Kerendia™ (finerenone) – New drug approval

- On July 9, 2021, the FDA announced the approval of Bayer's Kerendia (finerenone), to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease, cardiovascular death, nonfatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D).

- Diabetes is the leading cause of CKD in the U.S. CKD can sometimes progress to kidney failure and they are at increased risk of heart disease.

- Kerendia is a nonsteroidal mineralocorticoid receptor antagonist. Mineralocorticoid receptor overactivation is thought to contribute to fibrosis and inflammation.

- The efficacy of Kerendia was established in FIDELIO-DKD, a randomized, double-blind, placebo-controlled study in 5,674 adult patients with CKD associated with T2D. Patients were randomized to receive Kerendia or placebo and were followed for a median of 2.6 years. The primary composite endpoint was the incidence of a sustained decline in eGFR of ≥ 40%, kidney failure (defined as chronic dialysis, kidney transplantation, or a sustained decrease in eGFR to < 15 mL/min/1.73 m^2), or renal death.

    - Kerendia reduced the incidence of the primary composite endpoint (hazard ratio [HR] 0.82, 95% CI: 0.73, 0.93, p = 0.001). The event rate (100 patient year) was 7.6 and 9.1 for Kerendia and placebo, respectfully.
    - Kerendia also reduced the incidence of the composite endpoint of cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, or hospitalization for heart failure (HR 0.86, 95% CI: 0.75, 0.99, p = 0.034).

- Kerendia is contraindicated in patients:

    - Who are receiving concomitant treatment with strong CYP3A4 inhibitors
    - With adrenal insufficiency

- A warning and precaution for Kerendia is hyperkalemia.

- The most common adverse reactions (≥ 1% and more frequently than placebo) with Kerendia use were hyperkalemia, hypotension, and hyponatremia.

- The recommended starting dose of Kerendia is based on eGFR and is presented in the table below. The target daily dose of Kerendia is 20 mg.

    - Prior to initiation of Kerendia, measure serum potassium levels and eGFR. Treatment should not be initiated if serum potassium is > 5.0 mEq/L.

eGFR (mL/min/1.73m^2)	Starting dose
≥ 60	20 mg once daily
≥ 25 to < 60	10 mg once daily
< 25	Not recommended

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- Bayer plans to launch Kerendia beginning the end of July 2021. Kerendia will be available as a 10 mg and 20 mg tablet.

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