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
HER2-SELECTIVE TKI "ZONGERTINIB" ONCE AGAIN GRANTED BREAKTHROUGH THERAPEUTIC DESIGNATION BY CDE

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that "zongertinib", an HER2-selective tyrosine kinase inhibitor (TKI), was once again granted the Breakthrough Therapeutic Designation (BTD) by the Center for Drug Evaluation (CDE) of the National Medical Products Administration of China for the first-line treatment of adult patients with unresectable or metastatic non-small cell lung cancer (NSCLC) harbouring HER2 tyrosine kinase domain (TKD)-activating mutations.

The grant of this BTD was supported by the results of the Beamion LUNG-1 clinical trial, a Phase Ia/Ib, first-in-human, open-label trial to determine the safety, maximum tolerated dose (MTD), pharmacokinetics (PK), pharmacodynamics (PD) and preliminary efficacy of zongertinib in patients with solid tumours with changes in the HER2 gene (NCT04886804). The latest results will be released later this year.

Studies have shown that the 5-year survival rate for patients with NSCLC is less than 30%. Approximately 2–4% of NSCLC cases are driven by HER2 gene mutations. Currently, the first-line treatment for patients with advanced HER2-mutated NSCLC primarily consists of chemotherapy ± immunotherapy, and no new drugs for it have been officially approved in China. Due to the lack of targeted therapy, such patients often experience poor treatment outcomes, suffering both physically and psychologically.

Zongertinib is a covalently bound, orally administered, HER2-selective small molecule inhibitor developed by Boehringer Ingelheim. It covalently binds to both wild-type and mutant HER2 receptors while preserving wild-type EGFR signaling. It has good tolerability and safety while ensuring efficacy. Previously, zongertinib had been granted the Priority Review Designation as well as the BTD by the CDE for the indication of previously treated patients with HER2-mutated advanced NSCLC. In August 2025, zongertinib was granted accelerated approval by the United States Food and Drug Administration (FDA).

Strategic Partnership between Boehringer Ingelheim and the Group

Boehringer Ingelheim and the Group have established a strategic partnership, with a view to bringing innovative oncology therapies to the mainland China market. The partnership will leverage the complementary strengths of both companies to provide cancer patients in China with more and better treatment options. The companies will collaborate on various innovative oncology products from Boehringer Ingelheim that are in late-stage clinical development. Zongertinib is one of the products under the strategic collaboration between Boehringer Ingelheim and the Group in mainland China.

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

Hong Kong, 20 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.