

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



KELUN-BIOTECH
科伦博泰

Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd.

四川科伦博泰生物制药股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

(Stock Code: 6990)

VOLUNTARY ANNOUNCEMENT

NEW INDICATION APPLICATION FOR CORE PRODUCT TROP2 ADC SACITUZUMAB TIRUMOTECAN (sac-TMT) ACCEPTED BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION

The board (the “**Board**”) of directors (“**Directors**”) of Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (the “**Company**”) is pleased to announce that a new indication application of its trophoblast cell-surface antigen 2 (TROP2)-directed antibody drug conjugate (ADC) sacituzumab tirumotecan (sac-TMT, also known as SKB264/MK-2870) (佳泰莱®) has been accepted for review by the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of China, in combination with MSD¹'s anti-programmed cell death protein 1 (PD-1) monoclonal antibody pembrolizumab (KEYTRUDA®²) as first-line treatment for adult patients with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have a programmed cell death ligand 1 (PD-L1) tumor proportion score (TPS) <1% and are epidermal growth factor receptor (EGFR)-negative and anaplastic lymphoma kinase (ALK)-negative. This marks the seventh indication application for sac-TMT accepted for review by the NMPA.

This application is based on positive results from the Phase 3 registrational OptiTROP-Lung06 study evaluating the efficacy and safety of sac-TMT in combination with pembrolizumab compared with pembrolizumab plus chemotherapy as first-line treatment for patients with PD-L1-negative locally advanced or metastatic non-squamous NSCLC. This study directly compared two treatment strategies – “ADC plus immunotherapy” versus “immunotherapy plus chemotherapy”.

¹ MSD is the tradename of Merck & Co., Inc, Rahway, NJ, USA.

² KEYTRUDA® (pembrolizumab) is a registered trademark of Merck Sharp & Dohme LLC (MSD), a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

At a prespecified interim analysis, sac-TMT plus pembrolizumab demonstrated a statistically significant and clinically meaningful improvement in the primary endpoint of progression-free survival (PFS) as assessed by blinded independent central review (BICR) compared with pembrolizumab plus pemetrexed and platinum-based chemotherapy; a positive trend was also observed in the secondary endpoint of overall survival (OS). The safety profile of this combination regimen was consistent with that reported in previous studies, with no new safety signals observed.

The OptiTROP-Lung06 study has been selected as a late-breaking abstract (LBA) at the 2026 European Society for Medical Oncology (ESMO) Congress, and the detailed results had been presented as an oral report during the congress.

About sac-TMT(佳泰莱®)

Sac-TMT, a core product of the Company, is a novel TROP2 ADC in which the Company has proprietary intellectual property rights, targeting advanced solid tumors such as NSCLC, breast cancer (BC), gastric cancer (GC), gynecological tumors and genitourinary tumors, among others. Sac-TMT is developed with a unique, bifunctional linker that maximizes payload delivery to tumor cells both through its irreversible connection with the anti-TROP2 monoclonal antibody sacituzumab and its pH-sensitive cleavage from a belotecan-derivative topoisomerase I inhibitor payload (KL610023) in the lysosome, with a drug-to-antibody-ratio (DAR) of 7.4. Sac-TMT specifically recognizes TROP2 on the surface of tumor cells by recombinant anti-TROP2 humanized monoclonal antibodies, which is then endocytosed by tumor cells and releases the payload KL610023 intracellularly. KL610023 induces DNA damage to tumor cells, which in turn leads to cell-cycle arrest and apoptosis. In addition, it also releases KL610023 in the tumor microenvironment. Given that KL610023 is membrane permeable, it can enable a bystander effect, or in other words kill adjacent tumor cells.

In May 2022, the Company licensed the exclusive rights to MSD (the tradename of Merck & Co., Inc, Rahway, NJ, USA) to develop, use, manufacture and commercialize sac-TMT in all territories outside of Greater China (which includes Mainland China, Hong Kong, Macao and Taiwan).

To date, four indications for sac-TMT have been approved and marketed in China for: 1) unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) who have received at least two prior systemic therapies (at least one of them for advanced or metastatic setting); 2) EGFR mutant-positive locally advanced or metastatic non-squamous NSCLC following progression on EGFR-tyrosine kinase inhibitor (TKI) therapy and platinum-based chemotherapy; 3) EGFR mutant-positive locally advanced or metastatic non-squamous NSCLC who progressed after treatment with EGFR-TKI therapy; 4) unresectable or metastatic hormone receptor-positive (HR+)/human epidermal growth factor receptor 2-negative (HER2-) (Immunohistochemistry (IHC) 0, IHC 1+ or IHC 2+/In Situ Hybridization (ISH)-)

BC who have received prior endocrine therapy and at least one line of chemotherapy in advanced setting. The first two indications above have been included in China's National Reimbursement Drug List (NRDL). This inclusion is expected to bring clinically meaningful benefits to a greater number of patients with BC and NSCLC. Additionally, sac-TMT has been granted six Breakthrough Therapy Designations by the NMPA.

Sac-TMT is the world's first TROP2 ADC drug approved for marketing in lung cancer. Three new indication applications have been accepted for review by the NMPA: 1) sac-TMT in combination with pembrolizumab as first-line treatment for locally advanced or metastatic NSCLC who have PD-L1 TPS $\geq$ 1% and are EGFR-negative and ALK-negative; 2) sac-TMT as first-line treatment for patients with recurrent or metastatic TNBC who have a PD-L1 combined positive score (CPS) <10 or have recurred after prior PD-1/PD-L1 inhibitor therapy in the early stage, both of the above two applications have been included in the priority review and approval process; 3) sac-TMT in combination with pembrolizumab as first-line treatment of adult patients with locally advanced or metastatic non-squamous NSCLC whose tumors have PD-L1 TPS $<1\%$ and are EGFR-negative and ALK-negative. As of today, the Company has initiated 9 registrational clinical studies in China. MSD has initiated 18 ongoing global Phase 3 clinical studies of sac-TMT as a monotherapy or in combination with pembrolizumab or other anti-cancer agents for several types of cancer. These studies are sponsored and led by MSD.

RISK WARNING

SACITUZUMAB TIRUMOTECAN (SAC-TMT) FOR THE TREATMENT OF OTHER INDICATIONS NOT YET APPROVED MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED. THE COMPANY'S SHAREHOLDERS AND POTENTIAL INVESTORS ARE REMINDED TO EXERCISE CAUTION WHEN DEALING IN THE SECURITIES OF THE COMPANY.

By order of the Board
Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd.
LIU Gexin
Chairman of the Board and Non-executive Director

Hong Kong, October 27, 2026

As at the date of this announcement, the Board comprises Mr. LIU Gexin as the chairman of the Board and non-executive Director, Dr. GE Junyou as executive Director, Mr. LIU Sichuan, Mr. LAI Degui, Mr. FENG Hao, Ms. LIAO Yihong and Mr. ZENG Xuebo as non-executive Directors, and Dr. ZHENG Qiang, Dr. TU Wenwei, Dr. JIN Jinping and Dr. LI Yuedong as independent non-executive Directors.