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CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2616)

VOLUNTARY ANNOUNCEMENT
CSTONE AND HENGRUI ENTER INTO AN EXCLUSIVE PROMOTION
AGREEMENT OF AYWAKIT[®] (AVAPRITINIB TABLETS)
IN MAINLAND CHINA

CStone Pharmaceuticals (the “**Company**” or “**CStone**”) is pleased to announce that the Company has entered into an agreement with Jiangsu Hengrui Pharmaceuticals Co., Ltd. (“**Hengrui**”) to grant the exclusive promotion rights of precision therapy AYWAKIT[®] (avapritinib tablets) in mainland China to Hengrui. Except for promotion, CStone retains all rights to AYWAKIT[®] in mainland China, including rights to development, registration, manufacturing and distribution, etc.

Key Highlights

- With CStone’s outstanding clinical development capability, AYWAKIT[®] has become the first precision therapy approved in China for adults with unresectable or metastatic gastrointestinal stromal tumors (GIST) harboring the PDGFRA exon 18 mutation, including the PDGFRA D842V mutation, which helps address unmet medical needs for this patient population. AYWAKIT[®] has also been listed under the National Reimbursement Drug List (NRDL) in China.
- With Hengrui’s extensive and robust commercial infrastructure, this partnership is expected to further maximize the commercial potential of AYWAKIT[®].

Under the terms of the agreement, CStone will receive an upfront payment of RMB 35 million and will continue to book sales revenue from AYWAKIT[®] in mainland China in its financial reports, and Hengrui will charge CStone a service fee.

AYVAKIT[®], a potent, selective and orally available inhibitor of KIT and PDGFRA mutant kinases, was approved by the National Medical Products Administration of China (NMPA) in March 2021 for the treatment of adults with unresectable or metastatic GIST harboring the PDGFRA exon 18 mutation, including PDGFRA D842V mutations. The manufacturing localization registration application for AYWAKIT[®] (300mg) was approved by the NMPA in June 2024 and domestic supply is expected to be

available by the end of 2024 or early 2025.

As part of its commercialization efforts in Greater China, CStone has advanced the clinical implementation of precision medicine approaches through physician engagement and education, as well as the standardization of diagnosis and treatment. AYWAKIT[®] is now included in the NRDL, making it more accessible and affordable. It has also been recommended by multiple domestic and international guidelines, including the 2023 CSCO Guidelines for Gastrointestinal Stromal Tumor Diagnosis and Treatment, the 2022 Clinical Practice Guidelines for the Pathological Diagnosis of Gastrointestinal Stromal Tumors, the Chinese Guidelines for the Diagnosis and Treatment of Systemic Mastocytosis, the 2023 NCCN Guidelines for Gastrointestinal Stromal Tumors, and the 2023 NCCN Guidelines for Systemic Mastocytosis.

AYVAKIT[®] was discovered by CStone's partner Blueprint Medicines. In 2018, CStone entered into an exclusive collaboration and license agreement with Blueprint Medicines for the development and commercialization of AYWAKIT[®] in the Greater China Region, including mainland China, Hong Kong, Macau and Taiwan.

About AYWAKIT[®] (avapritinib tablets)

AYVAKIT[®] is a precision therapy 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. AYWAKIT[®] was approved by the Hong Kong Department of Health (DOH), and Taiwan Food and Drug Administration (TFDA) for the treatment of adults with unresectable or metastatic GIST harboring a PDGFRA D842V mutation.

AYVAKIT[®] is approved by the U.S. Food and Drug Administration (FDA) for the treatment of three indications: adults with unresectable or metastatic GIST harboring a PDGFRA exon 18 mutation, including PDGFRA D842V mutations, adults with advanced systemic mastocytosis (advanced SM), including aggressive SM (ASM), and SM with an associated hematological neoplasm (SM-AHN) and mast cell leukemia (MCL), and adults with indolent systemic mastocytosis (ISM). This medicine is approved in Europe (AYVAKYT[®]) for the treatment of adults with unresectable or metastatic GIST harboring the PDGFRA D842V mutation, adults with ASM, SM-AHN or MCL, after at least one systemic therapy, and adults with ISM with moderate to severe symptoms inadequately controlled on symptomatic treatment.

About CStone

CStone (HKEX: 2616), established in late 2015, is an innovation-driven biopharmaceutical company focused on the research and development of anti-cancer therapies. Dedicated to addressing patients' unmet medical needs in China and globally, the Company has made significant strides since its inception. To date, the Company has successfully launched 4 innovative drugs and secured approvals for 14 new drug applications (NDAs) covering 9 indications. The company's pipeline is balanced by 12 promising candidates, featuring potentially first-in-class or best-in-class antibody-drug conjugates (ADCs), multispecific antibodies, immunotherapies and precision medicines. CStone also prides itself on a management team with comprehensive experiences and capabilities that span the entire drug development spectrum, from preclinical and translational research to clinical development, drug manufacturing, business development, and commercialization.

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

Trademarks

Blueprint Medicines, AYWAKIT[®], AYWAKYT[®] and associated logos are trademarks of Blueprint

Medicines Corporation.

Cautionary Statement required by Rule 18A.05 of the Listing Rules: THE COMPANY CANNOT GUARANTEE THAT WE MAY BE ABLE TO ULTIMATELY DEVELOP AND MARKET AYWAKIT® SUCCESSFULLY. Shareholders and potential investors of the Company are advised to exercise due care when dealing in the shares of the Company.

Forward Looking Statement

There is no assurance that any forward-looking statements regarding the business development of the Group in this announcement or any of the matters set out herein are attainable, will actually occur or will be realized or are complete or accurate. The financial and other data relating to the Group as disclosed in this announcement has also not been audited or reviewed by its auditors. Shareholders and/or potential investors of the Company are advised to exercise caution when dealing in the securities of the Company and not to place any excessive reliance on the information disclosed herein. Any shareholder or potential investor who is in doubt is advised to seek advice from professional advisors.

By Order of the Board
CStone Pharmaceuticals
Dr. Wei Li
Chairman

Suzhou, the People's Republic of China, July 3, 2024

As at the date of this announcement, the board of directors of the Company comprises Dr. Wei Li as Chairman and non-executive director, Dr. Jianxin Yang as executive director, Mr. Kenneth Walton Hitchner III, Mr. Xianghong Lin and Mr. Edward Hu as non-executive directors, and Dr. Paul Herbert Chew, Mr. Ting Yuk Anthony Wu and Mr. Hongbin Sun as independent non-executive directors.