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

VOLUNTARY ANNOUNCEMENT
SUGEMALIMAB RECEIVES UK MHRA APPROVAL FOR STAGE III NSCLC

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 UK Medicines and Healthcare products Regulatory Agency (MHRA) has granted a new indication for sugemalimab as a monotherapy for adult patients with unresectable stage III non-small cell lung cancer (NSCLC) 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).

- Following approval by the European Commission (EC), sugemalimab has received a new indication approval from the UK MHRA for stage III NSCLC. This marks the second indication approved for the product in the UK.

- This approval is based on the GEMSTONE-301 study, a multicenter, randomized, double-blind Phase III trial. Results demonstrated that sugemalimab provided statistically significant improvement in progression-free survival (PFS) and a clinically meaningful prolongation of overall survival (OS) in patients with stage III NSCLC.

- To date, CStone has established four commercialization partnerships for sugemalimab across Europe, the Middle East and Africa, and Latin America, extending its reach to more than 60 countries and regions. The global commercial rollout is now actively underway.

Dr. Jason Yang, CEO, President of R&D, and Executive Director at CStone, stated, "Since its initial EU

approval in July 2024, sugemalimab has become one of only two PD-(L)1 antibodies approved for stage III NSCLC in Europe, providing a comprehensive treatment option spanning both locally advanced, unresectable stage III and metastatic stage IV NSCLC. Its commercial footprint has now expanded to over 60 countries and regions globally, with market access applications approved or under regulatory review in more than ten countries. Furthermore, sugemalimab has been included in multiple national reimbursement systems—an affirmation of its recognized clinical value and pharmacoeconomic benefit."

Dr. Qingmei Shi, Chief Medical Officer of CStone, added, "The MHRA's approval of sugemalimab for Stage III NSCLC represents another significant endorsement from a major international regulatory agency and will further unlock its global commercial potential. We are proud of CStone's clinical development and regulatory affairs teams for their effective execution, invaluable experience in global registration, and ability to navigate mature regulatory frameworks in Europe and the UK. Sugemalimab in combination with chemotherapy treating stage IV NSCLC has received the highest-level recommendation [I, A] in the first-line setting for both squamous and non-squamous NSCLC in the European Society for Medical Oncology (ESMO) Non-Oncogene-Addicted Metastatic NSCLC Living Guideline. We look forward to the potential inclusion of this newly approved stage III NSCLC indication in this authoritative guideline in the near future. CStone will continue to advance regulatory filings for sugemalimab in additional indications, including gastric cancer (GC) and esophageal squamous cell carcinoma (ESCC)."

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 EC and MHRA have approved sugemalimab for two indications:

- 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;and
- Monotherapy for adult patients with unresectable stage III NSCLC 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 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 CRT;
- 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 20 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, February 23, 2026

As at the date of this announcement, the Board 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. Kenneth Howard Jarrett, Ms. Fang Xie and Ms. Catherine Yen as independent non-executive directors.