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
DATA FROM TWO CLINICAL STUDIES OF M701 "CD3/EpCAM BISPECIFIC ANTIBODY" PRESENTED AT 2026 ASCO

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that the data from two clinical studies of M701 "CD3/EpCAM Bispecific Antibody", a national Category 1 innovative drug jointly developed by Chia Tai Tianqing Pharmaceutical Group Co. Ltd. ("**CTTQ**"), a subsidiary of the Group, will be presented at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting: the Phase III registrational clinical study in malignant ascites (MA) and the Phase II clinical study in malignant pleural effusion (MPE) associated with non-small cell lung cancer (NSCLC).

ORAL SESSION

Title:

Phase 3, multicenter, randomized, controlled open-label study: Efficacy and safety of M701 (EpCAM × CD3 bispecific antibody) intraperitoneal infusion in advanced epithelial solid tumor with malignant ascites vs paracentesis

Study Design:

This is a randomized, controlled, open-label Phase III registrational clinical study (Dayu Trial, NCT06432296). A total of 312 patients with MA caused by advanced epithelial solid tumours (including gastric cancer, colorectal cancer and ovarian cancer) were enrolled and randomised in a ratio of 2:1. The study group received intraperitoneal infusion of M701 in combination with systemic therapy, while the control group received paracentesis in combination with systemic therapy. The primary endpoint was puncture-free survival (PuFS), being defined as the time from the end of the core treatment period to the first re-puncture or death.

Clinical Data:

- Significantly prolonged PuFS: The M701 group demonstrated a clinically significant advantage in ascites control. The median PuFS in the M701 group and the control group were 87.59 days vs 49.96 days, respectively, with the median time to next paracentesis (TTNP) being 186.72 days vs 55.08 days, respectively. The 1-month and 2-month puncture-free survival rate in the M701 group were 76.9% and 62.0%, respectively, whereas those in the control group were only 69.4% and 38.4%, respectively.

- Improved quality of life: Patient-reported outcomes (PROs) indicated that the M701 group significantly delayed the timing of deterioration in patients' global health status.

- Survival and safety profile: The M701 group demonstrated a favorable safety profile, with the incidence of Grade ≥3 treatment-related adverse events (TRAEs) comparable to that of the control group. Overall survival (OS) was similar between the two groups, suggesting that the benefit in ascites control was primarily attributable to local treatment with M701, while the OS was not compromised by the additional local treatment.

Intraperitoneal infusion of M701 significantly prolonged the PuFS in patients with MA, improved quality of life, and was well tolerated. These positive Phase III results support M701 as a potential standard of care for MA associated with advanced gastric cancer, colorectal cancer and ovarian cancer, replacing simple paracentesis drainage and traditional intraperitoneal chemotherapy.

POSTER

Title:

An anti-EpCAM x anti-CD3 bispecific antibody, M701, for the treatment of malignant pleural effusion due to NSCLC: A prospective randomized controlled phase II trial

Clinical Data:

A total of 92 NSCLC patients with symptomatic MPE who had progressed after at least one line of systemic therapy were enrolled in this study. Patients in the study group received thoracentesis drainage in combination with intraperitoneal infusion of M701, while those in the control group received thoracentesis drainage in combination with intraperitoneal cisplatin or thoracentesis drainage alone.

In terms of efficacy, among NSCLC patients with negative driver mutations or those refractory to prior platinum-based therapy, the median PuFS in the M701 group were 176 days and 178 days, respectively, whereas those in the control group were only 42.5 days and 53.5 days, respectively, with hazard ratios (HR) of 0.34 and 0.67, respectively, indicating that M701 demonstrated significant pleural effusion control in both of the abovementioned patient populations. Among NSCLC patients with negative driver mutations the objective response rate (ORR) for pleural effusion in the M701 group was 64.9%, as compared with only 18.5% in the control group. The results from objective efficacy assessment based on CT imaging well aligned with the clinical benefits observed in the PuFS.

In terms of safety profile, the incidence of Grade ≥3 TRAEs in the M701 group and the control group were 2.2% and 6.4%, respectively. Common adverse reactions included anaemia and elevated lipase, whereas the common adverse reactions of the control group include nausea, vomiting, etc.

In the field of NSCLC, M701 offers a novel treatment option for patients with negative driver mutations or those resistant to platinum-based chemotherapy, characterised by high efficacy and low toxicity.

Clinical Significance: Filling the Gap in the Market for MPE and MA

MPE and MA have long lacked a standard-of-care treatment. Current clinical practice mainly depends on paracentesis to relieve symptoms, or intraperitoneal chemotherapy (such as cisplatin) and sclerosing agents. However, these approaches have encountered pain points such as limited options, low ORR, severe toxicity and side effects, etc. In advanced-stage patients, significant fluid accumulation often leads to chest tightness, chest pain, and dyspnoea, severely compromising quality of life.

M701 minimizes effusion at its source by activating local T cells to eliminate EpCAM-positive tumour cells. Clinical data indicates that M701 not only provides durable relief of pleural effusion symptoms but also effectively controls recurrence over time, thereby delivering dual benefits of addressing both the symptoms and the root causes to significantly improve patients' quality of life.

In the Phase III clinical study for MA and the Phase II clinical study for MPE, M701 demonstrated clear clinical benefits, marking the first immunotherapy-based local treatment for malignant effusions in advanced cancer that has been validated by large-scale clinical trials. Furthermore, both studies innovatively adopted PuFS as the primary endpoint. This metric directly reflects the period during which patients can survive without receiving paracentesis, thereby providing a more relevant indicator of improvement in quality of life compared with traditional endpoints such as radiographic response rates or fluid volume. This endpoint design has been highly recognised by the ASCO community and international experts in the field.

The marketing application for M701 was accepted by the Centre for Drug Evaluation (CDE) of the China's National Medical Products Administration in May 2026, positioning M701 as the potential first standard of care for MPE and MA in China. As compared with catumaxomab (approved in the EU), M701 demonstrates superior safety profile and practical clinical accessibility; as compared with paracentesis drainage or local chemotherapy, M701 exhibits higher response rates and more durable effusion control.

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

Hong Kong, 21 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.