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
PHASE III STUDY RESULTS OF ANLOTINIB HYDROCHLORIDE CAPSULES IN COMBINATION WITH PENPULIMAB INJECTION FOR FIRST-LINE TREATMENT OF ADVANCED HEPATOCELLULAR CARCINOMA WAS PRESENTED AT ESMO 2024

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that the latest research results of the Phase III clinical study (APOLLO) of Anlotinib Hydrochloride Capsules, a Category 1 innovative drug self-developed by the Group, in combination with Penpulimab Injection for the first-line treatment of advanced hepatocellular cancinoma (HCC) was presented at the European Society For Medical Oncology Congress 2024 (ESMO 2024): The median progression-free survival (PFS) was 6.9 months, the medium overall survival (OS) was 16.5 months, and both PFS and OS met the predefined endpoints. This is the second Phase III study in the world in which a combination of an oral anti-angiogenic multi-targeted small-molecule tyrosine kinase inhibitor and an immunotherapy drug showed positive results in the first-line treatment of advanced HCC.

APOLLO (ALTN-AK105-III-02, NCT04344158) is a multi-centre, randomised, open, parallel-controlled Phase III clinical study intended to evaluate the efficacy and safety of Anlotinib in combination with Penpulimab compared to Sorafenib for first-line treatment of advanced HCC. A total of 649 patients with advanced HCC 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 in terms of efficacy, the median PFS of Anlotinib in combination with Penpulimab vs. Sorafenib was 6.9 months vs. 2.8 months (HR 0.53, 95% CI 0.41-0.68, $p<0.0001$), and the median OS was 16.5 months vs. 13.2 months (HR 0.69, 95% CI 0.52-0.92, $p=0.0013$), with

both PFS and OS reaching the predefined endpoints. In terms of safety, the safety data for Anlotinib in combination with Penpulimab were consistent with the known risks, and no new safety signals were identified.

Primary liver cancer is one of the common malignant tumours in China. By statistic, primary liver cancer ranks the fourth in incidence rate and the second in mortality rate of malignant tumours in China[1,2]. HCC is the most common type of liver cancer, accounting for 75%-85% of primary liver cancers. 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.

The Group will soon submit a marketing application for the new indication of Anlotinib in combination with Penpulimab for the first-line treatment of advanced HCC to the Centre for Drug Evaluation (CDE) of the National Medical Products Administration of the PRC. At present, two new indications for Anlotinib, being second- and third-line treatment of endometrial cancer and first-line treatment of renal cell carcinoma, have already been submitted for marketing application. Meanwhile, the Group is also advancing the Phase III clinical trials of Anlotinib for first-line treatment of non-small cell lung cancer, first-line colorectal cancer, and maintenance therapy for non-small cell lung cancer after radiotherapy and chemotherapy. It is expected that the marketing applications will be filed in the next two years gradually, so as to further expand the indications of Anlotinib and benefit more cancer patients.

Sources:

[1] The Chinese Chapter of the International Hepato-Pancreato-Biliary Association, Group of Liver Surgery, Surgical Society of Chinese Medical Association, Expert Committee on Liver Cancer, Chinese Society of Clinical Oncology. Chinese multidisciplinary expert consensus on combined immunotherapy for hepatocellular carcinoma (2023 version)[J]. Chinese Journal of Hepatology, 2023, 31(1): 16-34.

[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] National Health Commission of the People's Republic of China, Diagnosis and Treatment Guideline for Primary Liver Cancer (2024 Version) (原發性肝癌診療指南 (2024年版)).

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

Hong Kong, 16 September 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.