SINO BIOPHARMACEUTICAL LIMITED
中國生物製藥有限公司

(Incorporated in the Cayman Islands with limited liability)
Website: www.sbpgroup.com
(Stock code: 1177)

VOLUNTARY ANNOUNCEMENT
ZONGERTINIB, A HER2 TYROSINE KINASE INHIBITOR, APPROVED FOR FIRST-LINE TREATMENT OF HER2-MUTANT NON-SMALL CELL LUNG CANCER

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**," together with its subsidiaries, the "**Group**") announces that 聖赫途® (Chinese generic name: 宗艾替尼, English generic name: zongertinib), which the Group co-promotes with Boehringer Ingelheim in mainland China, has received approval from the National Medical Products Administration (NMPA) of China for use as a monotherapy in the first-line treatment of adult patients with unresectable locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring HER2 (ERBB2) tyrosine kinase domain activating mutations. The approval marks another significant milestone following the Center for Drug Evaluation (CDE) of the NMPA granting Breakthrough Therapy designation to 聖赫途® for its first-line indication and NMPA's approval in August 2025 for the treatment of previously treated patients.

As the world's first approved oral HER2 tyrosine kinase inhibitor, the approval of 聖赫途® for first-line treatment marks a new era of precision-targeted first-line therapy for HER2-mutant advanced NSCLC in China. This approval addresses a long-unmet clinical need for an effective targeted first-line treatment in this patient population, while also offering greater convenience through oral administration.

The conditional approval of 聖赫途® for first-line treatment in China was based on the results from Cohort 2 of the Phase 1b Beamion-LUNG 1 clinical trial [1], which evaluated the efficacy and safety of zongertinib in treatment-naive patients with advanced NSCLC harboring HER2 (ERBB2)-activating mutations. Data showed that among treatment-naive patients in Cohort 1 (N=74), the confirmed objective response rate (ORR) reached 76%, with 11% of patients achieving complete response and 65% achieving partial response. The median duration of response (mDoR) was 15.2 months, and the median progression-free survival (mPFS) was 14.4 months. These data were presented at the European Lung Cancer Conference (ELCC) 2026, with study results simultaneously published in the *New England Journal of Medicine (NEJM)*. Additionally, the NEJM manuscript reported findings from 30 patients

with HER2-mutant advanced NSCLC with active brain metastases, of which, 47% experienced a confirmed intracranial objective response (iORR) by Response Assessment in Neuro-Oncology Brain Metastases (RANO-BM).

About HER2 (ERBB2)-mutant non-small cell lung cancer (NSCLC)

Lung cancer is one of the most lethal types of malignant tumors worldwide [2], with NSCLC being the most common type [3]. HER2 (ERBB2) mutations account for approximately 2–4% of NSCLC cases and are typically associated with poor prognosis and a higher incidence of brain metastasis [3,4]. Abnormal alterations in HER2 (ERBB2), including mutations, amplification, and overexpression, which can in turn result in uncontrolled cell production, inhibition of cell death and promotion of tumor growth and spread [4,5]. Traditional chemotherapy and immunotherapy have shown limited efficacy in patients with HER2 mutations [2]. Antibody-drug conjugates (ADCs) have demonstrated some efficacy in this setting, but they require intravenous administration and carry the risks of potential adverse events such as myelosuppression and interstitial lung disease [5,6]. Therefore, patients with HER2-mutant advanced NSCLC still face significant unmet clinical needs, and there is an urgent demand for a highly effective, safe, and convenient oral precision targeted therapy.

About 聖赫途® (Zongertinib Tablets)

聖赫途® (Zongertinib Tablets) is an irreversible tyrosine kinase inhibitor (TKI) that selectively inhibits HER2 (ERBB2) while sparing wild-type EGFR, thereby helping to reduce related toxicities [5,7]. Comprehensive biomarker testing determines a patient's eligibility for treatment with 聖赫途® by identifying HER2 (ERBB2)-mutant advanced NSCLC [3,7].

About the BEAMION Clinical Trial

BEAMION LUNG-1 (NCT04886804) is an open-label, Phase I dose-escalation clinical trial of zongertinib monotherapy in patients with unresectable or metastatic solid tumors harboring HER2 mutations, including dose confirmation and expansion. The study consists of two parts: Part 1 enrolls adult patients with various types of advanced cancer carrying HER2 gene alterations (including mutations, amplifications, overexpression, and fusions) who have progressed on prior therapy. Part 2 enrolls patients with HER2-mutant NSCLC. BEAMION LUNG-2 is a Phase III, open-label, randomized, active-controlled study designed to enroll 270 patients with unresectable or metastatic non-squamous NSCLC harboring HER2 tyrosine kinase domain mutations, with the aim of evaluating the efficacy of zongertinib compared to the standard of care.

About the Strategic Partnership Between Boehringer Ingelheim and SBP Group

Boehringer Ingelheim and SBP Group have established a strategic partnership dedicated to bringing innovative oncology therapies to the mainland Chinese market. The collaboration will leverage the complementary strengths of both parties to provide more and better treatment options for cancer patients in China. The two companies will collaborate on several of Boehringer Ingelheim's innovative oncology products currently in late-stage clinical development. Zongertinib is one of the strategic collaboration products between Boehringer Ingelheim and SBP Group in mainland China.

Sources:

[1] Key results from the Phase 1b Beamion LUNG-1 clinical trial of Zongatinib for first-line treatment of HER2-mutated advanced non-small cell lung cancer, published in the *New England Journal of Medicine*:

[2] Zeng J, Ma W, Young RB, Li T. Targeting HER2 genomic alterations in non-small cell lung cancer. J Natl Cancer Cent. 2021; 1(2): 58-73.

[3] Baraibar I, et al. Novel drugs targeting EGFR and HER2 exon 20 mutations in metastatic NSCLC. Crit Rev Oncol Hematol. 2020; 148: 102906.

[4] Li BT, Smit EF, Goto Y, et al. Trastuzumab Deruxtecan in HER2-Mutant Non-Small-Cell Lung Cancer. N Engl J Med. 2022; 386(3): 241-251.

[5] HERNEXEOS Prescribing Information.

[6] Zhang Liang, Yang Changliang, Li Peidong, Cheng Ying. Research Progress on HER2-Mutant Advanced Non-Small Cell Lung Cancer. Research on Cancer Prevention and Treatment. 2025. 52(02): 87-92.

[7] Wilding B, Woelflingseder L, Baum A, et al. Zongertinib (BI 1810631), an Irreversible HER2 TKI, Spares EGFR Signaling and Improves Therapeutic Response in Preclinical Models and Patients with HER2-Driven Cancers. Cancer Discovery. 2025; 15(1): 119-138.

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

Hong Kong, 21 May 2026

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.