Tibsovo approved for patients with R/R AML with IDH1 mutation

September 2018—Agios Pharmaceuticals announced that Tibsovo (ivosidenib) was granted FDA approval for the treatment of adult patients with relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 mutation, as detected by an FDA-approved test.

Tibsovo is an oral, targeted inhibitor of the IDH1 enzyme. The efficacy of the drug was studied in a single-arm trial of 174 adult patients with relapsed or refractory AML with an IDH1 mutation. The trial measured the percentage of patients with no evidence of disease and full recovery of blood counts after treatment, as well as patients with no evidence of disease and partial recovery of blood counts after treatment. With a median follow-up of 8.3 months, 32.8 percent of patients experienced complete remission or complete remission with partial hematologic recovery that lasted a median 8.2 months. Of the 110 patients who required transfusions of blood or platelets due to AML at the start of the study, 37 percent went at least 56 days without requiring a transfusion after treatment with Tibsovo.

The FDA granted approval to Abbott for the RealTime IDH1 Assay, a companion diagnostic that can be used to detect the IDH1 mutation.

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