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 ON PHASE III STUDY OF ANLOTINIB HYDROCHLORIDE CAPSULE IN COMBINATION WITH CHEMOTHERAPY FOR FIRST-LINE TREATMENT OF ADVANCED SOFT TISSUE SARCOMA

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(ALTN-III-04)of Anlotinib Hydrochloride Capsule, a Category 1 innovative drug self-developed by the Group, in combination with chemotherapy for the first-line treatment of advanced unresectable or metastatic soft tissue sarcoma has completed its protocol-prescribed interim analysis with the Independent Data Monitoring Committee (IDMC), determining that the primary study endpoint progression-free survival (PFS) met the protocol's predefined superiority threshold, and that the secondary endpoint overall survival (OS) was trending favourably. The Group has communicated with the Centre for Drug Evaluation (CDE) of the National Medical Products Administration of the PRC in relation to the marketing application for such indication, and has obtained consent of the CDE to submit a marketing application for this additional first-line indication of Anlotinib Hydrochloride Capsule in combination with chemotherapy. The Group will submit the marketing application in the near future.

Soft tissue sarcoma (STS) is a group of malignant tumours arising from non-epithelial extraosseous tissues, and accounts for 0.72%-1.05%[1,2,3] of all human malignancies. In China, the incidence of STS was about 2.91/100,000 per year with a rising trend[4,5,6]. STS is a highly heterogeneous tumour characterized by local aggressive, infiltrative or destructive growth, local recurrence and distant metastasis, with 19 tissue types and more than 50 different subtypes. For unresectable locally advanced or metastatic STS, palliative chemotherapy with anthracycline-based drugs is recommended as the first-line treatment, although the sensitivity of different sarcoma subtypes to chemotherapeutic agents varies. So far no combination solution of chemotherapy has been approved in China for the first-line treatment of advanced STS.

As the world's first pivotal phase III study of a combination of an anti-angiogenic drug and chemotherapy for the targeted treatment of advanced STS, ALTN-III-04 (NCT05121350) is a multicenter, randomized, double-blind, parallel-controlled phase III clinical study to evaluate the efficacy and safety of Anlotinib Hydrochloride Capsule in combination with chemotherapy compared with chemotherapy for the first-line treatment of advanced unresectable or metastatic STS. According to the results of the interim analysis of the study, compared with chemotherapy, Anlotinib Hydrochloride Capsule in combination with chemotherapy for the first-line treatment of advanced unresectable or metastatic STS significantly reduced the patients' risk of disease progression or death, while demonstrating a favourable trend in secondary endpoints such as objective response rate (ORR) and OS. Its safety data were consistent with known risks and no new safety signals were identified. Detailed study data will be presented at a forthcoming international academic congress.

First-line treatment of advanced soft tissue sarcoma is the ninth indication which Anlotinib Hydrochloride Capsule will apply for marketing, bringing new treatment hope to the patients with advanced soft tissue sarcoma, especially those who are not sensitive to chemotherapy. Meanwhile, as an anti-angiogenic small molecule tyrosine kinase inhibitor (TKI), Anlotinib Hydrochloride Capsule, in combination with chemotherapy, will reshape the landscape of the first-line treatment of soft tissue sarcoma. With the Group's continued investment in innovative research and development, breakthroughs in innovative products have been achieved and the innovation pipelines have entered the harvesting period.

Sources:

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[4] YANG Z, ZHENG R, ZHANG S, et al. Incidence, distribution of histological subtypes and primary sites of soft tissue sarcoma in China. Cancer Biol Med, 2019,16(3):565-574.

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

Hong Kong, 16 July 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.