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 BENMELSTOBART INJECTION FOR FIRST-LINE TREATMENT OF ADVANCED RENAL CELL 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 (ETER100) of Anlotinib Hydrochloride Capsules, a Category 1 innovative drug self-developed by the Group, in combination with Benmelstobart Injection for the first-line treatment of advanced renal cell cancinoma (RCC) was presented at the European Society For Medical Oncology Congress 2024 (ESMO 2024): The median progression-free survival (PFS) was 18.96 months, the objective remission rate (ORR) was 71.6%, and the overall survival (OS) showed a favourable trend.

ETER100 (NCT04523272) is a randomised, open, positive drug-parallel controlled, multi-centre Phase III clinical study intended to evaluate the efficacy and safety of Anlotinib in combination with Benmelstobart compared with Sunitinib for first-line treatment of advanced unresectable or metastatic RCC. Latest research data demonstrated that, the median PFS for the Anlotinib in combination with Benmelstobart group vs. Sunitinib group was 18.96 months vs. 9.76 months (HR 0.53, 95% CI 0.42-0.67, $p<0.0001$), with an ORR of 71.6% vs. 25.1%, and the median OS has not yet been reached.

Renal carcinoma is a common malignancy of the urinary system, and RCC accounts for 80%-90% of all cases of renal carcinoma[1]. Based on statistics, there were approximately 77,000 new cases of and 46,000 deaths due to renal carcinoma in China in 2022[2]. Distant metastasis occurred in 20%-30% of renal carcinoma patients at initial diagnosis[3-5]. For patients with primary non-metastatic RCC, recurrence or metastasis still occurred in about 20% of patients within 5 years even with treatment of curative nephrectomy[6-10]. Anlotinib in combination with Benmelstobart is expected to prolong the survival of patients with RCC and may become a new first-line standard of treatment for advanced RCC.

In August 2024, the new indication application for Anlotinib Hydrochloride Capsules in combination with Benmelstobart Injection for the first-line treatment of advanced unresectable or metastatic RCC has been accepted by the Centre for Drug Evaluation (CDE) of the National Medical Products Administration of the PRC. This is the eighth indication for which Anlotinib Hydrochloride Capsules has been filed for marketing, and the third indication for which Benmelstobart Injection has been filed for marketing.

Oncology is one of the four key therapeutic areas for the Group's strategic development. With the Group's continuous investment in innovative research and development, the results of innovations are continuously showing. In the future, the Group will continue to focus on unmet clinical needs and develop new innovations to bring benefits to more cancer patients.

Sources:

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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.