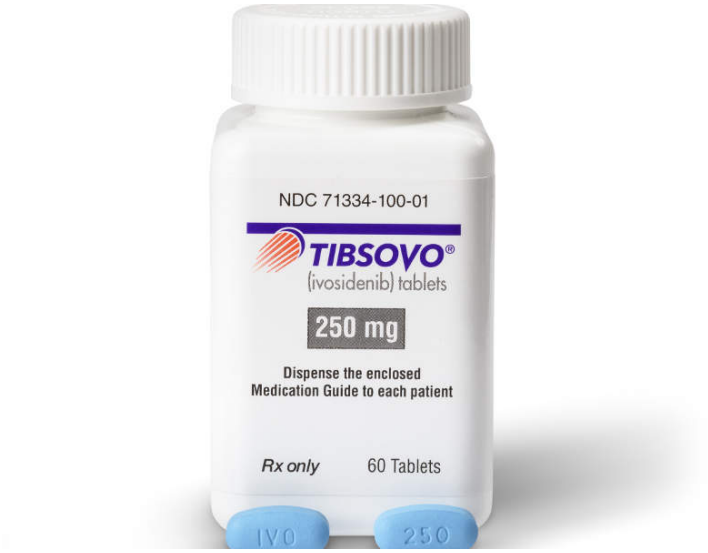
BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

CStone submits new drug application for TIBSOVO(R) for treatment of relapsed/refractory AML

03 June 2019 | News

First to-be-approved treatment of adult patients with relapsed or refractory (R/R) acute myeloid leukemia (AML) with a susceptible IDH1 mutation



CStone Pharmaceuticals announced that a new drug application (NDA) for TIBSOVO® (ivosidenib) has been submitted by a third-party to the Taiwan Food and Drug Administration (TFDA) as the first to-be-approved treatment of adult patients with relapsed or refractory (R/R) acute myeloid leukaemia (AML) with a susceptible IDH1 mutation. The application is the first market filing for CStone since its inception in 2015.

TIBSOVO is a first-in-class, oral, potent and selective inhibitor of the mutant isocitrate dehydrogenase-1 (IDH1) enzyme. The TFDA awarded TIBSOVO the NDA filing priority review status on April 24, 2019.

Dr Frank Jiang, CStone Chairman and CEO, commented: "The NDA filing for TIBSOVO in Taiwan is a significant milestone for the company. There are no currently approved treatments for AML patients with IDH1 mutation in the Greater China region. We are already actively building a commercial team and will be fully committed to introducing this product quickly to patients in Greater China."

AML is the most common acute leukaemia affecting adults and is characterized by rapid disease progression. The incidence rate is approx. 30,000 annual cases in China (five-year survival rate below 20%) and 800 annual cases in Taiwan (five-year survival rate of 26%). The prognosis for elderly and R/R AML patients after currently available treatment is poor and around 6%-10% of all AML cases have the IDH1 mutation.

TIBSOVO (ivosidenib) is an isocitrate dehydrogenase-1 (IDH1) inhibitor. Discovered by CStone's partner, Agios Pharmaceuticals, ivosidenib was first approved by the U.S. FDA for adults with R/R AML with an IDH1 mutation in 2018, and secured approval for a supplemental new drug application in 2019 for the treatment of newly diagnosed AML patients with an IDH mutation who are ? 75 years old or have comorbidities that preclude the use of intensive induction chemotherapy. The US FDA also granted Breakthrough Therapy Designation for ivosidenib in combination with

Azacitidine for this population of newly diagnosed AML patients with an IDH mutation who are ? 75 years old or have comorbidities that preclude the use of intensive induction chemotherapy.

The efficacy of TIBSOVO® was evaluated in 174 adult patients with oral administration of daily 500 mg, until disease progression, development of unacceptable toxicity, or undergoing hematopoietic stem cell transplantation. Trial data reported TIBSOVO as a monotherapy to treat R/R AML patients with an IDH1 mutation achieved complete remission (CR) and complete remission with partial hematologic improvement (CRh) rate of 32.8% (57 of 174 patients). The safety profile of TIBSOVO® also reported adverse health reaction.