

FDA approves drug to reduce risk of serious kidney and heart complications in adults with chronic kidney disease associated with type 2 diabetes

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FDA has approved Kerendia (finerenone) tablets to reduce the risk of kidney function decline, kidney failure, cardiovascular death, non-fatal heart attacks, and hospitalization for heart failure in adults with chronic kidney disease associated with type 2 diabetes.

Diabetes is the leading cause of chronic kidney disease and kidney failure in the United States. Chronic kidney disease occurs when the kidneys are damaged and cannot filter blood normally. Because of defective filtering, patients can have complications related to fluid, electrolytes (minerals required for many bodily processes), and waste build-up in the body. Chronic kidney disease sometimes can progress to kidney failure. Patients also are at high risk of heart disease.

The efficacy of Kerendia to improve kidney and heart outcomes was evaluated in a randomized, multicenter, double-blind, placebo-controlled study in adults with chronic kidney disease associated with type 2 diabetes. In this study, 5,674 patients were randomly assigned to receive either Kerendia or a placebo.

The study compared the two groups for the number of patients whose disease progressed to a composite (or combined) endpoint that included at least a 40% reduction in kidney function, progression to kidney failure, or kidney death. Results showed that 504 of the 2,833 patients who received Kerendia had at least one of the events in the composite endpoint compared to 600 of the 2,841 patients who received a placebo.

The study also compared the two groups for the number of patients who experienced cardiovascular death, a non-fatal heart attack, non-fatal stroke, or hospitalization for heart failure. Results showed that 367 of the 2,833 patients receiving Kerendia had at least one of the events in the composite endpoint compared to 420 of the 2,841 patients who received a placebo, with the treatment showing a reduction in the risk of cardiovascular death, non-fatal heart attack, and hospitalization for heart failure.

Side effects of Kerendia include hyperkalemia (high levels of potassium), hypotension (low blood pressure), and hyponatremia (low levels of sodium). Patients with adrenal insufficiency (when the body does not produce enough of certain hormones) and those receiving simultaneous treatment with strong CYP3A4 inhibitors should not take Kerendia.

Kerendia received priority review and fast track designations for this application.

FDA granted the approval of Kerendia to Bayer Healthcare.