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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 ASCO ANNUAL MEETING

The board (the “**Board**”) of directors (“**Directors**”) of Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (the “**Company**”) is pleased to announce that at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting to be held in Chicago, Illinois, USA from May 29 to June 2, 2026, the Company will present results from multiple clinical studies led by the Company, where two registrational studies of the trophoblast cell-surface antigen 2 (TROP2)-directed antibody drug conjugate (ADC) sacituzumab tirumotecan (sac-TMT) (佳泰莱[®]) and the next-generation selective rearranged during transfection (RET) inhibitor lunbotinib fumarate (A400/EP0031, 宁泰莱^{®1}) have been selected for oral presentation session on Lung Cancer – Non-Small Cell Metastatic. Key highlights are summarized as follows:

STUDY#1

Sacituzumab tirumotecan (sac-TMT) plus pembrolizumab versus pembrolizumab as first-line treatment for PD-L1 positive advanced non-small cell lung cancer (NSCLC): Results from the randomized, controlled Phase III OptiTROP-Lung05 study, to be presented as an oral presentation scheduled on May 29, 2026, 3:12 PM-3:24 PM CDT (Abstract #8506: Lung Cancer – Non-Small Cell Metastatic)

¹ Trade name to be approved by NMPA.

A total of 413 patients with previously untreated locally advanced or metastatic NSCLC without epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) alterations and with programmed death ligand 1 (PD-L1) positive (defined as tumor proportion score (TPS) $\geq 1\%$), covering both squamous and non-squamous histologies, were enrolled and randomized (1:1) to receive sac-TMT (4 mg/kg once every 2 weeks (Q2W)) plus pembrolizumab (400 mg Q6W) or pembrolizumab monotherapy (400 mg once every 6 weeks (Q6W)). The primary endpoint was progression-free survival (PFS) assessed by blinded independent central review (BICR), and the key secondary endpoint was overall survival (OS). As of September 29, 2025, the median follow-up was 10.5 months.

The results demonstrated that:

- Significant PFS improvement: PFS assessed by BICR was significantly improved in the sac-TMT plus pembrolizumab group compared with the pembrolizumab group, with a median PFS of not reached (NR) versus 5.7 months (hazard ratio (HR)=0.35; 95% confidence interval (CI): 0.26–0.47; $p < 0.0001$);
- Substantially higher response rate: The objective response rate (ORR) assessed by BICR was 70.2% in the sac-TMT plus pembrolizumab group versus 42.0% in the pembrolizumab group;
- Positive OS trend though immature (HR=0.55; 95% CI: 0.36–0.85);
- Consistent benefit across prespecified subgroups: the HR for PFS in patients with PD-L1 TPS 1–49% and TPS $\geq 50\%$ were 0.28 (95% CI, 0.19–0.41) and 0.47 (95% CI, 0.29–0.77), respectively; the HR for PFS in patients with non-squamous and squamous NSCLC were 0.28 (95% CI, 0.18–0.43) and 0.44 (95% CI, 0.29–0.66).

In terms of safety, grade ≥ 3 treatment-emergent adverse events (TEAEs) occurred in 55.3% of patients in the sac-TMT plus pembrolizumab group versus 31.4% in the pembrolizumab group. TEAEs leading to permanent discontinuation of sac-TMT and pembrolizumab occurred in 3.8% and 5.3% of patients, respectively, while TEAEs leading to permanent discontinuation occurred in 4.9% of patients in the pembrolizumab group.

OptiTROP-Lung05 is the first Phase 3 clinical study demonstrating a significant improvement in PFS and a positive trend in OS with an ADC combined with pembrolizumab compared to pembrolizumab in first-line treatment for PD-L1 positive advanced NSCLC. Based on these results, a supplemental New Drug Application (sNDA) for this combination regimen has been accepted for review and included in the priority review and approval process by the National Medical Products Administration (NMPA) in China.

STUDY#2

Efficacy and safety of lunbotinib (A400/EP0031), a next-generation selective RET inhibitor (SRI), from a pivotal phase II study in patients with advanced RET-fusion positive non-small cell lung cancer (NSCLC), to be presented as an oral presentation scheduled on May 29, 2026, 2:36 PM-2:48 PM CDT (Abstract #8505: Lung Cancer – Non-Small Cell Metastatic)

As of October 29, 2025, 71 patients with prior platinum-based chemotherapy and immunotherapy (pre-treated patients) and 92 patients who had not received prior systemic therapy (treatment-naïve patients) were enrolled, with median follow-up of 22.6 and 20.7 months.

The study demonstrated that:

- Independent Review Committee (IRC)-assessed confirmed ORR was 87.1% (95% CI: 77.0–93.9) in pre-treated patients and 81.3% (95% CI: 71.8–88.7) in treatment-naïve patients;
- mPFS was 27.5 months in pre-treated patients (immature) and NR in treatment-naïve patients, with 24-month PFS rates of 52.1% and 59.9%, respectively;
- Median OS was not reached in either group, with 24-month OS rates of 65.7% in pre-treated patients and 74.1% in treatment-naïve patients;
- Among patients with baseline brain metastases (23 pre-treated, 16 treatment-naïve), ORR was 82.6% and 75.0%, respectively, and 6 patients in each cohort had complete intracranial response.

The safety profile was manageable, with no new signals identified. Grade $\geq$ 3 treatment-related adverse events (TRAEs) occurred in 40.5% of patients. Only two patients (1.2%) permanently discontinued treatment due to TRAEs. No fatal TRAEs occurred.

Based on the results of this study, the NDA for lunbotinib fumarate for the treatment of adult patients with RET fusion-positive locally advanced or metastatic NSCLC has been accepted for review by the NMPA.

Additionally, results of an open-label, first-in-human study of SKB500 in patients with locally advanced or metastatic solid tumors will be presented as a rapid oral report on June 2, 2026, 9:57 AM-10:03 AM CDT (Abstract #3011, Molecular Targeted Agents and Tumor Biology).

The full text of the above abstracts has been published on the ASCO official website² on May 21, 2026, local time.

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 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 (BTDs) by the NMPA.

² <https://meetings.asco.org/meetings/2026-asco-annual-meeting/335/program-guide/scheduled-sessions>.

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^{®3}) as first-line treatment for locally advanced or metastatic NSCLC who have PD-L1 TPS $\geq$ 1% and are EGFR-negative and ALK-negative has been accepted for review by the NMPA, and has entered the priority review and approval process. As of today, Kelun-Biotech has initiated 9 registrational clinical studies in China. MSD is evaluating 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.

ABOUT LUNBOTINIB FUMARATE (A400/EP0031) (宁泰莱[®])

Lunbotinib fumarate is a novel, next-generation selective RET inhibitor for NSCLC, medullary thyroid cancer (MTC) and other solid tumors with a high prevalence of RET alterations. The NDA of lunbotinib fumarate has been accepted for review by the NMPA of China for the treatment of adult patients with RET-fusion positive locally advanced or metastatic NSCLC. The Company is also conducting a Phase 1b/2 clinical study in China for the treatment of RET-positive solid tumors.

In March 2021, the Company granted Ellipses Pharma Limited, a U.K.-based international oncology drug development company, an exclusive license to develop, manufacture and commercialize this agent outside Greater China and certain Asian countries. In April 2024, lunbotinib fumarate was cleared by the Food and Drug Administration (FDA) to progress into a Phase 2 clinical trial (NCT05443126) which is currently recruiting in the United States, United Kingdom, Europe and United Arab Emirates, where it is being evaluated as a monotherapy and in combination with chemotherapy in RET fusion positive advanced NSCLC.

ABOUT SKB500

SKB500 is a novel B7-H3-targeted ADC independently developed by the company using its OptiDC[™] platform technology. It targets a validated target and employs a differentiated antibody and payload-linker strategy. In the Phase I clinical study, SKB500 demonstrated robust efficacy and manageable safety profiles across multiple advanced solid tumors. Currently, a Phase 2 exploratory study of SKB500 in combination with immunotherapy with or without chemotherapy as first-line treatment for extensive-stage small cell lung cancer (ES-SCLC) is ongoing in China.

³ KEYTRUDA[®] (pembrolizumab) is a registered trademark of Merck Sharp & Dohme LLC (MSD), a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

RISK WARNING

SACITUZUMAB TIRUMOTECAN (SAC-TMT) FOR THE TREATMENT OF OTHER INDICATIONS NOT YET APPROVED, LUNBOTINIB FUMARATE 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, May 22, 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.