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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 LM-302 "CLDN18.2 ADC" INCLUDED IN THE BREAKTHROUGH THERAPEUTIC DESIGNATION PROCESS

The board of directors (the "Board") of Sino Biopharmaceutical Limited (the "Company", together with its subsidiaries, the "Group") announces that the innovative drug LM-302 "CLDN18.2 ADC" independently developed by LaNova Medicines Limited ("LaNova Medicines"), a wholly-owned subsidiary of the Group, has been included in the Breakthrough Therapeutic Designation (BTD) process by the Center for Drug Evaluation (CDE) of the National Medical Products Administration of China. The drug is used in combination with a PD-1 monoclonal antibody as first-line therapy for CLDN18.2-positive locally advanced or metastatic gastric and gastroesophageal junction adenocarcinoma.

LM-302 is a potential first-in-class antibody-drug conjugate (ADC) targeting CLDN18.2, which has demonstrated clinical efficacy in patients with gastric cancer, pancreatic cancer and biliary tract cancer. It has also shown clinical benefits in patients with low Claudin 18.2 expression and low PD-L1 expression.

At the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, LaNova Medicines presented the latest results from a study on LM-302 in combination with a PD-1 monoclonal antibody for the treatment of gastric cancer: among 41 efficacy-evaluable patients, the overall response rate (ORR) was 65.9% and the disease control rate (DCR) was 85.4%; among 32 patients with CLDN18.2 expression in ≥25% of tumour cells, the ORR was 71.9% and the DCR was 96.9%. The results demonstrate that the LM-302 combination regimen exhibited good anti-tumour activity and manageable safety in CLDN18.2-positive patients^[1].

A Phase III clinical trial of LM-302 is currently underway in China for the treatment of CLDN18.2-positive locally advanced or metastatic gastric and gastroesophageal junction adenocarcinoma that has progressed after two or more lines of systemic therapy. The inclusion of LM-302 in the BTD process is expected to expedite its marketing, thereby bringing an innovative treatment option to more CLDN18.2-positive gastric cancer patients as soon as possible.

Source:

[1] Haiping Jiang, Mingzhu Huang, et al. Efficacy and safety of LM-302 (anti-claudin 18.2 ADC) in combination with anti-PD-1 therapy for advanced gastric, gastroesophageal junction cancer and esophageal adenocarcinoma: Early-phase study results. ASCO 2025.

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

Chairwoman

Hong Kong, 19 August 2025

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.