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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 ZONGERTINIB TABLETS APPROVED FOR MARKETING

The board of directors (the "Board") of Sino Biopharmaceutical Limited (the "Company", together with its subsidiaries, the "Group") announces that the zongertinib tablets (brand name: Hernexeos®) jointly promoted by the Group and Boehringer Ingelheim in mainland China have been approved by the National Medical Products Administration of China for marketing. The drug is used for the treatment of adult patients with unresectable locally advanced or metastatic non-small cell lung cancer (NSCLC) harbouring HER2 (ERBB2)-activating mutations who have previously received at least one prior systemic therapy.

Hernexeos® is the world's first and currently only approved oral HER2 tyrosine kinase inhibitor. The conditional approval for its marketing in China was supported by the positive results from the Beamion-LUNG 1 study, which evaluated the efficacy and safety of zongertinib in patients with HER2 (ERBB2)-mutant advanced NSCLC.

Data showed that among the pretreated patients of cohort 1 (N=75), the objective response rate (ORR) was 71% (95% confidence interval (CI): 60-80), with 7% complete responses and a disease control rate (DCR) as high as 96%. The median duration of response (DoR) was 14.1 months, with a median progression-free survival (PFS) of 12.4 months. These data were presented at the American Association for Cancer Research (AACR) Annual Meeting 2025 and simultaneously published in *The New England Journal of Medicine*^[1]. Zongertinib also demonstrated a manageable safety profile, with a discontinuation rate of only 2.9% during the study^[2].

Lung cancer is the leading cancer both globally and in China, and there are still significant unmet clinical needs for treatment of the disease. The approval of Hernexeos® in China will provide a more effective and better-tolerated treatment option for numerous patients in China with HER2-mutant NSCLC. It will also further enrich the Group's product line in the oncology field, as the Group strives to deliver therapeutic benefits to more patients, with a view to building a healthier world with science.

- Heymach, J. et al. Zongertinib in previously treated HER2-mutant non-small cell lung cancer. N Engl J Med. 2025;01-13.
- [2] Hernexeos® Prescribing Information

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

Chairwoman

Hong Kong, 29 August 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.