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
ACCEPTANCE OF NEW INDICATION APPLICATION FOR MARKETING OF CULMERCICLIB CAPSULE FOR FIRST-LINE TREATMENT OF BREAST CANCER

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that it has submitted a new indication application for marketing of the Group's self-developed CDK2/4/6 inhibitor "Culmerciclib Capsule (TQB3616)" in combination with fulvestrant injection for the treatment of previously untreated HR-positive, HER2-negative (HR+/HER2-) locally advanced or metastatic breast cancer to the Centre for Drug Evaluation ("**CDE**") of the National Medical Products Administration of the PRC, which has been accepted.

TQB3616-III-02 (NCT04523272) was a randomized, double-blind, parallel-controlled, multicenter Phase III clinical study designed to evaluate the efficacy and safety of TQB3616 in combination with fulvestrant versus placebo in combination with fulvestrant in previously untreated patients with HR+/HER2- advanced breast cancer. The study has met its primary endpoint, with its details to be presented at an upcoming international academic conference.

Breast cancer is one of the most common malignant tumours in women, with HR+/HER2- breast cancer accounting for approximately 65%-70% of all breast cancers, making it the most common subtype of breast cancer[1]. Approximately 4%-6% of breast cancer patients are diagnosed at an advanced stage, and even among early-stage patients who receive standard adjuvant therapy, 30%-40% of them progress to an advanced stage[2]. Authoritative guidelines including the "Chinese Society of Clinical Oncology (CSCO) Breast Cancer Guidelines (2025 Edition)" unanimously recommend the use of CDK4/6 inhibitors combined with endocrine therapy for the first-line treatment of HR+/HER2- advanced breast cancer[3, 4].

In July 2024, the Group submitted a new drug application for Culmerciclib in combination with fulvestrant for the treatment of HR+/HER2- locally advanced or metastatic breast cancer following endocrine treatment, which was accepted by CDE. The acceptance of the marketing application for the first-line indication for the drug has further confirmed the huge potential of the combination therapy in different treatment stages of advanced breast cancer.

Sources:

[1] Wu Hao, Lv Qing. Epidemiological trends and prevention and control implications of breast cancer in the world and in China: Interpretation of the 2018–2022 Global Cancer Statistics Report[J]. Chinese Journal of Bases and Clinics in General Surgery, 2024, 31(07): 796-802.

[2] Yan Xueqi, Huang Xiang, Li Wei, et al. Progress in stratified endocrine therapy for advanced breast cancer[J]. Journal of Practical Oncology, 2023, 38(02): 105-109.

[3] National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guideline). Breast Cancer, version 5. 2023[EB/OL]. [2024-01-12].

[4] Working Committee of Chinese Society of Clinical Oncology Guidelines, ed. Chinese Society of Clinical Oncology Breast Cancer Diagnosis and Treatment Guidelines 2024[M]. Beijing: People's Medical Publishing House.

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

Hong Kong, 10 July 2025

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.