SINO BIOPHARMACEUTICAL LIMITED
中國生物製藥有限公司

(Incorporated in the Cayman Islands with limited liability)
Website: www.sbpgroup.com
(Stock code: 1177)

VOLUNTARY ANNOUNCEMENT
BENMELSTOBART IN COMBINATION WITH CHEMOTHERAPY FOLLOWED BY SEQUENTIAL COMBINATION WITH ANLOTINIB APPROVED AS FIRST-LINE TREATMENT FOR SQUAMOUS NON-SMALL CELL LUNG CANCER

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company,**" together with its subsidiaries, the "**Group**") announces that Benmelstobart Injection (trade name: 安得衛®), a Category 1 innovative drug independently developed by the Group's subsidiary, Chia Tai Tianqing Pharmaceutical Group Co., Ltd. ("**CTTQ**"), in combination with chemotherapy and sequentially followed by Anlotinib Hydrochloride Capsules (trade name: 福可維®), has been granted marketing approval by the China's National Medical Products Administration (NMPA) for the first-line treatment of locally advanced or metastatic squamous non-small cell lung cancer (sq-NSCLC). This marks the 12th approved indication for anlotinib and the 6th approved indication for benmelstobart.

This approval is based on the positive results from a randomized, double-blind, parallel-controlled, multicenter Phase III clinical trial (ETER700). The study was designed to evaluate the efficacy and safety of benmelstobart in combination with paclitaxel and carboplatin, sequentially followed by anlotinib in combination with benmelstobart (study group), versus tislelizumab in combination with paclitaxel and carboplatin (control group), as first-line treatment for sq-NSCLC. The results showed that, compared with the current standard of care, the anlotinib combination regimen demonstrated significant and clinically meaningful improvements across multiple endpoints.

I. PFS and OS Benefit

The median progression-free survival (PFS) was 11.20 months in the study group versus 8.28 months in the control group, hazard ratio (HR) = 0.68 (95% CI: 0.53–0.88, P = 0.0026), representing a 32% reduction in the risk of disease progression or death. The study met its primary endpoint. The median overall survival (OS) has not yet been reached in the study group versus 26.45 months in the control group, HR = 0.75 (95% CI: 0.59–0.96, P = 0.0199), demonstrating a clear OS benefit.

II. Improved ORR and DoR

In addition to a significant improvement in PFS, the anlotinib combination regimen also demonstrated superior results in terms of the depth and duration of tumor response. The objective response rate (ORR) was 76.33% in the study group versus 71.78% in the control group; the median duration of response (DoR) was 13.14 months in the study group versus 11.07 months in the control group. These results indicate that the anlotinib combination regimen enables more patients to achieve tumor shrinkage and maintain a longer duration of response, which holds positive clinical implications for improving patients' long-term survival.

III. Broad Subgroup Benefits with Favorable Clinical Applicability

Subgroup analysis demonstrated that the PFS benefit was consistently observed across nearly all clinical subgroups, including those defined by age, ECOG performance status, and PD-L1 expression level. In particular, PFS improvement was more pronounced in patients with an ECOG PS of 0, and in those with a PD-L1 TPS of 1–49%. The finding that the benefit extended across the full spectrum of PD-L1 expression levels underscores the favorable generalizability of the anlotinib combination regimen, supporting its broad use as a first-line treatment option for a diverse patient population with advanced sq-NSCLC in real-world clinical practice.

IV. Manageable Safety Profile and Favorable Tolerability

The safety profile of the anlotinib combination regimen was consistent with expectations, with no new safety signals identified and an overall manageable safety profile. The rates of treatment discontinuation due to adverse events was slightly lower in the study group compared with the control group (8.8% vs. 9.8%), suggesting favorable tolerability of the anlotinib combination regimen, which may support better patient adherence to therapy.

Sq-NSCLC is one of the major histological subtypes of lung cancer. Due to its unique biological characteristics, the development of targeted therapies for this subtype has progressed relatively slow. In recent years, immunotherapy, represented by PD-1/PD-L1 inhibitors, combined with chemotherapy has become the standard first-line treatment for advanced sq-NSCLC, significantly improving survival outcomes in the overall patient population. However, challenges remain in clinical practice, including some patients who do not derive sustained benefit or who develop acquired resistance to therapy.

Studies have shown that anti-angiogenic agents can produce synergistic effects with immunotherapy by promoting tumor vascular normalization and remodeling the tumor microenvironment[1]. Based on this, the ETER700 study departed from conventional study designs by adopting a sequential regimen in which the multi-targeting tyrosine kinase inhibitor anlotinib was added following induction therapy with chemotherapy plus an immune checkpoint inhibitor. This regimen was intended to validate a novel maintenance treatment strategy leveraging the synergistic effects of dual inhibition of immuno-oncology and angiogenic pathways, with the goal of providing robust evidence to support enhanced long-term efficacy in first-line therapy.

The combination of anlotinib and benmelstobart represents the first-in-class regimen to demonstrate superior efficacy over the standard immunochemotherapy backbone in a head-to-head Phase III study for the first-line treatment of sq-NSCLC. This regimen not only offers a novel option to address existing unmet clinical needs, but also reinforces the compelling rationale for combining antiangiogenic and immune-checkpoint blockade. As such, it has the potential to deliver more durable survival benefits for a substantial proportion of patients with advanced sq-NSCLC.

Source:

[1] Yi M, Jiao D, Qin S, Chu Q, Wu K, Li A. Synergistic effect of immune checkpoint blockade and anti-angiogenesis in cancer treatment. Mol Cancer. 2019;18(1):60. doi:10.1186/s12943-019-0974-6

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

Hong Kong, 7 August 2026

As at the date of this announcement, the Board of the Company comprises five executive directors, namely Ms. Tse, Theresa Y Y, Mr. Tse Ping, Ms. Cheng Cheung Ling, Mr. Tse, Eric S Y and Mr. Tse Hsin and six independent non-executive directors, namely Mr. Lu Zhengfei, Ms. Lu Hong, Mr. Zhang Lu Fu, Dr. Li Kwok Tung Donald, Dr. Chen Lieping and Dr. Lu Bai.