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

VOLUNTARY ANNOUNCEMENT

EUROPEAN COMMISSION APPROVED SUGEMALIMAB FOR STAGE III NON-SMALL CELL LUNG CANCER

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 European Commission (EC) has approved a new indication for sugemalimab as 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 sensitizing EGFR mutations, or ALK, ROS1 genomic aberrations and whose disease has not progressed following platinum-based chemoradiotherapy (CRT).

Dr. Jason Yang, CEO, President of R&D, and Executive Director at CStone, stated, "Coming about a year after the initial EC approval for first-line metastatic NSCLC, this second approval expands the indication for sugemalimab to cover the full spectrum of the disease—from locally advanced, unresectable Stage III to metastatic Stage IV—across Europe. This provides a new treatment option for a broader patient population. CStone remains committed to enhancing the global accessibility of sugemalimab and fulfilling our long-term promise to patients."

Dr. Qingmei Shi, Chief Medical Officer of CStone, added, "With its approval as the second PD-(L)1 antibody in Europe for Stage III NSCLC, sugemalimab is poised to address a critical unmet medical need. This achievement was made possible by the exceptional efforts of our clinical development and regulatory teams, which facilitated the European Medicines Agency (EMA)'s smooth and quick review process. We are committed to further enhancing our global capabilities to deliver our innovative pipeline to patients

around the world."

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 EC has 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 (This indication has also been approved by the Medicines and Healthcare products Regulatory Agency [MHRA]);
- Monotherapy for adult patients with unresectable stage III NSCLC 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 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 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, November 25, 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, Mr. Kenneth Howard Jarrett and Ms. Fang Xie as independent non-executive directors.