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 PD-L1 MAB TAGITANLIMAB GRANTED BREAKTHROUGH THERAPY DESIGNATION FOR FIRST-LINE TREATMENT OF LOCALLY ADVANCED, METASTATIC NON-SQUAMOUS NSCLC WITHOUT ACTIONABLE GENOMIC ALTERATIONS 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) (佳泰萊®) in combination with the anti-programmed death ligand 1 (PD-L1) monoclonal antibody (mAb) tagitanlimab (科泰萊®) was granted Breakthrough Therapy Designation by the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of China for the first-line treatment of locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) without actionable genomic alterations. Breakthrough Therapy Designation is granted for treatment options that demonstrate significant clinical advantages over currently available treatments and is aimed at expediting the research, development and marketing of innovative treatment options that address clinically urgent medical needs.

This is the fifth Breakthrough Therapy Designation for sac-TMT granted by the NMPA. Previously, sac-TMT was granted Breakthrough Therapy Designation for locally advanced or metastatic triple negative breast cancer (TNBC) in July 2022, for epidermal growth factor receptor (EGFR)-mutant locally advanced or metastatic NSCLC after progression on EGFR-tyrosine kinase inhibitor (TKI) therapy in January 2023, for 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 systematic chemotherapy in June 2023, and for first-line treatment of unresectable locally advanced, recurrent or metastatic PD-L1 negative TNBC in March 2024.

Results from a Phase 2 OptiTROP-Lung01 study of sac-TMT in combination with tagitanlimab in first-line advanced or metastatic non-squamous NSCLC patients were presented in a poster session at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting[1].

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 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 (includes Mainland China, Hong Kong, Macao, and Taiwan).

To date, two indications for sac-TMT have been approved and marketed in China for the treatment of adult patients with 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) and EGFR mutation-positive locally advanced or metastatic non-squamous NSCLC following progression on EGFR-TKI therapy and platinum-based chemotherapy. Sac-TMT became the first domestic ADC with global intellectual property rights to be fully approved for marketing. It is also the world's first TROP2 ADC to be approved for marketing in a lung cancer indication. In addition, two new indication applications for sac-TMT for the treatment of adult patients with EGFR-mutant locally advanced or metastatic NSCLC who progressed after treatment with EGFR-TKI therapy and with unresectable locally advanced, metastatic HR+/HER2- BC who have received prior endocrine therapy and other systemic treatments in the advanced or metastatic setting were accepted by the CDE, and were included in the priority review and approval process. As of today, the Company has initiated 8 registrational clinical studies in China. MSD has initiated 14 ongoing Phase 3 global clinical studies of sac-TMT as a monotherapy or with pembrolizumab[2] or other agents for several types of cancer. These studies are sponsored and led by MSD.

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1 Abstract #8529: Lung Cancer – Non-Small Cell Metastatic, ASCO Annual Meeting, 2025.

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

ABOUT Tagitanlimab(科泰莱®)

Tagitanlimab is the first PD-L1 mAb globally to receive authorization for the first-line treatment of NPC. Previously, the NMPA has approved the marketing in China of tagitanlimab used in combination with cisplatin and gemcitabine for the first-line treatment of patients with R/M NPC and monotherapy for the treatment of patients with recurrent or metastatic NPC who have failed after prior 2L+ chemotherapy, respectively.

RISK WARNING

SACITUZUMAB TIRUMOTECAN (SAC-TMT) AND TAGITANLIMAB 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, June 11, 2025

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, Mr. ZENG Xuebo and Mr. LI Dongfang as non-executive Directors, and Dr. ZHENG Qiang, Dr. TU Wenwei, Dr. JIN Jinping, and Dr. LI Yuedong as independent non-executive Directors.