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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 SACITUZUMAB TIRUMOTECAN (sac-TMT) APPROVED FOR MARKETING FOR THIRD INDICATION BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION IN EGFRm NSCLC FOLLOWING PROGRESSSION ON EGFR-TKI THERAPY

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) (佳泰莱®) was approved for marketing by the National Medical Products Administration (NMPA) for its third indication, the treatment of adult patients with epidermal growth factor receptor (EGFR) mutant-positive locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) who progressed after treatment with EGFR-tyrosine kinase inhibitor (TKI) therapy. Sac-TMT is the first and only ADC globally to show an overall survival (OS) benefit compared with platinum doublet chemotherapy and be approved for advanced NSCLC following progression on only TKI therapy (second line). In a pre-specified interim analysis of OS, compared with the current standard of care of platinum-based doublet chemotherapy, sac-TMT monotherapy demonstrated a statistically significant and clinically meaningful improvement in both progression-free survival (PFS) and OS, and significantly extends PFS and OS for these patients.

The approval is based on a randomized, open-label, multi-center Phase III study (OptiTROP-Lung04) that has been selected as a late-breaking abstract (LBA) at the 2025 European Society for Medical Oncology (ESMO) Congress and will be presented as an oral report in the Presidential Symposium session (Presentation # LBA5). The OptiTROP-Lung04 study evaluates the efficacy and safety profile of sac-TMT monotherapy at 5mg/kg every other week (Q2W) as an intravenous injection versus pemetrexed plus platinum chemotherapy for the treatment of patients with EGFR-mutant locally advanced or metastatic non-squamous NSCLC who have failed after treatment with EGFR-TKI therapy.

In March 2025, sac-TMT has been approved for EGFR mutant-positive locally advanced or metastatic non-squamous NSCLC following progression on EGFR-TKI therapy and platinum-based chemotherapy. Compared with current standard of care, sac-TMT monotherapy significantly extends the overall survival for these patients. Additionally, patient enrollment for a Phase III registrational study in China of sac-TMT combined with osimertinib as first-line treatment of locally advanced or metastatic non-squamous EGFR-mutant NSCLC has been completed.

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

To date, three indications for sac-TMT have been approved and marketed in China for the treatment of adult patients with 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), EGFR mutation-positive locally advanced or metastatic non-squamous NSCLC following progression on EGFR-TKI therapy and platinum-based chemotherapy and EGFR mutant-positive locally advanced or metastatic non-squamous NSCLC who progressed after treatment with EGFR-TKI therapy. Sac-TMT is the first TROP2 ADC drug approved for marketing in lung cancer globally. In addition, the new indication application for sac-TMT for the treatment of adult patients with unresectable locally advanced, metastatic hormone receptor positive (HR+) and human epidermal growth factor receptor 2-negative (HER2-) BC who have received prior endocrine therapy and other systemic treatments in the advanced or metastatic setting was accepted by the Center for Drug Evaluation of the NMPA, 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 14 ongoing Phase 3 global clinical studies of sac-TMT as a monotherapy or with pembrolizumab[1] 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 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 12, 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, 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.

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