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CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 2616)

VOLUNTARY ANNOUNCEMENT

CSTONE'S PARTNER BLUEPRINT MEDICINES ANNOUNCED U.S. FDA HAS APPROVED GAVRETOTM (PRALSETINIB) FOR THE TREATMENT OF PATIENTS WITH ADVANCED OR METASTATIC RET-MUTANT AND RET FUSION-POSITIVE THYROID CANCERS

The partner of CStone Pharmaceuticals (the "Company" or "CStone"), Blueprint Medicines Corporation (NASDAQ: BPMC) ("Blueprint Medicines") recently announced that the United States ("U.S.") Food and Drug Administration ("FDA") has approved GAVRETOTM (pralsetinib) for the treatment of patients with rearranged during transfection ("RET") -altered thyroid cancers. The accelerated approval expands the labeled indications for GAVRETOTM to include adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer who require systemic therapy, or with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory, if appropriate. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

Earlier in 2020, the U.S. FDA granted accelerated approval to GAVRETOTM for the treatment of adults with metastatic RET fusion-positive non-small cell lung cancer ("NSCLC") as detected by a test approved by the U.S. FDA. The therapy is jointly commercialized in the U.S. by Blueprint Medicines and Genentech, a wholly owned member of the Roche Group, under Blueprint Medicines' collaboration with Roche. Developed by CStone's partner Blueprint Medicines, pralsetinib is an once-daily oral treatment designed to potently and selectively target RET alterations that drive multiple tumor types.

"We are pleased that pralsetinib has been approved by the U.S. FDA for the treatment of patients with RETaltered thyroid cancers," said Dr. Frank Ningjun Jiang, executive director, chairman and chief executive officer of CStone, "the National Medical Products Administration of China has accepted pralsetinib's new drug application with priority review designation for the treatment of patients with RET fusion-positive NSCLC. We hope to deliver pralsetinib to a wide range of patients with RET-altered cancers in China."

CStone has an exclusive collaboration and license agreement with Blueprint Medicines for the development and commercialization of pralsetinib in greater China, which encompasses mainland of the People's Republic of China, the Special Administrative Region of Hong Kong, the Special Administrative Region of Macau and Taiwan.

For more details, please visit: http://blueprintmedicines.com/GAVRETOthyroid.

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 at the end of 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 16 drug candidates with a strategic emphasis on immuno-oncology combination therapies. Currently, five late-stage candidates are at 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 a world-renowned biopharmaceutical company that is leading the way to conquering cancer.

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, December 10, 2020

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.