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News Release

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Bayer submits application for next indication of Kerendia in China

- Regulatory submission of new indication for patients with non-diabetic chronic kidney disease is based on positive data from the Phase III FIND-CKD study, presented at the 63rd European Renal Association (ERA) Congress 2026 and simultaneously published in the [New England Journal of Medicine](#)
 - In FIND-CKD, finerenone significantly delayed disease progression and reduced cardiovascular-kidney events versus placebo in addition standard of care in patients with non-diabetic chronic kidney disease
 - FIND-CKD is the largest Phase III study to date focused on non-diabetic CKD of diverse etiologies, and the fifth completed Phase III study to report positive results with finerenone, a selective, non-steroidal mineralocorticoid receptor antagonist (nsMRA), which so far was studied in more than 20,000 patients across multiple populations with chronic kidney disease and/or heart failure
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Berlin, July 30, 2026 – Bayer today announced the submission of a New Drug Application to the Center of Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA), seeking approval to extend the indication of finerenone in China to include adult patients with non-diabetic chronic kidney disease. The regulatory submission is supported by the positive results from the Phase III FIND-CKD study, which were presented at ERA Congress 2026 and simultaneously published in the [New England Journal of Medicine](#).

Approximately 850 million people worldwide are living with chronic kidney disease (CKD) and more than half of them have non-diabetic CKD. Worldwide, 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. Non-diabetic CKD can have a range of etiologies, of which the most common include kidney disease linked to hypertension and glomerulonephritis (including IgAN and FSGS). Despite standard of care, patients

with non-diabetic CKD remain at risk for kidney failure and cardiovascular events. Chronic kidney disease linked to hypertension is the second most common cause of kidney failure. In addition, patients with advanced non-diabetic CKD face a significantly increased risk for a fatal cardiovascular event, about 2.6 times higher than that of the general population without CKD, which increases further as kidney function declines.

“People living with non-diabetic chronic kidney disease (CKD) face a substantial risk for progressive kidney function decline and cardiovascular events. The FIND-CKD study adds robust evidence supporting the potential of finerenone to address this risk across a diverse range of non-diabetic CKD etiologies, including CKD due to hypertension and glomerular diseases,” said Dr. Christian Rommel, Global Head of Research and Development at Bayer’s Pharmaceuticals Division. “Building on the evidence generated across the finerenone clinical development program, the submission of these data marks an important step in our efforts to bring finerenone to more patients who may benefit from its cardio-kidney protective effects and reflects our commitment to advancing innovation for people living with heart and kidney diseases worldwide.”

Since 2021, finerenone has been marketed as Kerendia™ or, in selected countries, as Firalta™, 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 left ventricular ejection fraction (LVEF) $\geq 40\%$ in the U.S., the EU, in Japan, and in China, with additional applications under regulatory review.

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 non-diabetic CKD. 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.

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 non-diabetic CKD. The study investigated finerenone in a broad patient population spanning different etiologies of non-diabetic CKD, adding to the positive data and breadth of evidence of finerenone in CKD associated with diabetes. FIND-CKD (**F**inerenone, in addition to standard of care, on the progression of kidney disease in patients with **N**on-**D**iabetic **C**hronic **K**idney **D**isease) investigated the efficacy and safety of finerenone compared to placebo in addition to standard of care in more than 1,500 patients with non-diabetic chronic kidney disease etiologies, 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 the FIND-CKD study, finerenone showed a statistically significant and clinically meaningful improvement of kidney function compared with placebo: The mean annual decline in eGFR from baseline to 32 months (total slope) was $-4.0 \text{ ml/minute/1.73 m}^2/\text{year}$ with placebo and $-3.3 \text{ ml/minute/1.73 m}^2/\text{year}$ with finerenone, corresponding to a $0.7 \text{ ml/minute/1.73 m}^2/\text{year}$ slower decline with finerenone [95% CI, 0.3-1.1; $p<0.001$]. Finerenone also significantly reduced the risk of the key secondary composite cardiovascular-kidney outcome, by 23% (HR 0.77 [95% CI, 0.60-0.99; $p=0.04$]). The result for the secondary endpoints of the composite of sustained $\geq 57\%$ eGFR decline or kidney failure was HR 0.78 (95% CI, 0.60-1.01; $p=0.06$), and the composite of hospitalization for heart failure or cardiovascular death was HR 0.60 (95% CI, 0.27-1.33).

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

About Chronic Kidney Disease

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. Chronic Kidney Disease (CKD) represents a major global health challenge, affecting 850 million people worldwide – in fact, as the ninth leading cause of death, it results in 1.5 million fatalities each year, translating to one death every 20 seconds. In the U.S., 1 in 3 adults is at risk for the disease. At advanced stages of CKD, patients may need dialysis or a kidney transplant to stay alive. Healthy kidneys act as the body's filter, removing waste products from the blood. They also control how much water and electrolytes are in the body, regulating blood pressure. As kidney function goes down, patients may experience a range of symptoms including leg swelling, tiredness in the day, nausea, muscle cramps, joint pain and confusion, trouble focusing, memory problems. Major underlying causes of CKD include diabetes, hypertension, and glomerular diseases such as immunoglobulin A nephropathy, focal segmental glomerulosclerosis and membranous nephropathy.

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 market by transforming Bayer's portfolio into precision cardiology, 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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Forward-Looking Statements

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