 c4c aims to enhance the development of better medicines for babies, children and young people, by generation of a sustainable infrastructure across Europe, that optimizes the delivery of clinical trials in children, and the use of innovative trial designs and new quantitative methods.

About ESCAPE

The ESCAPE Network (**E**uropean **S**tudy **C**onsortium for Chronic Kidney Disorders **A**ffecting **Pe**diatric Patients) is a group of 30 pediatric nephrology expert centers from 9 European countries. The Network aims to improve the management of chronic kidney disease in children and adolescents and has performed numerous clinical trials and cohort studies over more than two decades. In the landmark ESCAPE Trial, the consortium established the efficacy of strict blood pressure control and ACE inhibition in slowing renal failure progression in children. Further information on the ESCAPE Network can be found at http://www.escapenet.eu.

About NAPRTCS:
The North American Pediatric Renal Trials and Collaborative Studies (NAPRTCS) is a multicenter, registry-based research effort. NAPRTCS has partnered with industry sponsors since 1994 to conduct clinical trials to advance knowledge about pediatric kidney disease and to study best practices for treatment of various pediatric kidney disorders. Further information on NAPRTCS can be found at https://naprtcs.org.

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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Forward-Looking Statements
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