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News Release

Not intended for U.S. and UK Media

U.S. FDA grants Priority Review for finerenone in chronic kidney disease associated with type 1 diabetes

- The supplemental New Drug Application (sNDA) was based on the Phase III FINE-ONE study, which demonstrated that finerenone significantly reduced urine albumin-to-creatinine ratio (UACR) by 25% from baseline over 6 months compared to placebo in patients with chronic kidney disease (CKD) associated with type 1 diabetes (T1D), in conjunction with pooled Phase III FIDELIO-DKD and FIGARO-DKD data in CKD associated with type 2 diabetes (T2D), which showed that more than 80% of the kidney benefit of finerenone was explained by UACR reduction
- The FDA grants Priority Review designation for the evaluation of medicines that, if approved, would offer significant improvements in the efficacy or safety of the treatment, diagnosis, or prevention of serious conditions when compared to available therapies
- If approved, finerenone would become the first new treatment option in over 30 years for adults with chronic kidney disease (CKD) associated with type 1 diabetes (T1D)
- CKD associated with T1D is a major public health challenge: 30% of people with T1D develop CKD, and 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

Berlin, May 21, 2026 – Bayer announced today that the U.S. Food and Drug Administration (FDA) has accepted its supplemental New Drug Application (sNDA) and granted Priority Review designation for Kerendia™ (finerenone) for the treatment of chronic kidney disease (CKD) associated with type 1 diabetes (T1D). The regulatory submission is supported by the positive results from 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.

The pivotal FINE-ONE study demonstrated that finerenone in addition to standard of care is superior to placebo in showing a statistically significant reduction in the primary endpoint of relative change in urine albumin-to-creatinine ratio (UACR) by 25% from baseline over 6 months versus placebo in adults with chronic kidney disease (CKD) associated with type 1 diabetes (T1D). UACR is an important predictor of kidney and cardiovascular events in diabetes-associated chronic kidney disease, with elevated levels indicating worsening kidney damage and increased CV risk. Reduction of UACR is highly correlated with fewer kidney and cardiovascular events: In the pivotal Phase III studies in CKD associated with type 2 diabetes (FIDELIO-DKD, FIGARO-DKD), reduction of UACR with finerenone was strongly associated with delay of kidney disease progression and kidney failure, as well as with a reduction of cardiovascular events.

“The FDA’s priority review designation underscores the strength of the growing evidence base for finerenone and the importance of our ongoing study program across broad patient populations evaluating finerenone for cardiovascular and kidney outcomes,” said Dr. Christian Rommel, Global Head of Research and Development at Bayer’s Pharmaceuticals Division. “Finerenone targets a key driver of heart and kidney damage, and, if approved, has the potential to address a critical treatment gap for people with type 1 diabetes and chronic kidney disease.”

The FDA grants Priority Review designation for the evaluation of medicines that, if approved, would offer significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to available therapies. Priority review designation expedites the review of a (supplemental) New Drug Application, with the FDA’s goal being to take action on a New Drug Application within 6 months of submission, compared to 10 months under standard review.

CKD affects 30% of people with T1D and approximately one in four of these individuals will progress to end-stage kidney disease. In 2025, more than 9.5 million people are living with T1D worldwide, with prevalence projected to rise to between 13.5 - 17.4 million in 2040. People with both T1D and CKD face a significantly increased risk of kidney failure and cardiovascular disease (CVD). In the U.S., 1.4 million adults aged 20 years or older are living with T1D, representing 5.2% of all US adults with diagnosed diabetes. More than half of new T1D diagnoses in the U.S. occur in people aged 20 and older, and around 85% of these cases arise in people with no known family history of the condition.

Finerenone, a selective, nonsteroidal mineralocorticoid receptor antagonist (nsMRA), is the first drug targeting the MR pathway to demonstrate clinically proven heart and/or kidney benefits in five pivotal Phase III studies, for patients with heart failure with left ventricular ejection fraction (LVEF) ≥40%, CKD associated with type 2 diabetes, CKD associated with type 1 diabetes, and non-diabetic CKD. Finerenone is currently approved in more than 100 countries worldwide in CKD associated with type 2 diabetes. In the U.S., in Japan, the EU and several other markets, finerenone is also approved in heart failure with left ventricular ejection fraction (LVEF) ≥ 40%.

About Kerendia™ / Firialta™ (finerenone)

Kerendia™ and Firialta™ are globally protected trademarks for finerenone. Finerenone is a non-steroidal, selective mineralocorticoid receptor (MR) antagonist 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.

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. Following priority review designation, finerenone has been approved for the treatment of heart failure with LVEF ≥ 40% in the U.S. since July 2025. In Japan, several other markets, and recently in the EU, finerenone is also approved in heart failure with LVEF ≥ 40%. Applications for marketing authorization in HF with LVEF ≥ 40% have been filed in additional markets, including in China.

The clinical study program with finerenone, FINEOVATE, currently comprises ten Phase III studies with dedicated programs in HF and CKD respectively. The MOONRAKER program includes the completed pivotal Phase III study FINEARTS-HF, as well as the ongoing collaborative, investigator-sponsored studies REDEFINE-HF, CONFIRMATION-HF, and FINALITY-HF. 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 paediatric patient populations FIONA, and FIONA-OLE.

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.

In FINE-ONE, finerenone significantly reduced the primary endpoint of relative change in UACR by 25% (percentage reduction, least squares geometric mean (LSGM) ratio 0.75 [95% CI, 0.65-0.87; p=0.0001]) from baseline over 6 months versus placebo. At any time post-baseline, 81 out of 119 participants (68.1%) in the finerenone arm, versus 54 out of 116 (46.6%) participants in the placebo arm achieved at least a 30% reduction in UACR, 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. The safety profile of finerenone in FINE-ONE was consistent with previous studies and no new safety signals were identified.

FINE-ONE is a global, randomized, placebo-controlled, double-blind, multicenter Phase III study in people with CKD and T1D. The primary objective was to demonstrate whether the addition of finerenone to standard of care is superior to placebo in reducing UACR from baseline over six months. Secondary endpoints included the number of participants with treatment emergent adverse events and hyperkalemia (adverse event of special interest).

Participants were randomly assigned 1:1 to finerenone (10 or 20 mg OD) or a finerenone-matched placebo. The starting dose depended on estimated glomerular filtration rate (eGFR) level (10 mg for eGFR ≥25–<60 mL/min/1.73 m^2; 20 mg for eGFR ≥60 mL/min/1.73 m^2. Finerenone was uptitrated to the 20 mg target dose after 30 days if the serum/plasma [K+] is ≤4.8 mmol/L and the eGFR decrease is <30% compared with the value measured at the prior visit. Safety was assessed at all scheduled visits, including serum potassium determined both centrally and locally. Blood pressure was assessed at screening and all follow-up visits. UACR was assessed at screening, baseline, month 3, month 6 and at the follow-up visit one month post treatment.

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 30% of people with T1D. In a systematic analysis for the Global Burden of Disease study, it was reported that the prevalence of CKD associated with T1D had increased by 58.2% from 1990 to 2007 and by 21.7% from 2007 to 2017. 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 cardiovascular events and kidney failure, contributing to CKD being a leading cause of death in T1D.

About Bayer’s Commitment in Cardiovascular and Kidney Diseases

Bayer is a leader in the area of cardiology and is advancing a portfolio of innovative treatments. The heart and the kidneys are closely linked in health and disease, and Bayer is working on new treatment approaches for cardiovascular and kidney diseases with high unmet medical needs. The strategy is to unlock the strong potential of the future cardiovascular and kidney market by transforming Bayer’s portfolio into precision medicine, addressing the high disease burden, and driving long-term growth. 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 and kidney diseases are 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.

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