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
COMPLETION OF ENROLLMENT OF THE FIRST PATIENT IN PHASE III CLINICAL TRIAL OF TECOTABART VEDOTIN "CLDN18.2 ADC" FOR FIRST-LINE TREATMENT OF GASTRIC AND GASTROESOPHAGEAL JUNCTION ADENOCARCINOMA

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that tecotabart vedotin (research and development code: LM-302) "CLDN18.2 ADC", a national Category 1 innovative drug independently developed by LaNova Medicines Limited ("**LaNova Medicines**", a wholly-owned subsidiary of the Group), has successfully completed the enrollment of the first patient in its Phase III registrational clinical trial (LM302-03-101) for the first-line treatment of CLDN18.2-positive locally advanced or metastatic gastric and gastroesophageal junction adenocarcinoma (GC/GEJ) in combination with a PD-1 monoclonal antibody. This study is the second Phase III clinical trial of LM-302 and the first Phase III clinical trial of a CLDN18.2 ADC using a chemotherapy-free regimen for the first-line treatment of gastric cancer in the world.

LM-302 is an antibody-drug conjugate (ADC) targeting CLDN18.2, composed of a recombinant humanized monoclonal antibody conjugated to the small-molecule toxin monomethyl auristatin E (MMAE). LM-302 not only precisely targets CLDN18.2-positive tumor cells but also eliminates surrounding heterogeneous tumor cells with its "bystander effect." Also, it can induce immunogenic cell death (ICD), thereby producing significant synergistic antitumor effects when combined with a PD-1 monoclonal antibody. Such combination strategy featuring "ADC + immunotherapy" is expected to deliver deeper tumor remissions in patients with CLDN18.2-positive gastric cancers.

Gastric cancer is a highly invasive and heterogeneous malignant tumor. In 2025, approximately 1.04 million new cases of gastric cancer and approximately 705,000 deaths were recorded globally, among which China accounted for approximately 383,000 new cases and approximately 277,000 deaths[1]. Currently, chemotherapy in combination with immune checkpoint inhibitors serves as the standard first-line treatment regimen for advanced unresectable gastric cancer. However, the median overall survival (mOS) for patients is limited to 14–20 months, indicating restricted clinical benefits[2]. In addition, although CLDN18.2 monoclonal antibody in combination with chemotherapy has been approved for population with high CLDN18.2 expression (≥75% tumor cells membrane with staining intensity of 2+/3+), its survival benefits in the broader population of CLDN18.2-positive patients remain unclear.

This Phase III clinical trial plans to enroll patients with locally advanced unresectable or metastatic GC/GEJ who are CLDN18.2-positive (≥25% tumor cell membrane with staining intensity of 2+/3+) and HER2-negative, and those who have not received prior systemic therapy. The primary endpoint is progression-free survival (PFS) assessed by blinded independent central review (BICR) according to RECIST 1.1 criteria. The key secondary endpoint is overall survival (OS). This study employs current standard-of-care therapy as the positive control, aiming to directly validate the superior efficacy and safety profile of the LM-302 combination therapy.

In addition to this initiated Phase III clinical trial for LM-302 combination therapy as the first-line treatment for CLDN18.2-positive GC/GEJ, the Phase III clinical study of LM-302 monotherapy for the third-line or higher treatment of CLDN18.2-positive GC/GEJ has completed the enrollment of all subjects. Furthermore, multiple indications for LM-302 have been included in the Breakthrough Therapeutic Designation (BTD) process by the Center for Drug Evaluation (CDE) of the National Medical Products Administration of China. Also, the drug has received three Orphan Drug Designations (ODD) from the U.S. Food and Drug Administration (FDA), covering three highly unmet clinical needs in gastrointestinal oncology, namely gastric cancer, pancreatic cancer, and biliary tract cancer.

Since LaNova Medicines joined the Group, both parties have leveraged complementary strengths, integrated resources, and achieved efficient synergy. Leveraging the early-stage research and development expertise and robust pipeline assets from LaNova Medicines, combined with the mature clinical development capabilities and commercialization layout from the Group, multiple innovative pipelines have been accelerated, enabling these promising outcomes to benefit a broad patient population expeditiously.

Sources:

[1] Ferlay J, Laversanne M, Ervik M, Lam F, Colombet M, Mery L, Piñeros M, Znaor A, Soerjomataram I, Bray F (2024). Global Cancer Observatory: Cancer Tomorrow (version 1.1). Lyon, France: International Agency for Research on Cancer. https://gco.iarc.who.int/tomorrow.

[2] CSCO Clinical Guidelines for the Diagnosis and Treatment of Gastric Cancer, 2025

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

Hong Kong, 15 April 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.