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 II STUDY OF TQB2868 "PD-1/TGF-β BI-FUNCTIONAL FUSION PROTEIN" 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 phase II clinical study of TQB2868 "PD-1/TGF- β bi-functional fusion protein" combined with anlotinib and chemotherapy as first-line treatment for metastatic pancreatic ductal adenocarcinoma (mPDAC) at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting.

CLINICAL DATA DEMONSTRATING ROBUST EFFICACY

TQB2868-ALTN-II-01 is a phase II clinical study evaluating the effectiveness and safety of TQB2868 combined with anlotinib and AG chemotherapy (gemcitabine + nab-paclitaxel) as first-line treatment for mPDAC.

As of January 2025, 40 patients suffering stage IV mPDAC have been enrolled in the study, 36 of which were evaluable. The preliminary data showed that: the objective remission rate (ORR) of TQB2868 combined with anlotinib and AG chemotherapy was 63.9%, which was 2-3 times that of the historical data of the AG chemotherapy regimen (23%-36%); the disease control rate (DCR) was 100%, which was 1.6 times that of the AG chemotherapy regimen (62.3%); the median progression-free survival (PFS) was not yet achieved, and the 6-month PFS rate was 86%, which was 2 times that of the AG chemotherapy regimen (43.2%); the median overall survival (OS) was not yet achieved, and it is expected to be over 1 year[1-4].

In terms of safety, the TQB2868 combination therapy is safe and well-tolerated. The incidence of adverse events of grade 3 and above was 52.5% (68.1%-77% for the AG chemotherapy regimen)[1-4].

THE TRIPLE SYNERGISTIC MECHANISM OF "IMMUNITY – TARGETING – CHEMOTHERAPY"

TQB2868 is a PD-1/TGF- β bi-functional fusion protein independently developed by the Group, which blocks the interaction between PD-1 and its ligand PD-L1 to relieve the inhibition of T cells by tumor cells and activate the attack of T cells on tumors; meanwhile, TQB2868 reverses the immune escape of tumor cells by neutralizing the TGF- β signal to strengthen the efficacy of anti-tumor activities. The unique triple synergistic mechanism of "immunity – targeting – chemotherapy" of TQB2868 combined with anlotinib and AG chemotherapy achieves a multi-target synergy of immunity activation, vascular remodeling and tumor killing, thereby showing significant anti-tumor effects in the clinical study.

A MUCH-NEEDED BREAKTHROUGH IN THE TREATMENT DILEMMA OF PANCREATIC CANCER

Pancreatic cancer is one of the most malignant solid tumors with a five-year survival rate of less than 10%, and is known as the "king of cancers" in the field of cancer treatment. Among them, over 80% of the patients are confirmed to suffer mPDAC at the time of diagnosis, and there are scarce treatment options for such patients. AG chemotherapy remains the current regimen of first-line standard therapy, but its median OS struggles to exceed 1 year, resulting in an urgent need for treatment regimens with better efficacy[1-3].

The Group is communicating with the Center for Drug Evaluation (CDE) of the National Medical Products Administration of China regarding the Phase III clinical study for the registration of TQB2868 combination regimen. The regimen may become the first immune checkpoint inhibitor as a first-line treatment regimen for pancreatic cancer, thus bringing fundamental improvement to the overall survival and the quality of living of patients suffering pancreatic cancer.

Sources:

[1] D, El-Maraghi RH, Hammel P, et al. nab-Paclitaxel plus gemcitabine for metastatic pancreatic cancer: long-term survival from a phase III trial. J Natl Cancer Inst.2015;107(2): dju413.

[2] Conroy T, Desseigne F, Ychou M, et al. FOLFIRINOX versus gemcitabine for metastatic pancreatic cancer. N Engl J Med. 2011;364(19):1817-25.

[3] Wainberg ZA, Melisi D, Macarulla T, et al. NALIRIFOX versus nab-paclitaxel and gemcitabine in treatment-naive patients with metastatic pancreatic ductal adenocarcinoma (NAPOLI 3): a randomised, open-label, phase 3 trial. Lancet. 2023 Oct 7;402(10409):1272-81.

[4] Si Shi, Xianjun Yu, Xiaobing Chen, et al. TQB2868 combined with anlotinib and nab-paclitaxel plus gemcitabine as first-line treatment for metastatic pancreatic cancer: A prospective, multicenter, single-arm, phase 2 study. 2025 ASCO (#4159).

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

Hong Kong, 29 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.