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News Release

Not intended for U.S. and UK Media

The American Society of Nephrology (ASN) Kidney Week 2022:

Bayer to present new cardiorenal data from comprehensive Kerendia™ (finerenone) clinical trial program across a broad range of patients with chronic kidney disease and type 2 diabetes

- FIDELITY: Late-breaking data from pooled, post-hoc analysis will provide new insights into the efficacy and safety of Kerendia in patients with chronic kidney disease (CKD) and type 2 diabetes (T2D) who have sustained an acute change in estimated glomerular filtration rate (eGFR)
- FIDELIO-DKD: Post-hoc analysis explored the cardiorenal effects of Kerendia in patients with CKD and T2D from Asia
- FIDELIO-DKD: Subgroup analysis evaluated the efficacy and safety of Kerendia in patients with CKD and T2D from China
- FINE-REAL: Study design of the first prospective observational study of patients with CKD and T2D treated with Kerendia

Berlin, October 26, 2022 – Bayer will present new renal and cardiovascular (CV) data from the comprehensive Kerendia™ (finerenone) clinical trial program in patients with chronic kidney disease (CKD) and type 2 diabetes (T2D) at the American Society of Nephrology’s (ASN) Kidney Week 2022, from 1-6 November. Four new sets of data will be presented including a late-breaking pooled, post-hoc analysis of FIDELITY, further analyses of FIDELIO-DKD, and the design of the first prospective observational study, FINE-REAL.

Kerendia FIDELITY study data:

The prespecified pooled analysis FIDELITY, including the FIDELIO-DKD and FIGARO-DKD studies, comprises data in >13,000 patients with CKD and T2D. FIDELITY
investigated the efficacy and safety of Kerendia across a broad range of patients with early to late-stage CKD and T2D, and provided insights into the relationship between CKD stage (based on baseline Kidney Disease: Improving Global Outcomes – KDIGO – risk categories) and the effects of Kerendia on composite CV and kidney-specific endpoints.

Late-breaking data from pooled, post-hoc analysis of FIDELITY will investigate the efficacy and safety of Kerendia in patients with CKD and T2D who have sustained an acute change in estimated glomerular filtration rate (eGFR).

- Efficacy and Safety of Finerenone in Patients With an Acute Change in Estimated Glomerular Filtration Rate: FIDELITY Analysis
  - November 3, 2022, 10:00am-12:00pm (EDT)/ 15:00-17:00pm (CET)
  - Late-Breaking Clinical Trials (Posters)

Kerendia FIDELIO-DKD study data:

FIDELIO-DKD investigated the efficacy and safety of Kerendia 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.

Post-hoc analysis of the study will explore the cardiorenal effects of Kerendia in patients with CKD and T2D from Asia.

- Cardiorenal Outcomes With Finerenone in Asian Patients With CKD and Type 2 Diabetes: Post Hoc Analysis from FIDELIO-DKD
  - November 5, 2022, 10:00am-12:00pm (EDT)/ 15:00-17:00pm (CET)
  - Diabetic Kidney Disease: Clinical - II

Additional subgroup analysis will evaluate the efficacy and safety of Kerendia in patients with CKD and T2D from China.

- Effect of Finerenone on CKD Outcomes in Type 2 Diabetes: A Chinese Subgroup Analysis of the FIDELIO-DKD Study
  - November 5, 2022, 10:00am-12:00pm (EDT)/ 15:00-17:00pm (CET)
  - Diabetic Kidney Disease: Clinical - II
Kerendia FINE-REAL study design:

FINE-REAL is the first prospective observational study with Kerendia in patients with CKD and T2D. The study is expected to provide insights into the use of Kerendia in routine clinical practice, and inform decision-making on initiating use of Kerendia in patients with CKD and T2D.

- Design and Rationale of FINE-REAL: A Prospective Study Providing Insights Into the Use of Finerenone in Routine Clinical Settings
  - November 3-5, 2022, 10:00am-12:00pm (EDT)/ 15:00-17:00pm (CET)
  - Informational Posters

About Kerendia™ (finerenone)
Kerendia is a non-steroidal, selective mineralocorticoid receptor (MR) antagonist that has been shown to block harmful effects of MR overactivation. MR overactivation contributes to CKD progression and cardiovascular damage which can be driven by metabolic, hemodynamic, or inflammatory and fibrotic factors.

Based on the positive results of the FIDELIO-DKD Phase III study, Kerendia™ was granted marketing authorization by the U.S. Food and Drug Administration (FDA) in July 2021, the European Commission in February 2022, and the Chinese National Medical Products Administration (NMPA) in June 2022. In September 2022, Bayer announced that it received approval from the U.S. FDA for a label update for Kerendia™ to include findings from the Phase III FIGARO-DKD CV outcomes study. In March 2022, Bayer submitted a Type II Variation application based on the data from FIGARO-DKD to the European Medicines Agency (EMA) to seek an extension of the marketing authorization for Kerendia™ to include early stages of CKD associated with T2D. Based on the positive results of both pivotal Phase III studies, FIDELIO-DKD and FIGARO-DKD, Kerendia™ was approved in March 2022 by the Japanese Ministry of Health, Labour, and Welfare (MHLW). Further regulatory approvals by other health authorities in multiple other countries have been granted or are currently pending following submissions for marketing authorization.

The Phase III study programme with finerenone, FINEOVATE, currently comprises five Phase III studies, FIDELIO-DKD, FIGARO-DKD, FINEARTS-HF, FIND-CKD, and FIONA, as well as the Phase II study CONFIDENCE.
About Chronic Kidney Disease in Type 2 Diabetes

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 is one of the most frequent complications arising from diabetes and is also an independent risk factor of cardiovascular disease. Up to 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. Patients with chronic kidney disease and type 2 diabetes are three times more likely to die from a cardiovascular-related cause than those with type 2 diabetes alone.

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 the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating 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 2021, the Group employed around 100,000 people and had sales of 44.1 billion euros. R&D expenses before special items amounted to 5.3 billion euros. For more information, go to www.bayer.com.

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Forward-Looking Statements
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