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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

**PHASE III STUDY RESULTS OF CULMERCICLIB IN COMBINATION WITH
FULVESTRANT FOR TREATMENT OF HR+/HER2- ADVANCED BREAST CANCER
FOLLOWING ENDOCRINE TREATMENT TO BE PRESENTED AT 2024 CSCO**

The board of directors (the “**Board**”) of Sino Biopharmaceutical Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) announces that the latest results of the phase III study of the innovative drug “Culmerciclib (TQB3616)” self-developed by the Group in combination with Fulvestrant for the treatment of patients with hormone receptor-positive, human epidermal growth factor receptor 2-negative (HR+/HER2-) advanced breast cancer following endocrine treatment (TQB3616-III-01) will be presented at the National Congress of Clinical Oncology and 2024 CSCO Annual Meeting (2024 CSCO) to be held on 25th to 29th of September.

Culmerciclib is a novel cyclin-dependent kinases 2, 4, and 6 (CDK2/4/6) inhibitor with varying degrees of inhibitory effects on CDK2, CDK4, and CDK6, and a strong inhibitory ability on CDK4.^[1] The results of the study revealed that Culmerciclib had an inhibitory impact on CDK2, and its enhanced CDK2 and CDK4 inhibitory effects may help to overcome the prevailing problem of resistance to CDK4/6 inhibitors in the clinical setting.^[1]

Title of Abstract: TQB3616 in combination with Fulvestrant for the treatment of hormone receptor-positive, HER2-negative advanced breast cancer: a randomised, double-blind, parallel-controlled phase III study

Session Type: Innovation Oral Report

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In July 2024, a new drug marketing application was submitted to and accepted by the Centre for Drug Evaluation (CDE) of the National Medical Products Administration of the People's Republic of China for the treatment of patients with HR+/HER2- locally advanced or metastatic breast cancer who have experienced disease progression following endocrine treatment.

TQB3616-III-01 (NCT05375461) is a randomised, double-blind, parallel-controlled, multicentre phase III clinical study designed to evaluate the efficacy and safety of Culmerciclib in combination with Fulvestrant versus Fulvestrant alone in patients with HR+/HER2-advanced breast cancer following endocrine treatment. The results of the study showed that, compared to the control group, Culmerciclib combined with Fulvestrant significantly reduced the risk of disease progression or death in patients with HR+/HER2-advanced breast cancer, while improving secondary endpoints such as overall survival (OS), objective remission rate (ORR), and clinical benefit rate (CBR). Details of the study will be presented at 2024 CSCO.

Breast cancer is one of the most prevalent malignant tumors in women, and Culmerciclib is expected to be the first innovative drug of the Group approved for marketing in this area. The Group also has TQB2102 (HER2 Bispecific Antibody ADC), TQB2930 (HER2 Bispecific Antibody), TQB3912 (AKT Inhibitor), TQB3915 (SERCA Antagonist), PARP1 Inhibitor, ER PROTAC Degradar, and other innovative drugs under development in the field of breast cancer.

The Group has built up a strong innovative product cluster and a rich pipeline of innovative drugs in the field of oncology and will present a number of latest research results at 2024 CSCO, which will comprehensively demonstrate the breakthroughs made by the Group in various fields of tumor treatment. In the future, the Group will continue to focus on innovation and explore cutting-edge innovative drugs and treatment solutions to warm more lives with health technology.

Source of Information:

[1] Xu Z, Liu Y, Song B, et al. Discovery and preclinical evaluations of TQB3616, a novel CDK4-biased inhibitor. *Bioorganic & Medicinal Chemistry Letters* 2024; 107.

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

Hong Kong, 29 August 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.