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
POSITIVE RESULTS ON PHASE III STUDY OF CULMERCICLIB IN COMBINATION WITH FULVESTRANT FOR FIRST-LINE TREATMENT OF HR-POSITIVE AND HER2-NEGATIVE ADVANCED BREAST CANCER

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that the phase III clinical study (TQB3616-III-02) of "Culmerciclib (TQB3616)", a Category 1 innovative drug self-developed by the Group, in combination with Fulvestrant for the treatment of previously untreated hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer, has completed its protocol-prescribed interim analysis with the Independent Data Monitoring Committee (IDMC), determining that the effectiveness has met the predefined superiority threshold. The Group has communicated with the Centre for Drug Evaluation (CDE) of the National Medical Products Administration of the PRC in relation to the marketing application for such indication, and has obtained written consent of the CDE to submit the marketing application for this additional first-line breast cancer indication of Culmerciclib in combination with Fulvestrant. The Group will submit the marketing application in the near future.

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. The results of the study revealed that 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]. In July 2024, the CDE accepted the marketing application of Culmerciclib in combination with Fulvestrant for the treatment of HR-positive, HER2-negative locally advanced or metastatic breast cancer following endocrine treatment. The data from the phase III study (TQB3616-III-01) for that indication was presented in September 2024 at the Innovation Session of the 2024 CSCO by oral presentation[2].

The TQB3616-III-02 study (NCT04523272) 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 placebo combined with Fulvestrant in patients with previously untreated HR-positive, HER2-negative advanced breast cancer. As the first domestic pivotal phase III study of a CDK2/4/6 inhibitor in combination with Fulvestrant for the first-line treatment of advanced breast cancer, the results of the interim analysis indicated that, the combination therapy significantly reduced the risk of disease progression or death in patients with advanced first-line breast cancer. The primary endpoint achieved statistical significance and clinical relevance, and the combination therapy was generally safe and tolerable.

Breast cancer is the most prevalent malignant tumor in women, with up to 2.3 million new cases per year globally and 360,000 new cases per year in China[3]. In recent years, both incidence and mortality rates of breast cancer in China have been on the rise[4]. Different molecular subtypes of breast cancer exhibit varying biological behaviors and treatment sensitivities. Luminal A and Luminal B breast cancers are both HR-positive, HER2-negative breast cancers, which are the most common subtypes of breast cancer, accounting for 65% to70% of the total breast cancer population. There is a significant unmet clinical need[5] for these subtypes.

The Group is actively expanding its presence in the field of breast cancer and its current pipeline covers multiple subtypes of breast cancer, including HR-positive, HER2-positive, HER2-low expression and triple negative breast cancer, which is expected to provide a wider range of treatment options for more female patients.

References:

[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.

[2] 2024 National Congress of Clinical Oncology (2024 CSCO), 27 September Innovation Session.

[3] Bray F, Laversanne M, Sung H, et al. Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA: A Cancer Journal for Clinicians 2024; 74(3): 229-63.

[4] ZHANG Xue, DONG Xiaoping, GUAN Yazhe, REN Meng, GUO Dongli, HE Yutong. Research Progress on Epidemiological Trend and Risk Factors of Female Breast Cancer[J]. Cancer Research on Prevention and Treatment, 2021, 48(1): 87-92.

[5] XIAO Hongyan, ZHANG Lina, GU Lin. Research progress in CDK4/6 inhibitors in neoadjuvant therapy of HR-positive HER2-negative breast cancer. Tumor. 2022, 42(12): 835-844.

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

Hong Kong, 24 March 2025

As of 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.