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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)
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(Stock code: 1177)

VOLUNTARY ANNOUNCEMENT ACCEPTANCE OF THE NEW INDICATION APPLICATION FOR MARKETING OF ANLOTINIB HYDROCHLORIDE CAPSULES AND ANTI PD-L1 "BENMELSTOBART (TQB2450 INJECTION)"

The board of directors (the "Board") of Sino Biopharmaceutical Limited (the "Company", together with its subsidiaries, the "Group") announces that the Anlotinib Hydrochloride Capsules and Anti PD-L1"Benmelstobart (TQB2450 Injection)" developed by Chia Tai Tianqing Pharmaceutical Group Co., Ltd., a subsidiary of the Company, have filed a new indication application for marketing to the Center for Drug Evaluation (the "CDE") of the National Medical Products Administration (the "NMPA") of China and the application is accepted, for the indication of recurrent or metastatic endometrial cancer that is not microsatellite instability-high (non-MSI-H) or not DNA mismatch repair deficient (non-dMMR) and that has been previously treated by a first or second line chemotherapy regimen that was either unsuccessful or not tolerated.

Benmelstobart is a novel fully humanized anti PD-L1 monoclonal antibody with a new sequence self-developed by the Group. In April 2022, Benmelstobart in combination with Anlotinib Hydrochloride Capsules was included in the breakthrough therapy category by the CDE for the treatment of recurrent or metastatic endometrial cancer. In January 2023, the new drug application for Benmelstobart was formally accepted by the CDE for first-line treatment of small cell lung cancer in combination with Anlotinib Hydrochloride Capsules. In January 2024, Benmelstobart in combination with Anlotinib Hydrochloride Capsules was included in priority review and approval procedures of the CDE for the treatment of recurrent or metastatic endometrial cancer.

Anlotinib Hydrochloride Capsules is a novel oral small molecule multi-targeted tyrosine kinase inhibitor (TKI) independently developed by the Group. In May 2018, Anlotinib Hydrochloride Capsules was approved for marketing by the NMPA and was the first drug approved for utilisation in the third-line treatment of advanced non-small cell lung cancer in China. In January 2023, Anlotinib Hydrochloride

Capsules' application for marketing of its sixth indication was formally accepted by the CDE for use in conjunction with Benmelstobart for the first-line treatment of small cell lung cancer. Anlotinib Hydrochloride Capsules was previously approved for five indications: third-line non-small cell lung cancer, third-line small cell lung cancer, soft tissue sarcoma, medullary thyroid cancer and differentiated thyroid cancer.

Endometrial cancer ranks second among malignant tumors of the female reproductive system in China, and first in developed countries [1]. With the increasing prevalence of high-fat and high-calorie dietary patterns and the gradual spread of unhealthy lifestyles, the incidence of endometrial cancer continues to rise, especially among younger women in China [1]. In 2016, the number of new cases of endometrial cancer reached 71,000 in China, with an incidence rate of 10.54 per 100,000 people [2]. Currently, platinum-based chemotherapy is the first-line therapy for endometrial cancer in China. However, for patients with progress after first-line treatment, there is no standard clinical treatment protocol; patients have limited clinical treatment options and poor prognosis; thus, there is urgent need for effective treatment modalities.

Benmelstobart in combination with Anlotinib Hydrochloride Capsules may bring new treatment hope to endometrial cancer patients, and is expected to become the first PD-L1 inhibitor and small molecule anti-angiogenic drug combination therapy approved for recurrent or metastatic endometrial cancer in China, addressing the unmet clinical needs and benefiting patients in China. At the same time, it also signifies that Benmelstobart has successfully laid out another important area after small cell lung cancer. In addition, Benmelstobart in combination with Anlotinib Hydrochloride Capsules is currently undergoing a number of Phase III clinical trials, including first-line renal cancer, first-line non-small cell lung cancer, and post-radiotherapy and chemotherapy maintenance for non-small cell lung cancer. The Group will continue to advance the development of Benmelstobart and Anlotinib Hydrochloride Capsules to bring new treatment options to more patients.

Notes:

- [1] Chinese Expert Consensus Compilation Group for Multiple Disciplinary Treatment in Endometrial Cancer Desiring Fertility Preserving Treatment Writers, Chinese expert consensus on multiple disciplinary treatment in endometrial cancer desiring fertility preserving treatment [J]. Journal of Reproduction and Contraception, 2023, 43(4): 346-356.
- [2] 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, 28 February 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.