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 WITH OR WITHOUT ANLOTINIB HYDROCHLORIDE CAPSULES AS CONSOLIDATION THERAPY AFTER CHEMORADIOTHERAPY FOR 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 clinical study (TQB2450-III-05) of the Group's self-developed Category 1 innovative drugs Benmelstobart Injection with or without Anlotinib Hydrochloride Capsules as consolidation therapy in patients with locally advanced/unresectable (Stage III) non-small cell lung cancer (NSCLC) who have not progressed after concurrent/sequential chemoradiotherapy 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 of the PRC regarding the marketing application for the indication and has obtained written consent from the CDE to submit the marketing application. The Group will submit the marketing application in the near future.

Consolidation therapy for locally advanced/unresectable (Stage III) NSCLC that has not progressed after concurrent/sequential chemoradiotherapy will be the 11th indication of Anlotinib and the 4th indication of Benmelstobart for which the Group has submitted marketing application, which will bring new hope of treatment to patients with NSCLC.

According to the data of "Global cancer statistics 2022", lung cancer was the malignant tumour with the highest number of new cases and deaths in the world.[1] In China, the number of new lung cancer cases reached 1.061 million, accounting for 42.7% of the world's total new lung cancer cases.[2] NSCLC was the most common type of lung cancer, accounting for 85% of all lung cancer cases.[3] Currently, the treatment options for locally advanced/unresectable Stage III NSCLC are limited (mainly concurrent/sequential chemoradiotherapy), while consolidative immunotherapy is available for patients without disease progression.

TQB2450-III-05 (NCT04325763) is a randomized, double-blind, double-simulated, placebo-parallel controlled, multicenter Phase III clinical study intended to evaluate the efficacy and safety of Benmelstobart with or without Anlotinib as consolidation therapy in patients with locally advanced/unresectable (Stage III) NSCLC who have not progressed after concurrent/sequential chemoradiotherapy. The interim analysis of the study demonstrated that Benmelstobart with or without Anlotinib significantly prolonged patients' PFS and significantly reduced their risk of disease progression or death compared with the control group. Its safety data were consistent with known risks and no new safety signals were identified. The Group intends to present the detailed data from the study at an authoritative and international academic conference in the near future.

With the Group's continuous investment in innovative research and development, new breakthroughs have been made in innovative products, and its innovation pipeline has ushered in a harvest period.

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
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

No.	Drug	Indication	Status
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

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. CA Cancer J Clin. 2024 May-Jun;74(3):229-263.

[2] 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.

[3] Zhao J, Xiong J. Advances on driver oncogenes of non-small cell lung cancer. Zhongguo Fei Ai Za Zhi. 2015 Jan;18(1):42-7.

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

Hong Kong, 18 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.