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ASIA EDITION

# CStone receives IND approval in China for avapritinib study

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CStone Pharmaceuticals has announced that the National Medical Products Administration (NMPA) recently approved the initiation of a Phase I/II clinical trial in China evaluating avapritinib, a drug candidate discovered by the company's partner Blueprint Medicines, in patients with unresectable or metastatic gastrointestinal stromal tumors (GIST).

This is a stand-alone bridging trial consisting of a Phase I dose-escalation study and Phase II dose-expansion study, with the aim of determining the safety, pharmacokinetics and efficacy of avapritinib in Chinese patients.

GIST, which is classified as a rare disease, is a sarcoma most commonly found in the stomach wall or small intestine, and accounts for about 0.1 to 3.0 percent of all gastrointestinal malignant diseases. GIST is typically diagnosed between the ages of 50 and 80. Approximately 90 percent of GIST cases are linked to mutations that produce over-activation of the KIT or PDGFRA tyrosine kinases, resulting in deregulated cell growth.

Avapritinib has been shown to have broad inhibitory effects on KIT and PDGFRA-driven (primary including D842V mutation) GIST. In January 2019, Blueprint Medicines reported top-line data from the NAVIGATOR Phase 1 clinical trial of avapritinib in patients with advanced GIST, as of a data cutoff date of November 16, 2018.

In June 2018, CStone and Blueprint Medicines entered into a license and collaboration agreement in which Blueprint Medicines granted exclusive rights to develop and commercialize three drug candidates, including avapritinib, in Mainland China, Hong Kong, Macau and Taiwan. Blueprint Medicines retains development and commercial rights for avapritinib in the rest of the world.

CStone Chairman and CEO Dr. Frank Jiang commented: "Avapritinib has been granted Breakthrough Therapy Designation by the U.S. FDA based on the treatment's promising data. Currently there are no approved drugs that target the PDGFRA D842V mutation. We hope to leverage the data that will be submitted to the U.S. FDA by Blueprint Medicines and the

bridging study results to support an NDA submission in China."