CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2616)

INSIDE INFORMATION ANNOUNCEMENT

CSTONE TO REGAIN DEVELOPMENT AND COMMERCIALIZATION RIGHTS TO SUGEMALIMAB AND NOFAZINLIMAB

This announcement is made by CStone Pharmaceuticals (the "**Company**" or "**CStone**", together with its subsidiaries, the "**Group**") pursuant to Rule 13.09 of the Rules Governing the Listing of the Securities on The Stock Exchange of Hong Kong Limited (the "**Listing Rules**") and the inside information provision (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong).

Reference is made to the announcements (the "**Announcements**") of the Company dated October 27, 2020 and November 20, 2020, in relation to the exclusive license agreement for sugemalimab (CS1001, anti-PD-L1) and nofazinlimab (CS1003, anti-PD-1) with EQRx, Inc. Unless otherwise expressly indicated, capitalized terms used herein shall have the same meaning as those defined in the Announcements.

Pursuant to the License Agreement, the Company as licensor granted an exclusive license to permit EQRx to develop and commercialize its sugemalimab (CS1001), an anti-PD-L1 monoclonal antibody, and nofazinlimab (CS1003), an anti-PD-1 monoclonal antibody, outside of Greater China. As at the date of this announcement, the Company announces that it will regain the development and commercialization rights to sugemalimab and nofazinlimab outside of Greater China upon the termination of the License Agreement. The Company and EQRx are committed to ensuring a smooth transition with the length of the transition period to be determined. The termination of the License Agreement will not affect the upfront and milestone payments previously received by the Company from EQRx.

The marketing authorization applications (the "**MAAs**") with the European Medicines Agency (the "**EMA**") and the Medicines and Healthcare products Regulatory Agency (the "**MHRA**") in the United Kingdom for sugemalimab as a first-line treatment for metastatic NSCLC are under review. Upon completion of the transition, the Company will lead the regulatory process for sugemalimab MAAs reviews by the EMA and the MHRA.

The Company believes that there are significant market opportunities for sugemalimab and nofazinlimab and is delighted to take back the development and commercialization rights outside of Greater China for the two assets. Sugemalimab has achieved success in five registrational clinical trials, covering indications of stage III NSCLC, stage IV NSCLC, lymphoma, gastric cancer, and esophageal cancer. The multi-regional phase 3 registrational trial of nofazinlimab in combination with lenvatinib as a first-line treatment for advanced hepatocellular carcinoma is ongoing to support the new drug applications globally. The clinical data of sugemalimab and nofazinlimab have been presented at international academic conferences. The results from multiple studies of sugemalimab have been published in journals such as *The Lancet Oncology and Journal of Clinical Oncology*.

Given the promising results from multiple clinical trials of these two assets, the Company remains confident in global market for sugemalimab and nofazinlimab, and will continue to engage health authorities, such as the U.S. Food and Drug Administration (the "**FDA**"), the EMA and the MHRA.

Meanwhile, the Company will explore partnership for the development and commercialization for the two products outside of Greater China.

The board of directors of the Company is of the view that the termination of the License Agreement will not have any material adverse impact on the business operations or financial position of the Group.

Conference Call Information

CStone will host a live conference call in Mandarin for investors at 9:00 a.m. Beijing time on May 9th, 2023. The conference call may be accessed via https://zoom.us/j/95657885602?pwd=S3VTNUZseXhDTUdGMEsxZUdTeHJNZz09.

About Sugemalimab (PD-L1)

The anti-PD-L1 monoclonal antibody sugemalimab was discovered 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.

Currently, sugemalimab is approved by the National Medical Products Administration of China (the "**NMPA**") for the treatment of patients with unresectable Stage III NSCLC whose disease has not progressed following concurrent or sequential platinum-based chemoradiotherapy and in combination with chemotherapy for the first-line treatment of patients with metastatic squamous and non-squamous NSCLC.

The NMPA accepted the supplemental biologics license applications for sugemalimab for the treatment of patients with relapsed/refractory extranodal NK/T-cell lymphoma, as well as in combination with chemotherapy for first-line treatment of locally advanced or metastatic gastric/gastroesophageal junction adenocarcinoma, and in combination with chemotherapy for first-line treatment of unresectable locally advanced, recurrent, or metastatic esophageal squamous cell carcinoma.

About Nofazinlimab (PD-1)

Nofazinlimab is a humanized recombinant IgG4 monoclonal antibody targeting human programmed cell death protein 1 (PD-1) being developed in solid tumors. Nofazinlimab shows comparable high binding affinities to the PD-1 of humans, cynomolgus monkey, and mouse, and can block the interaction of PD-1 with its ligands PD-L1 and PD-L2.

The FDA has granted nofazinlimab orphan drug designation in July 2020 for the treatment of patients with hepatocellular carcinoma. In March 2022, the global multi-regional phase 3 registrational trial of nofazinlimab in combination with lenvatinib as first-line treatment for patients with advanced hepatocellular carcinoma, CS1003-305, has successfully reached its prespecified enrollment target.

About CStone

CStone is a biopharmaceutical company focused on research, development, and commercialization of innovative immuno-oncology and precision medicines to address the unmet medical needs of cancer patients in China and worldwide. Established in 2015, CStone has assembled a management team with extensive experience in innovative drug development, clinical research, and commercialization. The company has built an oncology-focused pipeline of 15 drug candidates with a strategic emphasis on immuno-oncology combination therapies. Currently, CStone has received ten new drugs application approvals for its four drugs. Multiple late-stage drug candidates are now under pivotal clinical trials or registration. CStone's vision is to bring innovative oncology therapies to cancer patients worldwide.

For more information about CStone, please visit: **www.cstonepharma.com**.

Cautionary Statement required by Rule 18A.05 of the Listing Rules: We cannot guarantee that we will be able to develop, or ultimately market sugemalimab successfully. Shareholders of the Company and potential investors are advised to exercise due care when dealing in the shares of the Company.

By Order of the Board
CStone Pharmaceuticals
Dr. Wei Li
Chairman

Suzhou, the People's Republic of China, May 9, 2023

As at the date of this announcement, the board of Directors 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.