Gilteritinib gets expanded approval

February 2019—The Food and Drug Administration approved gilteritinib (Xospata, Astellas Pharma) for treatment of adult patients who have relapsed or refractory acute myeloid leukemia with an FLT3 mutation as detected by an FDA-approved test.

The FDA also approved an expanded indication for a companion diagnostic to include use with gilteritinib. The LeukoStrat CDx FLT3 Mutation Assay, developed by Invivoscribe Technologies, is used to detect the FLT3 mutation in patients with AML.

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