SINO BIOPHARMACEUTICAL LIMITED
中國生物製藥有限公司

(Incorporated in the Cayman Islands with limited liability)
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(Stock code: 1177)

VOLUNTARY ANNOUNCEMENT
POSITIVE RESULTS ON PHASE III STUDY OF BENMELSTOBART INJECTION IN COMBINATION WITH ANLOTINIB HYDROCHLORIDE CAPSULES FOR FIRST-LINE TREATMENT OF ADVANCED RENAL CELL CARCINOMA

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that the randomised, open, positive drug-parallel controlled, multi-centre Phase III clinical study for the first-line treatment of advanced unresectable or metastatic renal cell carcinoma (RCC) (the ETER100 study) of "Benmelstobart Injection (TQB2450)", a Category 1 innovative drug independently developed by the Group, in combination with the Category 1 innovative drug Anlotinib Hydrochloride Capsules has completed its protocol-prescribed interim analysis, with the Independent Data Monitoring Committee (IDMC) determining that the primary study endpoint progression-free survival (PFS, based on an independent imaging assessment) met the protocol's predefined superiority threshold, and that the secondary endpoint overall survival (OS) was trending favourably. 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 the consent of the CDE to submit a marketing application for this additional indication of Benmelstobart Injection in combination with Anlotinib Hydrochloride Capsules. The Group will submit the marketing application in the near future.

Renal carcinoma is the third most common malignancy of the urinary system globally, 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 about one-third of renal carcinoma patients at initial diagnosis, and in 20%-50% of localized patients after nephrectomy[3,4]. According to the risk classification of the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), the median overall survival (OS) of patients with low, medium and high risk metastatic RCC receiving anti-vascular targeted treatment were 35.3, 16.6 and 5.4 months, respectively[1,5]. In recent years, PD-(L)1 inhibitor combined with anti-vascular targeted drugs have achieved success in the first-line treatment of advanced RCC overseas, replacing anti-vascular targeted drugs monotherapy as the new standard first-line treatment for advanced RCC[6]. Compared to anti-vascular targeted drugs monotherapy, the combination of PD-(L)1 monoclonal antibody and anti-vascular targeted drugs can significantly prolong patients' PFS and improve the objective response rate (ORR), together with significant improvement of OS observed.

As the first pivotal phase III study of a dual domestic innovative drugs combination for the immunotherapy of advanced renal cancer, ETER100 study (NCT04523272) is a randomised, open, positive drug-parallel controlled, multi-centre phase III clinical study to evaluate the efficacy and safety of Benmelstobart Injection in combination with Anlotinib Hydrochloride Capsules compared to sunitinib malate capsule for the treatment of advanced unresectable or metastatic RCC in the first-line setting. According to the results of the interim analysis of the study, compared with sunitinib, Benmelstobart in combination with Anlotinib Hydrochloride Capsules for the first-line treatment of advanced RCC significantly reduced patients' risk of disease progression or death, while improving secondary endpoints such as ORR and OS. The safety data for Benmelstobart Injection were consistent with known risks and no new safety signals were identified. Detailed study data will be presented at a forthcoming international congress.

Benmelstobart Injection in combination with Anlotinib Hydrochloride Capsules will bring new treatment hope to the majority of advanced renal cancer patients and address the unmet clinical needs for the benefit of domestic patients. At the same time, it also signifies that Benmelstobart Injection has successfully laid out another important area after small cell lung cancer and endometrial cancer. First-line advanced RCC will be the third indication for Benmelstobart Injection and the eighth indication for Anlotinib Hydrochloride Capsules. In addition, Benmelstobart Injection in combination with Anlotinib Hydrochloride Capsules are currently undergoing a number of clinical phase III studies, including first-line non-small cell lung cancer, and maintenance therapy after non-small cell lung cancer radiotherapy and chemotherapy. The Group will continue to advance the development of Benmelstobart Injection and Anlotinib Hydrochloride Capsules to bring new treatment options to more patients. With the Group's continuous investment in innovative research and development, breakthroughs in innovative products have been achieved and the innovation pipelines have entered the harvesting period.

Sources:

[1] National Health Commission of the People's Republic of China, Diagnosis and Treatment Guideline for Renal Cell Carcinoma (2022 Version) (腎細胞癌診療指南(2022年版)), 2022.

[2] Xia C, Dong X, Li H, et al. Cancer statistics in China and United States, 2022: profiles, trends, and determinants. Chin Med J (Engl) 2022;135:584-90.

[3] Padala SA, Barsouk A, Thandra KC, et al. Epidemiology of Renal Cell Carcinoma. World J Oncol 2020;11:79-87.

[4] Janzen NK, Kim HL, Figlin RA, Belldegrun AS. Surveillance after radical or partial nephrectomy for localized renal cell carcinoma and management of recurrent disease. Urol Clin North Am 2003;30:843-52.

[5] Heng DY, Xie W, Regan MM, et al. Prognostic factors for overall survival in patients with metastatic renal cell carcinoma treated with vascular endothelial growth factor-targeted agents: results from a large, multicenter study. J Clin Oncol 2009;27:5794-9.

[6] Xu W, Atkins MB, McDermott DF. Checkpoint inhibitor immunotherapy in kidney cancer. Nat Rev Urol 2020;17:137-50.

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

Hong Kong, 23 May 2024

As at the date of this announcement, the Board of the Company comprises seven executive directors, namely Ms. Tse, Theresa Y Y, Mr. Tse Ping, Ms. Cheng Cheung Ling, Mr. Tse, Eric S Y, Mr. Tse Hsin, Mr. Tian Zhoushan and Ms. Li Mingqin, 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.