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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
RESULTS FROM MULTIPLE STUDIES OF INNOVATIVE DRUGS AT
2026 ESMO CONGRESS

The board (the “**Board**”) of directors (“**Directors**”) of Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (the “**Company**”) is pleased to announce that at the 2026 European Society for Medical Oncology (ESMO) Congress held in Madrid, Spain from October 23 to 27, the Company has presented results from multiple clinical studies, including data from 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®) and B7-H3-targeted ADC SKB500.

TWO STUDIES OF sac-TMT (佳泰莱®) SELECTED FOR LATE BREAKING ABSTRACT (LBA) ORAL REPORT

Among these, the results of a Phase 3 OptiTROP-Lung06 study for sac-TMT (佳泰莱®) in combination with MSD¹'s anti-programmed cell death protein 1 (PD-1) monoclonal antibody therapy pembrolizumab (KEYTRUDA®²) versus platinum-based doublet chemotherapy plus pembrolizumab as first-line treatment for programmed cell death ligand 1 (PD-L1)-negative advanced non-squamous non-small cell lung cancer (NSCLC) (LBA66; Proffered paper | NSCLC, metastatic) and the prespecified final overall survival (OS) analysis results of a Phase 3 OptiTROP-Lung04 study for sac-TMT (佳泰莱®) monotherapy versus platinum-based doublet chemotherapy in epidermal growth factor receptor (EGFR)-mutated locally advanced or metastatic non-squamous NSCLC after progression on EGFR-tyrosine kinase inhibitor (TKI) (LBA67; Proffered paper | NSCLC, metastatic) were presented as oral presentations. The key highlights are summarized as follows:

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

OptiTROP-Lung06 is a randomized, multicenter, open-label Phase 3 study. A total of 455 patients were enrolled and randomized (1:1) to receive sac-TMT plus pembrolizumab or platinum-based doublet chemotherapy (pemetrexed plus cisplatin or carboplatin) plus pembrolizumab. The primary endpoint is PFS assessed by BICR, and secondary endpoints include OS. As of the data cut-off date of June 9, 2026, the median follow-up was 9.7 months. The findings of OptiTROP-Lung06 have also been simultaneously published in the medical journal *The New England Journal of Medicine* (Impact Factor=84.5). This is the world's first Phase III 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, PD-L1-negative non-squamous NSCLC.

The interim analysis data showed that:

- The sac-TMT plus pembrolizumab demonstrated significant improvement in progression-free survival (PFS) compared with the platinum-based doublet chemotherapy plus pembrolizumab in first-line treatment of patients with PD-L1-tumor proportion score (TPS)<1%, EGFR mutation-negative and anaplastic lymphoma kinase (ALK)-negative advanced non-squamous NSCLC—median PFS assessed by blinded independent central review (BICR) was 15.0 months (95% confidence interval (CI) 9.9-not evaluable) vs 5.7 months (95% CI 5.5-7.4), with a 51% reduction in the risk of disease progression or death (hazard ratio (HR) 0.49; 95% CI 0.36-0.65, $P<0.0001$);
- As assessed by BICR, the median duration of response was 13.6 months and 6.8 months in both groups, respectively (HR 0.47; 95% CI 0.29-0.77); the objective response rate was 50.2% and 47.3% in the two groups, respectively; the deep response rate was 28.8% and 17.3%, respectively. Deep response was defined as achieving complete or partial response with at least a 50% reduction in the sum of target lesion diameters from baseline;
- A favorable trend toward benefit in OS was observed—at this PFS interim analysis, the OS HR was 0.58 (95% CI 0.38-0.88), and median OS was not reached in both groups.

In terms of safety, the safety profile of sac-TMT plus pembrolizumab was generally consistent with those known to individual agents. No new safety signals were observed. Compared with the platinum-based doublet chemotherapy plus pembrolizumab group, the sac-TMT combination treatment group had lower incidences of Grade $\geq$ 3 treatment-emergent adverse events (TEAEs), and lower incidences of TEAEs leading to dose reduction or permanent discontinuation. The incidence of interstitial lung disease/pneumonitis was similar between the two groups.

OptiTROP-Lung04

OptiTROP-Lung04 is a randomized, multicenter, open-label Phase 3 study. A total of 376 patients were enrolled and randomized (1:1) to receive sac-TMT monotherapy (5 mg/kg Q2W) or platinum-based doublet chemotherapy (pemetrexed plus platinum). The primary endpoint was BICR-assessed PFS, and OS was a key secondary endpoint. The results of the final PFS analysis and interim OS analysis were published online in *The New England Journal of Medicine* in 2025. The final PFS analysis assessed by BICR showed a 51% reduction in the risk of disease progression or death (HR 0.49; 95% CI 0.39-0.62). Based on these results, sac-TMT was approved by the NMPA of China in September 2025 for the treatment of adult patients with EGFR mutant-positive locally advanced or metastatic non-squamous NSCLC who progressed after treatment with EGFR-TKI therapy. At this congress, the final OS analysis results after extended follow-up were presented. As of the data cut-off date of August 6, 2026, the median follow-up was 32.3 months.

The data showed that:

- Sac-TMT monotherapy demonstrated a sustained OS benefit compared with platinum-based doublet chemotherapy, with an 8.5-month improvement in median OS (25.9 months vs 17.4 months) and a 31% reduction in the risk of death (HR 0.69; 95% CI 0.54-0.89; one-sided P=0.0021);
- the 2-year OS rate was 54.1% vs 37.2%, an improvement of 16.9%;
- 22.6% of patients in the platinum-based doublet chemotherapy group received subsequent therapy with an ADC. After adjustment using the prespecified rank-preserving structural failure time (RPSFT) model, median OS showed a 9.3-month improvement in the sac-TMT group compared with the chemotherapy group (25.9 months vs 16.6 months), with a 43% reduction in the risk of death (HR 0.57), providing supplemental support for the OS primary analysis.

In terms of safety, no new safety signals were identified during the extended follow-up. The most common treatment-related adverse events were hematological adverse events and stomatitis. Stomatitis was mostly Grade 1-2 and manageable, with the incidences of Grade 3 events being 4.8%. Interstitial lung disease/pneumonitis was reported in only 1 case (0.5%) in the sac-TMT group and 2 cases (1.1%) in the platinum-based doublet chemotherapy group, all of which were Grade 1-2.

The details of the Company's other studies are as follows:

Breast cancer	
Final OS analysis of sacituzumab tirumotecan versus chemotherapy in previously treated locally recurrent or metastatic triple-negative breast cancer: Phase 3 OptiTROP-Breast01	4639RO, Rapid oral Breast cancer, advanced stage October 26, 10:15 to 11:45 local time
Lung cancer	
SKB500 (a novel B7-H3-targeted antibody-drug conjugate) in patients with extensive-stage small cell lung cancer (ES-SCLC): Results from a Phase 1 study	3816RO, Rapid oral Non-metastatic NSCLC and other thoracic malignancies October 26, 10:15 to 11:45 local time
Genitourinary cancers	
Sacituzumab tirumotecan (sac-TMT) + pembrolizumab (pembro) for locally advanced or metastatic urothelial carcinoma (la/mUC): Results from a Phase 2 Study (2870-002/SKB264-II-06)	4739RO, Rapid oral Genitourinary tumours, renal and urothelial October 24, 10:15 to 11:45 local time
Gynecologic cancers	
Sacituzumab tirumotecan (sac-TMT) + pembrolizumab (pembro) in post-platinum advanced mismatch repair proficient (pMMR) endometrial cancer (EC): Results from a Phase 2 study (2870-002/SKB264-II-06)	1259P, Poster Gynaecological cancers October 26, 12:00 to 12:45 local time

Full abstracts for the abovementioned studies were published on ESMO's official website³.

³ <https://cslide.ctimeetingtech.com/esmo2026/attendee/confcal>

About sac-TMT (佳泰莱®)

Sac-TMT, a core product of the Company, is a novel 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 (KL610023) 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 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 EGFR-TKI therapy and platinum-based chemotherapy; 3) 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 by the NMPA.

Sac-TMT is the world's first TROP2 ADC drug approved for marketing in lung cancer. Two new indication applications have been accepted for review by the NMPA: 1) sac-TMT in combination with pembrolizumab as first-line treatment for locally advanced or metastatic NSCLC who have PD-L1 TPS $\geq 1\%$ and are EGFR-negative and ALK-negative; and 2) sac-TMT as first-line treatment for patients with recurrent or metastatic TNBC who have a PD-L1 combined positive score (CPS) < 10 or have recurred after prior PD-1/PD-L1 inhibitor therapy

in the early stage, both of the above two applications have been included in the priority review and approval process. As of today, the Company has initiated 9 registrational clinical studies in China. MSD has initiated 18 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.

About SKB500

SKB500 is a B7-H3-targeted ADC independently developed by the company using its OptiDC™ platform technology, featuring a site-specific cleavable linker and a potent topoisomerase I inhibitor. In the Phase 1 clinical study, SKB500 demonstrated robust efficacy and manageable safety profiles across multiple advanced solid tumors. Currently, Phase 2 studies of SKB500 in extensive-stage small cell lung cancer (ES-SCLC) and advanced esophageal squamous cell carcinoma (ESCC), etc. are ongoing in China.

RISK WARNING

SACITUZUMAB TIRUMOTECAN (SAC-TMT) FOR THE TREATMENT OF OTHER INDICATIONS NOT YET APPROVED AND SKB500 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, October 25, 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.