SINO BIOPHARMACEUTICAL LIMITED
中國生物製藥有限公司

(Incorporated in the Cayman Islands with limited liability)
Website: www.sinobiopharm.com
(Stock code: 1177)

VOLUMTARY ANNOUNCEMENT
APPROVAL FOR MARKETING OF CATEGORY 1 INNVOATIVE DRUG UNECRITNIB FUMARATE CAPSULES "UNECRITINIB (TQ-B3101)"

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that the category 1 Unecritinib Fumarate Capsules "Unecritinib (TQ-B3101)" (Trade name: 安柏尼) self-developed by the Group has obtained approval for marketing from the National Medical Products Administration of China for the treatment of ROS1-positive adult patients with advanced or metastatic non-small cell lung cancer ("**NSCLC**"). This is the first domestically produced targeted drug approved for the treatment of ROS1-positive adult patients with advanced or metastatic non-small cell lung cancer.

Unecritinib is a small molecule inhibitor of the tyrosine kinase ROS1/ALK/c-Met self-developed by the Group. Its research results have been published in international academic conferences and well-known journals such as the American Society of Clinical Oncology (ASCO) Annual Meeting, American Society of Haematology (ASH) Annual Meeting, European Lung Cancer Congress (ELCC), Frontiers in Pharmacology and Signal Transduction and Targeted Therapy. In June 2022, based on a" Phase II Single-Arm, Multi-Centre Clinical Study to Evaluate the Efficacy and Safety of TQ-B3101 Capsule Monotherapy in Subjects with ROS1-Positive NSCLC" (TQ-B3101-II-01), an application for marketing of Unecritinib as a new drug was filed in China.

Clinical Data: Good Efficacy and Safety

As of 20 June 2022, the objective remission rate (ORR) for the primary efficacy measure, as assessed by an Independent Review Committee (IRC), was 81.08% (95% CI: 72.55, 87.89). Other efficacy metrics included median duration of remission (mDOR) of 20.30 months (95% CI: 12.88, 26.12), median progression-free survival (mPFS) of 17.25 months (95% CI: 11.86, 26.71), and median overall survival (mOS) was not yet achieved (95% CI: 36.53, NE). In this study, Unecritinib is safe and well-tolerated, with adverse incidents being mainly hepatotoxicity and hematotoxicity, and with a low incidence of grade 3 and higher adverse incidents and no treatment-related deaths.

Market Size and Competitive Landscape: The First Domestic ROS1-Targeted Drug to Address Huge Unmet Demand

Unecritnib is the first domestically produced targeted drug approved for the treatment of ROS1-positive adult patients with advanced or metastatic non-small cell lung cancer. Research report Cancer incidence and mortality in China, 2016 released by the National Cancer Centre in 2022[1] shows that the number of new cases of lung cancer in China is as high as 0.828 million per year, and the number of deaths reaches 0.657 million per year, with the incidence rate and mortality rate ranking the highest among all cancers, which poses a serious threat to the health of the people. NSCLC accounts for approximately 85% of all lung cancers[2], in which ROS1 gene fusion is one of the important driver genes in NSCLC. China has a large number of NSCLC patients, and there is still an unmet clinical demand for ROS1-positive NSCLC.

The pivotal Phase II clinical data demonstrated that Unecritinib's efficacy in systemic palliation was confirmed. ORR and DOR based on IRC assessment indicated that Unecritinib's efficacy in the treatment of ROS1-positive NSCLC overcomes the existing therapeutic bottleneck, with deep and durable palliation in subjects with or without brain metastases, and taking into account its dual advantages of "high efficacy and low toxicity", Unecritinib provides a new treatment option for patients.

Sources:

[1]. Rong S, Si W, Hong M, et al. Cancer incidence and mortality in China, 2016. Journal of the National Cancer Center. 2 (2022) 1–9.

[2]. Siegel R, Naishadham D, Jemal A. Cancer statistic, 2012. CA Cancer J Clin. 2012;62(1):10–29. doi: 10.3322/caac.20138.

By order of the Board
Sino Biopharmaceutical Limited
Tse, Theresa Y Y
Chairwoman

Hong Kong, 30 April 2024

As at the date of this announcement, the Board of the Company comprises seven executive directors, namely Ms. Tse, Theresa Y Y, Mr. Tse Ping, Ms. Cheng Cheung Ling, Mr. Tse, Eric S Y, Mr. Tse Hsin, Mr. Tian Zhoushan and Ms. Li Mingqin and five independent non-executive directors, namely Mr. Lu Zhengfei, Mr. Li Dakui, Ms. Lu Hong, Mr. Zhang Lu Fu and Dr. Li Kwok Tung Donald.