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
APPROVAL OBTAINED FROM CDE TO INITIATE PHASE III REGISTRATIONAL CLINICAL STUDY OF TQB2868 INJECTION "PD-1/TGF-β BI-FUNCTIONAL FUSION PROTEIN"

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that TQB2868 injection "PD-1/TGF-β bi-functional fusion protein", a Class 1 innovative drug developed by the Group, combined with anlotinib hydrochloride capsules and chemotherapy as first-line treatment for metastatic pancreatic ductal adenocarcinoma (mPDAC) demonstrated excellent efficacy and good safety in early clinical trials. The Group recently submitted an application for a Phase III clinical study of the drug to the Center for Drug Evaluation (CDE) of the National Medical Products Administration of China and has received written approval from the CDE to initiate the study. TQB2868 is currently the fastest developing PD-1/TGF-β bi-functional fusion protein in the world.

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 tumour cells and activate the attack of T cells on tumours. TQB2868 also reverses the immune escape of tumour cells by neutralizing the TGF-β signal to strengthen the efficacy of anti-tumour activities. The unique triple synergistic mechanism of "immunity – targeting – chemotherapy" of TQB2868 combined with anlotinib and chemotherapy achieves a multi-target synergy of immunity activation, vascular remodeling and tumour killing, thereby showing significant anti-tumour effects in clinical studies.

The preliminary data from a Phase II clinical study (TQB2868-ALTN-II-01) was already presented at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting: the objective response rate (ORR) of TQB2868 combined with anlotinib and chemotherapy was 63.9%; the disease control rate (DCR) was 100%; the median progression-free survival (PFS) was not yet achieved; the 6-month PFS rate was 86%; the median overall survival (OS) was not yet achieved, and is expected to be over 1 year[1]. The combination regimen demonstrated significant improvement in efficacy compared to the current standard treatment. The Group will initiate a Phase III registrational clinical study to validate the efficacy and safety of the combination regimen compared to the standard treatment in a larger sample size of mPDAC patients.

Pancreatic cancer is one of the most malignant solid tumours with a five-year survival rate of less than 10% and is known as the "king of cancers" in the field of cancer treatment. In 2022, there were over 510,000 new cases of pancreatic cancer worldwide, with 460,000 deaths, while China reported 120,000 new cases and 110,000 deaths[2,3]. Among these cases, over 80% of patients were diagnosed with mPDAC at the time of diagnosis, with scarce treatment options available for them. Systematic chemotherapy remains the current standard for first-line treatment, but its median OS does not exceed 1 year, resulting in an urgent need for treatment options with better efficacy[4,5,6].

Currently, no PD-1/TGF-β bi-functional fusion protein has been approved for marketing in the world, and TQB2868 ranks first in the world in terms of its research and development progress. The regimen of TQB2868 combined with anlotinib and chemotherapy has the potential to become the first first-line treatment option for pancreatic cancer with immune checkpoint inhibitors, which may drastically improve the overall survival and quality of life of patients with pancreatic cancer.

Sources:

[1] 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).

[2] Bray F, Laversanne M, Sung H, et al. Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries[J]. CA Cancer J Clin, 2024, 74(3): 229-263.

[3] Bingfeng Han, Rongshou Zheng, Hongmei Zeng, et al. Cancer incidence and mortality in China, 2022, Journal of the National Cancer Center, Volume 4, Issue 1, 2024, 47-53.

[4] 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.

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

[6] 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.

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

Hong Kong, 10 June 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.