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Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd.
四川科倫博泰生物醫藥股份有限公司
(A joint stock company incorporated in the People's Republic of China with limited liability)
(Stock Code: 6990)

VOLUNTARY ANNOUNCEMENT
CORE PRODUCT TROP2 ADC SACITUZUMAB TIRUMOTECAN (SAC-TMT) IN COMBINATION WITH IMMUNOTHERAPY PEMBROLIZUMAB GRANTED BREAKTHROUGH THERAPY DESIGNATION FOR FIRST-LINE TREATMENT OF PD-L1 POSITIVE LOCALLY ADVANCED, METASTATIC NSCLC 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 the Company's trophoblast cell-surface antigen 2 (TROP2)-directed antibody-drug conjugate (ADC) sacituzumab tirumotecan (sac-TMT, also known as SKB264/MK-2870) (佳泰萊®) in combination with MSD's anti-programmed cell death protein 1 (PD-1) monoclonal antibody (mAb) pembrolizumab (KEYTRUDA®[1]) was granted Breakthrough Therapy Designation (BTD) by the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of China for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) who have 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.

BTD is granted for treatment regimens that provide effective treatment or prevention for conditions with no currently available therapy, or that demonstrate significant clinical advantages over currently available treatments. For drugs included in the breakthrough therapy process, if relevant conditions are met, applications for conditional approval and priority review and approval can be submitted when applying for marketing authorization.

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

Previously, the company announced that results from the Phase 3 clinical trial of OptiTROP-Lung05, evaluating sac-TMT in combination with pembrolizumab as first-line treatment for PD-L1-positive NSCLC, demonstrated a statistically significant and clinically meaningful improvement in its primary endpoint of progression-free survival (PFS). A positive trend was also observed in overall survival (OS). OptiTROP-Lung05 is the first Phase 3 study of an immunotherapy and ADC combination to meet its primary endpoint in the first-line treatment of NSCLC. Granting of BTD for the first-line treatment of PD-L1-positive NSCLC indication offers pathways to expedite the review and potential approval process of sac-TMT for this indication.

To date, sac-TMT has received five BTDs for:

- locally advanced or metastatic triple-negative breast cancer (TNBC) in July 2022;
- locally advanced or metastatic EGFR-mutant NSCLC after progression on EGFR-tyrosine kinase inhibitor (TKI) therapy in January 2023;
- locally advanced or metastatic hormone-receptor positive (HR+) and human epidermal growth factor receptor 2-negative (HER2-) breast cancer (BC) in patients who have previously received at least two lines of systemic chemotherapy in June 2023;
- first-line treatment of unresectable locally advanced, recurrent or metastatic PD-L1 negative TNBC in March 2024;
- In combination with anti-PD-L1 monoclonal antibody tagitanlimab for the first-line treatment of locally advanced or metastatic non-squamous NSCLC without actionable genomic alterations in June 2025.

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, BC, gastric cancer (GC), gynecological tumors, among others. Sac-TMT is developed with a novel linker to conjugate the payload, a belotecan-derivative topoisomerase I inhibitor 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, three indications for sac-TMT have been approved and marketed in China for: EGFR mutant-positive locally advanced or metastatic non-squamous NSCLC following progression on EGFR-TKI therapy and platinum-based chemotherapy; unresectable locally advanced or metastatic TNBC who have received at least two prior systemic therapies (at least one of them for advanced or metastatic setting); EGFR mutant-positive locally advanced or metastatic non-squamous NSCLC who progressed after treatment with EGFR-TKI therapy. The first two indications listed above have been included in China's National Reimbursement Drug List (NRDL). This inclusion is expected to bring clinical benefits to a greater number of cancer patients.

Sac-TMT is the world's first TROP2 ADC drug approved for marketing in lung cancer. In addition, the supplemental NDA for sac-TMT for second-line and above treatment of HR+/HER2- BC was accepted by the Center for Drug Evaluation of the National Medical Products Administration, and was included in the priority review and approval process.

As of today, the Company has initiated 9 registrational clinical studies in China. MSD has initiated 15 ongoing Phase 3 global clinical studies of sac-TMT as a monotherapy or 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, January 5, 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.