三生制药
3SBIO INC.

(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 1530)

VOLUNTARY ANNOUNCEMENT OF 3SBIO INC.
3SBIO INC. HAS ENTERED INTO LICENSING AGREEMENT WITH CSTONE PHARMACEUTICALS IN RESPECT OF ANTI-PD-1 MONOCLONAL ANTIBODY NOFAZINLIMAB

3SBio Inc. (the "**Company**") wishes to provide to the shareholders of the Company the attached press release regarding the entering into of an exclusive licensing agreement and a manufacturing technology transfer agreement between Shenyang Sunshine Pharmaceutical Co., Ltd., a subsidiary of the Company, and CStone Pharmaceuticals (Suzhou) Co., Ltd., a subsidiary of CStone Pharmaceuticals. According to the exclusive licensing agreement, 3SBio Inc. obtained an exclusive license from CStone Pharmaceuticals of its anti-PD-1 monoclonal antibody nofazinlimab (CS1003), encompassing development, registration, manufacturing and commercialization in mainland China. Both parties agreed that CStone Pharmaceuticals will be responsible for completing the ongoing global pivotal Phase III clinical study of nofazinlimab in combination with lenvatinib as first-line treatment for advanced hepatocellular carcinoma (HCC). According to the terms of the agreement, 3SBio Inc. will pay CStone Pharmaceuticals an upfront payment of RMB60 million and contingent development and registration milestone payments of up to nearly RMB100 million, as well as sales milestone payments and tiered royalties during the commercialization stage. According to the manufacturing technology transfer agreement, 3SBio, through its CDMO facility, will be solely and exclusively responsible for manufacturing and commercial supply of the licensed product in mainland China in the future.

This is a voluntary announcement made by the Company. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By order of the Board
3SBio Inc.
Dr. LOU Jing
Chairman

Shanghai, the PRC
1 November 2023

As at the date of this announcement, the Board comprises Dr. LOU Jing and Ms. SU Dongmei as executive Directors; Mr. HUANG Bin as non-executive Director; and Mr. PU Tianruo, Ms. YANG, Hoi Ti Heidi, Mr. NG, Joo Yeow Gerry, and Dr. ZHANG Dan as independent non-executive Directors.

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Press Release

3SBIO INC. HAS ENTERED INTO LICENSING AGREEMENT WITH CSTONE PHARMACEUTICALS IN RESPECT OF ANTI-PD-1 MONOCLONAL ANTIBODY NOFAZINLIMAB

(1 November 2023, Shanghai, China) 3SBio Inc. (1530.HK), one of the leading biopharmaceutical companies in China, today announced that Shenyang Sunshine Pharmaceutical Co., Ltd., a subsidiary of the Company, has entered into a licensing agreement and a manufacturing technology transfer agreement with CStone Pharmaceuticals (Suzhou) Co., Ltd., a subsidiary of CStone Pharmaceuticals (2616.HK), whereby 3SBio Inc. obtained the exclusive rights to develop, register, manufacture and commercialize the anti-PD-1 monoclonal antibody nofazinlimab (CS1003) of CStone Pharmaceuticals in mainland China.

Both parties agreed that CStone Pharmaceuticals will be responsible for completing the ongoing global pivotal Phase III clinical study of nofazinlimab in combination with lenvatinib as first-line treatment for advanced hepatocellular carcinoma (HCC) .

According to the agreements, 3SBio Inc. will pay CStone Pharmaceuticals an upfront payment of RMB60 million and contingent development and registration milestone payments of up to nearly RMB100 million, as well as sales milestone payments and tiered royalties during the commercialization stage. According to the manufacturing technology transfer agreement, 3SBio, through its CDMO facility, will be solely and exclusively responsible for manufacturing and commercial supply of the licensed product in mainland China in the future.

The international multi-center Phase III study of CS1003-305 of nofazinlimab, a PD-1 antibody, in combination with Lenvatinib compared with placebo in combination with Lenvatinib as the first-line treatment of patients with advanced hepatocellular carcinoma has met the prespecified patient enrollment target. The research is currently underway steadily. Disclosure of the topline results is expected in the first quarter of 2024.

The results of a number of research on nofazinlimab have also been published in international academic conferences and well-known journals. The preliminary data from the first-in-human CS1003-101 study was promulgated at the 2020 European Society for Medical Oncology (ESMO) Annual Meeting and published in British Journal of Cancer, an internationally renowned oncology journal, in September 2023. The data showed that nofazinlimab monotherapy was safe and well-tolerated, with no dose-limiting toxicity (DLT) observed, and preliminary anti-tumor activity observed in multiple tumor types. In addition, the data of the Phase Ib study (CS1003-102-1b) of nofazinlimab in combination with Lenvatinib for the first-line treatment of unresectable advanced hepatocellular carcinoma patients in China was also announced at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting. The data showed that the Objective Response Rate (ORR) of nofazinlimab in combination with Lenvatinib for the first-line treatment of unresectable advanced hepatocellular carcinoma patients reached 45%; and Median Duration of Response (DoR) was not reached by the time of data cutoff, ranging from 4.2 to 18.7+ months; Median Progression-free Survival (PFS) was 10.4 months; and was safe and well-tolerated.

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 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."

Dr. Jason Yang, CEO 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."

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 are 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].

Reference:

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 nofazinlimab

Nofazinlimab is a humanized recombinant IgG4 monoclonal antibody targeting human programmed cell death protein 1 (PD-1) being developed in immunotherapy for 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. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to nofazinlimab in July 2020 for the treatment of hepatocellular carcinoma.

About 3SBio Inc.

3SBio Inc. is a leading biopharmaceutical company integrating research and development ("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, the Group 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. The Group 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 the Group's active pipeline, 25 are being developed as innovative drugs in mainland China. The Group 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. Please visit www.3sbio.com for additional information.

About CStone

CStone (HKEX: 2616) is a biopharmaceutical company focused on developing and commercializing innovative immune 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. CStone has received twelve NDA approvals for four products. CStone's vision is to become globally recognized as a world-renowned biopharmaceutical company by bringing innovative oncology therapies to cancer patients worldwide.

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