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CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2616)

VOLUNTARY ANNOUNCEMENT

CSTONE ANNOUNCES INCLUSION OF AYWAKIT® (AVAPRITINIB) IN 2023 CHINA'S NATIONAL REIMBURSEMENT DRUG LIST

CStone Pharmaceuticals (the “**Company**” or “**CStone**”) is pleased to announce that AYWAKIT® (avapritinib) has been added to the National Reimbursement Drug List for National Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (2023) (the “NRDL”) in China, for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring the PDGFRA exon 18 mutation, including PDGFRA D842V mutations. The updated NRDL will take effect from January 1, 2024.

Dr. Jason Yang, CEO and executive director of CStone, stated, “We sincerely appreciate the National Healthcare Security Administration for including AYWAKIT® in the NRDL. AYWAKIT is the first approved precision treatment in China for PDGFRA exon 18 mutant (including D842V mutation) GIST, which has addressed the significant gap in domestic medical treatment landscape in China. The inclusion of AYWAKIT into the NRDL will increase the accessibility of this breakthrough cancer treatment at an affordable price in China, ultimately reducing the financial burden on patients. This also reflects the government’s commitment to clinical value-oriented approaches in improving medication accessibility by including more clinically essential high-value innovative drugs into NRDL. It further boosts our confidence in the availability and accessibility of innovative medicines for patients in China. CStone remains committed to our mission to develop clinically important, medicines and to provide more accessible, affordable, innovative drugs to Chinese patients.”

AYVAKIT has been approved by the National Medical Products Administration (NMPA) of China for the treatment of adults with unresectable or metastatic GIST harboring the PDGFRA exon 18 mutation, including PDGFRA D842V mutations. As part of the company’s commercialization efforts in Greater China, CStone has helped advance the clinical implementation of precision medicine approaches through physician engagement and continuous education, collaboration with industry associations pertaining to the standardization of diagnosis and treatment, and partnerships with diagnostic companies. The inclusion of AYWAKIT in commercial insurance programs has expanded its accessibility and affordability to patients. It has been recommended in multiple domestic and international treatment guidelines, including

the Chinese Guidelines for the Diagnosis and Treatment of Systemic Mastocytosis in Adult Patients.

Discovered by CStone's partner Blueprint Medicines, AYVAKIT is a potent, selective and orally available inhibitor of KIT and PDGFRA mutant kinases. CStone has an exclusive collaboration and license agreement with Blueprint Medicines for the development and commercialization of AYVAKIT in Greater China, including Mainland China, Hong Kong, Macau and Taiwan.

About Gastrointestinal Stromal Tumor (GIST)

GIST is a sarcoma, or tumor of bone or connective tissue, of the GI tract. Tumors arise from cells in the wall of the GI tract and occur most often in the stomach or small intestine. Most patients are diagnosed between the ages of 50 to 80, and diagnosis is typically triggered by GI bleeding, incidental findings during surgery or imaging, and in rare cases, tumor rupture or GI obstruction. About 5 to 6 percent of primary GIST cases are caused by a PDGFRA D842V mutation, the most common PDGFRA exon 18 mutation.

About AYVAKIT® (avapritinib)

AYVAKIT is a precision therapy approved by the NMPA of China 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 Department of Health (DOH), Hong Kong, China, 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 indolent systemic mastocytosis (ISM), adults with advanced systemic mastocytosis (advanced SM), including aggressive SM (ASM), SM with an associated hematological neoplasm (SM-AHN) and mast cell leukemia (MCL), and adults with unresectable or metastatic GIST harboring a PDGFRA exon 18 mutation, including PDGFRA D842V mutations. This medicine is approved by the European Commission (AYVAKYT®) for the treatment of adults with ASM, SM-AHN or MCL, after at least one systemic therapy, and adults with unresectable or metastatic GIST harboring the PDGFRA D842V mutation.

About CStone

CStone (HKEX: 2616) is a biopharmaceutical company focused on research, development, and commercialization of innovative immuno-oncology and precision medicines to address the unmet medical needs of cancer patients in China and worldwide. Established in 2015, CStone has assembled a management team with extensive experience in innovative drug development, clinical research, and commercialization. The company has built an oncology-focused pipeline of 14 drug candidates with a strategic emphasis on immuno-oncology combination therapies. Currently, CStone has received 13 NDA approvals for its four drugs. Multiple late-stage drug candidates are now under pivotal clinical trials or registration. CStone's vision is to bring innovative oncology therapies to cancer patients worldwide.

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

Trademarks

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

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, December 13, 2023

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.