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 "ERIBULIN MESILATE INJECTION"

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that "Eribulin Mesilate Injection" (trade name: Ailelin (艾樂林)) developed by the Group has obtained approval for marketing from the National Medical Products Administration (NMPA) of China for the treatment of patients with locally advanced or metastatic breast cancer who have received at least two chemotherapeutic regimens (including anthracyclines and taxanes). This is one of the first three eribulin mesilate injections approved for marketing in China.

Eribulin is a synthetic structural analog of halichondrin B and a new type of non-taxane microtubule protein inhibitor. Since its mechanism of action is different from that of the traditional microtubule inhibitor taxane, it is still effective for taxane-resistant patients[1]. At present, eribulin has been recommended by a number of domestic and foreign authoritative guidelines. The Guidelines of Chinese Society of Clinical Oncology (CSCO) on Diagnosis and Treatment of Breast Cancer (2023 version) recommends eribulin as Level I single drug for triple negative advanced breast cancer that has failed taxane, whereas the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology for Breast Cancer (2023V4) recognizes eribulin as a preferred regimen for HER2-negative advanced breast cancer.

With many chiral centers in its molecular structure and a long synthesis process, eribulin is one of the most structurally complex non-peptide drugs produced only by chemical synthesis in the pharmaceutical industry to date. Leveraging on its profound research and development (R&D) strength and production experience, the Group has further enhanced the controllability of its processes and stability of drug quality through rigorous experimental design, advanced manufacturing technologies and stringent production control strategies, in order to meet patients' demand for high-quality drugs.

In the field of breast cancer, the Group has a number of products which have obtained approval for marketing such as Trastuzumab, Palbociclib, Fulvestrant and Docetaxel. In addition, the Group has a range of blockbuster innovative drugs under development, including TQB3616 (CDK2/4/6 Inhibitor), for which marketing application has been submitted to the Centre for Drug Evaluation of the NMPA of China; TQB2102 (HER2 Bispecific Antibody ADC), which is in clinical Phase III; and TQB2930 (HER2 Bispecific Antibody), which is in clinical Phase II. The Group will accelerate product R&D and strive to provide more quality treatment options for breast cancer patients.

Sources:

[1] Wu Xinyu, Huang Xiang. Efficiency and safety of eribulin in patients with HER2-negative metastatic breast cancer: a real world study [J]. Journal of Nanjing Medical University (Natural Sciences), 2023 (2): 236-242.

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

Hong Kong, 11 December 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.