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
PERMISSION OBTAINED TO SUBMIT MARKETING APPLICATION FOR THE INDICATION OF BENMELSTOBART INJECTION IN COMBINATION WITH ANLOTINIB HYDROCHLORIDE CAPSULES FOR TREATMENT OF ADVANCED ALVEOLAR SOFT PART SARCOMA

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that the Group has communicated with the Centre for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of the PRC regarding the marketing application for the new indication of the Group's self-developed Category 1 innovative drug Benmelstobart Injection in combination with Anlotinib Hydrochloride Capsules for the treatment of advanced alveolar soft part sarcoma (ASPS) and has obtained written consent from the CDE to submit the marketing application. The Group will submit the marketing application in the near future.

ASPS will be the 12th indication of Anlotinib and the 5th indication of Benmelstobart for which the Group has submitted marketing application, which will bring new hope of treatment to patients with ASPS.

ASPS was an extremely rare and highly malignant soft tissue sarcoma with a global incidence of less than 1 per 1,000,000 persons and accounting for 0.5%-1% of all soft tissue sarcomas, and it was classified as an ultra-rare sarcoma by the Connective Tissue Oncology Society[1, 2]. ASPS occurred most frequently in adolescents, with a slow progression but a poor prognosis. It had a high tendency to metastasis and spread in early stages, as well as a high insensitivity to chemotherapy. Current treatment options for ASPS are very limited, with a 5-year overall survival rate of only 20%-46%, resulting in an urgent need for more effective treatment options[3, 4].

In June 2019, Anlotinib was approved by the NMPA as a monotherapy for the treatment of patients with ASPS, clear cell sarcoma and other advanced soft tissue sarcomas who have progressed or relapsed after at least one prior anthracycline-containing chemotherapy regimen. As a result, Anlotinib became the first targeted drug approved in the field of soft tissue sarcomas in China. In November 2024, Benmelstobart in combination with Anlotinib for the treatment of patients with ASPS was included in the Breakthrough Therapeutic Designation process by the CDE.

Benmelstobart in combination with Anlotinib is expected to become the first combination therapy of PD-L1 inhibitor and small molecule anti-angiogenic drug approved for the treatment of ASPS in China. The Group will continue to promote the development of Benmelstobart and Anlotinib to bring new treatment options to more 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
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

No.	Drug	Indication	Status
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

Sources:

[1] Liu Yueping, Li Yexiong, Jin Jing, et al. Analysis of the clinical characteristics of and therapeutic efficacy in alveolar soft part sarcoma [J]. Chinese Journal of Clinical Oncology, 2012, 39(8): 461-464.

[2] Stacchiotti S, Frezza AM, Blay J-Y, et al. Ultra-rare sarcomas: a consensus paper from the Connective Tissue Oncology Society community of experts on the incidence threshold and the list of entities. Cancer 2021;127:2934-2942.

[3] Chen AP, Sharon E, O'Sullivan-Coyne G, et al. Atezolizumab for Advanced Alveolar Soft Part Sarcoma. N Engl J Med. 2023;389(10):911-921.

[4] CSCO Guideline for the Diagnosis and Treatment of Bone and Soft Tissue Tumours (2023 Edition)

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

Hong Kong, 19 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.