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

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCES PUBLICATION OF POPULATION PHARMACOKINETICS MODELLING OF CEJEMLY (SUGEMALIMAB) IN BRITISH JOURNAL OF CLINICAL PHARMACOLOGY

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that the population pharmacokinetics ("**PopPK**") modelling results of its self-developed anti-PD-L1 antibody, sugemalimab (brand name: Cejemly®), have been published in the renowned *British Journal of Clinical Pharmacology*.

ORIGINAL ARTICLE

Comprehensive population pharmacokinetic modelling of sugemalimab, an anti-programmed death-ligand 1 (PD-L1) human monoclonal antibody, in patients with solid tumours or lymphomas across multiple Phase I–III studies

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Dr. Jason Yang, CEO, President of R&D, and Executive Director at CStone, commented, "The PopPK modelling results have characterized the pharmacokinetic profile of sugemalimab and provided robust scientific evidence supporting the rationale of applying a standard dosing regimen across diverse patient populations. We remain committed to advancing the global development and commercialization of sugemalimab, to provide innovative treatment options to more patients.

This study employed PopPK modeling and integrated data from 1,628 patients across nine Phase I-III clinical trials, involving various types of indications including non-small cell lung cancer (NSCLC), NK/T-cell lymphoma, and esophageal squamous cell carcinoma (ESCC). As demonstrated by the trial results, the PopPK model adequately described the pharmacokinetic properties of sugemalimab in patients. While factors such as weight, albumin levels, sex, anti-drug antibodies, tumor burden, and tumor type slightly influenced drug clearance (less than 20%), none of these variables had a significant impact from clinical perspectives.

The analyses further supported the use of the approved standard dosage of sugemalimab (1200 mg, administered every three weeks) across different patient groups. The results demonstrated that patients, including the elderly, those of different ethnicities, and those with mild to moderate hepatic or renal impairment, achieve adequate drug exposure at the prescribed dosage, without the need for dose adjustment, which highlighted the convenience of sugemalimab treatment and its potential to improve patient compliance. In addition, the model could also be used to guide the drug dosing in certain extreme cases (e.g., patients weighing over 115 kg).

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. 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 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 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 sensitising EGFR mutations, or ALK, ROS1 or RET genomic tumor aberrations.

The Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom has accepted 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 tumor aberrations. The application is currently under review.

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 15 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 28, 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.