三生制药
3SBIO INC.

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

VOLUNTARY ANNOUNCEMENT

APPROVAL OBTAINED FOR "INETETAMAB", THE FIRST INNOVATIVE ANTI-HER2 MONOCLONAL ANTIBODY INDEPENDENTLY DEVELOPED IN CHINA

3SBio Inc. (the "**Company**") wishes to inform the shareholders of the Company of the attached press release in respect of the formal approval obtained from the National Medical Products Administration of the PRC for "Inetetamab", the first innovative anti-HER2 monoclonal antibody ("**Cipterbin®**") independently developed in China by Sunshine Guojian Pharmaceutical (Shanghai) Co., Ltd, a subsidiary of the Company.

This is a voluntary announcement made by the Company. The Company cannot guarantee that Cipterbin® will be successfully and eventually launched. 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

Shenyang, the PRC
19 June 2020

As at the date of this announcement, the directors of the Company are Dr. LOU Jing and Ms. SU Dongmei as executive directors; Mr. HUANG Bin and Mr. TANG Ke as non-executive directors; and Mr. PU Tianruo, Mr. David Ross PARKINSON and Dr. WONG Lap Yan as independent non-executive directors.

Press Release

Breaking the monopoly of imported anti-HER2 monoclonal antibody drugs Approval obtained for "Inetetamab", the first innovative anti-HER2 monoclonal antibody independently developed in China

(19 June 2020, Shanghai, China) 3SBio (01530.HK), a leading innovative biopharmaceutical company in China, announced today that the anti-HER2 antibody for injection, Inetetamab (commercial name: Cipterbin®/ 赛普汀 ®), which is independently developed by its subsidiary, Sunshine Guojian Pharmaceutical (Shanghai) Co., Ltd. ("**Sunshine Guojian**") has been formally approved by the National Medical Products Administration of the PRC ("**NMPA**"). The first approved indication of Cipterbin® is for the treatment of HER2-positive metastatic breast cancer combining with chemotherapy.

As a project under the 863 Program of China, the National Major Scientific and Technological Special Project for "Significant New Drugs Development" and the key science and technological project for Shanghai, the approval of the domestically manufactured innovative anti-HER2 monoclonal antibody, Inetetamab, is expected to satisfy the unmet medical need for the clinical treatment of breast cancer patients in China, break the monopoly of imported drugs for anti-HER2 monoclonal antibody and enhance the accessibility of national innovative drugs, thereby benefitting more patients in China.

Rapid development of the anti-HER2 monoclonal antibody market

Breast cancer is the malignancies with the highest incidence rate for female and one of the types of cancers with relatively more treatment options among many other types of cancers. In recent years, the number of new incidents of breast cancer continued to grow. The report published by the National Cancer Centre in 2019 indicated that the number of new patients with breast cancer in China in 2015 was 304,000[1]; among them, 20%-25% of the patients with breast cancer were HER2-positive[2]. As a huge demand for the treatment in relation to clinical practice for HER2-positive breast cancers has not been satisfied, patients still encounter multiple problems such as recurrence and drug resistance.

HER2 target antibody treatment is currently applicable for two indications, which are HER2-positive breast cancers and stomach cancers. Since the first HER2 target monoclonal antibody has been approved for sale in the United States in 1998, the therapy of combining anti-HER2 drugs with chemotherapy drugs and other drugs has been widely adopted in clinical practice. Following the future development of HER2 target treatment in colorectal cancer, lung cancer, cholangiocarcinoma and pancreatic cancer, etc., there remains a huge potential for the market growth of the anti-HER2 drugs including anti-HER2 monoclonal antibody and anti-HER2 small molecule compounds in China.

According to a report from Frost & Sullivan[3], the market for anti-HER2 monoclonal antibody in China grew from approximately 1.4 billion yuan in 2014 to approximately 3.2 billion yuan in 2018, with a compound annual growth rate (CAGR) of 23.9%. As the number of patients with breast cancer increases, the market for anti-HER2 monoclonal antibody drugs will grow rapidly with a CAGR of approximately 23.9% from 2018 to 2023 and the market size is expected to reach approximately 9.4 billion yuan in 2023 and approximately 13.6 billion yuan in 2030.

Inetetamab took the lead in breaking the monopoly of the imported anti-HER2 monoclonal antibody drug

Inetetamab is a "mimetic combination" of an anti-HER2 monoclonal antibody, which is a drug independently developed by Sunshine Guojian for anti-HER2 treatments, leveraging on its own platform technology. It is also a project under the 863 Program, the National Major Scientific and Technological Special Project for "Significant New Drugs Development" and the key science and technological project for Shanghai and was granted with a priority review status. An in vitro research has shown that[4] the Fab region of Inetetamab is consistent with trastuzumab. With the engineered Fc region and optimized production process, it has a stronger ADCC effect, which better achieves the therapeutic goal of the anti-HER2 monoclonal antibody. In addition to directly inhibiting proliferation and growth of tumor cells by blocking the pathway of HER2, the Fab region of Inetetamab can also induce the ADCC effect, recognizing and killing tumor cells through the immune system.

The 2019 American ASCO meeting has published a research result of SOPHIA of the anti-HER2 monoclonal antibody (Margetuximab). Such monoclonal antibody has a stronger ADCC effect after the reconstruction of the Fc region. The SOPHIA research has shown that such monoclonal antibody can reduce the risk of disease progression by 24% in patients with metastatic breast cancer[5] when compared with the trastuzumab treatment; the stronger ADCC effect after reconstructing monoclonal antibody will be converted to the survival benefit of patients to a certain extent. As the first innovative anti-HER2 monoclonal antibody with engineered Fc region and optimized production process in China, it has a stronger ADCC effect, and Inetetamab is expected to bring clinical benefits to more Chinese HER2-positive cancer patients.

Analysts believe that the approval of Inetetamab will take the lead in breaking the monopoly of imported drugs of the anti-HER2 monoclonal antibody in the domestic market. It is expected that, among the fierce competition between imported anti-HER2 monoclonal antibodies and domestic biosimilars in the future market, Inetetamab, with its advantages of the stronger ADCC effect and stronger bargaining power in pricing of the innovative anti-HER2 monoclonal antibody, etc., will facilitate the market growth of anti-HER2 drugs rapidly, thereby reconstructing the competition landscape for the market of anti-HER2 drugs in China.

Focus on development of antibody drugs and the pipeline of subsequent research and development is worth paying attention to

Sunshine Guojian currently has 4 clinical products under research, and 6 pre-clinical products under research in the anti-tumor area, covering breast cancer, non-Hodgkin lymphoma caner, metastasis colon and rectal cancer, non-small cell lung cancer, gastric cancer and various solid tumors and carried out a multi-target deployment in anti-HER2, CD20, PD1, EGFR, VEGF and other areas. At the same time, Sunshine Guojian is actively deploying the research and development of innovative therapies, including new monoclonal antibodies, bi-specific antibodies, fusion proteins and cell therapeutics to bring multiple treatment options to patients.

Dr. Lou Jing, the Chairman of the Board of Sunshine Guojian, commented, "Cipterbin is the third antibody drug of Sunshine Guojian that is approved to be launched. As a leading innovative biopharmaceutical company in China with three approved antibody therapeutic drugs (including Yisaipu and Xenopax) the company is equipped with a mature system with comprehensive research and development and experience for industrialization and commercialization of antibody drugs, which provides the support and guarantees for maintaining our competitive edge. In the future, the company will continue to strengthen the research and increase the investment in innovative antibody drugs to further consolidate our position as the leader in antibody drugs, realising a stable growth of the company."

As one of the first batch of innovative biopharmaceutical companies focusing on antibody drugs in China, Sunshine Guojian launched Yisaipu® in 2005, which is a first-to-market Tumour Necrosis Factor (TNF-α) inhibitor product in the area of rheumatology in China filling the blank of development in antibody drugs of domestic enterprises. Yisaipu® is in a leading position in the Chinese market, with a market share of 60.9% in 2019, and has obtained approvals for launch from 15 overseas markets. The Company's another independently developed anti-CD25 humanized monoclonal antibody, Xenopax®, was also launched in 2019, and it has promoted the academic development of the area of transplantation.

About Cipterbin®

Cipterbin® (Inetetamab) is the first innovative anti-HER2 monoclonal antibody in China with the engineered Fc region, optimized production process and a stronger ADCC effect. Combining with chemotherapy drugs, it has been proved to be capable of delaying the disease progression for and bringing survival benefits to HER2-positive metastatic breast cancer patients.

About Sunshine Guojian

Sunshine Guojian was established in 2002 and is one of the first batch of innovative biopharmaceutical companies focusing on antibody drugs in China. It is a domestic pharmaceutical company that has two launched therapeutic antibody drugs, and had emerged as a leader in antibody drug with its capabilities of independent R&D, industrialization and commercialization in China. Sunshine Guojian orients its R&D efforts primarily towards innovative therapeutic antibody drugs, and provides high-quality, safe and effective clinical solutions to the therapeutic areas of major diseases such as auto-immune diseases and tumors. Currently, Sunshine Guojian has 15 antibody drug candidates which are under different development stages (including 8 drug candidates in clinical and post-clinical stage and 7 drug candidates in pre-clinical stage), targeting tumor, auto-immune diseases and ophthalmological diseases. Most of those drug candidates are Category I biological products for therapeutic use or monoclonal antibodies, 2 of which are in application for launching, and 6 are in clinical stage. Some of those drug candidates may have their applications be submitted to both the NMPA and the U.S. FDA, while some may be admitted for priority evaluation.

Please visit www.3s-guojian.com for additional information.

Cautionary Note and Forward-Looking Statements

This press release contains forward-looking statements, such as those relating to business or products outlook, or Company's intent, plans, beliefs, expectation and strategies. These forward-looking statements are based on information currently available to the Company and are stated herein on the basis of the outlook at the time of this press release. They are based on certain expectations, assumptions and premises, some of which are subjective or beyond our control. These forward-looking statements may prove to be incorrect or may not be realized in the future. With respect to any new product or new indication, we cannot guarantee that we will be able to successfully develop or eventually launch and market such product or indication. Underlying the forward-looking statements is a large number of risks and uncertainties. Further information regarding such risks and uncertainties may be found in our other public disclosure documents. The scientific information involved may only be preliminary and empirical. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

References:

1. National Cancer Centre: National Cancer Report 2019
2. Clin Cancer Res. 2009 Dec 15; 15(24): 7479–7491.
3. Frost & Sullivan Report
4. Wang Xiaowen et al., Chinese Pharmaceutical Journal, 2015, 50 (12)
5. Hope S. Rugo, Abstracts: 2019 San Antonio Breast Cancer Symposium; December 10-14, 2019; San Antonio, Texas