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CStone to initiate ivosidenib Phase I study in China

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CStone receives approval in China to initiate ivosidenib Phase I bridging registrational study for the treatment of IDH1 mutant relapsed or refractory AML

CStone Pharmaceuticals has received approval from China National Medical Products Administration (NMPA) to initiate a Phase I bridging registrational study of ivosidenib (TIBSOVO) for the treatment of relapsed or refractory acute myeloid leukemia (R/R AML) with an IDH1 mutation. This stand-alone trial is designed to evaluate the efficacy, safety and pharmacokinetics of ivosidenib in Chinese patients with IDH1 mutant R/R AML.

AML is the most common type of acute leukemia in adults and is characterized by rapid disease progression. There are approximately 20,000 new cases of AML in the U.S. each year, with a five-year survival rate of approximately 27%, as compared to 30,000 new cases in China annually and a five-year survival rate of below 20%. The majorities of AML patients develop tolerance to treatments or eventually relapse, leading to R/R AML which has a poor prognosis.

With an increasing life expectancy and aging population in China, the incidence of AML may rise significantly in the country. Interruption to the differentiation of hematopoietic stem cells due to IDH1 mutation is associated with around 6%-10% of all AML cases. Among the currently approved treatments for AML in China, there is no effective therapy for this patient population.

Discovered and developed by CStone's partner Agios Pharmaceuticals, ivosidenib was approved by the U.S. FDA in July 2018 for the treatment of adult R/R AML patients with an IDH1 mutation as detected by an FDA-approved test.

"Ivosidenib is the first and only approved precision therapy in the U.S. that targets IDH1 mutation in R/R AML and the only asset in CStone's pipeline that has obtained a marketing authorization. This approval for the registrational study in China marks a big milestone for us," commented Dr. Frank Jiang, Chairman and CEO of CStone. "Through precision therapies, patients can potentially benefit from treatments targeting the specific genetic mutations that drive the cancer. CStone remains committed to advancing precision therapies and bringing more targeted treatment options to patients."