FDA NEWS RELEASE

FDA approves new treatment for a type of heart failure

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Today, the U.S. Food and Drug Administration approved Farxiga (dapagliflozin) oral tablets for adults with heart failure with reduced ejection fraction to reduce the risk of cardiovascular death and hospitalization for heart failure. Heart failure occurs when the heart does not pump enough blood to support the body's needs, and this type of heart failure happens when the heart's main pumping chamber, the left ventricle, is weakened. With the approval, Farxiga is the first in this particular drug class, sodium-glucose co-transporter 2 (SGLT2) inhibitors, to be approved to treat adults with New York Heart Association's functional class II-IV heart failure with reduced ejection fraction.

"Heart failure is a serious health condition that contributes to one in eight deaths in the U.S. and impacts nearly 6.5 million Americans," said Norman Stockbridge, M.D., Ph.D., director of the Division of Cardiology and Nephrology in the FDA's Center for Drug Evaluation and Research. "This approval provides patients with heart failure with reduced ejection fraction an additional treatment option that can improve survival and reduce the need for hospitalization."

Farxiga was shown in a clinical trial to improve survival and reduce the need for hospitalization in adults with heart failure with reduced ejection fraction. Farxiga's safety and effectiveness were evaluated in a randomized, double-blind, placebo-controlled study of 4,744 participants. The average age of participants was 66 years and more participants were male (77%) than female. To determine the drug's effectiveness, investigators examined the occurrence of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits. Participants were randomly assigned to receive a once-daily dose of either 10 milligrams of Farxiga or a placebo (inactive treatment). After about 18 months, people who received Farxiga had fewer cardiovascular deaths, hospitalizations for heart failure, and urgent heart failure visits than those receiving the placebo.

Farxiga can cause dehydration, serious urinary tract infections and genital yeast infections. Elderly patients, patients with kidney problems, those with low blood pressure, and patients on diuretics should be assessed for their volume status and kidney function. Patients with signs and symptoms of metabolic acidosis or ketoacidosis (acid buildup in the blood) should also be assessed. Farxiga can cause serious cases of necrotizing fasciitis of the perineum (Fournier's Gangrene) in people with diabetes and low blood sugar when combined with insulin.

This application received Priority Review (/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review) designation, meaning the agency planned to take action on the application within six months, because the drug, if approved, would significantly improve the safety or effectiveness of treating, diagnosing or preventing a serious condition.

Farxiga is also FDA-approved to improve glycemic control in adults with type 2 diabetes in addition to diet and exercise, and to reduce the risk of hospitalization for heart failure among adults with type 2 diabetes and known cardiovascular disease or other risk factors.

The FDA granted the approval of Farxiga related to heart failure to AstraZeneca Pharmaceuticals LP Wilmington, DE.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Inquiries

Media:

Monique Richards (mailto:monique.richards@fda.hhs.gov)

240-402-3014

Consumer:

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