

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.



KELUN-BIOTECH
科伦博泰

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

PRIMARY ENDPOINT MET FOR PHASE 3 STUDY OF CORE PRODUCT TROP2 ADC SACITUZUMAB TIRUMOTECAN (sac-TMT) IN COMBINATION WITH PEMBROLIZUMAB AS FIRST-LINE TREATMENT OF PATIENTS WITH PD-L1-NEGATIVE LOCALLY ADVANCED OR METASTATIC NON-SQUAMOUS NSCLC

The board (the “**Board**”) of directors (“**Directors**”) of Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (the “**Company**”) is pleased to announce that the Independent Data Monitoring Committee (IDMC) concluded that the Phase 3 clinical study (OptiTROP-Lung06) of its trophoblast cell-surface antigen 2 (TROP2)-directed antibody drug conjugate (ADC) sacituzumab tirumotecan (sac-TMT, also known as SKB264/MK-2870) (佳泰莱®), in combination with MSD’s¹ anti-programmed cell death protein 1 (PD-1) therapy KEYTRUDA^{®2} (pembrolizumab) as a first-line treatment for programmed death-ligand 1 (PD-L1)-negative locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) has met its primary endpoint of progression-free survival (PFS) at a prespecified interim analysis. This is the world’s first Phase 3 clinical study of an ADC combined with an immune checkpoint inhibitor to meet its primary endpoint in the first-line treatment of driver gene-negative and PD-L1-negative non-squamous NSCLC.

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.

OptiTROP-Lung06 is a randomized, open-label, multicenter Phase 3 clinical study evaluating the efficacy and safety of sac-TMT in combination with pembrolizumab versus chemotherapy plus pembrolizumab as first-line treatment for patients with locally advanced or metastatic non-squamous NSCLC who have PD-L1 tumor proportion score (TPS)<1%. The primary endpoint of the study was PFS assessed by blinded independent central review (BICR); secondary endpoints included overall survival (OS), safety and others. At a pre-specified interim analysis, the sac-TMT plus pembrolizumab therapy demonstrated a statistically significant and clinically meaningful improvement in PFS compared with pembrolizumab combined with pemetrexed and platinum-based chemotherapy, and a positive trend in OS was also observed. The safety profile of sac-TMT plus pembrolizumab was consistent with that observed in previously reported studies, and no new safety signals were observed. The Company plans to communicate with the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of China based on the results of this sac-TMT study.

Previously, the Phase 3 registrational OptiTROP-Lung05 study of sac-TMT in combination with pembrolizumab as first-line treatment for PD-L1-positive NSCLC had successfully met its primary endpoint, supporting the submission of a new indication application to the CDE. The findings of the OptiTROP-Lung05 study were presented as an oral report at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting and simultaneously published in The Lancet. The positive results from the OptiTROP-Lung06 study mark the further expansion of sac-TMT plus immunotherapy into the PD-L1-negative population in first-line non-squamous NSCLC, providing clinical support for this combination strategy to cover a broader first-line NSCLC population and are expected to drive the optimization of first-line treatment landscape for driver gene-negative non-squamous NSCLC.

Sac-TMT is currently being evaluated in ten registrational studies in lung cancer, including five registrational studies in China and five global multicenter Phase 3 studies.

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 epidermal growth factor receptor tyrosine kinase inhibitor (EGFR-TKI) therapy and platinum-based chemotherapy; 3) epidermal growth factor receptor (EGFR) mutant-positive locally advanced or metastatic non-squamous NSCLC who progressed after treatment with EGFR-TKI therapy; 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 Breakthrough Therapy Designations (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 $\geq$ 1% and are EGFR-negative and anaplastic lymphoma kinase (ALK)-negative has been accepted for review by the NMPA, and has entered 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, July 15, 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.