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

INSIDE INFORMATION ANNOUNCEMENT

CSTONE ANNOUNCED ACCEPTANCE OF MARKETING AUTHORIZATION APPLICATION BY UK MHRA FOR SUGEMALIMAB IN METASTATIC NON-SMALL CELL LUNG CANCER

This announcement is issued pursuant to Rule 13.09 of the Rules Governing the Listing of the Securities on The Stock Exchange of Hong Kong Limited (the "**Listing Rules**") and the inside information provision (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong).

CStone Pharmaceuticals (the "**Company**" or "**CStone**", together with its subsidiaries, the "**Group**") is pleased to announce that The Medicines and Healthcare products Regulatory Agency ("**MHRA**") in the United Kingdom has accepted the marketing authorization application ("**MAA**") submitted by its partner EQRx for sugemalimab in combination with chemotherapy as first-line treatment of patients with metastatic non-small cell lung cancer ("**NSCLC**").

Key Highlights

- This is the first marketing authorization application of sugemalimab outside of China.

- Application is based on data from the phase III GEMSTONE-302 trial evaluating sugemalimab plus chemotherapy versus placebo plus chemotherapy as first-line treatment of metastatic NSCLC, which has met its primary and secondary endpoint of progression-free survival ("**PFS**") and overall survival ("**OS**"), respectively.

- In 2021, the National Medical Products Administration of China ("**NMPA**") approved sugemalimab in combination with chemotherapy as first-line treatment of patients with metastatic squamous or non-squamous NSCLC.

Dr. Jason Yang, CEO and executive director of CStone, said, "the acceptance of the first international marketing authorization application for sugemalimab is an important milestone for our global strategy under the collaboration with EQRx that we believe reflects the potential relevance of an innovative drug developed in China in a global market. We look forward to supporting our partner, with the goal of making sugemalimab available to patients in the UK."

In 2021, sugemalimab was granted Innovation Passport designation in the U.K. through the Innovative Licensing and Access Pathway ("**ILAP**") from the ILAP partner organizations including the MHRA. The ILAP was established in early 2021 to accelerate the development of and access to medicines in the U.K.

This MAA for sugemalimab is supported by clinical data from the CStone-sponsored GEMSTONE-302 study, a multicenter, randomized, double-blind phase III study to evaluate the efficacy and safety of sugemalimab in combination with chemotherapy in first-line treatment-naïve patients with stage IV NSCLC as compared to placebo in combination with chemotherapy.

The GEMSTONE-302 study met its primary and secondary endpoints, demonstrating statistically significant and clinical meaningful improvement in PFS and OS, respectively. The data has been published in the Lancet Oncology and presented in several international conferences (2022 ASCO, 2021 WCLC, 2020 ESMO Asia).

About Sugemalimab

The anti-PD-L1 monoclonal antibody sugemalimab was discovered by CStone using OmniRat® transgenic animal platform, which allows creation of fully human antibodies in one step. Sugemalimab is a fully human, full-length anti-PD-L1 immunoglobulin G4 (IgG4) monoclonal antibody, which may allow a reduced risk of immunogenicity and toxicity for patients, a unique advantage over similar drugs.

Currently, sugemalimab is approved by the NMPA for the treatment of patients with unresectable Stage III NSCLC whose disease has not progressed following concurrent or sequential platinum-based chemoradiotherapy and in combination with chemotherapy for the first-line treatment of patients with metastatic squamous and non-squamous NSCLC. Sugemalimab is the first anti-PD-(L)1 monoclonal antibody approved for both stage III and stage IV NSCLC.

In addition, the NMPA of China has accepted and granted priority review to the supplemental new drug application (sNDA) for sugemalimab in the treatment of patients with relapsed/refractory extranodal NK/T cell lymphoma (R/R ENKTL). A registrational study of sugemalimab in combination with chemotherapy for first-line treatment of unresectable locally advanced or metastatic gastric adenocarcinoma (GC)/gastro-esophageal junction (GEJ) adenocarcinoma has met its primary endpoint. The other registrational study designed to evaluate the efficacy and safety of sugemalimab in combination with chemotherapy as first-line treatment of patients with unresectable locally advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC) has completed patient enrollment.

CStone has a strategic collaboration agreement with EQRx, under which EQRx holds the exclusive rights for development and commercialization of sugemalimab outside of Greater China.

About CStone

CStone 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 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, CStone has received nine NDA approvals for its four drugs. Multiple late-stage drug candidates are now under pivotal clinical trials or registration. CStone's vision is to become globally recognized as a world-renowned biopharmaceutical company by bringing innovative oncology therapies to cancer patients worldwide.

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 CEJEMLY® (SUGEMALIMAB) 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 realised 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 19, 2022

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. Yanling Cao, 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.