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

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCES CHMP POSITIVE OPINION FOR SUGEMALIMAB, EXPANDING ITS POTENTIAL USE TO COVER BOTH STAGE III AND IV NSCLC IN EUROPE

This announcement is made by CStone Pharmaceuticals (the "**Company**," together with its subsidiaries, collectively referred to as the "**Group**" or "**CStone**") on a voluntary basis for the purpose of keeping the shareholders of the Company and potential investors abreast of the latest business development of the Group.

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CStone today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion, recommending approval of sugemalimab as monotherapy for the treatment of unresectable stage III non-small cell lung cancer (NSCLC) adults with PD-L1 expression on ≥ 1% of tumour cells and no sensitising EGFR mutations, or ALK, ROS1 genomic aberrations and whose disease has not progressed following platinum-based chemoradiotherapy (CRT).

Dr. Jason Yang, Chief Executive Officer (CEO), President of R&D, and Executive Director at CStone, remarked, "We are encouraged that the EMA review for our sugemalimab in stage III NSCLC in Europe has progressed so rapidly and positively. Coming just one year after sugemalimab's first approval by EMA in Europe for first-line metastatic squamous and non-squamous NSCLC in 2024, this marks the second positive opinion and recommendation from CHMP. If approved, sugemalimab's role as a core immunotherapy for lung cancer will be further solidified, significantly enhancing its market presence and commercial potential. We will work closely with our partners to expedite the full commercialization of sugemalimab across European markets, making this high-quality and accessible treatment option available to more patients."

Dr. Qingmei Shi, Chief Medical Officer (CMO) of CStone, added, "CHMP's recommendation for sugemalimab's new indication is primarily based on the compelling results from the pivotal Phase III

GEMSTONE-301 study, a multicenter, randomized, double-blind clinical trial that demonstrated dual benefits of sugemalimab in progression-free survival and overall survival among patients with stage III NSCLC. If approved, sugemalimab will become the second PD-(L)1 antibody available in Europe for stage III NSCLC, addressing a critical unmet need and bringing new hope to patients. CHMP's swift positive opinion also serves as strong validation of the capabilities of CStone's clinical development and regulatory team. We remain dedicated to fulfilling our commitment to meet the urgent medical needs of patients in China and globally."

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.

The European Commission (EC) and the Medicines and Healthcare products Regulatory Agency (MHRA) of the U.K. 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. In October 2025, CHMP issued a positive opinion recommending approval of sugemalimab as monotherapy for the treatment of unresectable stage III NSCLC adults with PD-L1 expression on ≥ 1% of tumour cells and no sensitizing EGFR mutations, or ALK, ROS1 genomic aberrations and whose disease has not progressed following platinum-based CRT.

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 with no EGFR or ALK genomic tumor aberrations and metastatic 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 therapies for oncology, autoimmune/inflammation, and other key disease areas. 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 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 Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: 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, October 17, 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 and Mr. Edward Hu as non-executive directors, and Mr. Ting Yuk Anthony Wu, Ms. Yip Betty Ho and Mr. Kenneth Howard Jarrett as independent non-executive directors.