FDA News Release

FDA approves Jardiance to reduce cardiovascular death in adults with type 2 diabetes

Study links Jardiance to improved survival in patients with type 2 diabetes with cardiovascular disease

For Immediate Release

December 2, 2016

Release

Español (/NewsEvents/Newsroom/ComunicadosdePrensa/ucm531872.htm)

The U.S. Food and Drug Administration today approved a new indication for Jardiance (empagliflozin) to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and cardiovascular disease.

“Cardiovascular disease is a leading cause of death in adults with type 2 diabetes mellitus,” said Jean-Marc Guettier, M.D., C.M., director of the Division of Metabolism and Endocrinology Products in FDA’s Center for Drug Evaluation and Research. “Availability of antidiabetes therapies that can help people live longer by reducing the risk of cardiovascular death is an important advance for adults with type 2 diabetes.”

According to the **Centers for Disease Control and Prevention (http://www.cdc.gov/diabetes/data/statistics/2014StatisticsReport.html)**, death from cardiovascular disease is 70 percent higher in adults with diabetes compared to those without diabetes, and patients with diabetes have a decreased life expectancy driven in large part by premature cardiovascular death.

The FDA’s decision is based on a postmarketing study required by the agency when it **approved (/NewsEvents/Newsroom/PressAnnouncements/ucm407637.htm)** Jardiance in 2014 as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Jardiance was studied in a postmarket clinical trial of more than 7,000 patients with type 2 diabetes and cardiovascular disease. In the trial, Jardiance was shown to reduce the risk of cardiovascular death compared to a placebo when added to standard of care therapies for diabetes and atherosclerotic cardiovascular disease.

Jardiance can cause dehydration and low blood pressure (hypotension). Jardiance can also cause increased ketones in the blood (ketoacidosis), serious urinary tract infection, acute kidney injury and impairment in renal function, low blood glucose (hypoglycemia) when used with insulin or insulin secretagogues (e.g. sulfonylurea, a medication used to treat type 2 diabetes by increasing the release of insulin in the pancreas), vaginal yeast infections and yeast infections of the penis (genital mycotic infections), and increased cholesterol.

The most common side effects of Jardiance are urinary tract infections and female genital infections.

Jardiance is not intended for patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Jardiance is contraindicated in patients with a history of serious hypersensitivity reactions to Jardiance, severe renal impairment, end-stage renal disease, or dialysis.

Jardiance is distributed by Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield,

Connecticut.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency is also 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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Related Information

- June 28, 2016, Meeting of the Endocrinologic and Metabolic Drugs Advisory Committee (/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm491062.htm)
- Guidance for Industry: Diabetes Mellitus — Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes (PDF - 47KB) (/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM071627.pdf)

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