



NEWS DETAILS

Bayer's KERENDIA® (finerenone) Receives U.S. FDA Approval for Treatment of Patients with Chronic Kidney Disease Associated with Type 2 Diabetes

July 9, 2021

- KERENDIA is indicated to slow chronic kidney disease progression, reduce the risk of kidney failure, heart attack, heart failure hospitalization and cardiovascular death in adult patients with chronic kidney disease associated with type 2 diabetes¹
- First and only nonsteroidal mineralocorticoid receptor antagonist (MRA) approved for adults with chronic kidney disease associated with type 2 diabetes¹
- Despite guideline-directed therapies, many people with chronic kidney disease associated with type 2 diabetes are at risk for chronic kidney disease progression and cardiovascular events^{2,3,4,5}

WHIPPANY, N.J.--(BUSINESS WIRE)-- Bayer announced today the United States (U.S.) Food and Drug Administration (FDA) has approved KERENDIA® (finerenone), a first-in-class nonsteroidal mineralocorticoid receptor antagonist (MRA) indicated to reduce the risk of sustained eGFR decline, kidney failure, cardiovascular death, non-fatal myocardial infarction (MI) and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D).¹ The approval is based on the results of the pivotal Phase III FIDELIO-DKD trial data that demonstrated positive kidney and cardiovascular outcomes in patients with CKD associated with T2D, published in the *New England Journal of Medicine* in October 2020, and follows priority review designation granted by the FDA.^{1,6}

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Courtesy of Bayer

"The patient population included in the trial that supported the approval of KERENDIA were at risk of chronic kidney disease progression despite receiving standard of care treatment to control blood pressure and blood glucose,"^{1,6} said George Bakris, M.D., University of Chicago and lead FIDELIO-DKD study investigator. "In people with chronic kidney disease associated with type 2 diabetes, physicians now have a new treatment to provide kidney protection."^{1,3,6}

The KERENDIA label contains a Warning and Precaution that KERENDIA can cause hyperkalemia.¹ For more information, see "Important Safety Information" below.

Despite guideline-directed therapies, many people with CKD associated with T2D are at risk for CKD progression and cardiovascular events.^{2,3,4,5} Type 2 diabetes is the leading cause of end stage kidney disease, when patients may need dialysis or a kidney transplant to stay alive.^{7,8,9} Blacks or African Americans and Hispanic Americans have higher rates of kidney failure than their non-

Hispanic white counterparts.¹⁰

KERENDIA works by blocking overactivation of the mineralocorticoid receptor (MR). Mineralocorticoid receptor overactivation is thought to contribute to fibrosis and inflammation.¹ Fibrosis and inflammation can contribute to permanent structural kidney damage.^{4,11}

"KERENDIA is the first and only nonsteroidal mineralocorticoid receptor antagonist proven to significantly slow chronic kidney disease progression and reduce cardiovascular risk in people with chronic kidney disease associated with type 2 diabetes,"^{1,6} said Amit Sharma, M.D., Vice President

of Cardiovascular and Renal, Bayer U.S. Medical Affairs. "We are excited to bring this new kidney-focused treatment to people living with this condition."¹

"Chronic kidney disease associated with type 2 diabetes can have such a debilitating impact on patients' lives.¹⁰ Unfortunately, this disease is far reaching, as up to 40 percent of all patients with type 2 diabetes develop chronic kidney disease,"¹² said Kevin Longino, CEO, National Kidney Foundation, and a kidney transplant patient. "It is important for physicians and patients to have new treatment options that can slow chronic kidney disease progression."

KERENDIA is expected to be available in the U.S. beginning the end of July 2021. Finerenone has also been submitted for marketing authorization in the European Union.

About KERENDIA

INDICATION:

- KERENDIA is indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D).¹

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS:

- Concomitant use with strong CYP3A4 inhibitors¹
- Patients with adrenal insufficiency¹

WARNINGS AND PRECAUTIONS:

- *Hyperkalemia:* KERENDIA can cause hyperkalemia. The risk for developing hyperkalemia increases with decreasing kidney function and is greater in patients with higher baseline potassium levels or other risk factors for hyperkalemia. Measure serum potassium and eGFR in all patients before initiation of treatment with KERENDIA and dose accordingly. Do not initiate KERENDIA if serum potassium is > 5.0 mEq/L.¹

Measure serum potassium periodically during treatment with KERENDIA and adjust dose accordingly. More frequent monitoring may be necessary for patients at risk for hyperkalemia, including those on concomitant medications that impair potassium excretion or increase serum potassium.¹

MOST COMMON ADVERSE REACTIONS:

Adverse reactions reported in ≥ 1% of patients on KERENDIA and more frequently than placebo: hyperkalemia (18.3% vs. 9%), hypotension (4.8% vs. 3.4%), and hyponatremia (1.4% vs. 0.7%)¹

DRUG INTERACTIONS:

- *Strong CYP3A4 Inhibitors:* Concomitant use of KERENDIA with strong CYP3A4 inhibitors is contraindicated. Avoid concomitant intake of grapefruit or grapefruit juice.¹
- *Moderate and Weak CYP3A4 Inhibitors:* Monitor serum potassium during drug initiation or dosage adjustment of either KERENDIA or the moderate or weak CYP3A4 inhibitor and adjust KERENDIA dosage as appropriate.¹
- *Strong and Moderate CYP3A4 Inducers:* Avoid concomitant use of KERENDIA with strong or moderate CYP3A4 inducers.¹

USE IN SPECIFIC POPULATIONS:

- *Lactation:* Avoid breastfeeding during treatment with KERENDIA and for 1 day after treatment.¹
- *Hepatic Impairment:* Avoid use of KERENDIA in patients with severe hepatic impairment (Child Pugh C) and consider additional serum potassium monitoring with moderate hepatic impairment (Child Pugh B).¹

Please read the Prescribing Information for KERENDIA.

FIDELIO-DKD Clinical Trial Results

The approval of KERENDIA is supported by FIDELIO-DKD trial, which is part of the Phase III program for finerenone in CKD associated with T2D.

The FIDELIO-DKD study was a randomized, double-blind, placebo-controlled, multicenter study in adult patients with CKD associated with T2D, defined as either having an UACR of 30 to 300 mg/g, eGFR 25 to 60 mL/min/1.73 m² and diabetic retinopathy, or as having an UACR of ≥300 mg/g and an eGFR of 25 to 75 mL/min/1.73 m².¹ The trial excluded patients with known significant non-diabetic kidney disease and a clinical diagnosis of chronic heart failure with reduced ejection fraction and persistent symptoms (NYHA class II to IV).¹ All patients were to have a serum potassium ≤4.8 mEq/L at screening and be receiving standard of care background therapy, including a maximum tolerated labeled dose of an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB).¹ A total of 5,674 patients were randomized to receive KERENDIA

(N=2833) or placebo (N=2841) and were followed for a median of 2.6 years.¹ The mean age of the study population was 66 years, and 70% of patients were male.¹ The trial population was 63% White, 25% Asian, and 5% Black.¹

KERENDIA reduced the incidence of the primary composite endpoint of a sustained decline in eGFR of $\geq 40\%$, kidney failure, or renal death (HR 0.82, 95% CI 0.73-0.93, $p=0.001$).¹ The treatment effect reflected a reduction in a sustained decline in eGFR of $\geq 40\%$ and progression to kidney failure.¹ There were few renal deaths during the trial.¹

KERENDIA also reduced the incidence of the composite endpoint of cardiovascular death, non-fatal MI, non-fatal stroke or hospitalization for heart failure (HR 0.86, 95% CI 0.75-0.99, $p=0.034$).¹ The treatment effect reflected a reduction in cardiovascular death, non-fatal MI, and hospitalization for heart failure.¹

Adverse reactions that occurred more commonly on KERENDIA than on placebo, and in at least 1% of patients treated with KERENDIA were hyperkalemia (18.3% vs. 9%), hypotension (4.8% vs. 3.4%), and hyponatremia (1.4% vs. 0.7%).¹

Please see Prescribing Information for KERENDIA® (finerenone) HERE.

About Bayer's Commitment in Cardiovascular and Kidney Diseases

Bayer is an innovation leader in the area of cardiovascular diseases, with a long-standing commitment to delivering science for a better life by advancing a portfolio of innovative treatments. The heart and the kidneys are closely linked in health and disease, and Bayer is working in a wide range of therapeutic areas on new treatment approaches for cardiovascular and kidney diseases with high unmet medical needs. The cardiology franchise at Bayer already includes a number of products and several other 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 diseases are treated.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to help people and planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to drive sustainable development and generate 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 2020, the Group employed around 100,000 people and had sales of 41.4 billion euros. R&D expenses before special items amounted to 4.9 billion euros. For more information, go to www.bayer.com.

Please see Prescribing Information for KERENDIA® (finerenone) HERE.

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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.

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