CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT
CSTONE ANNOUNCES STRATEGIC PARTNERSHIP AND EXCLUSIVE LICENSING AGREEMENT WITH 3SBIO FOR NOFAZINLIMAB (ANTI-PD-1 ANTIBODY) IN MAINLAND CHINA

CStone Pharmaceuticals (the "**Company**" or "**CStone**") today announced a strategic partnership and exclusive licensing agreement with Shenyang Sunshine Pharmaceutical Co., Ltd., a subsidiary of 3SBio Inc. (1530.HK) ("**3SBio**"), for nofazinlimab (anti-PD-1 antibody) in mainland China on November 1, 2023. This strategic partnership marks another milestone in CStone's mission to introduce innovative oncology therapies in mainland China.

Key Highlights

- CStone to grant 3SBio exclusive rights for the development, registration, manufacturing, and commercialization of nofazinlimab (anti-PD-1 antibody) in mainland China. CStone to retain the rights to nofazinlimab outside mainland China

- This partnership will combine the strengths of CStone and 3SBio in research and development, manufacturing, and commercialization, thus accelerating the clinical development and commercialization of nofazinlimab and benefitting more patients in mainland China

- The global multi-regional Phase III study CS1003-305 of nofazinlimab in combination with lenvatinib versus placebo in combination with lenvatinib as first-line treatment for advanced hepatocellular carcinoma ("**HCC**") has completed patient enrollment and been making steady progress. Disclosure of the topline results is expected in the first quarter of 2024

- Proof-of-concept ("**PoC**") data reported at the 2022 American Society of Clinical Oncology ("**ASCO**") annual meeting indicated that the combination of nofazinlimab and lenvatinib achieved robust and durable efficacy and manageable safety profile as the first-line treatment of advanced HCC. Data from the first-in-human ("**FIH**") trial of nofazinlimab (CS1003-101), published in the British Journal of Cancer in September 2023, indicated that nofazinlimab monotherapy was well

tolerated without observing dose-limiting toxicities ("**DLT**") and demonstrated preliminary anti-tumor activity in multiple tumor types

Under the terms of the agreement, CStone will receive an upfront payment of RMB60 million, development and registration milestone payments reaching approximately RMB100 million, and additional payments for future sales-based milestones and tiered sales royalties. 3SBio will obtain the exclusive rights for the development, registration, manufacturing, and commercialization of nofazinlimab in mainland China. CStone retains the rights to nofazinlimab outside mainland China and is actively looking for partners.

Dr. Jason Yang, CEO and executive director of CStone, stated, "We are excited to announce this strategic collaboration with 3SBio. Nofazinlimab, developed by CStone, has the potential to become the first anti-PD-(L)1 antibody in combination with lenvatinib approved in the first-line setting for advanced HCC. It will provide a novel and superior first-line treatment option to this patient population. With 3SBio's strong commercialization capability and pipeline synergy with nofazinlimab, we truly believe that the joint efforts will further expand the indication of nofazinlimab and maximize its clinical value and market potential in mainland China. We look forward to forging our strategic collaboration with 3SBio to deliver more cancer therapies to patients."

Dr. Lou Jing, Chairman and CEO of 3SBio Inc., said, "We are very pleased to reach a licensing agreement with CStone Pharmaceuticals for nofazinlimab CS1003. 3SBio has extensive experience of research and development ("**R&D**") and registration in the antibody field, high-quality and cost-effective production capabilities, as well as mature and strong oncology commercialization team. With those, CS1003 will enjoy a high degree of synergies, and will be an important supplement to the Company's pipeline. 3SBio is always committed to leveraging its integrated R&D, production and commercialization platform to bring more high-quality and imminently-needed-for-clinical-use biopharmaceutical products to the market. CS1003 has demonstrated in early-stage excellent clinical data. We are very much looking forward to its subsequent R&D and commercialization potential. Through our mutual collaborations, we will further boost the development process of nofazinlimab, explore more effective drug combinations, and eventually make it a more effective and affordable treatment option for cancer patients."

Nofazinlimab is an anti-PD-1 antibody developed by CStone. It's global multi-regional Phase III study CS1003-305, evaluating the efficacy and safety of nofazinlimab in combination with lenvatinib in first-line treatment for advanced HCC patients, has successfully achieved its prespecified patient enrollment target in March 2022. The topline results are expected to be announced in the first quarter of 2024. The study results will be used to support the new drug applications of nofazinlimab in countries and regions including China, the United States, and Europe.

Multiple research results of nofazinlimab have been published in international academic conferences and renowned journals. Preliminary data from the FIH trial, CS1003-101, were initially presented at the 2020 European Society for Medical Oncology ("**ESMO**") Annual Conference and were subsequently published in full in the prestigious international oncology journal, the British Journal of Cancer, in September 2023. The data indicates that nofazinlimab monotherapy was well tolerated and demonstrated preliminary anti-tumor activity in multiple tumor types, no DLT was observed. Additionally, data from the Phase Ib study (CS1003-102-1b) of nofazinlimab in combination with lenvatinib as a first-line treatment for unresectable advanced HCC patients in China were presented at the 2022 ASCO Annual Meeting. The results showed an objective response rate ("**ORR**") of 45%, with a median duration of response ("**DoR**") not yet reached at the data cutoff, ranging from 4.2 to 18.7+ months. The median progression-free survival ("**PFS**") was 10.4 months, and the safety and tolerability were favorable.

This announcement is made by the Company on a voluntary basis. The entering into strategic partnership and exclusive licensing agreement is of a revenue nature in the ordinary and usual course of business of

the Group and does not constitute notifiable transaction under Chapter 14 of the Rules Governing the Listing of Securities on the Stock Exchange of Hong Kong Limited.

About hepatocellular carcinoma (HCC)

Liver cancer is a common malignant tumor of digestive system worldwide. According to GLOBOCAN 2020 (Global Cancer Incidence, Mortality and Prevalence) data of the International Agency for Research on Cancer ("**IARC**"), a specialized agency of the World Health Organization, global new cases of liver cancer is more than 900,000, and death cases are more than 830,000 per year. The number of death cases is close to the number of new cases. Liver cancer is the second leading cause of cancer- related death and its incidence is increasing globally[1]. HCC is the most common form of liver cancer and accounts for ~90% of cases[2]. Systemic antitumor therapy plays an important role in the treatment of advanced HCC. Despite the expanding implementation of surgical and locoregional therapies worldwide, estimates suggest that ~50–60% of patients with HCC will ultimately be treated with systemic therapies[1]. A median survival for symptomatic advanced-stage HCC cases treated with systemic therapies is ~1–1.5 years[2]. Poor prognosis of HCC is attributed primarily to tumor presentation at an advanced stage when there is no effective treatment to achieve the long-term survival of patients[3].

About Nofazinlimab

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 U.S. FDA has granted nofazinlimab Orphan Drug Designation ("**ODD**") in July 2020 for the treatment of patients with HCC. In March 2022, the Phase III global multi-regional registrational study CS1003-305, evaluating the efficacy and safety of nofazinlimab in combination with lenvatinib in first-line treatment for advanced HCC patients, has already achieved the prespecified patient enrollment target.

About CStone

CStone (HKEX: 2616) 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 14 drug candidates with a strategic emphasis on immuno-oncology combination therapies. Currently, CStone has received twelve NDA 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.

[1] Llovet JM et al, Nat Rev Clin Oncol. 2022 Mar;19(3):151-172. Immunotherapies for hepatocellular carcinoma.
[2] Llovet JM et al, Nat Rev Dis Primers. 2021 Jan 21;7(1):6. Hepatocellular carcinoma.
[3] Ahn JC et al, Hepatology. 2021 Jan;73(1):422-436. Detection of Circulating Tumor Cells and Their Implications as a Biomarker for Diagnosis, Prognostication, and Therapeutic Monitoring in Hepatocellular Carcinoma

About 3Sbio Inc.

3SBio Inc. is a leading biopharmaceutical company integrating R&D, production and sales, with a focus on improving the life quality of patients with high quality medicines to benefit human health. At present, 3SBio owns more than 100 national invention patents and has launched more than 40 products into the market, covering several treatment fields, including, among others, nephrology, oncology, autoimmune, ophthalmology and dermatology. 3SBio includes the National Engineering Research Center of Antibody Medicine and four R&D bases with dual platforms for biopharmaceutical and chemical medicines. Amongst the 30 product candidates within 3SBio's active pipeline, 25 are being developed as innovative drugs in mainland China. 3SBio also owns five production bases that are GMP-compliant. In the future, 3SBio Inc. will continue to uphold the vision of "Care for Life, Cherish Life, Create Life" to build a world-leading biopharmaceutical company in China. 3SBio is an independent third party of the Company.

For more information about 3SBio, please visit: www.3sbio.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 NOFAZINLIMAB 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 1, 2023

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.