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 PENPULIMAB FOR FIRST-LINE TREATMENT OF ADVANCED HEPATOCELLULAR CARCINOMA

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-AK105-III-02) of Anlotinib Hydrochloride Capsule, a Category 1 innovative drug self-developed by the Group, in combination with Penpulimab for the first-line treatment of advanced hepatocellular carcinoma (HCC) has completed its protocol-prescribed interim analysis with the Independent Data Monitoring Committee (IDMC), determining that both the primary study endpoint progression-free survival (PFS) and overall survival (OS) 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 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 Penpulimab. The Group will submit the marketing application in the near future.

The study was the second successful phase III clinical study around the globe for an oral multi-targeted small molecule tyrosine kinase inhibitor (TKI) in combination with an immunotherapeutic drug for first-line advanced HCC. ALTN-AK105-III-02(NCT04344158)is a multicenter, randomized, open, parallel-controlled phase III clinical study intended to evaluate the efficacy and safety of Anlotinib Hydrochloride Capsule in combination with Penpulimab compared with Sorafenib for the first-line treatment of advanced HCC. The results of interim analysis demonstrated that, compared with Sorafenib, first-line treatment of advanced HCC with Anlotinib Hydrochloride Capsule in combination with Penpulimab significantly reduced patients' risk of disease progression or death, and significantly prolonged patients' PFS and OS. The safety data were consistent with known risks, and no new safety signals were identified.

The Group will present the detailed data from the study in the European Society for Medical Oncology (ESMO) Congress 2024 by means of Late Breaking Abstract.

Abstract title: LBA40: Primary results from the phase III ALTN-AK105-III-02 study: Anlotinib plus penpulimab versus sorafenib as first-line (1L) therapy for advanced hepatocellular carcinoma (aHCC)

Global cancer statistics in 2022 showed that primary liver cancer ranked the sixth in incidence rate and the third in mortality rate of malignant tumours in the world, of which, the number of new cases of primary liver cancer in China reached 367,700, accounting for approximately 42.5% of the global new cases[1][2]. Among the primary liver cancers, 75%-85% are HCC. Due to the insidious onset of HCC and the lack of obvious early symptoms, most of the patients are in the advanced stage when diagnosed, losing the opportunity of radical surgical treatment[3]. In recent years, the rapid development of immunotherapy has rewritten the therapeutic landscape of advanced HCC, especially targeted immunotherapy has become an important first-line treatment mode for advanced HCC.

First-line treatment of advanced HCC is the 10th indication which Anlotinib Hydrochloride Capsules will apply for marketing and the 5th indication which Penpulimab Injection will apply for marketing soon, which will bring new hope of treatment to the majority of patients with advanced HCC. 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.

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[J]. CA: a cancer journal for clinicians, 2024, 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] Guideline for Treatment of Primary Liver Cancer (原發性肝癌診療指南) (2024 Edition)

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

Hong Kong, 28 August 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.