



Bayer AG
Communications
51368 Leverkusen
Germany
Phone +49 214 30-1
www.bayer.com/en/media

News Release

Not intended for U.S. and UK Media

U.S. FDA accepts Bayer's supplemental New Drug Application for finerenone in chronic kidney disease without diabetes

- The supplemental New Drug Application (sNDA) was based on the positive Phase III FIND-CKD study results, which demonstrated that finerenone significantly delayed kidney disease progression and reduced cardiovascular-kidney events in addition to standard of care versus placebo in adults with chronic kidney disease (CKD) without diabetes
 - Approximately 850 million people worldwide, and more than 35 million adults in the U.S. have CKD. An estimated 50% to 70% of these patients have CKD without diabetes
 - Patients who have CKD without diabetes are underserved, with few guideline-directed treatment options and a significantly increased risk of cardiovascular complications, kidney disease progression, and kidney failure
-

Berlin, October 8, 2026 – Bayer today announced that the U.S. Food and Drug Administration (FDA) has accepted its supplemental New Drug Application (sNDA) for finerenone (Kerendia™), supporting a potential new indication in adults with chronic kidney disease (CKD) without diabetes. The application is based on results from the pivotal Phase III FIND-CKD study, which showed that finerenone significantly delayed kidney disease progression and reduced cardiovascular-kidney events versus placebo, in addition to standard of care, in a broad population of adults with CKD without diabetes.

“For many people living with CKD without diabetes, kidney function can decline silently for years before symptoms become apparent, while the risk of kidney failure and cardiovascular complications continues to rise,” said Dr. Christian Rommel, Global Head of Research and Development at Bayer’s Pharmaceuticals Division. “The FDA’s acceptance of our application marks an important step toward potentially expanding the use of finerenone, a non-steroidal mineralocorticoid receptor antagonist (nsMRA), to a

broader group of patients who still have few treatment options and may benefit from the cardio-kidney protective effects of finerenone. By targeting mineralocorticoid receptor overactivation, finerenone addresses a pathway implicated in kidney disease progression and cardiovascular damage.”

Approximately 850 million people worldwide, and more than 35 million adults in the U.S. have CKD. An estimated 50-70% of these patients have CKD without diabetes. Additionally, more than 3.5 million people with kidney failure are treated with dialysis, which is associated with a 5-year survival rate of about 40% after treatment initiation. CKD without diabetes can have a range of etiologies, of which the most common include kidney disease linked to hypertension and glomerulonephritis (including immunoglobulin A nephropathy (IgAN) or focal segmental glomerulosclerosis (FSGS)). Despite standard of care, patients with CKD without diabetes remain at risk of kidney failure and cardiovascular events. CKD linked to hypertension is the second most common cause of kidney failure. Patients with advanced CKD without diabetes also face a markedly higher risk of fatal cardiovascular events, about 2.6 times that of the general population without CKD, which increases further as kidney function declines.

About Kerendia™ / Firalta™ (finerenone)

Kerendia™ and Firalta™ are globally protected trademarks for finerenone. Finerenone is the first drug targeting the mineralocorticoid receptor (MR) pathway that in five pivotal Phase III studies has demonstrated cardiovascular and/or kidney benefits across a broad range of patient populations, including patients with HF with left ventricular ejection fraction (LVEF) $\geq 40\%$, patients with CKD associated with type 2 diabetes, patients with CKD associated with type 1 diabetes, and patients with CKD without diabetes. Finerenone is a selective, non-steroidal mineralocorticoid receptor antagonist (nsMRA) 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.

Since 2021, finerenone has been marketed as Kerendia™ or, in selected countries, as Firalta™, and has been approved for the treatment of adult patients with CKD associated with type 2 diabetes (T2D) in more than 100 countries worldwide, including in China, Europe, Japan, and the U.S. Finerenone is also approved for the treatment of heart failure with left ventricular ejection fraction (LVEF) $\geq 40\%$ in the U.S., the EU, Japan, and China

among other Health Authorities, with additional applications under regulatory review. Finerenone is currently not approved for the treatment of CKD without diabetes.

The clinical study program with finerenone, FINEOVATE, currently comprises twelve Phase III studies with dedicated programs in CKD and HF respectively. The THUNDERBALL CKD program consists of the completed Phase III studies FIDELIO-DKD, FIGARO-DKD, FIND-CKD, and FINE-ONE, and the Phase II study CONFIDENCE; as well as the ongoing Phase III studies in pediatric patient populations FIONA, and FIONA-OLE. The MOONRAKER program includes the completed pivotal Phase III study FINEARTS-HF, the ongoing investigator-sponsored, collaborative studies REDEFINE-HF, CONFIRMATION-HF, and FINALITY-HF, as well as the ongoing Phase III studies in pediatric patient populations, FIORE and FIORELLO.

About FIND-CKD

FIND-CKD is the largest Phase III study to date focused on CKD without diabetes. The study investigated finerenone in a broad patient population spanning different etiologies of CKD without diabetes, adding to the positive data and breadth of evidence of finerenone in CKD. FIND-CKD investigated the efficacy and safety of finerenone compared to placebo in addition to standard of care in more than 1,500 patients with CKD without diabetes, including kidney disease linked to hypertension and glomerular diseases. Patients were randomized to receive either finerenone 10mg or 20mg or placebo on top of maximum tolerated 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 FIND-CKD, finerenone significantly delayed kidney disease progression and reduced cardiovascular-kidney events versus placebo, in addition to standard of care. Over 32 months, patients treated with finerenone experienced a statistically significant 0.7 ml/minute/1.73 m²/year slower annual decline in eGFR than those receiving placebo. Finerenone also significantly reduced the risk of the key secondary composite cardiovascular-kidney outcome by 23% compared with placebo. Additional secondary endpoints, including composites of sustained $\geq 57\%$ eGFR decline or kidney failure, and of hospitalization for heart failure or cardiovascular death, showed results consistent with the overall positive profile of finerenone.

Finerenone was well-tolerated in the FIND-CKD study, which is consistent with the well-established safety profile of finerenone.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. In line with its mission, "Health for all, Hunger for none," the company's products and services are designed to support efforts to master major challenges presented by a growing and aging global population and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2025, the Group employed around 88,000 people and had sales of 45.6 billion euros. R&D expenses amounted to 5.8 billion euros. For more information, go to www.bayer.com.

Contact for media inquiries:

Dr. Daniela Esser, phone +49 30 2215-41588

Email: daniela.esser@bayer.com

Contact for investor inquiries:

Bayer Investor Relations Team, phone +49 214 30-72704

Email: ir@bayer.com

www.bayer.com/de/investoren/ir-team

Find more information at www.bayer.com/en/portfolio/pharmaceuticals

Follow us on Facebook: <http://www.facebook.com/bayer>

de (2026-0142e)

Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

Bayer AG is a holding company with operating subsidiaries worldwide. References to "Bayer" or "the company" herein may refer to one or more subsidiaries as context requires.