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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

**ACCEPTANCE OF NEW INDICATION APPLICATION FOR MARKETING OF
ANLOTINIB HYDROCHLORIDE CAPSULES 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 Capsules, a Category 1 innovative drug developed by the Group, in combination with chemotherapy for the first-line treatment of advanced unresectable or metastatic soft tissue sarcoma has completed its interim analysis. With the evaluation by the Independent Data Monitoring Committee (IDMC), the study has reached its predetermined primary efficacy endpoint. Recently, the Group has submitted a new drug application for marketing to the Centre for Drug Evaluation (CDE) of the National Medical Products Administration of the PRC, which has been accepted.

Soft tissue sarcoma (STS) is a type of malignant tumour arising from non-epithelial extraosseous tissues. In China, the incidence was about 2.91/100,000 per year with a rising trend year-on-year^{1,2,3}. STS is a type of highly heterogeneous tumour characterized by local aggressiveness, infiltrative or destructive growth, as well as likelihood of local recurrence and distant metastasis, with 19 tissue types and more than 50 different subtypes. For unresectable locally advanced or metastatic STS, the current first-line treatment still mainly relies on palliative chemotherapy solution based on anthracycline-based drugs, although the sensitivity of various sarcoma subtypes to chemotherapeutic agents varies. Currently, no combination therapy with drugs in combination with chemotherapy has been officially approved for the first-line treatment of advanced STS in the world.

As an anti-angiogenic small molecule tyrosine kinase inhibitor (TKI), Anlotinib Hydrochloride Capsules, in combination with chemotherapy, demonstrated excellent efficacy and satisfactory safety at the early exploration stage for the first-line treatment of STS⁴. ALTN-III-04(NCT05121350) is the first pivotal phase III study adopting anti-angiogenic drug in combination with chemotherapy in the world, with an aim to proving the effect of the targeted treatment of such combination therapy on advanced STS. The detailed results of such study will be published in top academic journals or key international academic conferences.

First-line treatment of advanced STS is the ninth indication for which Anlotinib Hydrochloride Capsules applied for marketing, and Anlotinib in combination with chemotherapy is expected to bring a glimmer of hope for new treatment to numerous patients with advanced STS, especially those who are less sensitive to traditional chemotherapy. The Group continues its investment in innovative research and development, and has entered the intensive harvesting period for its innovation results.

Sources:

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- [4] Wang Z, Zhuang R, Guo X, et al. Anlotinib plus epirubicin followed by anlotinib maintenance as first-line treatment for advanced soft-tissue sarcoma: an open-label, single-arm, phase II trial[J]. *Clinical Cancer Research*, 2022, 28(24): 5290-5296.

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

Hong Kong, 21 October 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.