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
TQB2102 "HER2 BISPECIFIC ADC" RECEIVES THIRD BREAKTHROUGH THERAPY DESIGNATION FROM THE CDE

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that TQB2102 "HER2 bispecific ADC", a national Category 1 innovative drug independently developed by the Group's subsidiary, Chia Tai Tianqing Pharmaceutical Group Co., Ltd. ("**CTTQ**"), has been granted Breakthrough Therapy Designation by the Center for Drug Evaluation (CDE) of the China's National Medical Products Administration, for adult patients with unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer who have not received any chemotherapy at the relapsed or metastatic stage. This marks the third Breakthrough Therapy Designation granted to TQB2102, following those for the neoadjuvant therapy of HER2-positive early-stage breast cancer and HER2 IHC 3+ advanced colorectal cancer, thereby further demonstrating its broad potential for application in the treatment of HER2-expressing solid tumours.

TQB2102 is a next-generation HER2 dual-epitope bispecific ADC independently developed by the Group, which achieves an optimal balance of efficacy and safety through three core technological breakthroughs:

1) Dual-epitope targeting: The antibody end employs an asymmetric structural design that can simultaneously bind to both ECD II and ECD IV domains of HER2 and can significantly enhance selectivity toward tumor cells and endocytosis efficiency, thereby boosting anti-tumor activity;

2) Cleavable linker: TQB2102 employs an enzyme-cleavable linker to achieve efficient payload release and retain the "bystander effect," thus broadening the killing range against heterogeneous tumors;

3) Optimised drug-to-antibody ratio (DAR): DAR value is regulated to 5.8-6.0 and is conjugated with a topoisomerase I inhibitor payload, thereby optimising the balance between anti-tumour efficacy and toxicity.

These differentiated designs have overcome the limitations of conventional HER2 monoclonal antibodies or single-target ADCs. In particular, the dual-epitope binding mode can enhance the cross-link to receptors and endocytosis efficiency, thereby possessing clearly differentiated advantages in the treatment of patients with HER2-low expression.

In May 2026, the preclinical and Phase I clinical study results of TQB2102 in advanced solid tumours were published online in the *Annals of Oncology* (IF: 65.4), the flagship journal of the European Society for Medical Oncology (ESMO), confirming the differentiated features of TQB2102 as a dual-epitope HER2 ADC[1]. In 2025, the Group presented the Phase Ib study results of TQB2102 in HER2-low advanced breast cancer at the American Society of Clinical Oncology (ASCO) Annual Meeting[2]: among patients with HER2-low breast cancer who had failed multiple prior lines of therapy (median of 4 lines), the overall objective response rate (ORR) was 53.4%, with the target dose group (7.5 mg/kg) achieving an ORR of 58.3%; among patients who had progressed on prior ADC therapy, 44.4% still responded to TQB2102 treatment.

Breast cancer is the most prevalent malignant tumour among women worldwide. In China, there were an estimated 357,000 new cases and 75,000 death cases from breast cancer in 2022, representing a substantial disease burden. Of all breast cancer patients, approximately 45%–55% are classified as HER2-low expression (IHC 1+ or 2+/FISH–). In the past, treatment for HER2-low breast cancer has been stratified primarily by hormone receptor (HR) status: for HR-positive patients who have developed resistance to endocrine therapy and are unsuitable for further endocrine therapy, current treatment options are limited, under which clinical practices and guidelines still primarily recommend palliative chemotherapy; for HR-negative patients, the optimal treatment follows those principles of triple-negative breast cancer, also mainly with chemotherapy. However, existing palliative chemotherapy regimens offer limited clinical benefits and are associated with significant toxicity for such patients. Accordingly, there are substantial unmet needs, which necessitate the development of novel targeted drugs to offer additional treatment options[3,4].

TQB2102 is currently undergoing several Phase III clinical trials, including in chemotherapy-naïve advanced HER2-low breast cancer, advanced HER2-positive breast cancer after prior anti-HER2 therapy, neoadjuvant HER2-positive breast cancer; first-line advanced HER2-positive breast cancer, later-line advanced HER2-positive biliary tract cancer, and advanced HER2-positive colorectal cancer that has failed treatment with oxaliplatin, irinotecan and fluorouracil-based regimens. The Group is proactively advancing the clinical development and registration filings of TQB2102, with the goal of securing early marketing approval and delivering novel treatment options to cancer patients.

Sources:

[1] Ruan DY, Lin SY, Huang JJ, et al. Preclinical characterization and phase 1 results of TQB2102, a first-in-class HER2 biparatopic antibody-drug conjugate, in patients with advanced solid tumors. Ann Oncol. 2026.

[2] S Wang, et al. Preliminary efficacy and safety of TQB2102 in patients with HER2 low-expressing recurrent/metastatic breast cancer: Results from a phase 1b study. 2025 ASCO #1090.

[3] Louis Fehrenbacher, et al. NSABP B-47/NRG Oncology Phase III Randomized Trial Comparing Adjuvant Chemotherapy With or Without Trastuzumab in High-Risk Invasive Breast Cancer Negative for HER2 by FISH and With IHC 1+ or 2. J Clin Oncol. 2020 Feb 10;38(5):444-453.

[4] Howard A Burris 3rd, et al. Phase II study of the antibody drug conjugate trastuzumab-DM1 for the treatment of human epidermal growth factor receptor 2 (HER2)-positive breast cancer after prior HER2-directed therapy. J Clin Oncol. 2011 Feb 1;29(4):398-405.

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

Hong Kong, 3 August 2026

As at the date of this announcement, the Board of the Company comprises five executive directors, namely Ms. Tse, Theresa Y Y, Mr. Tse Ping, Ms. Cheng Cheung Ling, Mr. Tse, Eric S Y and Mr. Tse Hsin and six independent non-executive directors, namely Mr. Lu Zhengfei, Ms. Lu Hong, Mr. Zhang Lu Fu, Dr. Li Kwok Tung Donald, Dr. Chen Lieping and Dr. Lu Bai.