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

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCES MHRA APPROVAL OF SUGEMALIMAB FOR FIRST-LINE TREATMENT OF NON-SMALL CELL LUNG CANCER IN THE UK

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that the UK Medicines and Healthcare products Regulatory Agency (MHRA) has approved sugemalimab in combination with platinum-based chemotherapy as a first-line treatment for adult patients with metastatic non-small cell lung cancer (NSCLC) without EGFR-sensitive mutations or ALK, ROS1, RET genomic alterations. This marks the second overseas authorization for sugemalimab following its recent authorization by the European Commission (EC).

Key Highlights

- Following its recent approval by the EC, this approval marks the second authorization for sugemalimab outside of China.
- The approval is based on results from the Phase 3 GEMSTONE-302 clinical trial, which demonstrated that sugemalimab in combination with chemotherapy significantly prolonged progression-free survival (PFS) and overall survival (OS) in treatment-naive patients with metastatic NSCLC.
- Long-term survival data from the GEMSTONE-302 study were presented at the 2024 European Society for Medical Oncology (ESMO) Annual Meeting.
- CStone is actively communicating with regulatory authorities, including the European Medicines Agency (EMA) for marketing authorization applications for additional indications of sugemalimab.
- CStone has entered into a strategic commercialization partnership with Ewopharma AG for sugemalimab in Central & Eastern Europe and Switzerland, with further collaborations expected soon in regions including Western Europe, Latin America, the Middle East, and Southeast Asia.

Dr. Jason Yang, CEO, President of R&D and Executive Director at CStone, said, "This approval is a significant milestone in our global expansion strategy. Sugemalimab is the first domestic anti-PD-L1 antibody to receive approval outside of China and has already entered the world's second-largest pharmaceutical market, the EU. Now, with the UK approval, sugemalimab continued to expand its presence in the European market. The long-term survival data, recently presented at this year's ESMO

Annual Meeting, further confirmed sugemalimab's value in the frontline treatment landscape for metastatic NSCLC. Regarding overseas commercialization and registration progress, we are actively pursuing additional partnerships across Western Europe, Latin America, the Middle East, Southeast Asia, and Canada, and expect to finalize some of these agreements shortly. Meanwhile, we are communicating with the EMA and other agencies for additional regulatory applications for other sugemalimab indications, including Stage III NSCLC, first-line gastric cancer, and first-line esophageal squamous cell carcinoma, aiming to bring innovative treatment options to more patients globally."

The MHRA's approval is primarily based on the data from GEMSTONE-302, a multicenter, randomized, double-blind phase 3 trial. The study demonstrated that sugemalimab in combination with chemotherapy significantly prolonged PFS and OS compared to placebo in combination with chemotherapy in treatment-naive patients with metastatic NSCLC. Study results have been published in The Lancet Oncology and Nature Cancer, and have been presented at multiple international academic conferences in both oral and poster sessions.

About Sugemalimab

The anti-PD-L1 monoclonal antibody sugemalimab was developed by CStone using OmniRat® transgenic animal platform licensed from Ligand Pharmaceuticals in the United States, 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. Sugemalimab's unique molecular design enables a dual mechanism of action that not only blocks PD-1/PD-L1 interaction, but also induces antibody dependent cellular phagocytosis (ADCP) by cross-linking PD-L1 expressing tumor cells with tumor associated macrophages (TAMs) without harming Effector T-cells. This differentiation has resulted in potentially best-in-class efficacy/safety across a variety of tumor types.

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 a 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 (Combined Positive Score [CPS] ≥5).

The 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 tumour aberrations.

The MHRA in the UK has approved the marketing authorization application for sugemalimab in combination with platinum-based chemotherapy for first-line treatment of metastatic NSCLC with no sensitising EGFR mutations, or ALK, ROS1 or RET genomic tumour 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 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, October 31, 2024

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 and Mr. Hongbin Sun as independent non-executive directors.