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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

(Stock code: 1177)

VOLUNTARY ANNOUNCEMENT

**APPROVAL FOR MARKETING OF BENMELSTOBART INJECTION IN
COMBINATION WITH ANLOTINIB HYDROCHLORIDE CAPSULE FOR THE
INDICATION OF TREATMENT FOR ENDOMETRIAL CANCER**

The board of directors (the “**Board**”) of Sino Biopharmaceutical Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) announces that Benmelstobart Injection, a Category 1 innovative drug self-developed by the Group, in combination with Anlotinib Hydrochloride Capsule has obtained approval for marketing from the National Medical Products Administration of China for use in treatment for patients with recurrent or metastatic endometrial cancer that is non-microsatellite instability-high (non-MSI-H) or non-mismatch repair-deficient (non-dMMR) who have failed prior systemic therapy but are not candidates for radical surgery or radiation. This is the second indication approved for Benmelstobart Injection in China, and the seventh indication approved for Anlotinib Hydrochloride Capsule in China.

Some of the data from the Phase II study of Benmelstobart Injection in combination with Anlotinib Hydrochloride Capsule for the treatment of recurrent or metastatic endometrial cancer (ETER200/NCT04574284) was presented at the 2024 International Gynecologic Cancer Society (IGCS) Annual Meeting. As of 9 May 2024, a total of 85 patients were enrolled in the cohort, with an objective response rate (ORR) of 34.1%. Among the patients, 2 achieved complete response (CR), 27 achieved partial response (PR) and 37 had stable disease (SD), with a disease control rate (DCR) of 77.7%, a median progression-free survival (mPFS) of 8.8 months and a median overall survival (mOS) of 21.8 months. The results showed that Benmelstobart Injection in combination with Anlotinib Hydrochloride Capsule had good anti-tumour effect against endometrial cancer¹.

Endometrial cancer is a common malignant tumour in women. Its incidence ranked second among malignant tumours of the female reproductive system in China and ranked first among such tumours in developed countries². With the increasing popularity of high-fat, high-calorie diets and the spread of unhealthy lifestyles, the incidence of endometrial cancer continues to rise, especially in China, where there is a significant trend of early-onset endometrial cancer. In 2016, the number of new cases of endometrial cancer in China exceeded 70,000³. Currently, the first-line treatment option for endometrial cancer in China is platinum-based chemotherapy. However, there is no standard clinical treatment option for patients who have progressed after first-line treatment. Such patients have limited treatment options and a poor prognosis. Thus, there is an urgent need for effective treatment options.

In addition to the approved indication, the combination therapy of Benmelstobart Injection with Anlotinib Hydrochloride Capsule is undergoing multiple Phase III clinical trials, covering first-line treatment of non-small cell lung cancer, maintenance therapy for non-small cell lung cancer after radiotherapy and chemotherapy, first-line treatment of renal cancer and other important therapeutic areas. The Group will continue to actively advance the development of innovative products and unleash the full potential of its products, with a view to providing better treatment options for more patients.

Sources:

- [1] Xiaohua Wu, et al. 2024 IGCS LB011.
- [2] MSH, M. (2021). Guideline for the Diagnosis and Treatment of Endometrial Cancer (2021 edition). China Oncology, 31(6).
- [3] Rongshou Zheng et al. Cancer incidence and mortality in China, 2016, Journal of the National Cancer Center, 2022, 2(1): 1-9.

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

Hong Kong, 27 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.