AMLGlobalPortal

FLT3

Addition of survival data on gilteritinib labeling approved by FDA

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The US Food and Drug Administration has approved the addition of overall survival (OS) data in the labeling for gilteritinib indicated for patients with relapsed or refractory acute myeloid leukemia (R/R AML) with FLT3 mutation.

The ADMIRAL trial (NCT 02421939) was the basis of approval, and enrolled 371 adult patients with R/R AML, and either a FLT3 ITD, D835 or I836 mutation (identified through the LeukoStrat® CDx FLT3 Mutation Assay).

During the study patients randomly (2:1) received gilteritinib 120 mg once daily (n = 247), over 28-day cycles, or salvage chemotherapy (n = 124), which included either intensive cytotoxic chemotherapy, or a low-intensity regimen.

OS was measured from randomization until death by any cause. The median OS was 9.3 months for patients in the gilteritinib cohort and 5.6 months for patients in the chemotherapy cohort. Results were consistent in the intensive chemotherapy arm and the low-intensity chemotherapy arm.

Adverse reactions occurring in at least 20% of patients who received gilteritinib were transaminase, myalgia/arthralgia, fatigue/malaise, fever, mucositis, edema, rash, noninfectious diarrhea, dyspnea, nausea, cough, constipation, eye disorders, headache, dizziness, hypotension, vomiting, and renal impairment.

The recommended dose of gilteritinib is 120 mg orally once daily. Full prescribing information can be found here, and contains a Boxed Warning alerting health care professionals and patients about the risk of differentiation syndrome, which may be life-threatening or fatal if not treated.

Reference

FDA approves addition of survival data to gilteritinib label for refractory AML with a FLT3 mutation. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-addition-survival-data-gilteritinib-label-refractory-aml-flt3-mutation [accessed 31.05.2019]