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

VOLUNTARY ANNOUNCEMENT
CSTONE AND PHARMALINK ENTER INTO STRATEGIC PARTNERSHIP FOR SUGEMALIMAB IN MIDDLE EAST AND NORTH AFRICA REGION AND SOUTH AFRICA

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce a strategic commercial collaboration with Pharmalink Store - L.L.C - O.P.C ("Pharmalink"), a prominent pharmaceutical company based in the United Arab Emirates (UAE). Under the license and commercialization agreement (the "**Agreement**"), Pharmalink will gain the commercial rights for sugemalimab in the Middle East and North Africa (MENA) Region, including Saudi Arabia, UAE, Kuwait, Qatar, Oman, Bahrain, Algeria, Tunisia, Egypt, Morocco and Libya, and South Africa.

Key Highlight

- CStone will receive upfront and regulatory milestone payments from Pharmalink and be entitled to royalties on net sales of sugemalimab in the MENA Region and South Africa. The partnership with Pharmalink marks CStone's second major international collaboration for sugemalimab's commercialization, following the strategic cooperation with Ewopharma in Central & Eastern Europe and Switzerland in the first half of 2024. The expansion into the MENA Region and South Africa markets strengthens sugemalimab's global footprint, with further partnerships expected to be reached in regions including Western Europe, Latin America, Southeast Asia and Canada.
- CStone has received marketing authorization for sugemalimab in the European Union (EU), European Economic Area (EEA) countries（Iceland, Liechtenstein and Norway), as well as the United Kingdom (UK) and is in active communication with regulatory authorities for additional indications.

Under the Agreement, CStone will receive upfront and regulatory milestone payments as well as royalties on net sales of sugemalimab from Pharmalink, while Pharmalink will be responsible for the regulatory activities and commercialization of sugemalimab in the abovementioned regions. CStone will be responsible for the supply of sugemalimab.

Dr. Jason Yang, CEO, President of R&D, and Executive Director at CStone, commented, "Sugemalimab is the first anti-PD-L1 antibody developed by a China biopharmaceutical enterprise to enter the EU, the world's second largest pharmaceutical market, and the UK. Pharmalink is an excellent pharmaceutical marketing and commercialization partner with strong regulatory and commercial capabilities in the MENA Region and South Africa. This collaboration will further maximize sugemalimab's clinical and commercial value and benefit patients in the MENA Region and South Africa. The long-term survival data, recently presented at 2024 European Society for Medical Oncology (ESMO) Congress, further confirmed sugemalimab's value as a frontline treatment for metastatic non-small cell lung cancer (NSCLC). We are actively pursuing additional partnerships across Western Europe, Latin America, Southeast Asia and Canada, and expect to reach several commercial cooperations shortly. We are also advancing discussions with regulatory authorities on registration for other indications, including Stage III NSCLC, first-line gastric cancer and first-line esophageal squamous cell carcinoma, aiming to provide more innovative treatment options to global patients. We look forward to propeling on internationalization with Pharmalink."

Dr.Abdul Rauf Eljbour, CEO of Pharmalink said, "We are happy to enter into strategic partnership with CStone for commercialization of sugemalimab in MENA region and South Africa. Pharmalink endeavors to ensure reach of lifesaving, innovative and advanced therapies across therapeutic segments to patients in MENA region. We are well poised today in terms of resources, experience and knowledge to successfully commercialize sugemalimab across our region and are looking forward to further expand our cooperation with CStone Pharmaceuticals."

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 a 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 a 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 European Commission (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 Medicines and Healthcare products Regulatory Agency (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 sensitizing 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 18 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.

About Pharmalink

Pharmalink established in 1993 is a leading company based out of United Arab Emirates engaged in commercialization of innovative, niche and lifesaving pharmaceutical and biotech products across MENA region. Pharmalink has a fully integrated set up for registration, import, marketing, distribution and retail of pharmaceutical products. Apart from excellent marketing and distribution platforms in place it owns two chain pharmacies including hospital pharmacies across strategic locations under the brand – Medicina and Al Manara. Pharmalink is well equipped with its resources and expertise to optimally cover private as well as institutional markets thereby ensuring access of latest therapies to patients in the MENA region.

For more information about Pharmalink, please visit: www.pharmalink.ae

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, November 21, 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.