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
INDICATION OF ANLOTINIB HYDROCHLORIDE CAPSULES IN COMBINATION WITH CHEMOTHERAPY FOR FIRST-LINE TREATMENT OF SOFT TISSUE SARCOMA APPROVED FOR MARKETING

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that the regimen of the Group's self-developed anlotinib hydrochloride capsules in combination with chemotherapy has been approved by the National Medical Products Administration of the PRC for the first-line treatment of patients with locally advanced or metastatic soft tissue sarcoma. This is the ninth indication for anlotinib approved in the PRC. The approval marks the first combination therapy with chemotherapy officially approved for the first-line treatment of advanced or metastatic soft tissue sarcoma in the world. Previously, anlotinib monotherapy had been recommended by the guidelines of the Chinese Society of Clinical Oncology (CSCO) for the second-line treatment of advanced or metastatic soft tissue sarcoma, and was the only targeted therapy drug recommended by them as a Grade I recommendation.

At the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, interim analysis data from a Phase III clinical study (NCT05121350) of anlotinib in combination with chemotherapy for the first-line treatment of unresectable advanced or metastatic soft tissue sarcoma were presented: as at 15 February 2024, 272 patients had been randomly enrolled for the study (135 in the treatment group and 137 in the control group), with a median follow-up duration of 7.16 months. The treatment group demonstrated a significant improvement in median progression-free survival (PFS) compared to the control group (8.6 months vs. 3.0 months; HR=0.30, 95% CI 0.21-0.44, P<0.001), with an objective response rate (ORR) nearly six times as high (17.8% vs 2.9%) and a significantly improved disease control rate (DCR) (79.3% vs 54.7%). The overall survival (OS) data was not mature (HR=0.78, 95% CI 0.49-1.25), but a trend toward benefit was emerging. Pre-specified subgroup analyses (including leiomyosarcoma, synovial sarcoma and other pathological subtypes) all showed consistent trends toward benefit in the treatment group. These results indicated the clear antitumour efficacy as demonstrated by anlotinib in combination with chemotherapy for the first-line therapy of soft tissue sarcoma[1].

Soft tissue sarcomas are a group of malignant tumours originating from non-epithelial extraosseous tissues, accounting for approximately 0.8%-1.1% of all malignant tumours. In China, the annual incidence is approximately 2.91 per 100,000 population, and is on a steady upward trend. Soft tissue sarcomas exhibit high heterogeneity, encompassing 19 tissue types and over 50 pathological subtypes. Over the past few decades, anthracycline-based chemotherapy regimens have remained the cornerstone of first-line treatment for soft tissue sarcomas[2-4]. However, despite ongoing global efforts to explore new therapies, significant breakthroughs in treatment efficacy have yet to be achieved, and clinical needs remain far from being met.

In addition to soft tissue sarcoma, anlotinib has been approved for multiple cancer indications, including non-small cell lung cancer, small cell lung cancer, medullary thyroid cancer, differentiated thyroid cancer, endometrial cancer and renal cell carcinoma. Moreover, the marketing application for anlotinib in combination with benmelstobart for the treatment of alveolar soft part sarcoma will be submitted. The Group will continue to actively advance the development of innovative products and unleash the full potential of its products, with a view to providing better treatment options for more patients.

Sources:

[1] Yuhong Zhou, Xiaohui Niu, Yu Jiang, et al. Anlotinib in combination with epirubicin followed by maintenance anlotinib versus placebo plus epirubicin as first-line treatment for advanced soft tissue sarcoma (STS): A randomized, double-blind, parallel-controlled, phase III study. 2025 ASCO (#11501).

[2] Siegel RL, Miller KD, Jemal A. Cancer statistics, 2020. CA Cancer J Clin. 2020 Jan;70(1):7-30. doi: 10.3322/caac.21590. Epub 2020 Jan 8.

[3] Surveillance, Epidemiology, and End Results (SEER) Program (www.seer.cancer.gov). Based on the Nov. 2020 data.

[4] Yang Z, Zheng R, Zhang S, Zeng H, Li H, Chen W. Incidence, distribution of histological subtypes and primary sites of soft tissue sarcoma in China. Cancer Biol Med. 2019 Aug;16(3):565-574.

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

Hong Kong, 30 June 2025

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.