

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.



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 (the “**Application**”) for the Company’s trophoblast cell-surface antigen 2 (TROP2)-directed antibody-drug conjugate (ADC) sacituzumab tirumotecan (sac-TMT, also known as SKB264/MK-2870) (佳泰莱®) was accepted for review by the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of China. The application is for sac-TMT in combination with MSD¹’s anti-programmed cell death protein 1 (PD-1) monoclonal antibody (mAb) pembrolizumab (KEYTRUDA®²) as first-line treatment for adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) who have programmed 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 acceptance is based on the positive results from the OptiTROP-Lung05 registrational Phase 3 study, and the application is the fifth indication application for sac-TMT that has been accepted by the NMPA.

The OptiTROP-Lung05 is a randomized, open-label, multicenter, Phase 3 clinical study that evaluates the efficacy and safety profile of sac-TMT in combination with pembrolizumab versus pembrolizumab monotherapy as first-line treatment for PD-L1-positive locally advanced or metastatic NSCLC. At a pre-specified interim analysis, the study has met its primary endpoint of progression-free survival (PFS) and demonstrated a statistically

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.

significant and clinically meaningful improvement as concluded by the Independent Data Monitoring Committee (IDMC). A positive trend in overall survival (OS) was also observed. Notably, the OptiTROP-Lung05 study is the first Phase 3 study of an immunotherapy and ADC combination to meet its primary endpoint in first-line NSCLC treatment. The study has also been selected for an oral presentation at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting (Abstract number #8506, Lung Cancer – Non-Small Cell Metastatic).

Previously, sac-TMT in combination with intravenous and subcutaneous pembrolizumab for the first-line treatment of patients with locally advanced or metastatic NSCLC who have PD-L1 TPS $\geq$ 1% and are EGFR-negative and ALK-negative was granted Breakthrough Therapy Designation (BTD) by the NMPA. On April 9, 2026, the CDE's official website announced that the Application has entered the priority review and approval process. This marks the fifth sac-TMT indication to enter the CDE's priority review and approval process. Through this process, the review time will be significantly shortened, potentially expediting its approval pathways.

ABOUT sac-TMT (佳泰莱®)

Sac-TMT, a core product of the Company, is a novel human 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 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, as a topoisomerase I inhibitor, 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; and 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 BTDs by the NMPA.

Sac-TMT is the world's first TROP2 ADC drug approved for marketing in lung cancer. A new indication application for sac-TMT in combination with pembrolizumab (KEYTRUDA®) as first-line treatment for locally advanced or metastatic NSCLC who have PD-L1 TPS≥1% and are EGFR-negative and ALK-negative has been accepted for review by the NMPA, and has entered the the priority review and approval process.

As of today, the Company has initiated 9 registrational clinical studies in China. MSD has initiated 17 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, May 8, 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.