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**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](http://www.sinobiopharm.com)*

**(Stock code: 1177)**

**VOLUNTARY ANNOUNCEMENT**

**ACCEPTANCE OF NEW INDICATION APPLICATION FOR MARKETING OF  
BENMELSTOBART INJECTION IN COMBINATION WITH  
ANLOTINIB HYDROCHLORIDE CAPSULE FOR  
FIRST-LINE TREATMENT OF ADVANCED RENAL CELL CARINOMA**

The board of directors (the “**Board**”) of Sino Biopharmaceutical Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) announces that the Category 1 innovative biological drug Benmelstobart Injection in combination with Category 1 innovative drug Anlotinib Hydrochloride Capsule, which are self-developed by the Group, have submitted a new indication application for marketing to the Centre for Drug Evaluation (CDE) of the National Medical Products Administration of the PRC (NMPA), which have been accepted for the first-line treatment of advanced unresectable or metastatic renal cell carcinoma (RCC).

Benmelstobart Injection is a novel fully humanized anti PD-L1 monoclonal antibody with a new sequence self-developed by the Group, and was approved for marketing by NMPA in May 2024 for the use in the first-line treatment of extensive small cell lung cancer in combination with Anlotinib Hydrochloride Capsule and chemotherapy. In February 2024, the application for marketing for the new indication of Benmelstobart Injection in combination with Anlotinib Hydrochloride Capsule for the treatment of recurrent or metastatic endometrial cancer was accepted by CDE and included in the priority review and approval procedure.

Renal carcinoma is one of the most common malignant tumors in urinary system, among which RCC accounts for 80% – 90% of renal malignant tumors<sup>1</sup>. Based on statistics, there were approximately 77,000 new cases and 46,000 deaths of renal carcinoma in China in 2022<sup>2</sup>. Phase III clinical (ETER100) data indicated that, compared with Sunitinib, the first-line treatment of advanced RCC with Benmelstobart Injection in combination with Anlotinib Hydrochloride Capsule can significantly prolong the progression-free survival (PFS) of patients, and improve the objective response rate (ORR), overall

survival (OS) and other secondary endpoints. Detailed study data will be presented at a forthcoming international academic congress.

First-line treatment of advanced renal cell carcinoma is the third indication which Benmelstobart Injection applied for marketing and the eighth indication which Anlotinib Hydrochloride Capsule applied for marketing. The Group will continue to promote the development of Benmelstobart Injection and Anlotinib Hydrochloride Capsule under its mission of Science for a Healthier World. With the Group's continued 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.

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

Hong Kong, 1 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.*