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# News Release

**Not intended for U.S. and UK Media**

The American Society of Nephrology (ASN)'s Kidney Week 2021:

## Bayer to present new data from comprehensive finerenone clinical trial program

- New analysis from the Phase III FIGARO-DKD study will be presented, which investigated the impact of finerenone on renal outcomes in patients with chronic kidney disease (CKD) and type 2 diabetes (T2D)
- A subgroup analysis from FIDELITY, a prespecified pooled analysis of FIDELIO-DKD and FIGARO-DKD, will be presented, which investigated the impact of finerenone on renal outcomes on top of standard of care
- Additional finerenone data from the FIDELIO-DKD study and the pooled analysis FIDELITY will be presented as late-breaking posters

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**Berlin, October 27, 2021** – Bayer will present new renal and cardiovascular (CV) analyses from the comprehensive finerenone (Kerendia®) clinical trial program, including the Phase III FIGARO-DKD and FIDELIO-DKD studies, and the prespecified pooled analysis FIDELITY at the American Society of Nephrology (ASN)'s Kidney Week 2021 from 4-7 November. These data will be presented in two oral presentations and two late-breaking posters, continuing to highlight Bayer's ongoing commitment to improving the lives of patients with kidney and CV diseases.

**Finerenone FIGARO-DKD study data:**

The results of Bayer's Phase III study FIGARO-DKD, which evaluated finerenone in addition to standard of care in a broad patient population with CKD and T2D for CV outcomes, were presented at ESC Congress in August 2021 and simultaneously published in the *New England Journal of Medicine*. The FIGARO-DKD study met its primary endpoint, showing that finerenone significantly reduced the composite risk of time

to first occurrence of CV death, non-fatal myocardial infarction, non-fatal stroke, or hospitalization for heart failure. At the ASN Kidney Week 2021, Bayer will present analysis from FIGARO-DKD, examining the impact of finerenone on renal outcomes.

- Finerenone and Kidney Outcomes in Patients with CKD and Type 2 Diabetes: Results from FIGARO-DKD (Abstract SA-OR21)
    - November 6, 2021, 4:30-6:00pm (PDT) / November 7, 12:30-2:00am (CEST)
    - Session: OR0602. Diabetic Kidney Disease: Recent Advances

**Finerenone FIDELITY study data:**

Bayer will also present new findings from FIDELITY, the prespecified pooled analysis of both FIDELIO-DKD and FIGARO-DKD studies. The aim of FIDELITY was to evaluate the efficacy and safety of finerenone in more than 13,000 patients with CKD and T2D. These new analyses investigated the impact of finerenone on renal outcomes across the spectrum of CKD and T2D in addition to standard of care and in combination with sodium-glucose cotransporter 2 inhibitors (SGLT-2is).

- Finerenone and Kidney Outcomes in Patients with CKD and T2D: Results from FIDELITY
    - November 4, 2021, 10am (PDT) / 6pm (CEST)
    - Session: Late-Breaking Clinical Trials Posters
    - Poster: PO2531

- Finerenone in Patients with CKD and Type 2 Diabetes by SGLT-2i Treatment: The FIDELITY Analysis (Abstract SA-OR22)
    - November 6, 2021, 4:30-6:00pm (PDT) / November 7, 12:30-2:00am (CEST)
    - Session: OR0602. Diabetic Kidney Disease: Recent Advances

**Finerenone FIDELIO-DKD study data:**

The results of Bayer's Phase III study FIDELIO-DKD, the first trial in the finerenone clinical trial program, which evaluated finerenone in addition to standard of care (SoC) in patients with CKD and T2D for kidney-specific outcomes, were presented in October 2020 at the ASN Kidney Week and simultaneously published in the *New England Journal of Medicine*. The FIDELIO-DKD study met its primary and key secondary endpoint, showing

that finerenone significantly reduced renal and cardiovascular outcomes in patients with CKD and T2D. At the ASN Kidney Week 2021, Bayer will present new analysis from FIDELIO-DKD, which investigated the impact of finerenone on renal outcomes in patients with CKD and T2D.

- Association of Urine Albumin-to-Creatinine Ratio and Its Early Change with Cardiorenal Outcomes in FIDELIO-DKD: A Mediation Analysis
    - November 4, 2021, 10am (PDT) / 6pm (CEST)
    - Session: Late-Breaking Clinical Trials Posters
    - Poster: PO2531

**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. In T2D, 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.

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. 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) 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. FIGARO-DKD (**FI**nerenone in reducin**G** c**A**rdiovascular 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.

In September 2021, Bayer announced the initiation of the FIND-CKD study, a multicenter, randomized, double-blind, placebo-controlled Phase III study which will investigate finerenone in patients with non-diabetic chronic kidney disease. FIND-CKD will investigate the efficacy and safety of finerenone in addition to guideline-directed therapy on the progression of chronic kidney disease (CKD) in more than 1,500 patients with non-

diabetic chronic kidney disease etiologies, including hypertension and chronic glomerulonephritis (inflammation of the kidneys). 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 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 ≥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).

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. 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 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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