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

News Release

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Bayer submits application in Japan for expanded use of Kerendia in chronic kidney disease therapeutic area

- Submission supported by positive Phase III FIND-CKD results in patients with non-diabetic chronic kidney disease
- In FIND-CKD, finerenone significantly delayed kidney disease progression and reduced cardiovascular-kidney events versus placebo, in addition to standard of care
- FIND-CKD is the largest Phase III study to date in non-diabetic CKD of diverse etiologies and the fifth completed Phase III study to report positive results with finerenone

Berlin, August 28, 2026 – Bayer today announced that it has submitted a marketing authorization application in Japan to expand the use of finerenone in chronic kidney disease (CKD). The submission is supported by positive Phase III FIND-CKD results in adults with non-diabetic CKD.

Approximately 850 million people worldwide live with CKD, and more than half have non-diabetic CKD. 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. Non-diabetic CKD 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 glomerularsclerosis (FSGS)). Despite standard of care, patients with non-diabetic CKD 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 non-diabetic CKD 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.

“With almost 20 million adults in Japan living with CKD, including many with non-diabetic CKD who remain at substantial risk of kidney disease progression and cardiovascular events, there is a clear need for new treatment options,” said Dr. Christian Rommel, Global Head of Research and Development at Bayer’s Pharmaceuticals Division. “This submission in Japan marks an important step toward potentially bringing finerenone to adult patients living with non-diabetic chronic kidney disease and addressing this high unmet medical need. Supported by the positive Phase III FIND-CKD data, this filing reflects the growing body of evidence for finerenone across a broad range of cardio-kidney diseases and underscores our commitment to patients in Japan and worldwide.”

About Kerendia™ / Firialta™ (finerenone)

Kerendia™ and Firialta™ 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) ≥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 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 Firialta™, 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 China, Europe, Japan, and the U.S. Finerenone is also approved for the treatment of heart failure with left ventricular ejection fraction (LVEF) ≥ 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 non-diabetic CKD.

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. FIND-CKD (**FI**nerenone, 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 CKD 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 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 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 ≥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.

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Contact for media inquiries:

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

Email: daniela.esser@bayer.com

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