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) BY CHINA NMPA

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce the approval of the manufacturing localization registration application for AYVAKIT® (avapritinib tablets, 300mg) by the China National Medical Products Administration (NMPA). Imported products are expected to be gradually replaced from late 2024 or early 2025, so as to achieve overall domestic supply.

Dr. Jason Yang, CEO, President of R&D and Executive Director of the Board at CStone, said, "The approval of the manufacturing localization application for AYVAKIT® marks a significant milestone for CStone in the Chinese market. AYVAKIT® is now included in the NRDL, making it more accessible and affordable. Moreover, the local manufacturing approval will largely increase the supply flexibility of AYVAKIT®, allowing us to better meet domestic demands and benefit more patients and continue to enhance the market presence of AYVAKIT® in China. This approval represents a holistic achievement and a multidimensional recognition by the regulatory agency in manufacturing processes, quality specifications, and human bioequivalence for locally manufactured AYVAKIT®. CStone will remain committed to advanced manufacturing technologies and strict compliance on manufacturing and quality management systems to ensure supplying patients in China with high quality domestically produced drugs."

According to the Company's registration plan, the manufacturing localization registration application for the 100 mg specification of AYVAKIT® is expected to be approved soon, providing physicians and patients with greater flexibility in dosage specification selection. Additionally, the manufacturing localization registration application for GAVRETO® (pralsetinib capsules), another precision therapy of CStone was also accepted in April this year and is currently under review.

AYVAKIT® was approved by the 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. As the world's first precision therapy for GIST approved based on a driver gene, AYVAKIT®

has demonstrated remarkable efficacy in multiple clinical trials. As part of its commercialization efforts in Greater China, CStone has strengthened AYVAKIT®'s market presence through extensive physician education and treatment protocols standardization. AYVAKIT® has been 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.

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 AYVAKIT® in the Greater China Region, including Mainland China, Hong Kong, Macau and Taiwan.

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.

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.

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 of the Company and potential investors 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, June 13, 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.