FDA approves Farxiga for heart failure with reduced ejection fraction

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The U.S. Food and Drug Administration has granted approval for Farxiga (dapagliflozin) oral tablets to treat adults with heart failure with reduced ejection fraction, the agency announced Tuesday.

Farxiga is the first approved sodium-glucose cotransporter 2 inhibitor to treat adults with New York Heart Association functional class II to IV heart failure with reduced ejection fraction. The drug is indicated to reduce the risk for cardiovascular death and hospitalization for heart failure in this patient population. Farxiga has already been FDA-approved to improve glycemic control in patients with type 2 diabetes and to reduce the risk for hospitalization in patients with type 2 diabetes and known cardiovascular disease or other risk factors.

Approval of Farxiga was based on data from a randomized, double-blind, placebo-controlled study of 4,744 patients who were aged 66 years on average. Patients were randomly assigned to a once-daily dose of 10 mg of Farxiga or placebo. At about 18 months of follow-up, patients treated with Farxiga versus placebo had fewer cardiovascular deaths, heart failure hospitalizations, and urgent heart failure visits.

Potential side effects of Farxiga include dehydration, serious urinary tract infections, and genital yeast infections. The FDA notes that physicians should monitor the volume status and kidney function of elderly patients, those with kidney problems or low blood pressure, patients taking diuretics, and those with signs and symptoms of metabolic acidosis or ketoacidosis. When combined with insulin, Farxiga can also cause Fournier gangrene in people with diabetes and low blood sugar.

Approval was granted to AstraZeneca Pharmaceuticals.

More information: More Information