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
STUDY RESULTS FOR CORE PRODUCT SACITUZUMAB TIRUMOTECAN (SAC-TMT) AT 2024 ASCO ANNUAL MEETING

The board (the "**Board**") of directors (the "**Directors**") of Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (the "**Company**") is pleased to announce that at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting to be held in Chicago, Illinois, the United States of America from May 31 to June 4, 2024, the Company will present results from the Phase 3 OptiTROP-Breast01 study of its anti-TROP2 ADC sacituzumab tirumotecan (sac-TMT) (formerly SKB264/MK-2870) in patients with previously treated locally recurrent or metastatic triple-negative breast cancer (TNBC) in an special clinical science symposium (Abstract #104; Next-Generation Antibody-Drug Conjugates: The Revolution Continues), which is scheduled on June 2, 2024, 9:45 AM to 11:15 AM local time. In addition, results from the Phase 2 OptiTROP-Lung01 study of sac-TMT in combination with KL-A167 (an anti-PD-L1 mAb) as first-line treatment for patients with advanced non-small cell lung cancer (NSCLC) will be presented in an oral abstract session (Abstract #8502; Lung Cancer – Non-Small Cell Metastatic) scheduled on May 31, 2024, 2:45 PM to 5:45 PM local time. Sac-TMT is jointly developed by the Company and MSD (the tradename of Merck & Co., Inc., Rahway, NJ, USA) at clinical stage.

The abstracts for the above studies were published on ASCO's official website on May 23, 2024, local time. The study results are summarized as follows:

TNBC

Patients were randomly assigned (1:1) to receive sac-TMT (n = 130) or chemotherapy (n = 133). The median age was 51 years; 87% had visceral metastases; 26% received prior PD-1/PD-L1 inhibitors; 48% received three or more prior lines of chemotherapy for advanced disease. The primary endpoint of progression free survival (PFS) was met based on interim analysis (data cut-off: Jun 21, 2023) with a 69% reduction in risk of progression or death (HR 0.31; 95% CI, 0.22 to 0.45; P <0.00001).

The median PFS, as assessed by BICR, was 5.7 months (95% CI, 4.3 to 7.2) with sac-TMT and 2.3 months (95% CI, 1.6 to 2.7) with chemotherapy; PFS rate at 6 months was 43.4% vs 11.1%. In the subset of patients with trophoblast cell-surface antigen 2 (TROP2) H-score > 200, the median PFS was 5.8 months with sac-TMT and 1.9 months with chemotherapy (HR 0.28; 95% CI, 0.17 to 0.48). At the first planned interim analysis for overall survival (OS) (data cut-off: Nov 30, 2023) with median follow-up of 10.4 months, OS was statistically significant in favor of sac-TMT (HR 0.53; 95% CI, 0.36 to 0.78; P =0.0005); the median OS was not reached (95% CI, 11.2 to NE) with sac-TMT and 9.4 months (95% CI, 8.5 to 11.7) with chemotherapy. The objective response rate (ORR) assessed by BICR was 43.8% with sac-TMT and 12.8% with chemotherapy.

Most common grade ≥ 3 treatment-related adverse events (TRAEs) (sac-TMT vs. chemotherapy) were neutrophil count decreased (32.3% vs. 47.0%), anemia (27.7% vs. 6.1%) and white blood cell count (WBC) decreased (25.4% vs. 36.4%).

A Phase 3 global study led by MSD of sac-TMT plus pembrolizumab versus treatment of physician's choice (TPC) in TNBC who received neoadjuvant therapy and did not achieve a pathological complete response (pCR) at surgery (NCT06393374) and a Phase 3 study led by the Company of sac-TMT in China for 1L treatment of unresectable locally advanced, recurrent or metastatic PD-L1 negative TNBC (NCT06279364) are ongoing.

NSCLC

Patients with treatment naive advanced NSCLC without actionable genomic alterations were enrolled to receive sac-TMT 5 mg/kg Q3W plus KL-A167 1200 mg Q3W (cohort 1A) or sac-TMT 5 mg/kg Q2W plus KL-A167 900 mg Q2W (cohort 1B) in a non-randomized manner until disease progression or unacceptable toxicity. As of January 2, 2024, 40 and 63 patients have been enrolled in cohort 1A and 1B, respectively. Median ages were 63/63 years (cohort 1A/1B); 97.5%/85.7% had Eastern Cooperative Oncology Group (ECOG) Performance status (PS) of 1; 30.0%/33.3%, 32.5%/30.2% and 37.5%/36.5% of patients had programmed death ligand 1 (PD-L1) expression < 1%, 1%-49% and ≥ 50% of tumor cells by IHC 22C3 pharmDx assay, respectively.

After median follow up of 14.0 months for cohort 1A, the ORR was 48.6% (18/37, 2 pending confirmation), disease control rate (DCR) was 94.6% and median PFS was 15.4 months (95% CI: 6.7, NE) with a 6-month PFS rate of 69.2%. After median follow-up of 6.9 months for cohort 1B, the ORR was 77.6% (45/58, 5 pending confirmation), DCR was 100% and median PFS was not reached with a 6-month PFS rate of 84.6%. Additional subgroup analyses of cohort 1B are shown in the following table:

	ORR, % (n/N)*	**6-month PFS rate, % (95% CI)**
Overall (N=63)	77.6 (45/58)	84.6 (71.4, 92.1)
Histology type		
Non-squamous (N=34)	72.7 (24/33)	93.8 (77.3, 98.4)
Squamous (N=29)	84.0 (21/25)	73.5 (49.9, 87.2)
PD-L1 TPS		
< 1% (N=21)	63.2 (12/19)	82.2 (54.3, 93.9)
1%-49% (N=19)	81.3 (13/16)	76.6 (41.2, 92.3)
≥ 50% (N=23)	87.0 (20/23)	91.3 (69.5, 97.8)

* Including confirmed or unconfirmed response. ORR was calculated based on response evaluable population defined as patients with ≥ 1 on-study scans.

In cohorts 1A and 1B, the most common Grade ≥ 3 TRAEs were neutrophil count decreased (30.0%/30.2%), WBC decreased (5.0%/17.5%), anemia (5.0%/15.9%), rash (5.0%/6.3%) and drug eruption (7.5%/0). Treatment-related adverse events leading to discontinuation of sac-TMT occurred in 1 patient of cohort 1B due to drug hypersensitivity, and there were no treatment-related deaths.

Two Phase 3 global studies led by MSD of sac-TMT in patients with 3L+ EGFR mutant NSCLC (NCT06074588), and 2L EGFR mutant NSCLC (NCT06305754) and a Phase 3 study led by the Company of sac-TMT in China in patients with 2L EGFR mutant NSCLC (NCT05870319) are ongoing. Additionally, Three Phase 3 global studies led by MSD of sac-TMT plus pembrolizumab are ongoing: one in patients with 1L Metastatic Squamous NSCLC (NCT06422143), a second in patients with metastatic NSCLC expressing PD-L1 ≥ 50% (NCT06170788), and the third in patients with resectable NSCLC not achieving a pathological complete response (NCT06312137).

RISK WARNING

SACITUZUMAB TIRUMOTECAN (SAC-TMT) 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 24, 2024

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 and Dr. WANG Jingyi as executive Directors, Mr. LIU Sichuan, Mr. FENG Hao, Mr. ZENG Xuebo and Mr. LI Dongfang as non-executive Directors, and Dr. ZHENG Qiang, Dr. TU Wenwei, Dr. JIN Jinping, and Dr. LI Yuedong as independent non-executive Directors.