**CStone Pharmaceuticals**

**基石藥業**

*(Incorporated in the Cayman Islands with limited liability)*

(**Stock Code: 2616**)

# VOLUNTARY ANNOUNCEMENT
# CSTONE ANNOUNCES RECEIPT OF GCP INSPECTION NOTIFICATION FROM THE EUROPEAN MEDICINES AGENCY FOR SUGEMALIMAB MARKETING AUTHORIZATION APPLICATION

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce receipt of a Good Clinical Practice (GCP) inspection notification from the European Medicines Agency (the "**EMA**") regarding the marketing authorization application (MAA) for sugemalimab in combination with chemotherapy as a first-line treatment for metastatic non-small cell lung cancer (NSCLC).

The EMA and the Medicines and Healthcare products Regulatory Agency in the United Kingdom (the "**U.K. MHRA**") have both accepted applications for sugemalimab combinational therapy as a first-line treatment for metastatic NSCLC, and the two MAAs are currently under review. The receipt of the GCP inspection notification, as anticipated, indicates that the sugemalimab registration process is progressing steadily at the EMA. CStone has been maintaining smooth communications with the EMA since the MAA acceptance and will continue to work closely with the Agency and investigators to ensure successful inspections.

Until the date of this announcement, sugemalimab has achieved success in five registrational clinical trials, covering indications of stage III NSCLC, stage IV NSCLC, lymphoma, gastric cancer, and esophageal cancer. The clinical data of sugemalimab have been presented at multiple international academic conferences and published in top-tier journals such as *The Lancet Oncology*, *Journal of Clinical Oncology*, *Nature Cancer*, etc.

Given its outstanding clinical results from multiple pivotal trials, the board of the Company believes that sugemalimab holds great potential for the global market. CStone will continue to engage health authorities, such as the EMA, the U.K. MHRA and the U.S. U.S. Food and Drug Administration. Meanwhile, CStone is actively exploring partnership for the development and commercialization of sugemalimab outside of Greater China.

**About Lung Cancer**

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.[1] Approximately fifty to seventy percent of lung cancer cases in Europe are diagnosed in Stage IV.[2] This contributes to a poor prognosis, with a 5-year survival rate of 13% in the region.[2] Globally, it is estimated that NSCLC accounts for approximately 85% of all lung cancers.[3]

**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.

Sugemalimab is approved by the National Medical Products Administration of China (the "**NMPA of China**") for the treatment of patients with unresectable Stage III non-small cell lung cancer (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.

The supplemental biologics license applications for sugemalimab for the treatment of patients with relapsed/refractory extranodal NK/T-cell lymphoma, as well as in combination with chemotherapy for first-line treatment of locally advanced or metastatic gastric/gastroesophageal junction adenocarcinoma, and in combination with chemotherapy for first-line treatment of unresectable locally advanced, recurrent, or metastatic ESCC have been accepted by the NMPA of China and are currently under review.

**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 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 seven NDA approvals for four drugs. CStone's vision is to bring 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 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 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

[1] Dyba T, et al. The European cancer burden in 2020: Incidence and mortality estimates for 40 countries and 25 major cancers. Eur J Cancer. 2021;157:308-347.

[2] van Meerbeeck, J. et al. Lung cancer screening in Europe: where are we in 2021? Transl Lung Cancer Res,2021;10(5) 2407-2417.

[3] Zhang, et al. The prevalence of EGFR mutation in patients with non-small cell lung cancer: a systematic review and meta-analysis. Oncotarget. 2016;7:78985-78993.

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, July 11, 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.*