FDA approves new treatment for acute myeloid leukemia

November 27 2018

(HealthDay)—The U.S. Food and Drug Administration recently

announced the approval of Daurismo (glasdegib) tablets for use in combination with a low dose of the chemotherapy cytarabine to treat newly diagnosed acute myeloid leukemia (AML). The treatment is indicated for patients aged 75 years or older who have comorbidities that may prevent the use of intensive chemotherapy.

Researchers investigated the efficacy of Daurismo in a randomized clinical trial of 111 adult patients with newly diagnosed AML. Patients were randomly assigned to treatment with Daurismo in combination with low-dose cytarabine or treatment with low-dose cytarabine alone. Data showed a significant improvement in overall survival with Daurismo from the date of random assignment to death from any cause. Median overall survival was 8.3 months for patients treated with Daurismo plus low-dose cytarabine compared with 4.3 months for patients treated with low-dose cytarabine alone.

Commonly reported side effects included anemia, fatigue, hemorrhage, febrile neutropenia, muscle pain, nausea, edema, thrombocytopenia, dyspnea, decreased appetite, dysgeusia, mucositis, constipation, and rash.

The prescribing information for Daurismo includes a Boxed Warning on the risk for embryo-fetal death or severe birth defects. The FDA indicated that Daurismo should not be used during pregnancy or while breastfeeding. Women of reproductive age should be tested for pregnancy before starting Daurismo treatment, and they should use effective contraception during treatment and for at least 30 days after the last dose. The Boxed Warning also indicates the potential risk for drug exposure through semen and advises men to use condoms with a pregnant partner or female partner who could become pregnant during treatment and for at least 30 days after the last dose. Health care providers should dispense the medication using a patient Medication Guide that describes information about the drug's uses and risks. They should also advise patients not to donate blood or blood products during

treatment. Health care providers should monitor patients for QT prolongation.

More information: More Information