FDA Approves New Treatment for Acute Myeloid Leukemia

Daurismo (glasdegib) plus chemotherapy improved overall survival in clinical trial.

November 21, 2018 By Food and Drug Administration (FDA)

The U.S. Food and Drug Administration today approved Daurismo (glasdegib) tablets to be used in combination with low-dose cytarabine (LDAC), a type of chemotherapy, for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adults who are 75 years of age or older or who have other chronic health conditions or diseases (comorbidities) that may preclude the use of intensive chemotherapy.

“Intensive chemotherapy is usually used to control AML, but many adults with AML are unable to have intensive chemotherapy because of its toxicities. Today’s approval gives health care providers another tool to use in the treatment of AML patients with various, unique needs. Clinical trials showed that overall survival was improved using Daurismo in combination with LDAC compared to LDAC alone for patients who would not tolerate intensive chemotherapy,” said Richard Pazdur, MD, director of the FDA’s Oncology Center of Excellence and acting director of the Office of Hematology and Oncology Products in the FDA’s Center for Drug Evaluation and Research.

AML is a rapidly progressing cancer that forms in the bone marrow and results in an increased number of abnormal white blood cells in the bloodstream and bone marrow. The National Cancer Institute at the National Institutes of Health estimates that in 2018, approximately 19,520 people will be diagnosed with AML and approximately 10,670 patients with AML will die of the disease. Almost half of the adults diagnosed with AML are not treated with intensive chemotherapy because of comorbidities and chemotherapy related toxicities.

The efficacy of Daurismo was studied in a randomized clinical trial in which 111 adult patients with newly diagnosed AML were treated with either Daurismo in combination with LDAC or LDAC alone. The trial measured overall survival (OS) from the date of randomization to death from any cause. Results demonstrated a significant improvement in OS in patients treated with Daurismo. The median OS was 8.3 months for patients treated with Daurismo plus LDAC compared with 4.3 months for patients treated with LDAC only.

Common side effects reported by patients receiving Daurismo in clinical trials include low red blood cell count (anemia), tiredness (fatigue), bleeding (hemorrhage), fever with low white blood

cell count (febrile neutropenia), muscle pain, nausea, swelling of the arms or legs (edema), low platelet counts (thrombocytopenia), shortness of breath (dyspnea), decreased appetite, distorted taste (dysgeusia), pain or sores in the mouth or throat (mucositis), constipation and rash.

The prescribing information for Daurismo includes a Boxed Warning to advise health care professionals and patients about the risk of embryo-fetal death or severe birth defects. Daurismo should not be used during pregnancy or while breastfeeding. Pregnancy testing should be conducted in females of reproductive age prior to initiation of Daurismo treatment and effective contraception should be used during treatment and for at least 30 days after the last dose. The Boxed Warning also advises male patients of the potential risk of drug exposure through semen and to use condoms with a pregnant partner or a female partner that could become pregnant both during treatment and for at least 30 days after the last dose. Daurismo must be dispensed with a patient Medication Guide that describes important information about the drug's uses and risks. Patients should also be advised not to donate blood or blood products during treatment. Health care providers should also monitor patients for changes in the electrical activity of the heart, called QT prolongation.

The FDA granted this application Priority Review designation. Daurismo also received Orphan Drug designation, which provides incentives to assist and encourage the development of drugs for rare diseases.

The FDA granted the approval of Daurismo to Pfizer.

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