CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2616)

VOLUNTARY ANNOUNCEMENT
CSTONE SUBMITS APPLICATION TO THE EUROPEAN MEDICINES AGENCY FOR NEW INDICATION OF SUGEMALIMAB IN STAGE III NON-SMALL CELL LUNG CANCER

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce the submission of a Type II variation application to the European Medicines Agency (EMA) for sugemalimab. The application seeks approval for the treatment of patients with unresectable stage III non-small cell lung cancer (NSCLC) who have not progressed following concurrent or sequential platinum-based chemoradiotherapy (CRT). This marks CStone's second regulatory submission for sugemalimab to the EMA, following its initial approval in Europe for metastatic squamous and non-squamous NSCLC in 2024. If this new indication is approved, sugemalimab would address a critical unmet need in stage III NSCLC, where only one PD-L1 antibody is currently approved in Europe. The drug's dual utility in stage III and IV NSCLC could solidify its role as a cornerstone immunotherapy in lung cancer.

The submission is supported by data from the GEMSTONE-301 Phase III trial, a multicenter, randomized, double-blind study evaluating sugemalimab as consolidation therapy in patients with unresectable stage III NSCLC post-CRT. Results published in The Lancet Oncology demonstrated:

- 36% reduction in risk of disease progression or death, significantly improved progression-free survival (PFS).
- 56% reduction in risk of death, with a strong positive trend toward overall survival (OS) benefit.
- Consistent clinical benefits across subgroups, regardless of prior CRT modality (concurrent or sequential).
- Favorable safety profile, no new safety signals identified.

Dr. Jason Yang, CEO, President of R&D, and Executive Director at CStone, commented: "Following sugemalimab's approval in Europe for stage IV NSCLC, we are working closely with EMA to expand its indications in earlier stage lung cancer and other malignancies. With its demonstrated outstanding

efficacy and safety profile, sugemalimab is poised to address critical unmet needs for stage III NSCLC patients. We remain steadfast in expanding global access through strategic partnerships and collaborations with regulatory authorities, ensuring this innovative therapy reaches patients worldwide."

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.

The European Commission (EC) and the Medicines and Healthcare products Regulatory Agency (MHRA) have approved sugemalimab 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.

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).

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 16 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, March 24, 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 as independent non-executive directors.