SINO BIOPHARMACEUTICAL LIMITED
中國生物製藥有限公司

(Incorporated in the Cayman Islands with limited liability)
Website: www.sbpgroup.com
(Stock code: 1177)

VOLUNTARY ANNOUNCEMENT
FIRST PATIENT ENROLLMENT IN THE PHASE III REGISTRATIONAL CLINICAL TRIAL OF CAFELKIBART "CCR8 MONOCLONAL ANTIBODY" FOR SECOND-LINE GASTRIC CANCER

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that the first patient has been successfully enrolled in a Phase III registrational clinical trial of cafelkibart "CCR8 Monoclonal Antibody" (development code: LM-108), a national Category 1 innovative drug independently developed by LaNova Medicines Limited ("**LaNova Medicines**"), a wholly-owned subsidiary of the Group. The trial is designed to evaluate LM-108 in combination with a PD-1 inhibitor as a second-line treatment for patients with CCR8-positive locally advanced or metastatic gastric cancer/gastroesophageal junction (G/GEJ) adenocarcinoma. This study marks the second pivotal registrational clinical trial initiated for LM-108.

LM-108 is a potential global first-in-class CCR8 monoclonal antibody. To date, it is the only CCR8-targeted drug to have received two Breakthrough Therapy Designations from the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA), namely: 1) in combination with toripalimab for the treatment of microsatellite instability-high (MSI-H)/mismatch repair-deficient (dMMR) advanced solid tumors that have progressed following prior immune checkpoint inhibitor therapy; 2) in combination with toripalimab for CCR8-positive advanced G/GEJ adenocarcinoma that has failed prior first-line standard of care.

In a Phase I/II study evaluating LM-108 in combination with toripalimab as second-line treatment for advanced gastric cancer, this combination regimen demonstrated promising anti-tumor activity and

a favorable safety profile. Preliminary data from 40 gastric cancer patients who received LM-108 in combination with toripalimab in the second-line setting showed:

- Significant benefits in the overall population: The objective response rate (ORR) was 32.5%, the disease control rate (DCR) was 67.5%, the median progression-free survival (PFS) was 5.32 months, and the median overall survival (OS) reached 22.64 months.

- Precision stratification based on CCR8 expression: Efficacy was strongly and positively correlated with CCR8 expression levels. In the CCR8-positive (CCR8 ≥ 1) subgroup, the ORR was 41.4% and the median OS reached 22.64 months; in the CCR8 high-expression (CCR8 ≥ 2) subgroup, the ORR was 62.5%, the DCR was 75%, the median PFS extended to 7.33 months, and the median OS has not yet been reached.

Compared with paclitaxel monotherapy, the current standard of care which has a reported median OS of approximately 7.4~8.4 months, the LM-108 combination regimen achieved significant survival benefits in the overall population, with a median OS of 22.64 months, demonstrating its breakthrough clinical value.

Gastric cancer is one of the most prevalent malignant tumors in China, with the majority of patients diagnosed at an advanced stage and consequently facing a poor overall prognosis. For patients who have failed first-line treatment, the current second-line standard of care remains primarily chemotherapy (such as paclitaxel) or chemotherapy in combination with targeted therapy, yet clinical benefits are extremely limited. PD-1/PD-L1 immunotherapy in the second-line setting has demonstrated efficacy only in a small number of patients with MSI-H/dMMR tumors, while the vast majority of patients still face issues of primary or secondary resistance[1].

Studies have shown that immunosuppression mediated by regulatory T cells (Tregs) in the tumor microenvironment is one of the key mechanisms leading to immunotherapy failure[2,3]. Cafelkibart selectively eliminates immunosuppressive Tregs within the tumor microenvironment by targeting the CCR8 receptor, which is highly expressed on the surface of tumor-infiltrating Tregs, with high affinity and selectivity. This approach restores the anti-tumor immune response. When combined with a PD-1 inhibitor, LM-108 is expected to produce powerful synergistic effects, offering a novel solution for second-line treatment of advanced gastric cancer.

Another pivotal registrational clinical trial of LM-108 is ongoing in patients with MSI-H/dMMR advanced solid tumors, positioning LM-108 as a potential first-in-class CCR8-targeted therapy to be approved for marketing worldwide. Through its innovative mechanism of selectively modulating immunosuppression within the tumor microenvironment, LM-108 has the potential not only to overcome resistance to existing immunotherapies but also to pioneer a novel Treg-targeting immunotherapeutic paradigm, thereby offering a more precise and effective treatment option to cancer patients in China and around the world.

Sources:

[1] Li Juan, Ye Sisi, Han Chun, et al. Efficacy Analysis of Second-Line Treatment Combining Immune Checkpoint Inhibitors with Chemotherapy and Anti-angiogenic Drugs in Patients with Advanced Gastric Cancer and Gastroesophageal Junction Adenocarcinoma [J]. Journal of the Medical School of Chinese PLA, 2023, 44(7):763-768.

[2] Tanaka A, Sakaguchi S. Regulatory T cells in cancer immunotherapy. Cell Res. 2017Jan;27(1):109-118.

[3] Villarreal DO, L'Huillier A, Armington S, et al. Targeting CCR8 Induces Protective Antitumor Immunity and Enhances Vaccine-Induced Responses in Colon Cancer. Cancer Res. 2018 Sep 15;78(18):5340-5348.

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

Hong Kong, 6 May 2026

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.