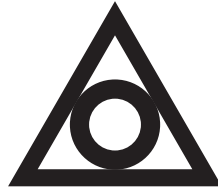


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**中國生物製藥有限公司**

*(Incorporated in the Cayman Islands with limited liability)*

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**(Stock code: 1177)**

**VOLUNTARY ANNOUNCEMENT**  
**TQB2102 “HER2 BISPECIFIC ADC” INCLUDED IN**  
**THE BREAKTHROUGH THERAPEUTIC DESIGNATION PROCESS**

The board of directors (the “**Board**”) of Sino Biopharmaceutical Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) announces that TQB2102 “HER2 bispecific antibody-drug conjugate (ADC)” for injection, being a national Class 1 new drug independently developed by the Group, has been included in the Breakthrough Therapeutic Designation (BTD) process by the Center for Drug Evaluation (CDE) of the National Medical Products Administration of China. The drug is used for the treatment of HER2 IHC 3+ advanced colorectal cancer that has failed in prior attempts with oxaliplatin, irinotecan, and fluorouracil-based regimens.

TQB2102 is a bispecific ADC drug concurrently targeting dual non-overlapping epitopes on the HER2 protein, namely ECD2 and ECD4, and has demonstrated potent advantages in the treatment for colorectal cancer with its differentiated design. The Group presented the preliminary data from the Phase I clinical study for TQB2102 at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting<sup>[1]</sup>. As of 1 October 2024, the study enrolled 181 treated patients suffering advanced solid tumors in total, and encompassed both HER2-positive and HER2-low expression cases. As shown in the results from the study, the objective response rate (ORR) is 34.8% in HER2-high expression (HER2 immunohistochemistry (IHC) 3+) colorectal cancer. The latest analysis indicates that the efficacy of TQB2102 for HER2 IHC 3+ advanced colorectal cancer continues to improve with prolonged treatment duration, while ensuring overall manageable safety.

Currently, there is still a lack of specific targeted treatment regimens for advanced colorectal cancer with HER2 overexpression. According to the guidelines for the diagnosis and treatment of colorectal cancer issued by the Chinese Society of Clinical Oncology (CSCO), the first-line and second-line treatments primarily consist of chemotherapy regimens based on oxaliplatin, irinotecan, and fluorouracil, which may be combined with or without anti-angiogenesis agents. Following the failure of standard second-line treatments, the third-line treatment options are extremely limited and demonstrate insufficient efficacy<sup>[2-4]</sup>: ORR merely ranges from 1.0% to 2.0%, accompanied by progression-free survival (PFS) of 1.9 to 3.7 months, and overall survival (OS) of 6.4 to 7.4 months. There is an extremely urgent clinical need for highly effective treatment regimens, which necessitates breakthroughs in more effective treatment regimens.

The official inclusion of TQB2102 in the BTD will accelerate its approval process, which is expected to bring benefits to patients sooner and reshape the treatment landscape for HER2 IHC 3+ colorectal cancer.

Sources:

- [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).
- [2] Mayer, et al.Randomized trial of TAS-102 for refractory metastatic colorectal cancer[J].The New England journal of medicine vol. 372,20 (2015): 1909-19.
- [3] Dasari, et al.AFRESCO-2 Study Investigators. Fruquintinib versus placebo in patients with refractory metastatic colorectal cancer (FRESCO-2): an international, multicentre, randomised, double-blind, phase 3 study[J].Lancet. 2023 Jul 1;402(10395):41-53.
- [4] Grothey A, et al.CORRECT Study Group. Regorafenib monotherapy for previously treated metastatic colorectal cancer (CORRECT): an international, multicentre, randomised, placebo-controlled, phase 3 trial[J].Lancet. 2013 Jan 26;381(9863):303-12

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

Hong Kong, 13 October 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.*