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
COMPLETION OF SUBJECT ENROLLMENT IN PHASE III CLINICAL TRIAL OF TQB2102 "HER2 BISPECIFIC ADC" FOR HER2-LOW BREAST CANCER

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, is currently undergoing a "Randomised, Open-label, Parallel-controlled Phase III Clinical Trial to Evaluate the Efficacy and Safety of TQB2102 for Injection Versus Investigator-selected Chemotherapy in HER2-Low Recurrent/Metastatic Breast Cancer (TQB2102-III-01)". The enrollment of all subjects has recently been completed.

TQB2102 is a next-generation HER2 dual-epitope bispecific antibody-drug conjugate (ADC) independently developed by the Group, which achieves an optimized balance between efficacy and safety through three core technological innovations.

1. Dual-epitope targeting design: The antibody end employs an asymmetric structural design that simultaneously binds to the ECD II/IV domains of HER2, which significantly enhances selectivity toward tumor cells and drug endocytosis efficiency, thereby boosting anti-tumor activity.

2. Cleavable linker: Utilizing an enzyme-cleavable linker, TQB2102 is capable of efficient cleavage to release toxins and possesses a "bystander effect," eliminating surrounding heterogeneous tumor cells to broaden the killing range.

3. Optimized drug-to-antibody ratio (DAR): TQB2102 maintains a stable DAR value of 5.8-6.0 and is conjugated with topoisomerase I (Topo I) inhibitor payloads, thereby enhancing therapeutic efficacy while reducing toxic side effects.

The integration of these core technologies has overcome the limitations of traditional HER2 monoclonal antibodies and single-target ADCs, demonstrating significant potential for TQB2102 in treating HER2-low tumors.

At the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, the Group announced the results of Phase Ib clinical study of TQB2102 for HER2-low advanced breast cancer [1], demonstrating favorable efficacy and showing a good safety profile:

Efficacy data: In HER2-low patients who had received multiple prior lines of therapy (median of 4 lines of late-stage systemic therapy and 2 lines of palliative chemotherapy), the overall objective response rate (ORR) was 53.4% (39/73), in which the ORR of the 7.5mg/kg cohort reached 58.3% (21/36). It is worth noting that even among patients who had previously progressed on ADC therapy, 44.4% achieved remission following TQB2102 treatment.

Safety data: Grade ≥3 treatment-related adverse events (TRAEs) primarily included neutropenia (23.3%), leukopenia (20.6%), anemia (8.2%), and hypokalemia (6.9%). Overall, TQB2102 was well-tolerated.

Breast cancer is the most prevalent malignant tumor among women worldwide. In 2022, China reported approximately 357,000 new cases of breast cancer and approximately 75,000 death cases[2]. Among which, approximately 45%-55% of breast cancers are classified as HER2-low expression (i.e. HER2 IHC 1+ or 2+/FISH-). This group of patients forms a heterogeneous population, for whom existing conventional HER2-targeted therapies offer limited clinical benefit, creating an urgent need for novel treatments to improve prognosis[3-4].

In the field of breast cancer, the Group has developed a comprehensive portfolio addressing all major subtypes, including HER2-positive, HER2-low, HR+/HER2-, and triple-negative breast cancer, with coverage spanning the entire treatment spectrum from neoadjuvant, first-line, second-line and later, to adjuvant therapy. This integrated strategy is dedicated to offering new treatment options for a broader patient population.

Sources:

[1] 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.

[2] Expert Consensus Writing Group on Tiered Diagnosis and Treatment for Breast Cancer (Single Disease Entity). Expert consensus on tiered diagnosis and treatment of single disease of breast cancer (2025 Edition) [J]. Chinese Journal of Oncology, 2025, 47(10): 961-980.

[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, 10 February 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.