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
"CULMERCICLIB CAPSULE" APPROVED FOR MARKETING

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that the culmerciclib capsule (brand name: 賽坦欣®), a national Category 1 innovative drug self-developed by the Group, has been approved by the China National Medical Products Administration (NMPA) for marketing. It is indicated for use in combination with fulvestrant for the treatment of patients with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer who have progressed following prior endocrine therapy.

Culmerciclib is a global First-in-Class triple inhibitor targeting CDK2/4/6 at the same time with varying degrees of inhibitory effects on CDK2, CDK4, and CDK6 kinases, and has particularly strong selective inhibition of CDK4 kinase. Due to its unique mechanism of action, culmerciclib not only helps delay the development of resistance to CDK4/6 inhibitors in clinical practice, but also reduces the risk of myelosuppression[1].

In the pivotal Phase III clinical trial (TQB3616-III-01), the combination therapy of culmerciclib and fulvestrant demonstrated promising efficacy. The results showed that the culmerciclib plus fulvestrant group achieved a median progression-free survival (mPFS) of 16.62 months as the primary endpoint, which was significantly prolonged by 9.16 months compared to the fulvestrant alone group (7.46 months), with a 64% reduction in the risk of disease progression or death (HR = 0.36, $p<0.0001$). The objective response rate (ORR) was also significantly improved (40.21% vs 12.12%, $p<0.0001$). In terms of safety, the most common treatment-related adverse events (TRAEs) were mostly grade 1-2 and manageable; hematological toxicities such as grade ≥3 myelosuppression were minimal; no TRAEs leading to treatment discontinuation or death were reported, indicating an overall tolerable safety profile[2].

Breast cancer is one of the most common malignant tumors in the world, with more than 2.3 million new cases worldwide in 2022[3]. HR+/HER2-breast cancer accounts for approximately 65%-70% of all breast cancer cases, making it the most common subtype[4]. Around 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 still progress to an advanced stage[5], indicating a significant unmet clinical need.

Following its approval for second-line treatment, the new drug application for culmerciclib plus fulvestrant in first-line HR+/HER2-breast cancer was submitted to the NMPA in July 2025, while the Phase III trial for adjuvant use has completed patients enrollment. These new indications are expected to be approved within the next two years.

Focusing on the field of breast cancer, the Group has built a pipeline covering all subtypes of breast cancer, including HR-positive, HER2-positive, HER2-low and triple negative breast cancer. This pipeline spans the entire treatment cycle, from (neo) adjuvant, first-line to subsequent lines of treatment. The Group will accelerate innovative research and development and strive to provide patients with a broader range of more effective and safer treatment options.

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] TQB3616 plus Fulvestrant for Hormone Receptor-Positive, HER2-Negative Advanced Breast Cancer: A Randomized, Double-Blind, Parallel-Controlled Phase 3 Clinical Trial. 2024 CSCO, Innovation Session, September 27.

[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[J]. CA: a cancer journal for clinicians, 2024, 74(3): 229-263.

[4] 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.

[5] 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.

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

Hong Kong, 12 December 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.