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ASIA EDITION

CStone announces first patient dosed in the Phase I study of ivosidenib

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The trial is designed to validate the efficacy, safety, and pharmacokinetics of ivosidenib in patients with IDH1mutant relapsed or refractory acute myeloid leukemia (R/R AML).

CStone Pharmaceuticals on 20 Nov 2019 announced that the first patient has been dosed in Phase I bridging the registrational study of ivosidenib (TIBSOVO®) in China. This stand-alone trial is designed to validate the efficacy, safety, and pharmacokinetics of ivosidenib in patients with IDH1 mutant relapsed or refractory acute myeloid leukemia (R/R AML).

Developed by CStone's partner, Agios Pharmaceuticals (NASDAQ: AGIO), ivosidenib was approved by the U.S. FDA in July 2018 for the treatment of adult patients with R/R AML with a susceptible IDH1 mutation as detected by an FDA-approved test. In May 2019, CStone submitted a new drug application (NDA) for ivosidenib in Taiwan for the treatment of adult patients with IDH1 mutant R/R AML.

The current standard of care treatment for newly diagnosed AML patients mainly includes intensive induction chemotherapy (IC), followed by consolidation therapy such as allogeneic hematopoietic stem cell transplantation (Allo-HSCT) in order to attain durable remission. Approximately 35% to 40% of those treated patients achieve complete remission, while only about 25% achieve 3 years or longer survival. The majority of AML patients develop acquired resistance to treatment or eventually relapse, leading to R/R AML, which has a very poor prognosis in the absence of a standard of care treatment options globally. With the emergence of DNA sequencing technology, the detection of genetic mutations has presented new opportunities and challenges in AML treatment. IDH1 mutations are associated with around 6% to 10% of all AML cases.

Dr Frank Jiang, Chairman and CEO of CStone, commented: "AML is the most common acute leukemia affecting adults with over 30,000 new cases estimated in China every year. AML is characterized by its rapid progression with a five-year survival rate below 20%. We are faced with the urgent need for clinical development, particularly for IDH1 mutant R/R AML patients, due to the lack of any effective treatment in China. We will rigorously press ahead with the clinical development of ivosidenib to achieve its regulatory approval in China which will allow more AML patients in Greater China to benefit from this precision therapy."

CStone's Chief Medical Officer, Dr Jason Yang, noted: "Ivosidenib is a potent and highly selective IDH1 inhibitor, and the only targeted therapy currently approved by the U.S. FDA for IDH1 mutant AML. It is very encouraging that we have already initiated two registrational studies of ivosidenib in China, including the global Phase III AGILE study of ivosidenib in combination with azacitidine in adult patients with newly diagnosed IDH1 mutant AML who are not eligible for intensive chemotherapy."

About TIBSOVO® (ivosidenib)

TIBSOVO® is indicated for the treatment of acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test in:

- Adult patients with newly-diagnosed AML who are ?75 years old or who have comorbidities that preclude the use of intensive induction chemotherapy.
- Adult patients with relapsed or refractory AML.