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

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCES INCLUSION OF SUGEMALIMAB (CEJEMLY®) AS FIRST-LINE COMBINATION THERAPY FOR NSCLC IN ESMO GUIDELINE

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that its key product, sugemalimab (Cejemly®), has been included in the European Society for Medical Oncology (ESMO) Non-Oncogene-Addicted Metastatic Non-Small-Cell Lung Cancer (NSCLC) Living Guideline ("**ESMO Guideline**"). Sugemalimab is recommended as a first-line combination therapy for both squamous and non-squamous NSCLC, with substantial clinical benefits. This is another significant milestone in sugemalimab's global journey and provides critical support for our efforts to expand global market access, enter into markets and benefit patients.

According to the latest edition of the ESMO Guideline:

- For patients with squamous NSCLC, Eastern Cooperative Oncology Group (ECOG) performance status (PS) grade 0-1, regardless of tumour PD-L1 status and without contraindications for immune checkpoint inhibitors, sugemalimab-platinum-doublet chemotherapy is recommended as a Level [I, A] first-line combination therapy, with an ESMO-Magnitude of Clinical Benefit Scale (ESMO-MCBS) v1.1 score of 4, indicating substantial

clinical benefit (Link to ESMO guideline: squamous NSCLC).

- For patients with non-squamous NSCLC, PS grade 0-1, regardless of tumour PD-L1 status and without contraindications for immune checkpoint inhibitors, sugemalimab-platinum-based chemotherapy is recommended as a Level [I, A] first-line combination therapy, with an ESMO-MCBS v1.1 score of 4, also indicating substantial clinical benefit (Link to ESMO guideline: non-squamous NSCLC).

These recommendations in the ESMO Guideline are supported by clinical data from the Phase III GEMSTONE-302 trial, which demonstrated significant benefits in progression-free survival (PFS) and overall survival (OS) with sugemalimab in combination with platinum-based chemotherapy, compared to placebo in combination with platinum-based chemotherapy. Moreover, sustained and consistent benefits were observed across various histological subtypes and PD-L1 expression levels. Long-term survival data from the GEMSTONE-302 study were presented at the 2024 ESMO Annual Meeting.

Currently, sugemalimab has been approved in China, the EU, and the UK for first-line treatment of advanced NSCLC. After successfully establishing commercial partnerships in several countries in Switzerland, Central and Eastern Europe, the Middle East, Africa, and Latin America, Our Company is actively pursuing strategic commercial partnerships in Western Europe, Southeast Asia, and Canada, in parallel with the overseas registration and launch process for other indications of sugemalimab.

About Sugemalimab

The anti-PD-L1 monoclonal antibody sugemalimab was developed 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.

To date, the National Medical Products Administration (NMPA) of China has approved sugemalimab for five indications:

- In combination with chemotherapy as first-line treatment of patients with metastatic squamous and non-squamous NSCLC;
- For the treatment of patients with unresectable Stage III NSCLC whose disease has not progressed following concurrent or sequential platinum-based chemoradiotherapy;
- For the treatment of patients with relapsed or refractory extranodal NK/T-cell lymphoma;
- In combination with fluorouracil and platinum-based chemotherapy as first-line treatment of patients with unresectable locally advanced, recurrent or metastatic ESCC; and
- In combination with fluoropyrimidine- and platinum-containing chemotherapy as first-line treatment for unresectable locally advanced or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma with a PD-L1 expression (CPS ≥5).

The European Commission (EC) has approved sugemalimab (brand name: Cejemly®) in combination with platinum-based chemotherapy for the first-line treatment of patients with metastatic NSCLC with no sensitizing EGFR mutations, or ALK, ROS1 or RET genomic tumor aberrations.

The Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom has approved the marketing authorization application for sugemalimab in combination with platinum-based chemotherapy for first-line treatment of metastatic NSCLC with no sensitizing EGFR mutations, or ALK, ROS1 or RET genomic tumor aberrations.

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 16 new drug applications (NDAs) covering 9 indications. The Company's pipeline is balanced by 17 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 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 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 10, 2025

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, Mr. Hongbin Sun and Ms. Yip Betty Ho independent non-executive directors.