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
POSITIVE RESULTS FROM PHASE III STUDY OF BENMELSTOBART INJECTION IN COMBINATION WITH CHEMOTHERAPY FOLLOWED BY SEQUENTIAL COMBINATION WITH ANLOTINIB HYDROCHLORIDE CAPSULES VERSUS TISLELIZUMAB INJECTION IN COMBINATION WITH CHEMOTHERAPY FOR FIRST-LINE TREATMENT OF ADVANCED 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 the Phase III study (TQB2450-III-12) of the Group's self-developed Category 1 innovative drugs 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) has completed its protocol-prescribed interim analysis with the Independent Data Monitoring Committee (IDMC) determining that the primary study endpoint progression-free survival (PFS) has met the protocol's predefined superiority threshold. The Group has communicated with the Centre for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of the PRC regarding marketing application for the indication and has obtained written consent from the CDE to submit the marketing application for the new first-line indication of Benmelstobart Injection and Anlotinib Hydrochloride Capsules. The Group will submit the marketing application in the near future.

Benmelstobart in combination with chemotherapy followed by sequential combination with Anlotinib for the first-line treatment of advanced sq-NSCLC will be the 13th indication of Anlotinib and the 6th indication of Benmelstobart for which the Group has submitted marketing application, which will bring new hope of clinical treatment to patients with sq-NSCLC.

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 accounting for 80-85% of all lung cancers.[1] sq-NSCLC was one of the major subtypes of non-small cell lung cancer, accounting for approximately 30% of all non-small cell lung cancers.[2] Currently, the research and treatment progress of sq-NSCLC lags significantly behind that of other non-small cell lung cancer subtypes. Moreover, the mutation rate of targets that could be targeted for treatment in that population was lower than 10%, which made it difficult for most patients to benefit from targeted therapy.[3, 4] Although immunotherapy in combination with chemotherapy has become the standard treatment for sq-NSCLC, its clinical efficacy is still limited, and there is an urgent need for new treatment options to further improve the prognosis of such patients.

TQB2450-III-12 (NCT05718167) is a multicenter, randomized, double-blind, parallel-controlled Phase III clinical study intended to evaluate the efficacy and safety of Benmelstobart in combination with chemotherapy followed by sequential combination with Anlotinib versus Tislelizumab in combination with chemotherapy for the first-line treatment of advanced sq-NSCLC. The interim analysis of the study demonstrated that, compared with Tislelizumab in combination with chemotherapy, Benmelstobart in combination with chemotherapy followed by sequential combination with Anlotinib significantly prolonged patients' PFS and significantly reduced their risk of disease progression. Its safety data were consistent with known risks and no new safety signals were identified. The study was the world's first Phase III clinical study comparing against immunotherapy (PD-1) in combination with chemotherapy for the first-line treatment of sq-NSCLC to achieve positive results. The Group intends to present the detailed data from the study at an authoritative and international academic conference in the near future.

Currently, Benmelstobart in combination with Anlotinib has been approved by the NMPA for use in first-line extensive-stage small cell lung cancer and second- and third-line endometrial cancer, with a marketing application submitted for a new indication in first-line renal cell carcinoma. A number of Phase III studies in the field of non-small cell lung cancer are also underway. The Group will expedite the clinical development of the combination therapy, using "immunotherapy in combination with anti-angiogenic therapy" to bring hope to more cancer patients.

Status of indications of Anlotinib

No.	Drug	Indication	Status
1	Anlotinib	Locally advanced or metastatic non-small cell lung cancer that has progressed or relapsed after at least two prior systemic chemotherapy regimens	Approval obtained for marketing
2	Anlotinib	Alveolar soft part sarcoma, clear cell sarcoma, and other advanced soft tissue sarcomas that have progressed or relapsed after at least one prior anthracycline-containing chemotherapy regimen	Approval obtained for marketing
3	Anlotinib	Small cell lung cancer that has progressed or relapsed after at least two prior chemotherapy regimens	Approval obtained for marketing

No.	Drug	Indication	Status
4	Anlotinib	Unresectable locally advanced or metastatic medullary thyroid cancer with clinical symptoms or unequivocal progression	Approval obtained for marketing
5	Anlotinib	Progressive, locally advanced or metastatic radioiodine-refractory differentiated thyroid cancer	Approval obtained for marketing
6	Anlotinib in combination with Benmelstobart, carboplatin and etoposide	First-line extensive-stage small cell lung cancer	Approval obtained for marketing
7	Anlotinib in combination with Benmelstobart	Recurrent or metastatic endometrial cancer that has failed prior systemic anti-tumour therapy and is not eligible for curative surgery or curative radiotherapy, that is non-microsatellite instability-high (non-MSI-H) or non-deficient mismatch repair (non-dMMR)	Approval obtained for marketing
8	Anlotinib in combination with Benmelstobart	First-line advanced unresectable or metastatic renal cell carcinoma	Application for marketing submitted
9	Anlotinib in combination with chemotherapy	First-line advanced unresectable or metastatic soft tissue sarcoma	Application for marketing submitted
10	Anlotinib in combination with Penpulimab	First-line advanced hepatocellular carcinoma	Application for marketing submitted
11	Benmelstobart with or without Anlotinib	As consolidation therapy in patients with locally advanced/unresectable (Stage III) non-small cell lung cancer who have not progressed after concurrent/ sequential chemoradiotherapy	Submission of application for marketing permitted
12	Anlotinib in combination with Benmelstobart	Advanced alveolar soft part sarcoma	Submission of application for marketing permitted
13	Benmelstobart in combination with chemotherapy followed by sequential combination with Anlotinib	First-line advanced squamous non-small cell lung cancer	Submission of application for marketing permitted

Sources:

[1] 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.

[2] 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.

[3] 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.

[4] 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, 27 December 2024

As at 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.