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)

VOLUNTARY ANNOUNCEMENT
APPROVAL GRANTED FOR CLINICAL TRIALS OF THE FOURTH-GENERATION EGFR INHIBITOR "TQB3002" IN THE UNITED STATES

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that the fourth-generation EGFR inhibitor "TQB3002" independently developed by the Group has been officially approved by the United States Food and Drug Administration (FDA) for the investigational new drug (IND) application and its Phase I clinical trials will be commenced soon.

The epidermal growth factor receptor (EGFR) is one of the genes with the highest mutation frequency. EGFR is also the most important driver gene in non-small cell lung cancer, of which the mutation rate was as high as 40%-50% in East Asian population, and 10%-20% in Western population[1]. TQB3002 inhibits the activity and intracellular phosphorylation processes of related tyrosine kinases by competitively binding to the ATP site of the intracellular tyrosine kinase binding domain, thereby inhibiting the downstream signalling of EGFR and ultimately resulting in the death of tumor cells. Currently, EGFR inhibitors of the first, second and third generations were widely used for clinical purposes. The research and development of each generation of drugs is aimed at addressing the drug resistance of the previous generation[2]. Based on the above, the Group has developed TQB3002, the fourth-generation oral small-molecule EGFR inhibitor.

Preclinical studies have shown that TQB3002 can inhibit the kinase activity of EGFR single mutations (EGFRd746-750 and EGFRL858R) and EGFR double mutations (EGFRd746-750/T790M and EGFRL858R/T790M). TQB3002 demonstrated its relatively strong inhibitory activity in cell lines with single, double and triple EGFR mutations. In all of the in vivo models with EGFR single, double and triple mutations, TQB3002 could dose-dependently inhibit tumor growth and was well tolerated. At the same time, TQB3002 has a good safety profile and a relatively high value for clinical development.

The Group will continue to focus on innovative research and development, accelerate the clinical development of TQB3002, continue to explore overseas markets and actively expand its international layout.

Sources:

[1] Gao G, Deng L. Association between EGFR, ALK and KRAS Gene Status and Synchronous Distant Organ Metastasis in Non-small Cell Lung Cancer. Zhongguo Fei Ai Za Zhi. 2018 Jul 20;21(7):536-542.

[2] Zhou J. Y., et al. Drug Resistance Mechanism of the Third-generation EGFR-TKI and Therapeutic Strategy of Drug Combination [J]. Chinese Journal of Biochemistry and Molecular Biology, 2024,40(02):170-179.

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

Hong Kong, 14 November 2024

As at the date of this announcement, the Board of the Company comprises six executive directors, namely Ms. Tse, Theresa Y Y, Mr. Tse Ping, Ms. Cheng Cheung Ling, Mr. Tse, Eric S Y, Mr. Tse Hsin, and Mr. Tian Zhoushan, 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.