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## News Release

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

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American Society of Nephrology (ASN)'s Kidney Week 2020 Reimagined:

### **Finerenone Phase III FIDELIO-DKD study in chronic kidney disease and type 2 diabetes to be presented as late-breaking clinical trial at ASN 2020**

- FIDELIO-DKD is the first large contemporary positive outcomes study in patients with chronic kidney disease (CKD) and type 2 diabetes (T2D) with a primary composite endpoint consisting exclusively of kidney-specific outcomes
  - Finerenone, a first-in-class investigational non-steroidal, selective mineralocorticoid receptor (MR) antagonist, demonstrated positive renal and cardiovascular outcomes in patients with CKD and T2D
  - Preclinical data on finerenone, as well as a range of poster presentations in cardiovascular and kidney diseases will be presented
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**Finerenone posters:** PO0646, PO0642, PO0439, PO0965, PO0623.

**Berlin, October 12, 2020** – Detailed results with finerenone from the Phase III FIDELIO-DKD study will be presented at the upcoming [American Society of Nephrology \(ASN\)](#)'s Kidney Week 2020 Reimagined. FIDELIO-DKD met both its composite primary renal endpoint and its composite key secondary cardiovascular endpoint. The study is part of the largest Phase III clinical trial program to date in CKD and T2D. ASN Kidney Week 2020 Reimagined will take place on October 22-25, 2020.

Full data from the FIDELIO-DKD study will be presented within the following live-streamed, late-breaker oral abstract session *High-Impact Clinical Trials*:

- [Effect of Finerenone on Chronic Kidney Disease Outcomes in Type 2 Diabetes](#)  
(Abstract FR-OR51)

October 23, 2020, 10:30 – 10:45 am (EDT)/ 4:30 – 4:45 pm (CET)

**Additional finerenone study data include:**

- [The Novel Nonsteroidal and Selective Mineralocorticoid Receptor Antagonist Finerenone Differentiates from SGLT2 Inhibitor Empagliflozin by Anti-Fibrotic Effects in a Progressive Mouse Kidney Fibrosis Model](#)
  - Session: CKD Mechanisms – 2
  - Poster: PO0646
  
- [Combined Efficacy of the Novel Nonsteroidal and Selective Mineralocorticoid Receptor Antagonist Finerenone and the SGLT2 Inhibitor Empagliflozin in a Non-Diabetic Cardiorenal Rat Model](#)
  - Session: CKD Mechanisms – 2
  - Poster: PO0642
  
- [Chronic Kidney Disease by Previous Diabetes or Hypertension: A Longitudinal Outcomes Study in Primary Care](#)
  - Session: CKD Epidemiology, Biomarkers, Predictors
  - Poster: PO0439

**Xarelto™ study data:**

- [Rivaroxaban Reduces Major Cardiovascular and Limb Events in Patients with CKD and Peripheral Artery Disease with Recent Lower Extremity Revascularization: Insights from VOYAGER PAD](#)
  - Session: CVD, BP, and Kidney Diseases: Exploring the Link
  - Poster: PO2115

**Miscellaneous study data includes:**

- [Results from a Phase 3 Study Comparing the Efficacy and Safety of Molidustat vs Darbepoetin Alfa in Patients Receiving Hemodialysis and Treated with Erythropoiesis-Stimulating Agents \(ESAS\)](#)
  - Session: Late-Breaking Clinical Trials Posters
  - Poster: PO2623

## 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 contributes to 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 (**F**inerenone in reducing **k**idney **f**ailure and **d**isease **p**rogression 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.

FIGARO-DKD (**F**inerenone in reducing **c**ardiovascular **m**ortality and **m**orbidity 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  $\geq 40\%$ . 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 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. CKD affects an estimated 185 million people with T2D worldwide. Chronic kidney disease in type 2 diabetes is the main cause of end stage kidney disease and kidney failure and at advanced stages, patients may need 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](http://www.bayer.com).

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**Forward-Looking Statements**

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