Generic Name:
Glasdegib
Trade Name:
Daurismo
Company:
Pfizer
Notes:

FDA has approved 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 aged 75 or older or who have other chronic health conditions or diseases that may preclude the use of intensive chemotherapy.

Efficacy of glasdegib was studied in a randomized clinical trial in which 111 adult patients with newly diagnosed AML were treated with either glasdegib 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 glasdegib. The median OS was 8.3 months for patients treated with glasdegib plus LDAC compared with 4.3 months for patients treated with LDAC only.

Common adverse effects in clinical trials were anemia, fatigue, hemorrhage, febrile neutropenia, muscle pain, nausea, edema, low platelet counts, shortness of breath, decreased appetite, distorted taste, pain or sores in the mouth or throat, constipation and rash.

The prescribing information includes a boxed warning about the risk of embryo-fetal death or severe birth defects. Glasdegib should not be used during pregnancy or while breastfeeding. Pregnancy testing should be conducted in females of reproductive age before treatment initiation, 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 who could become pregnant both during treatment and for at least 30 days after the last dose.

Glasdegib 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 QT prolongation.

Medication Monitor Categories:
New Drug Approvals