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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](http://www.sinobiopharm.com)*

**(Stock code: 1177)**

**VOLUNTARY ANNOUNCEMENT**  
**ACCEPTANCE OF NEW DRUG APPLICATION FOR**  
**CATEGORY 1 INNOVATIVE DRUG CULMERCICLIB CAPSULE**  
**“CULMERCICLIB (TQB3616)”**

The board of directors (the “**Board**”) of Sino Biopharmaceutical Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) announces that the interim analysis of phase III clinical trial of the Category 1 innovative drug Culmerciclib Capsule “Culmerciclib (TQB3616)” developed by the Group combined with Fulvestrant Injection for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer following endocrine treatment (NCT05375461) has been completed and has met the default primary endpoints as reviewed by the Independent Data Monitoring Committee (IDMC), the results of which will be published in academic journals or major academic conferences. The Group has submitted a new drug marketing application to the Center for Drug Evaluation (CDE) of the National Medical Products Administration of the People’s Republic of China (NMPA) and the application has been accepted.

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<sup>1</sup>. The results of the study revealed that Culmerciclib had a stronger inhibitory impact on CDK2 than Abemaciclib, 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.<sup>1</sup>

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<sup>2</sup>. In recent years, both incidence and mortality rates of breast cancer in China have been on the rise, of which about 60% to 70% of breast cancer patients are HR-positive and HER2-negative. In August 2020, the Fulvestrant Injection (trade name: Qingkeyi® (晴可依®)) of the Group obtained approval for marketing from the NMPA for the treatment of locally advanced or metastatic postmenopausal estrogen receptor-positive breast cancer with recurrence after or during the adjuvant anti-estrogen therapy, or progression in anti-estrogen therapy.

As a novel CDK2/4/6 inhibitor with superior activity and selectivity, Culmerciclib will provide a new treatment option for HR+/HER- breast cancer patients. The Group has been making breakthroughs in the research and development of innovative drugs and its innovative drug pipeline has progressively entered the harvesting phase.

*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. 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.

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

Hong Kong, 18 July 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.*