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FDA approves Tibsovo for AML patients

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Singapore – The U.S. Food and Drug Administration approved Tibsovo (ivosidenib) tablets for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) who have a specific genetic mutation. This is the first drug in its class (IDH1 inhibitors) and is approved for use with an FDA-approved companion diagnostic used to detect specific mutations in the IDH1 gene in patients with AML.

"Tibsovo is a targeted therapy that fills an unmet need for patients with relapsed or refractory AML who have an IDH1 mutation," said Richard Pazdur, M.D., director of the FDA's Oncology Center of Excellence and acting director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "The use of Tibsovo is associated with a complete remission in some patients and a reduction in the need for both red cell and platelet transfusions."

AML is a rapidly progressing cancer that forms in the bone marrow and results in an increased number of abnormal white blood cells in the bloodstream and bone marrow. The National Cancer Institute at the National Institutes of Health estimates that approximately 19,520 people will be diagnosed with AML this year; approximately 10,670 patients with AML will die of the disease in 2018.

Tibsovo is an isocitrate dehydrogenase-1 inhibitor that works by decreasing abnormal production of the oncometabolite 2-hydroxyglutarate (2-HG), leading to differentiation of malignant cells. If the IDH1 mutation is detected in blood or bone

marrow samples using an FDA-approved test, the patient may be eligible for treatment with Tibsovo. Today the agency also approved the Real*Time* IDH1 Assay, a companion diagnostic that can be used to detect this mutation.