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

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCED ACCEPTANCE OF MARKETING AUTHORIZATION APPLICATION BY THE EUROPEAN MEDICINES AGENCY FOR SUGEMALIMAB IN METASTATIC SQUAMOUS AND NON-SQUAMOUS NON-SMALL CELL LUNG CANCER

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that the Marketing Authorization Application ("**MAA**") for sugemalimab in combination with chemotherapy as first-line treatment for metastatic non-small cell lung cancer ("**NSCLC**") has been accepted by the European Medicines Agency (EMA). This marks the second MAA for sugemalimab outside of Greater China.

Key Highlights

- This is the second MAA for sugemalimab outside of Greater China.
- This MAA for sugemalimab is based on data from the phase 3 GEMSTONE-302 study, evaluating sugemalimab plus chemotherapy versus placebo plus chemotherapy as first-line treatment for metastatic NSCLC. This study met the endpoints of progression-free survival ("**PFS**") and overall survival ("**OS**"), respectively.
- Sugemalimab was approved by the National Medical Products Administration ("**NMPA**") of China in 2021 for first-line treatment in patients with metastatic squamous and non-squamous NSCLC in combination with chemotherapy.
- The MAA for sugemalimab as a treatment in first-line metastatic NSCLC is currently under review by the Medicines and Healthcare products Regulatory Agency in the United Kingdom.

Dr. Jason Yang, Chief Executive Officer and executive director of CStone, said, "we are delighted that sugemalimab's second MAA outside of Greater China has been accepted by EMA, following MAA acceptance in the United Kingdom. This marks a significant milestone in our global strategy. We look forward to supporting our partner with the goal of making this immunotherapy treatment available to patients around the globe as soon as possible."

This MAA for sugemalimab, submitted by CStone's partner EQRx, is supported by clinical data from the GEMSTONE-302 study, which is sponsored by CStone. The study is a multicenter, randomized, double-blind phase 3 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 endpoint and secondary endpoint, demonstrating statistically significant and clinically meaningful improvement in PFS and OS, respectively. The data has been published in The Lancet Oncology and presented at several international conferences, including the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting, the 2021 World Conference on Lung Cancer (WCLC), and the 2020 European Society for Medical Oncology Asia Congress (ESMO ASIA).

In 2020, lung cancer was the third most diagnosed cancer in Europe and the leading cause of cancer-related mortality, accounting for one fifth of cancer deaths. Approximately fifty to seventy percent of lung cancer cases in Europe are diagnosed in Stage IV. This contributes to a poor prognosis, with a 5-year survival rate of 13 percent in the region. Globally, it is estimated that NSCLC accounts for approximately 85% of all lung cancers.

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 reduce the risk of immunogenicity and toxicity for patients, a unique advantage over similar drugs.

Currently, sugemalimab is approved by the NMPA of China 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. Sugemalimab has received "Innovation Passport" recognition from the ILAP (Innovative Licensing and Access Pathway) partnering organizations, including the MHRA, through the ILAP program. Launched in early 2021, the ILAP aims to accelerate the development and market launch of drugs in the UK.

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 or refractory extranodal natural killer/T cell lymphoma (R/R ENKTL). Two registrational studies evaluating the efficacy and safety of sugemalimab in combination with chemotherapy for first-line treatment of unresectable locally advanced or metastatic gastric adenocarcinoma (GC)/gastro-esophageal junction (GEJ) adenocarcinoma and sugemalimab in combination with chemotherapy as first-line treatment of patients with unresectable locally advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC), respectively, have met their primary endpoints.

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 ten 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, February 23, 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.