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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 DATA FROM PHASE I STUDY OF TQB2102 (BISPECIFIC ANTI-HER2 ADC) PRESENTED AT 2025 ASCO ANNUAL MEETING

The board of directors (the "Board") of Sino Biopharmaceutical Limited (the "Company", together with its subsidiaries, the "Group") announces that the Group has presented the preliminary data from the first-in-human phase I clinical study for TQB2102 "bispecific anti-HER2 antibody-drug conjugate (ADC)" at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting.

As of 1 October 2024, the trial included 181 patients in total with advanced solid tumours treated with non-standard treatment options, including HER2-positive and HER2 low-expression. The results of the study showed that in terms of efficacy for the dose group of 6mg/kg and above, the objective remission rate (ORR) was 51.3% for HER2-positive breast cancer, 51.5% for HER2 low-expression breast cancer, 34.8% for HER2 high-expression (HER2 immunohistochemistry 3+) colorectal cancer, and 70% for HER2-positive gastric cancer or gastroesophageal junction cancer. Among them, the subgroup of HER2-positive breast cancer with brain metastasis showed an ORR of 70%, and one case of intracranial lesion was in complete remission; treatment with TQB2102 for 31% of breast cancer subjects remained effective after T-DM1/DS-8201 resistance^[1].

In terms of safety, Grade ≥ 3 adverse events (AEs) in the total population were mainly neutropenia (21.7%), decreased white blood cell count (10.6%), anaemia (8.9%) and decreased platelet count (6.1%). Notably, there was only one case (0.55%) of grade 2 interstitial lung disease (ILD), and the incidence was much lower than that of the comparable drug DS-8201 (incidence >10%)^[1].

Currently, there is no drug with bispecific antibody ADC approved for marketing in the world. TQB2102 has demonstrated significant clinical benefits in several advanced malignancies with low ILD incidence, thus achieving an effective balance between efficacy and safety. TQB2102 is currently undergoing phase III clinical trials, which are expected to reshape the treatment landscape of HER2 ADC.

Source:

[1] Ruihua Xu et al. Safety and efficacy of TQB2102, a novel bispecific anti-HER2 antibody-drug conjugate, in patients with advanced solid tumors: Preliminary data from the first-in-human phase 1 trial. 2025 ASCO (#3003).

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

Hong Kong, 27 May 2025

As of 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.