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 approves finerenone for new indication in patients with chronic kidney disease associated with type 1 diabetes

- Kerendia™ is the first FDA-approved treatment option in more than 30 years for adults with chronic kidney disease (CKD) associated with type 1 diabetes (T1D)
- Approval addresses an important unmet need for a population at increased risk of kidney failure, with approximately 30% of people with type 1 diabetes in the U.S. developing CKD
- New indication approval follows the U.S. Food and Drug Administration (FDA)'s Priority Review designation and is supported by the totality of evidence, including positive results from the pivotal Phase III FINE-ONE study, demonstrating a statistically significant reduction in the urine albumin-to-creatinine ratio (UACR) of 25% from baseline over 6 months with Kerendia in addition to standard of care versus placebo in adults with CKD associated with T1D
- This FDA approval represents the third approved indication for Kerendia in the U.S., further extending its role across populations living with heart and kidney diseases

---

Berlin, September 17, 2026 – Bayer announced today that the U.S. Food and Drug Administration (FDA) has approved Kerendia™ (finerenone), a selective, non-steroidal mineralocorticoid receptor antagonist (nsMRA), for the treatment of adult patients with chronic kidney disease (CKD) associated with type 1 diabetes (T1D). Finerenone (10mg, 20mg) is now indicated to reduce urinary albumin-to-creatinine ratio (UACR), which is expected to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline and end-stage kidney disease in adults with chronic kidney disease associated with type 1 diabetes.

Approximately 30% of people with type 1 diabetes in the U.S. develop chronic kidney disease, increasing their risk of kidney failure and cardiovascular events. Even with

recommended treatments for blood glucose and blood pressure management, many patients remain at risk of kidney disease progression and cardiovascular complications.

“For more than three decades, people with chronic kidney disease and type 1 diabetes have had limited options to address the risk of kidney disease progression," said Dr. Janet McGill, Professor of Medicine in the Division of Endocrinology, Metabolism, and Lipid Research at Washington University School of Medicine in St. Louis, and Co-Chair of the study’s Executive Committee. "The approval of Kerendia to reduce UACR, which is expected to slow chronic kidney disease progression in adults with type 1 diabetes, provides an important new treatment option for a population that has continued to face substantial unmet need.”

“Today’s approval in the U.S. marks an important advance for people living with chronic kidney disease associated with type 1 diabetes—a serious and often under-recognized condition. As the first new FDA-approved treatment option in more than 30 years for this patient population, Kerendia reflects Bayer’s commitment to addressing significant unmet needs and bringing meaningful new treatment options to patients,” said Christine Roth Executive Vice President, Global Product Strategy and Commercialization and Member of the Pharmaceuticals Leadership Team at Bayer.

In May 2026, the FDA granted Priority Review designation for Bayer’s supplemental New Drug Application for finerenone for the treatment of adult patients with CKD associated with T1D. The approval of finerenone by the FDA is based on the positive results of the Phase III FINE-ONE study, which were published in the *New England Journal of Medicine* in March 2026 and presented in November 2025 as “Featured High-Impact Clinical Trial” during the Opening Plenary session of the American Society of Nephrology’s (ASN) Kidney Week. These findings are supported by pooled analyses from the Phase III FIDELIO-DKD and FIGARO-DKD studies in CKD associated with type 2 diabetes (T2D), showing that more than 80% of finerenone's kidney benefit was explained by reductions in UACR.

In the U.S., Kerendia has been approved since 2021 for the treatment of adult patients with CKD associated with type 2 diabetes (T2D), since 2025 for the treatment of adult patients with symptomatic chronic heart failure with left ventricular ejection fraction (LVEF) ≥ 40%, and now for the treatment of adult patients with CKD associated with type 1 diabetes.

About Kerendia™ / Firialta™ (finerenone)
Kerendia™ and Firialta™ are globally protected trademarks for finerenone. 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 chronic kidney disease (CKD) progression and cardiovascular damage which can be driven by metabolic, hemodynamic, or inflammatory and fibrotic factors.

Finerenone so far has been studied in more than 20,000 patients across multiple populations with chronic kidney disease and/or heart failure. Finerenone is the first drug targeting the MR pathway that in five pivotal Phase III studies has demonstrated clinically proven heart and/or kidney benefits across a broad range of patient populations, for patients with HF LVEF ≥40%, CKD associated with T2D, CKD associated with T1D, and CKD without diabetes.

Since 2021, finerenone is marketed as Kerendia™ or, in selected countries, as Firialta™, and 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 LVEF ≥ 40% in the U.S., Europe, Japan, China, and several other markets. Applications for marketing authorization of finerenone in non-diabetic CKD have been filed in China and Japan; so far, finerenone is not approved in non-diabetic CKD in any country worldwide. With the new approval by the FDA, the U.S. are the only country where Kerendia is approved for the treatment of adult patients with CKD associated with type 1 diabetes.

About FINE-ONE
In FINE-ONE, 242 participants were randomized from more than 80 sites across 9 countries worldwide to receive either finerenone or placebo once daily. In addition, patients in the study received usual therapy to treat symptoms and comorbidities.

FINE-ONE is a global, randomized, placebo-controlled, double-blind, multicenter Phase III study in people with CKD and T1D. In FINE-ONE, finerenone in addition to standard of care significantly reduced the primary endpoint of relative change in urine albumin-to-creatinine ratio, or UACR, by 25% over six months compared with placebo. At Month 3 and at Month 6, UACR reduction with finerenone was 22%, and 28%, respectively, compared to placebo. At any time following baseline, 68.1% of participants receiving

finerenone achieved a reduction in UACR of at least 30%, compared with 46.6% receiving placebo. A reduction in UACR of 30% is a threshold established by the American Diabetes Association (ADA) as being associated with slower CKD progression in patients with CKD associated with type 2 diabetes. Reductions in UACR of this magnitude have been shown in prior Phase III studies in adults with CKD and T2D to be associated with a delay in kidney disease progression and a reduction in cardiovascular events. The safety profile of finerenone in FINE-ONE was largely consistent with the existing body of evidence in adults with chronic kidney disease associated with type 2 diabetes.

About Chronic Kidney Disease associated with Type 1 Diabetes

Type 1 Diabetes (T1D) is a chronic autoimmune disorder characterized by destruction of pancreatic beta cells leading to insulin deficiency and requiring lifelong insulin treatment. Among the US population overall, crude estimates for 2018 indicated that 1.4 million adults aged 20 years or older (or 5.2% of all US adults with diagnosed diabetes), reported both having T1D and using insulin.

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. CKD affects approximately 30% of people with T1D. The 2017 global prevalence of CKD due to T1D was an estimated 32.5 per 100,000 individuals.

The clinical course of CKD in people with T1D is characterized by an increased urinary albumin excretion rate, which is a first sign of kidney damage and may progress to macroalbuminuria and decrease in kidney function as measured by estimated glomerular filtration rate (eGFR). The treatment of T1D consists of insulin treatment to control hyperglycemia. In people with T1D, blood glucose intervention targeting HbA1c levels ≤7% can slow onset and progression of kidney disease. Despite guideline-recommended treatment with ACEIs and ARBs, residual risk remains high in people with CKD and T1D, with up to a quarter progressing to end-stage-kidney-disease. CKD associated with T1D significantly increases the risk of kidney failure and cardiovascular events, contributing to CKD being a leading cause of death in T1D.

About Bayer's Commitment in Cardiovascular, Kidney and Cerebrovascular Diseases

Bayer is a leader in the area of cardiology and is advancing a portfolio of innovative treatments for cardiovascular, kidney and cerebrovascular diseases with high unmet medical needs. The company has set a clear focus on developing therapies to treat such diseases (e.g., heart failure, cardiomyopathies, chronic kidney disease, and stroke), and it is its ambition to take a leading role in the care of patients with these diseases. Bayer's portfolio already includes several innovative products and 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, kidney, and cerebrovascular diseases are diagnosed and treated.

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 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 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 https://pharma.bayer.com
Follow us on Facebook: http://www.facebook.com/bayer

de (2026-0141E)

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.