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
NEW INDICATION OF LM-108 ("CCR8 MONOCLONAL ANTIBODY") INCLUDED IN BREAKTHROUGH THERAPY DESIGNATION PROCESS

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that LM-108, a "**CCR8 monoclonal antibody**" jointly developed by the Group and LaNova Medicines Limited ("**LaNova Medicines**"), has been included in the Breakthrough Therapy Designation (BTD) process by the Center for Drug Evaluation (CDE) of the National Medical Products Administration of China. The drug is intended for use in combination with toripalimab for the treatment of CCR8-positive advanced gastric/gastroesophageal junction (G/GEJ) adenocarcinoma in patients who have failed first-line standard therapy. Previously, in February 2025, LM-108 was included in the BTD process by the CDE for the treatment of advanced solid tumors with microsatellite instability high (MSI-H) or deficient mismatch repair (dMMR) that have progressed following treatment with immune checkpoint inhibitors.

LM-108 is an Fc-optimized humanized monoclonal antibody developed by LaNova Medicines using its proprietary multi-transmembrane protein (GPCR) antibody discovery platform. LM-108 specifically eliminates infiltrating regulatory T cells (Tregs) within the tumor microenvironment through an antibody-dependent cell-mediated cytotoxicity (ADCC) mechanism, while preserving peripheral Tregs, thereby significantly enhancing anti-tumor immune responses. Its unique mechanism of action enables it to overcome resistance to PD-1/PD-L1 inhibitors, offering a new therapeutic solution for patients who have failed immunotherapy.

LM-108 has been selected for oral presentation at the American Society of Clinical Oncology (ASCO) for two consecutive years, with cross-tumour clinical data validating its targeted therapeutic value

Breakthrough in gastric cancer: Phase I/II clinical data presented at the 2024 ASCO Annual Meeting showed that among 48 patients from China, the United States, and Australia, the objective response rate

(ORR) of LM-108 in combination with PD-1 monoclonal antibody for the treatment of advanced G/GEJ adenocarcinoma patients who had failed first-line therapy reached 36.1%, with a disease control rate (DCR) of 72.2%. Particularly, in the CCR8 high-expression subgroup (8 patients), the ORR reached 87.5% and the DCR was 100%. This clinical data revealed for the first time a positive correlation between CCR8 expression levels and treatment efficacy[1].

Breakthrough in pancreatic cancer: Phase I/II clinical data presented at the 2025 ASCO Annual Meeting showed that among 80 patients from China and Australia (65% of whom had liver metastases), the ORR of LM-108 in combination with PD-1 monoclonal antibody for the treatment of previously treated advanced pancreatic cancer reached 20.3%, with a median overall survival (OS) of 10.02 months. In the CCR8 high-expression subgroup, the ORR increased to 33.3%, suggesting that CCR8 has the potential to become the first stratification biomarker for immunotherapy in pancreatic cancer[2].

As the most clinically advanced CCR8 monoclonal antibody globally, LM-108 is currently the only CCR8 investigational drug that has received two Breakthrough Therapy Designation recognitions. Currently, LM-108 has initiated a registrational trial for use in combination with toripalimab in the treatment of patients with advanced malignant solid tumors with MSI-H/dMMR who have failed prior anti-PD-1/PD-L1 therapy.

LM-108 has demonstrated promising efficacy in gastrointestinal oncology including gastric cancer, pancreatic cancer, oesophageal cancer, and colorectal cancer, and is expected to become the Group's next "**Anlotinib**". The Group is working with LaNova Medicines to explore combination therapies for LM-108 in additional tumor types. LM-108 is expected to provide a new treatment option for patients who have failed PD-1/PD-L1 therapy and become a next-generation immunotherapy for tumors.

Sources:

[1] Jifang Gong, et al. Efficacy and safety of LM-108, an anti-CCR8 monoclonal antibody, in combination with an anti-PD-1 antibody in patients with gastric cancer: Results from phase 1/2 studies.. JCO 42, 2504-2504(2024).

[2] Jifang Gong et al. Efficacy and safety of cafelkibart (LM-108), an anti-CCR8 monoclonal antibody, in combination with anti-PD-1 therapy in patients with pancreatic cancer: Results from phase 1/2 studies.. JCO 43, 4010-4010(2025).

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

Hong Kong, 26 June 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.