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
ACCEPTANCE OF NEW DRUG APPLICATION FOR TECOTABART VEDOTIN "CLDN18.2 ADC"

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that a new drug application for tecotabart vedotin "CLDN18.2 ADC" (research and development code: LM-302), an innovative drug independently developed by LaNova Medicines Limited ("**LaNova Medicines**", a wholly-owned subsidiary of the Group), has been submitted to and accepted by the Center for Drug Evaluation (CDE) of China's National Medical Products Administration, for the treatment of CLDN18.2-positive, locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma (GC/GEJ) in patients who have received at least two prior lines of systemic therapy. On 22 May, this indication has been included in the priority review and approval procedures by the CDE.

LM-302 is a CLDN18.2-targeting antibody-drug conjugate (ADC), which consists of a recombinant humanised monoclonal antibody conjugated to the small-molecule toxin MMAE. Beyond its precise targeting of CLDN18.2-positive tumor cells, LM-302 leverages the "bystander effect" of MMAE to eradicate adjacent tumor cells with low or heterogeneous target expression. Furthermore, LM-302 can induce immunogenic cell death (ICD), and it produces a synergistic anti-tumour effect when used in combination with a PD-1 monoclonal antibody, thereby providing an important basis of mechanism for the combination treatment featuring "ADC + immunotherapy".

The acceptance of this marketing application for LM-302 is supported by positive outcomes from a pivotal Phase III clinical trial evaluating LM-302 as monotherapy in patients with CLDN18.2-positive locally advanced or metastatic GC/GEJ who have received at least two prior lines of systemic therapy. The trial has completed its interim analysis, achieving both endpoints. Detailed results are scheduled for formal disclosure at a major international academic conference in early 2027.

Gastric cancer ranks among the most prevalent and lethal malignancies worldwide. According to the 2022 global cancer burden statistics, there were approximately 970,000 new cases of gastric cancer annually worldwide, with China accounting for more than one-third of them. For patients with advanced gastric cancer, treatment options for prolonging survival are extremely limited, particularly when it comes to patients who have failed previous treatments and generally have a poor prognosis. The current median overall survival (OS) is even less than 10 months[1], thus necessitating treatment options with better efficacy. CLDN18.2, as the second clinically validated "druggable" target in the gastric cancer field after HER2, exhibits moderate-to-high expression in 31%–86% of GC/GEJ cases.

In addition to the current marketing application for the indication of CLDN18.2-positive locally advanced or metastatic GC/GEJ who have received at least two prior lines of systemic therapy, LM-302 is also being evaluated in a pivotal Phase III clinical trial in combination with a PD-1 monoclonal antibody as a first-line treatment of CLDN18.2-positive locally advanced or metastatic GC/GEJ. Both indications have been granted Breakthrough Therapy Designations (BTD) by the CDE. Additionally, LM-302 has obtained three Orphan Drug Designations (ODD) from the U.S. Food and Drug Administration (FDA), covering three major tumour types with highly unmet clinical needs, namely gastric cancer, pancreatic cancer and biliary tract cancer.

Source:

[1] Wilke H, Muro K, Van Cutsem E, et al.Ramucirumab plus paclitaxel versus placebo plus paclitaxel in patients with previously treated advanced gastric or gastro-oesophageal junction adenocarcinoma(RAINBOW): a double-blind, randomised phase 3 trial.Lancet Oncol.2014 Oct;15(11):1224-35.

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

Hong Kong, 23 June 2026

As at the date of this announcement, the Board of the Company comprises five executive directors, namely Ms. Tse, Theresa Y Y, Mr. Tse Ping, Ms. Cheng Cheung Ling, Mr. Tse, Eric S Y and Mr. Tse Hsin and six independent non-executive directors, namely Mr. Lu Zhengfei, Ms. Lu Hong, Mr. Zhang Lu Fu, Dr. Li Kwok Tung Donald, Dr. Chen Lieping and Dr. Lu Bai.