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CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT

CSTONE ANNOUNCES FIRST PATIENT DOSED IN CHINA FOR PHASE I/II REGISTRATIONAL BRIDGING TRIAL OF AVAPRITINIB IN ADVANCED GIST

CStone Pharmaceuticals (the "**Company**" or "**CStone**") announces that the first patient in China has been dosed in the Phase I/II bridging study of avapritinib, which was discovered by CStone's partner Blueprint Medicines Corporation (NASDAQ: BPMC) ("**Blueprint**"). This stand-alone registrational bridging study in China includes a Phase I dose-escalation study and Phase II dose-expansion study, with the aim of evaluating the safety, pharmacokinetics and efficacy of avapritinib in patients with unresectable or metastatic gastrointestinal stromal tumors ("**GIST**"). This study consists of patients with PDGFRA D842V-driven GIST, as well as second-line and third-line or later GIST patients.

GIST is a sarcoma most commonly found in the stomach wall or small intestine. Most GIST patients are diagnosed between the ages of 50 to 80. Approximately 90% of GIST cases are associated with dysregulation of cell growth due to mutations of KIT or PDGFRA. Currently, there are no effective therapies for patients with PDGFRA D842V-driven GIST.

Avapritinib is an orally available, potent and highly selective inhibitor of KIT and PDGFRA. Previously published preclinical results have shown that avapritinib has potent activity against KIT and PDGFRA mutant kinases associated with GIST.

In June 2018, CStone entered into an exclusive collaboration and license agreement with Blueprint to develop and commercialize three therapeutic candidates, including avapritinib, in mainland China, Hong Kong, Macau and Taiwan. Blueprint retains development and commercial rights for avapritinib in the rest of the world.

Dr. Frank Ningjun Jiang, chairman, executive director and chief executive officer of CStone, commented: "GIST is a rare disease with rising incidence rates in recent years, and PDGFRA D842V-mutant GIST patients still lack effective treatments. CStone is committed to the development of innovative therapies to meet urgent clinical needs. Our partner, Blueprint, has submitted a new drug application for avapritinib in the United States and a marketing authorization application in the European Union. We are following their footsteps in seeking to make this novel precision therapy accessible to patients in Greater China as soon as possible."

Dr. Jason Jianxin Yang, CStone's chief medical officer, noted: "Early symptoms of GIST are relatively unpronounced; as a result, some GIST patients are undiagnosed until advanced stages. The latest data presented at the 2019 American Society for Clinical Oncology Annual Meeting demonstrated an objective response rate of 86% and favorable tolerability in patients with PDGFRA Exon 18 mutant GIST in the global Phase I NAVIGATOR study of avapritinib. We have already initiated two registrational studies on avapritinib in China, both of which have enrolled their first patients. We will do our best to accelerate the development of this drug candidate and successfully bring it to the market in Greater China."

About Avapritinib

Avapritinib is an investigational and oral precision therapy that selectively and potently inhibits KIT and PDGFRA mutant kinases. It is a type 1 inhibitor designed to target the active kinase conformation; all oncogenic kinases signal via this conformation. Avapritinib has demonstrated broad inhibition of KIT and PDGFRA mutations associated with GIST, including potent activity against activation loop mutations that are associated with resistance to currently approved therapies. In contrast with existing tyrosine kinase inhibitors, avapritinib has shown marked selectivity for KIT and PDGFRA over other kinases inhibitors.

Blueprint is initially developing avapritinib for the treatment of advanced GIST, advanced systemic mastocytosis ("**SM**"), and indolent and smoldering SM. The United States Food and Drug Administration has granted Breakthrough Therapy Designation to avapritinib for two indications: one for the treatment of unresectable or metastatic GIST harboring the PDGFRA D842V mutation and one for the treatment of advanced SM, including the subtypes of aggressive SM, SM with an associated hematologic neoplasm and mast cell leukemia.

Data presented at the 2019 American Society for Clinical Oncology Annual Meeting from the global Phase I NAVIGATOR study of avapritinib are based on a data cut-off date of November 16, 2018.

About CStone

CStone is a biopharmaceutical company focused on developing and commercializing innovative immuno-oncology and molecularly-targeted drugs to address unmet medical needs for cancer patients in China and worldwide. Since the Company's establishment in 2015, CStone has assembled a world-class management team that has a full spectrum of complementary skillsets from preclinical research to clinical development and commercialization. With combination therapies as a core strategy, the Company has built a rich oncology pipeline of 15 oncology drug candidates. Currently, five late-stage drug candidates are at or near pivotal trials. With an experienced team, a rich pipeline, a robust clinical development-driven business model, and substantial funding, CStone's vision is to become globally recognized as a leading Chinese biopharmaceutical company by bringing innovative and differentiated oncology therapies to cancer patients worldwide.

For more information about CStone, please visit: www.cstonepharma.com.

By order of the Board
CStone Pharmaceuticals
Dr. Frank Ningjun Jiang
Chairman

Suzhou, People's Republic of China, August 25, 2019

As at the date of this announcement, the Board of Directors of the Company comprises Dr. Frank Ningjun Jiang as Chairman and Executive Director, Dr. Wei Li, Mr. Qun Zhao, Mr. Yanling Cao, Mr. Guobin Zhang and Dr. Lian Yong Chen as non-executive Directors, and Dr. Paul Herbert Chew, Mr. Ting Yuk Anthony Wu and Mr. Hongbin Sun as independent non-executive Directors.