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 III STUDY OF BENMELSTOBART WITH OR WITHOUT ANLOTINIB AS MAINTENANCE TREATMENT FOR NON-SMALL CELL LUNG CANCER WITHOUT PROGRESSION FOLLOWING CHEMORADIOTHERAPY 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 latest results of the phase III clinical study for benmelstobart injection with or without anlotinib hydrochloride capsules as maintenance treatment for non-small cell lung cancer (NSCLC) without progression following chemoradiotherapy at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting: the median progression-free survival (PFS) of the arm of benmelstobart in combination with anlotinib as compared with the arm of placebo was significantly prolonged (15.1 months vs. 4.2 months), with a 51% reduction in the risk of disease progression or death.

The study (R-ALPS) enrolled patients with pathologically diagnosed and locally advanced/unresectable stage III NSCLC without progression following concurrent/sequential chemoradiotherapy. As of 12 May 2023, 553 patients were randomized and enrolled, with arm 1 (209 subjects) receiving the treatment of benmelstobart in combination with anlotinib, arm 2 (212 subjects) receiving the treatment of benmelstobart in combination with placebo and the control arm (132 subjects) receiving the treatment of placebo. The median follow-up time was 19.4 months[1].

The preliminary results showed that the median PFS of arm 1 was significantly prolonged by 10.9 months (15.1 months vs. 4.2 months; HR=0.49, 95%CI 0.36-0.66, P<0.001) when compared with the control arm, with a 51% reduction in the risk of disease progression or death. The median PFS of arm 2 was significantly prolonged by 5.5 months (9.7 months vs. 4.2 months; HR=0.53, 95% CI 0.39-0.72, P<0.0001) when compared with the control arm, with a 47% reduction in the risk of disease progression or death. The safety profiles were consistent with the known risk spectrums of the drugs, and no new safety signals were observed. The incidence rates of grade ≥3 treatment-related adverse events were 48.8%, 29.4% and 19.7%, respectively[1].

Global cancer statistics show that lung cancer had the highest incidence and mortality rates among all malignant tumors in the world as well as in China. In 2022, there were 2.48 million cases of lung cancer worldwide, 1.061 million cases of which were in China[2,3]. NSCLC accounted for approximately 80%-85% of all lung cancers. The currently available treatment options for locally advanced/unresectable stage III NSCLC are limited and mainly consist of continued immune monotherapy as maintenance treatment following concurrent/sequential chemoradiotherapy[4,5].

As the world's first combination study in the field of stage III NSCLC without progression following concurrent/sequential chemoradiotherapy, the R-ALPS study validates the efficacy and safety of the combination of targeted therapy and immunotherapy as maintenance treatment, setting a new record of PFS benefits in that field. Based on the results of the study, the marketing application for the new indication of benmelstobart with or without anlotinib was accepted by the Centre for Drug Evaluation (CDE) of the National Medical Products Administration of the PRC in April 2025. The breakthrough from the results of the study may reshape clinical practice guidelines and benefit more NSCLC patients.

Sources:

[1] Ming Chen, Yongling Ji, Long Chen, et al. R-ALPS: A randomized, double-blind, placebo-controlled, multicenter phase III clinical trial of TQB2450 with or without anlotinib as maintenance treatment in patients with locally advanced and unresectable (stage III) NSCLC without progression following concurrent or sequential chemoradiotherapy. 2025 ASCO (#LBA8004).

[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. CA Cancer J Clin. 2024.

[3] Han B, Zheng R, Zeng H, et al. Cancer incidence and mortality in China, 2022[J]. Journal of the National Cancer Center, 2024, 4(1): 47-53.

[4] Antonia SJ, Villegas A, Daniel D, et al. Durvalumab after Chemoradiotherapy in Stage III Non-Small-Cell Lung Cancer. N Engl J Med. 2017;377(20):1919-1929.

[5] Qing Zhou, Ming Chen, et al. Sugemalimab versus placebo after concurrent or sequential chemoradiotherapy in patients with locally advanced, unresectable, stage III non-small-cell lung cancer in China (GEMSTONE-301): interim results of a randomised, double-blind, multicentre, phase 3 trial.The Lancet Oncology.2022;2(23).P209-219.

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

Hong Kong, 5 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.