

[New Drug Approvals](#)

Generic Name (Trade Name—Company)

November 29, 2018

Gilteritinib

(Xospata—Astellas Pharma)

New drug targets relapsed or refractory AML in adults with FLT3 mutation

Uses/Notes

FDA [approved](#) gilteritinib tablets to treat relapsed or refractory acute myeloid leukemia (AML) in adult patients with an FLT3 mutation as detected by an FDA-approved test, the LeukoStrat CDx FLT3 Mutation Assay (Invivoscribe Technologies).

Efficacy of gilteritinib was studied in a clinical trial of 138 patients with relapsed or refractory AML having a confirmed FLT3 mutation. Twenty-one percent of patients achieved complete remission (no evidence of disease and full recovery of blood counts) or complete remission with partial hematologic recovery (no evidence of disease and partial recovery of blood counts) with treatment.

Of the 106 patients who required red blood cell or platelet transfusions at the start of treatment, 31% became transfusion-free for at least 56 days.

Common adverse effects reported in clinical trials were muscle and joint pain, fatigue, and elevated liver enzymes.

Health care providers are advised to monitor patients for posterior reversible encephalopathy syndrome, which is characterized by headache, confusion, seizures, and visual loss; prolonged QT interval; and pancreatitis.

Rare cases of differentiation syndrome (symptoms of which may include fever, cough, trouble breathing, fluid around the lungs or heart, rapid weight gain, swelling, and renal or hepatic dysfunction) have been seen in patients taking the drug.

Women who are pregnant or breastfeeding should not take gilteritinib because it may cause harm to a developing fetus or newborn baby.

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