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 CAPSULE IN COMBINATION WITH PENPULIMAB INJECTION 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 independently developed by the Group, in combination with Penpulimab injection for the first-line treatment of advanced hepatocellular carcinoma has completed its protocol-prescribed interim analysis with the Independent Data Monitoring Committee (IDMC) determining that both the primary study endpoints progression-free survival (PFS) and overall survival (OS) met the protocol's predefined superiority threshold. Given such a positive result, the Group has recently submitted a new indication application for marketing to the Centre for Drug Evaluation (CDE) of the National Medical Products Administration of the PRC, which has been accepted.

Primary liver cancer is the seventh most common malignant tumor globally, of which hepatocellular cancinoma (HCC) accounts for 80-85%[1]. There is a high incidence of liver cancer in the PRC, where, in 2020, there were 410,000 new cases, accounting for 45% of the global new cases, with death cases of 390,000, accounting for 47%[2] of the global death cases. In the PRC, approximately 70% of the HCC patients are at the middle to advanced stage when initially diagnosed[2]. However, the treatment options targeting advanced HCC are currently limited. With the promotion of immunotherapy, its combination with antivascular therapy gradually becomes a new option for the first-line systematic treatment.

ALTN-AK105-III-02 study (NCT04344158) is a multi-centre, randomised, open, parallel-controlled Phase III clinical study intended to evaluate the efficacy and safety of Anlotinib Hydrochloride Capsule in combination with Penpulimab injection compared to Sorafenib for first-line treatment of advanced HCC. A total of 649 patients with advanced liver cancers were included in the study, of which, 40.9% of the subjects were associated with macrovascular invasion, and the proportion of subjects with alpha-fetoprotein (AFP) ≥400 ng/mL reached 49.2%. The results of the study showed that the median PFS of the trial group was 6.9 months, whereas the median PFS of the control group was 2.8 months, representing a significant decrease in the risk of disease progression or death by 47%; the median OS of the trial group was 16.5 months, whereas the median OS of the control group was 13.2 months, representing a significant decrease in the risk of death by 31%; both the PFS and the OS have reached their predefined endpoints[3].

First-line treatment of advanced hepatocellular carcinoma is the tenth indication for which Anlotinib Hydrochloride Capsule applied for marketing, which is expected to provide the patients suffering from advanced hepatocellular carcinoma with a more secure and convenient solution for treatment. With the Group's continuous investment in the innovative research and development, plus the new breakthroughs in innovative products continuously obtained, its innovative pipelines are heading for their harvesting periods.

Sources:

[1] Siegel RL, Miller KD, Fuchs HE, Jemal A: Cancer Statistics, 2021. CA Cancer J Clin 2021, 71(1):7-33.

[2] Chinese Association of Liver Cancer of Chinese Medical Doctor Association. Chinese expert consensus on the whole-course management of hepatocellular carcinoma (2023 edition) [J]. Chinese Journal of Digestive Surgery, 2023, 22(7): 824-842. DOI: 10.3760/cma.j.cn115610-20230605-00261.

[3] Jian Z, et al. 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). 2024 ESMO, LBA 40.

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

Hong Kong, 21 November 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.