CStone Pharmaceuticals
基石藥業
(Incorporated in the Cayman Islands with limited liability)
(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCES APPROVAL OF MANUFACTURING LOCALIZATION REGISTRATION APPLICATION FOR AYVAKIT® (AVAPRITINIB TABLETS, 100 MG) BY CHINA NMPA

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce today the approval of the manufacturing localization registration application for AYVAKIT® (avapritinib tablets, 100 mg) by the China National Medical Products Administration ("**NMPA**"). Following the approval of 300 mg strength of AYVAKIT® by the NMPA earlier in June 2024, the 100 mg strength will further expand the treatment flexibility of AYVAKIT®. Both strengths are expected to gradually replace the existing imported products, achieving domestic supply in late 2024 or early 2025.

Dr. Jason Yang, CEO, President of R&D and Executive Director of the Board at CStone, said, "The approval of the manufacturing localization registration application for both 100 mg and 300 mg strengths of AYVAKIT® will not only better meet the needs of diverse patient populations and provide greater convenience for patients, but also significantly enhance the accessibility and market competitiveness of AYVAKIT® in China. Additionally, the manufacturing localization registration application for another of our precision medicines, GAVRETO® (pralsetinib capsules), was accepted in April of this year and is currently under review by Center for Drug Evaluation, NMPA. We will continue to be committed to delivering high-quality medicines to the patients in China through advanced manufacturing technologies and rigorous production and quality management."

AYVAKIT® was approved by the NMPA of China in March 2021 for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumors (GIST) harboring the PDGFRA exon 18 mutation, including the PDGFRA D842V mutation. As the world's first precision therapy for GIST approved based on a driver gene, AYVAKIT® has demonstrated remarkable efficacy in multiple clinical trials. The inclusion of AYVAKIT® in the National Reimbursement Drug List (NRDL) has further enhanced its accessibility and affordability. AYVAKIT® is recommended in 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.

About AYVAKIT® (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. AYVAKIT® 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.

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

In July 2024, CStone entered into an agreement with Jiangsu Hengrui Pharmaceuticals Co., Ltd. ("**Hengrui**") to grant the exclusive promotion rights of precision therapy AYVAKIT® in mainland China to Hengrui. Except for promotion, CStone retains all rights under its exclusive license agreement with Blueprint Medicines to AYVAKIT® in mainland China, including rights to development, registration, manufacturing and distribution, etc.

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 15 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, AYVAKIT®, AYVAKYT® and associated logos are trademarks of Blueprint Medicines Corporation. GAVRETO® and associated logos are trademarks of Blueprint Medicines

Corporation outside of the United States.

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 AYVAKIT® 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, August 15, 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.