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

(Incorporated in the Cayman Islands with limited liability)
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(Stock code: 1177)

VOLUNTARY ANNOUNCEMENT
DATA FROM PHASE III STUDY OF BENMELSTOBART IN COMBINATION WITH ANLOTINIB AS FIRST-LINE TREATMENT FOR PD-L1 POSITIVE NON-SMALL CELL LUNG CANCER 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 at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, the Group has presented the latest results of the phase III clinical study for benmelstobart injection in combination with anlotinib hydrochloride capsules as first-line treatment for PD-L1 positive advanced non-small cell lung cancer (NSCLC) in comparison with pembrolizumab injection: the study has achieved the primary study endpoint of progression-free survival (PFS), in which, the median PFS was prolonged by more than 6 months in the population with TPS ≥50%, with a 40% reduction in the risk of disease progression/death as compared with the arm of pembrolizumab.

The CAMPASS study was a randomized and controlled phase III clinical study that enrolled 531 subjects with locally advanced (stage IIIB/C) or recurrent/metastatic NSCLC with PD-L1 positive expression (TPS ≥1%). Subjects were randomised in a ratio of 2:1 to receive treatments adopting benmelstobart in combination with anlotinib or pembrolizumab in combination with placebo, with the primary endpoint being PFS as assessed by the Independent Review Committee (IRC) according to RECIST 1.1.

The results in this presentation were the final analysis data for the primary endpoint of PFS, with median follow-up times of 11.4 months and 10.6 months in the arm of benmelstobart in combination with anlotinib and the arm of pembrolizumab, respectively, which represented a higher level of maturity of the data. In the overall population, the arm of benmelstobart in combination with anlotinib achieved a median PFS of 11.0 months, representing a 3.9-month improvement as compared the arm of pembrolizumab (7.1 months), and there was a 30% reduction in the risk of disease progression/death

(HR=0.70). The confirmed objective response rate (ORR) and disease control rate (DCR) in respect of tumour for the arm of benmelstobart in combination with anlotinib were 57.3% and 85.9%, respectively, both of which were significantly higher than those of the arm of pembrolizumab, which were 39.5% and 79.1%[1].

The analysis in the subgroups showed that almost all subgroups benefited from the treatment regimen with benmelstobart in combination with anlotinib. Notably, in the population with TPS ≥50%, the arm of benmelstobart in combination with anlotinib showed a 6.1-month prolongation of median PFS and a 40% reduction in the risk of disease progression/death as compared with the arm of pembrolizumab (HR=0.60)[1]. Currently, clinical practices tend to adopt regimens free of chemotherapy for patients with TPS ≥50% to a larger extent, thus further stressing the significant clinical value of the study.

In terms of safety, the common treatment-related adverse events in the arm of benmelstobart in combination with anlotinib were all common adverse events to multi-targeted anti-angiogenic tyrosine kinase inhibitors (TKIs) or immunotherapy, and no new safety signals were observed. Notably, in spite of the significantly longer median duration of treatment due to efficacy advantages in the arm of benmelstobart in combination with anlotinib, there was no significant impact on its tolerability, with a slightly lower incidence of treatment-related adverse events leading to permanent discontinuation of treatment with any drug (7.1%) and treatment-related adverse events leading to death (1.4%) than those found in the arm of pembrolizumab (8.0% and 2.3%, respectively) [1].

The CAMPASS study is the world's first phase III clinical study of anti-PD-L1 monoclonal antibody in combination with multi-targeted anti-angiogenic TKI as the first-line treatment for PD-L1 positive advanced NSCLC, which reached the primary endpoint of PFS, especially for the population with TPS ≥ 50%, where there was an improvement of median PFS by more than 6 months, which was of significant clinical value, and it is expected to offer better first-line treatment options for patients suffering PD-L1 positive advanced NSCLC in China.

Source:

[1] Baohui Han, Kai Li, Runxiang Yang, Yongzhong Luo, et al. CAMPASS: Benmelstobart in combination with anlotinib vs pembrolizumab in the first-line treatment of advanced non-small cell lung cancer (aNSCLC) – A randomized, single-blind, multicenter phase 3 study. 2025 ASCO (#LBA8502).

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

Hong Kong, 3 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.