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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 SUBMISSION OF NEW DRUG APPLICATION TO U.S. FDA FOR PRALSETINIB FOR THE TREATMENT OF ADVANCED RET MUTANT AND RET FUSION- POSITIVE THYROID CANCERS

The partner of CStone Pharmaceuticals (the “**Company**” or “**CStone**”), Blueprint Medicines Corporation (NASDAQ: BPMC) (“**Blueprint Medicines**”), announced on early July 2020 that the submission of a new drug application (“**NDA**”) to the United States (“**U.S.**”) Food and Drug Administration (“**FDA**”) for pralsetinib for the treatment of patients with advanced or metastatic RET mutant medullary thyroid cancer (“**MTC**”) and RET fusion-positive thyroid cancers. pralsetinib is an investigational, once-daily precision therapy designed to potently and selectively inhibit RET fusions and mutations, including predicted resistance mutations.

Blueprint Medicines submitted the NDA under the Real-Time Oncology Review pilot program (“**RTOR program**”), an initiative of the U.S. FDA’s Oncology Center of Excellence. The RTOR program aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible, while maintaining and improving review quality by the U.S. FDA.

In May 2020, Blueprint Medicines announced that the U.S. and European Union marketing applications for pralsetinib for the treatment of locally advanced or metastatic RET fusion-positive non-small cell lung cancer (“**NSCLC**”) were accepted by the U.S. FDA and validated by the European Medicines Agency, respectively.

About RET-Altered Solid Tumors

RET activating fusions and mutations are key disease drivers in many cancer types, including NSCLC and MTC. RET fusions are implicated in approximately 1 to 2 percent of patients with NSCLC and approximately 10 to 20 percent of patients with papillary thyroid cancer, while RET mutations are implicated in approximately 90 percent of patients with advanced MTC. In addition, oncogenic RET alterations are observed at low frequencies in colorectal, breast, pancreatic and other cancers, and RET fusions have been observed in patients with treatment-resistant EGFR-mutant NSCLC.

About pralsetinib

pralsetinib is an investigational, once-daily oral precision therapy specifically designed for highly potent and selective targeting of oncogenic RET alterations. Blueprint Medicines is developing pralsetinib for the treatment of patients with RET-altered NSCLC, thyroid cancer and other solid tumors. The U.S. FDA has granted a “Breakthrough Therapy Designation” recognition to pralsetinib for the treatment of RET-fusion positive NSCLC that has progressed following platinum-based chemotherapy, and RET-mutant medullary thyroid cancer that requires systemic treatment and for which there are no acceptable alternative treatments. In May 2020, Blueprint Medicines announced that the U.S. and European Union marketing applications for pralsetinib for the treatment of locally advanced or metastatic RET fusion-positive NSCLC were accepted by the U.S. FDA and validated by the European Medicines Agency, respectively.

pralsetinib was designed by Blueprint Medicines' research team, leveraging its proprietary compound library. In preclinical studies, pralsetinib consistently demonstrated sub-nanomolar potency against the most common RET fusions, activating mutations and predicted resistance mutations. In these studies, pralsetinib demonstrated markedly improved selectivity for RET compared to pharmacologically relevant kinases, including approximately 80-fold improved potency for RET compared with VEGFR2. By suppressing primary and secondary mutants, pralsetinib has the potential to overcome and prevent the emergence of clinical resistance. This approach may enable durable clinical responses across a diverse range of RET alterations, with a favorable safety profile.

Blueprint Medicines and CStone have an exclusive collaboration and license agreement for the development and commercialization of pralsetinib and certain other drug candidates in regions including the mainland of the People’s Republic of China, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan. Blueprint Medicines retains development and commercial rights for pralsetinib for the rest of the world.

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 15 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 globally recognized as a leading Chinese biopharmaceutical company by bringing innovative 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, July 20, 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. 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.