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 IN COMBINATION WITH ANLOTINIB FOR FIRST-LINE TREATMENT OF SQ-NSCLC PRESENTED IN 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 of Benmelstobart Injection in combination with chemotherapy followed by sequential combination with Anlotinib Hydrochloride Capsules versus Tislelizumab Injection in combination with chemotherapy for the first-line treatment of advanced squamous non-small cell lung cancer (sq-NSCLC) at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting. The results showed that the median progression-free survival (mPFS) in the trial group was 10.12 months, with a 36% reduction in the risk of disease progression compared to the control group.

The World's First Phase III Clinical Study Comparing Immune Checkpoint Inhibitors in Combination with Chemotherapy for the First-Line Treatment of Sq-NSCLC that Has Achieved Positive Results

The regimen of "benmelstobart in combination with chemotherapy followed by sequential combination with anlotinib" is the world's first head-to-head Phase III clinical study of PD-1 monoclonal antibodies in combination with chemotherapy for the first-line treatment of sq-NSCLC that has achieved significant positive results. The marketing application for the regimen was accepted by the Centre for Drug Evaluation (CDE) of the National Medical Products Administration of the PRC in April this year.

As of 1 March 2024, 565 patients were randomly assigned to the trial group and the control group in a 1:1 ratio, with baseline characteristics of the two groups largely balanced. Data from the study showed that the regimen of "benmelstobart in combination with chemotherapy followed by sequential combination with anlotinib" significantly prolonged mPFS compared with the regimen of "tislelizumab

in combination with chemotherapy" (10.12 months vs. 7.79 months, HR=0.64, P=0.0038), with a 36% reduction in the risk of disease progression/death in the trial group. The objective remission rate (ORR) was 71.9% in the trial group and 65.1% in the control group. The median duration of response (DoR) was significantly longer in the trial group than in the control group (9.69 months vs. 8.34 months, HR=0.58, P=0.0091). Subgroup analyses showed that almost all subgroups benefited from the treatment of "benmelstobart in combination with chemotherapy followed by sequential combination with anlotinib" (for the subgroup with a 1-49% PD-L1 expression level, HR=0.47 (95%CI: 0.30-0.73))[1].

The overall safety of the trial group was good. There was no significant difference in the incidence of treatment-emergent adverse events leading to death between the trial group and the control group, and the safety was controllable.

Addressing Unmet Clinical Needs and Bringing Significant Survival Benefits to Patients with Sq-NSCLC

According to Global cancer statistics 2022, lung cancer had the highest incidence and mortality rate among all malignant tumours in the Chinese population as well as in the world's population, with non-small cell lung cancer (NSCLC) accounting for 80-85% of all lung cancers[2]. sq-NSCLC was one of the major subtypes of NSCLC, accounting for approximately 30% of all NSCLCs[3]. The mutation rate of targets that could be targeted for treatment in NSCLCs patents was lower than 10%, which made it difficult for most patients to benefit from targeted therapy[4,5].

As the world's first randomized, double-blind, placebo-controlled head-to-head Phase III clinical study of PD-1 monoclonal antibodies in combination with chemotherapy that has achieved positive results, the regimen of "benmelstobart in combination with chemotherapy followed by sequential combination with anlotinib" may change the existing treatment model and provide an innovative first-line treatment model for patients with advanced sq-NSCLC, who currently have limited clinical treatment options.

Going forward, the Group will leverage its innovation and commercialization capabilities to expedite the entry of innovative products into the global market for the benefit of more patients, with a view to building a healthier world with science.

References:

[1] Yuankai Shi, et al. Phase 3 study of benmelstobart in combination with chemotherapy followed by sequential combination with anlotinib for the first-line treatment of locally advanced or metastatic squamous non-small cell lung cancer (sq-NSCLC), 2025 ASCO (#8514).

[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: a cancer journal for clinicians, 2024, 74(3): 229-263.

[3] Hirsh V. New developments in the treatment of advanced squamous cell lung cancer: focus on afatinib. Onco Targets Ther. 2017 May 11;10:2513-2526.

[4] Yuan H, Lu S. Research status on targeted therapy for squamous cell lung cancer. Zhongguo Fei Ai Za Zhi. 2013 Oct 20;16(10):559-63.

[5] Gao M, Zhou Q. Progress in Treatment of Advanced Squamous Cell Lung Cancer. Zhongguo Fei Ai Za Zhi. 2020 Oct 20;23(10):866-874.

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

Hong Kong, 23 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.