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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
RESULTS FROM MULTIPLE STUDIES OF INNOVATIVE DRUGS AT 2025 ESMO CONGRESS

The board (the "**Board**") of directors (the "**Directors**") of Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (the "**Company**") is pleased to announce that at the 2025 European Society for Medical Oncology (ESMO) Congress held in Berlin, Germany from October 17 to 21, 2025, 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) (佳泰莱®), human epidermal growth factor receptor 2 (HER2)-directed ADC trastuzumab botidotin (also known as A166) (舒泰莱®), and Claudin18.2 (CLDN18.2) ADC SKB315.

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

Among these, a Phase 3 OptiTROP-Lung04 study of sac-TMT in EGFR-mutated non-small cell lung cancer (NSCLC) following progression on epidermal growth factor receptor-tyrosine kinase inhibitors (EGFR-TKIs) (Presentation # LBA5, Presidential Symposium II) and a Phase 3 OptiTROP-Breast02 study of sac-TMT in previously treated locally advanced or metastatic hormone receptor-positive (HR+) and HER2-negative (HER2-) breast cancer (BC) (Presentation # LBA23, Proffered paper session 1: Breast cancer, metastatic) were presented as oral reports. The key highlights are summarized as follows:

OptiTROP-Lung04

A total of 376 patients were randomized (1:1) to receive sac-TMT monotherapy or chemotherapy. As at the data cutoff of July 06, 2025, the median follow-up is 18.9 months. The median progression-free survival (PFS) was 8.3 months in the sac-TMT group and 4.3

months in the chemotherapy group. Sac-TMT significantly improved PFS over chemotherapy with 51% lower risk of disease progression or death (hazard ratio (HR) 0.49; 95% confidence interval (CI), 0.39-0.62; P<0.0001). At the preplanned interim analysis of overall survival (OS), the OS was not reached in the sac-TMT group and 17.4 months in the chemotherapy group. Sac-TMT significantly improved OS over chemotherapy with 40% lower risk of death (HR 0.6; 95% CI: 0.44-0.82; two-sided P=0.001). In the supplemental analysis, when censoring patients at the date of initiation of subsequent ADCs, sac-TMT significantly improved OS over chemotherapy with 44% lower risk of death (HR, 0.56; 95% CI, 0.41-0.77). Sac-TMT significantly improved objective response rate (ORR) as compared to chemotherapy (60.6% vs 43.1%).

A consistent PFS and OS benefit of sac-TMT over chemotherapy was observed across all predefined subgroups, including prior EGFR-TKI therapy, presence of liver or brain metastases, and EGFR mutation subtype.

The incidence of any grade TRAEs and grade ≥3 TRAEs was similar between the two groups. The most common TRAEs for both sac-TMT and chemotherapy were hematologic toxicities. No TRAEs led to discontinuation or death, and no cases of interstitial lung disease/ pneumonitis were reported in the sac-TMT group. Ocular surface toxicity: occurred in 9.6% of patients in the sac-TMT group, all of which were grade 1-2.

The study results were simultaneously published at the New England Journal of Medicine (Impact Factor = 78.5).

OptiTROP-Breast02

A total of 399 patients with HR+/HER2- BC who had progression on CDK4/6 inhibitors and received at least one prior line of chemotherapy in the advanced/metastatic setting were randomized (1:1) to receive sac-TMT or investigator's choice of chemotherapy (ICC). As at the data cut-off date January 22, 2025, the median PFS was significantly longer in sac-TMT than in ICC (8.3 vs 4.1 months; HR, 0.35; 95% CI, 0.26-0.48; P<0.0001). Clinical benefit was seen in sac-TMT independent of HER2 expression (HR for PFS in HER2-zero: 0.39, 95% CI, 0.26-0.57; in HER2-low: 0.31, 95% CI, 0.20-0.48). Sac-TMT showed longer duration of response (DoR) versus chemotherapy; and ORR was also superior with sac-TMT to ICC (41.5% vs 24.1%). There was a trend in OS that favored sac-TMT over ICC (HR, 0.33; 95% CI, 0.18-0.61).

Grade ≥3 TRAEs occurred in 62.0% and 64.8% of patients in sac-TMT and ICC. TRAE led to discontinuation in 0% and 0.5% of patients; pneumonitis occurred in 1.5% and 1.0% of patients (all grade 1-2) in sac-TMT and ICC, respectively.

THE STUDY OF TRASTUZUMAB BOTIDOTIN (舒泰莱®) SELECTED FOR LBA ORAL REPORT

Results from a Phase 3 study of trastuzumab botidotin versus trastuzumab emtansine (T-DM1) in HER2-positive unresectable or metastatic BC was also presented as an oral report (Presentation # LBA24, Proffered paper session 1: Breast cancer, metastatic). A total of 365 patients with HER2+ unresectable or metastatic BC who had received at least one prior anti-HER2 therapy were randomized (1:1) to receive trastuzumab botidotin or T-DM1. 53% of patients had received ≥2 lines of anti-HER2 therapy, 61% of patients had HER2 Immunohistochemistry (IHC) 3+, and 60% of patients had been treated with TKIs, particularly pyrotinib (56%). As of April 26, 2025, median follow-up was 14.9 months. Median PFS was significantly longer in trastuzumab botidotin than in T-DM1 (11.1 months vs 4.4 months; HR: 0.39, 95% CI, 0.30-0.51, p<0.0001). PFS benefit with trastuzumab botidotin was consistently observed regardless of prior lines of anti-HER2 therapy (HR 0.36, 95% CI, 0.25-0.53, for 1 prior line; HR 0.39, 95% CI, 0.28-0.56, for ≥2 prior lines). ORR by blinded independent central review (BICR) was 76.9% vs 53.0%. A trend toward benefit in OS was observed in trastuzumab botidotin (HR 0.62; 95% CI, 0.38-1.03).

Grade ≥3 treatment emergent adverse events (TEAEs) occurred in 69.8% of patients in trastuzumab botidotin and 63.7% in T-DM1. The most common TEAEs associated with dose reduction were ocular AEs for trastuzumab botidotin, and were platelet count decreased for trastuzumab emtansine. Only two patients permanently discontinued trastuzumab botidotin due to TEAE. No on-treatment deaths were observed in trastuzumab botidotin, compared with 1.6% in T-DM1.

THE STUDY OF SKB315 SELECTED FOR THE POSTER SESSION

Additionally, the results from a Phase 1 study of SKB315 in patients with advanced solid tumors including gastric cancer/gastroesophageal junction cancer (GC/GEJC) was presented in a poster session (Presentation # 2139P). As of February 10, 2025, 73 patients were enrolled. Of 32 evaluable (≥1 on-study scan) CLDN18.2-expressing (H-score ≥80) patients with GC/GEJC at ≥2.4 mg/kg, the ORR and DCR were 37.5% and 84.4%, respectively. Median PFS was 8.2 months (95% CI: 2.7, 9.8), and median OS was 12.4 months (95% CI: 4.9, 17.8). In the subset of patients with GC/GEJC at 5.4 mg/kg Q2W, the ORR and DCR were 41.7% (5/12) and 91.7% (11/12), respectively. Dose-limiting toxicities (DLTs) were observed in 5 patients. Grade ≥3 TRAEs occurred in 39.7% of patients. TRAEs led to treatment discontinuation in 4 (5.5%) patients. No TRAE led to death.

Other studies presented in poster sessions are listed below:

Title	Presentation #
Sacituzumab Tirumotecan (sac-TMT) in Participants (pts) with Previously Treated, Advanced KRAS-Mutant NSCLC: Results From Cohort 5d of the SKB264-II-08 Study	1945P
Sacituzumab Tirumotecan (sac-TMT) + Pembrolizumab[1] (pembro) for Treatment-Naïve Advanced PD-L1 Positive NSCLC: Results From the Phase 2 MK-2870-003/SKB264-II-04 Study	1949P
Sacituzumab Tirumotecan (Sac-TMT) + Pembrolizumab (Pembro) in Metastatic Castration-Resistant Prostate Cancer (mCRPC): Results from Phase 2 MK-2870-002/SKB264-II-06 Study	2421P
Sacituzumab Tirumotecan (Sac-TMT) Monotherapy in Advanced/ Metastatic Endometrial Carcinoma (EC): Results From a Phase 1/2 Study (MK-2870-001/KL264-01)	1111P
Efficacy and Safety of Sacituzumab Tirumotecan (Sac-TMT) Monotherapy in Advanced/Metastatic Cervical Cancer: Results From a Phase 1/2 Study	1168P

The full abstracts for the abovementioned studies were published on ESMO's official website[2].

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, BC, 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.

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

[2] https://cslide.ctimeetingtech.com/esmo2025/attendee/confcal/session

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, 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 HR+/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 (CDE) of the National Medical Products Administration (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 15 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.

ABOUT TRASTUZUMAB BOTIDOTIN (舒泰萊®)

Trastuzumab botidotin is a differentiated HER2 ADC to treat advanced HER2+ solid tumors. As an innovative HER2 ADC developed by the Company, it conjugates a novel, monomethyl auristatin F (MMAF) derivative (a highly cytotoxic tubulin inhibitor, Duo-5) via a stable, enzyme-cleavable linker to a HER2 monoclonal antibody with a DAR of 2. Trastuzumab botidotin specifically binds to HER2 on the surface of tumor cells and is internalized by tumor cells, releasing the toxin molecule Duo-5 inside the cell. Duo-5 induces tumor cell cycle arrest in the G2/M phase, leading to tumor cell apoptosis. After targeting HER2, trastuzumab botidotin can also inhibit the HER2 signaling pathway; it has antibody-dependent cell-mediated cytotoxicity (ADCC) activity.

Based on the results of a multi-center, randomized, open-label, controlled, Phase 3 KL166-III-06 study, trastuzumab botidotin was approved for marketing by the NMPA in for adult patients with unresectable or metastatic HER2 positive BC who have received one or more prior anti-HER2 therapy. At a pre-specified interim analysis, trastuzumab botidotin demonstrated a statistically significant and clinically meaningful improvement in the primary endpoint of PFS as assessed by the BICR compared with T-DM1; the beneficial trend for OS of trastuzumab botidotin was also observed.

Currently, the Company has initiated an open, multi-center Phase 2 clinical study of trastuzumab botidotin in the treatment of HER2+ unresectable or metastatic BC that previously received a topoisomerase inhibitor ADC.

ABOUT SKB315

SKB315 is a novel CLDN18.2 ADC targeting advanced solid tumors configured with a proprietary, in-house developed humanized CLDN18.2 monoclonal antibody and a differentiated payload-linker design. Currently, the Company has initiated the exploration in combination with immunotherapy for GC/GEJC while advancing monotherapy studies for tumors expressing CLDN18.2, such as GC/GEJC and pancreatic cancer.

RISK WARNING

SACITUZUMAB TIRUMOTECAN (SAC-TMT) AND TRASTUZUMAB BOTIDOTIN FOR THE TREATMENT OF OTHER INDICATIONS NOT YET APPROVED AND SKB315 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 20, 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.