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) APPROVED FOR MARKETING FOR FOURTH INDICATION BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION IN 2L+ HR+/HER2- BC

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 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) (佳泰萊®) has been approved by the National Medical Products Administration (NMPA) of China for treatment of adult patients with 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)-) breast cancer (BC) who have received prior endocrine therapy (ET) and at least one line of chemotherapy in advanced setting. This approval for HR+/HER2- BC after at least one prior line of chemotherapy marks the fourth indication for sac-TMT approved for marketing in China.

The approval is based on the positive results from the Phase 3 OptiTROP-Breast02 study which was selected as a Late-Breaking Abstract (LBA) and presented as an oral report at the 2025 European Society for Medical Oncology (ESMO) Congress.

The OptiTROP-Breast02 study evaluated the efficacy and safety of sac-TMT monotherapy compared to investigator's choice of chemotherapy in patients with unresectable or metastatic HR+/HER2- BC. Of the patients enrolled in this Phase 3 study, 95.7% had visceral metastases, 75.9% had liver metastases; 52.9% were HER2-zero (IHC 0), while 47.1% were HER2-low (IHC 1+ or IHC 2+/ISH-). All patients had received prior CDK4/6 inhibitor and taxane therapy; 56.6% had received ≥2 lines of prior chemotherapy in the advanced or metastatic

setting. Results showed that sac-TMT demonstrated a statistically significant and clinically meaningful increase in progression-free survival (PFS) as assessed by the Blinded Independent Central Review (BICR) compared to chemotherapy (8.3 vs. 4.1 months; hazard ratios (HR), 0.35; 95% confidence interval (CI): 0.26-0.48; p<0.0001). Consistent PFS benefits were observed across all pre-specified subgroups, including HER2-zero and HER2-low, number of chemotherapy lines received in the advanced or metastatic setting, presence of baseline visceral and liver metastases and previous CDK4/6 inhibitor use. According to BICR-assessed PFS results, the HR in the HER2-zero and HER2-low (IHC 1+ or IHC 2+/ISH-) subgroups were 0.39 (95% CI: 0.26-0.57) and 0.31 (95% CI: 0.20-0.48), respectively. A trend towards overall survival (OS) benefit and a significantly higher objective response rate (ORR) (41.5% vs. 24.1%) were also observed compared to chemotherapy[1].

Currently, Phase 3 clinical studies of sac-TMT with or without pembrolizumab (KEYTRUDA®[2]) for the treatment of chemotherapy-naïve HR+/HER2- BC who have received prior ET have been initiated globally (NCT06312176) and in China (NCT07071337).

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 non-small cell lung cancer (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).

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1 Fan Y, Li H, Wang H, et al. ESMO Congress 2025, LBA23.

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

To date, four indications for sac-TMT have been approved and marketed in China for: epidermal growth factor receptor (EGFR) mutant-positive locally advanced or metastatic non-squamous NSCLC following progression on EGFR-tyrosine kinase inhibitor (TKI) therapy and platinum-based chemotherapy; 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 mutant-positive locally advanced or metastatic non-squamous NSCLC who progressed after treatment with EGFR-TKI therapy; unresectable or metastatic HR+/HER2- (IHC 0, IHC 1+ or IHC 2+/ISH-) BC who have received prior ET and at least one line of chemotherapy in advanced setting. 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 patients with BC and NSCLC. Additionally, sac-TMT has been granted six Breakthrough Therapy Designations (BTDs) by the NMPA.

Sac-TMT is the world's first TROP2 ADC drug approved for marketing in lung cancer. As of today, the Company has initiated 9 registrational clinical studies in China. MSD is evaluating 16 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, February 6, 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.