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## **CStone Pharmaceuticals**

**基石藥業**

*(Incorporated in the Cayman Islands with limited liability)*

**(Stock Code: 2616)**

### **INSIDE INFORMATION BUSINESS UPDATES**

This announcement is issued pursuant to Rule 13.09 of the Rules Governing the Listing of the Securities on The Stock Exchange of Hong Kong Limited (the “**Listing Rules**”) and the inside information provision (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong).

CStone Pharmaceuticals (the “**Company**” or “**CStone**”) is pleased to announce that the National Medical Products Administration (“**NMPA**”) of China has approved AYVAKIT (avapritinib) tablets for the treatment of adults with unresectable or metastatic gastrointestinal (“**GI**”) stromal tumor (“**GIST**”) harboring a platelet-derived growth factor receptor alpha (“**PDGFRA**”) exon 18 mutation, including PDGFRA D842V mutations. Discovered by CStone’s partner Blueprint Medicines Corporation (NASDAQ: BPMC), AYVAKIT is China’s first approved therapy for patients with PDGFRA exon 18 mutant GIST specifically designed to target the underlying molecular driver of their disease.

Dr. Frank Ningjun Jiang, executive director, chairman and chief executive officer of CStone, noted: “AYVAKIT is the second approved therapy in the same month for CStone and it is a first-in-class therapy for patients with PDGFRA exon 18 mutant GIST. The approval of AYVAKIT in China reflects the collective efforts and accomplishments of the CStone team. We would like to thank all the patients and investigators involved in the clinical study and the NMPA for their support during the priority review. Together, we are aiming to solve Chinese cancer patients’ urgent unmet medical needs. With our first two approvals, CStone will strive to bring more first-in-class and best-in-class innovative precision medicines and immuno-oncology therapies to patients.”

Dr. Lin Shen, Vice President of Peking University Cancer Hospital and Institute, said: “Historically, there has been a lack of treatment options for patients with GIST harboring PDGFRA exon 18 mutations. AYVAKIT has shown effective anti-tumor activity and a generally well-tolerated safety profile in Chinese patients with advanced PDGFRA exon 18 mutant GIST. We believe the approval of

AYVAKIT in China may bring important clinical benefit to Chinese patients with advanced PDGFRA exon 18 mutant GIST.”

### **About Gastrointestinal Stromal Tumor (GIST)**

GIST is a sarcoma, or tumor of bone or connective tissue, of the GI tract. Tumors arise from cells in the wall of the GI tract and occur most often in the stomach or small intestine. Most patients are diagnosed between the ages of 50 to 80, and diagnosis is typically triggered by GI bleeding, incidental findings during surgery or imaging and, in rare cases, tumor rupture or GI obstruction. About 5 to 6 percent of primary GIST cases are caused by a PDGFRA D842V mutation, the most common PDGFRA exon 18 mutation.

### **About AYVAKIT (avapritinib)**

AYVAKIT (avapritinib) is a kinase inhibitor approved by the China NMPA for the treatment of adults with unresectable or metastatic GIST harboring the PDGFRA exon 18 mutation, including PDGFRA D842V mutations.

The U.S. Food and Drug Administration (“**FDA**”) has approved AYVAKIT™ for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor harboring a PDGFRA exon 18 mutation, including PDGFRA D842V mutations. This medicine is approved by the European Commission under the brand name AYVAKYT® for the treatment of adults with unresectable or metastatic GIST harboring the PDGFRA D842V mutation.

AYVAKIT/AYVAKYT is not approved for the treatment of any other indication in China by the NMPA, in the U.S. by the FDA or in Europe by the European Commission, or for any indication in any other jurisdiction by any other health authority.

### **About CStone**

CStone is a biopharmaceutical company focused on developing and commercializing innovative immuno-oncology and precision medicines to address the unmet medical needs of cancer patients in China and worldwide. Established in 2015, CStone has assembled a world-class management team with extensive experience in innovative drug development, clinical research, and commercialization. The company has built an oncology-focused pipeline of 14 drug candidates with a strategic emphasis on immuno-oncology combination therapies. Currently, two products have been approved by the China NMPA and multiple late-stage candidates are at pivotal trials or registration stages. CStone’s vision is to become globally recognized as a world-renowned biopharmaceutical company by bringing innovative oncology therapies to cancer patients worldwide.

For more information about CStone, please visit: [www.cstonepharma.com](http://www.cstonepharma.com).

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

Suzhou, People’s Republic of China, March 31, 2021

*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. Xianghong*

*Lin 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.*