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 AACR ANNUAL MEETING 2024

The board (the "**Board**") of directors (the "**Directors**") of Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (the "**Company**") is pleased to announce that at the American Association for Cancer Research (AACR) Annual Meeting 2024 to be held in San Diego, California, the United States of America from April 5 to 10, 2024, the Company will present updated efficacy and safety results for its anti-TROP2 ADC sacituzumab tirumotecan (sac-TMT) (formerly SKB264/MK-2870) in patients with previously treated advanced non-small cell lung cancer (NSCLC) from a phase 2 study in a poster session scheduled on April 9 2024, 1:30 PM – 5:00 PM local time (Abstract Presentation Number: CT247), and present preliminary efficacy and safety results for its anti-TROP2 ADC sac-TMT in patients with previously treated advanced gastric or gastroesophageal junction (GEJ) cancer from a phase 2 study in an oral presentation, which is scheduled in a session on April 9 2024, 2:30 PM – 4:30 PM local time (Abstract Presentation Number: CT038).

The abstracts for the above studies were published on AACR's official website on April 5, 2024, local time. The study results are summarized as follows:

NSCLC

Patients with previously treated advanced NSCLC were enrolled to receive sac-TMT at 5 mg/kg Q2W until disease progression or unacceptable toxicity (KL264-01, NCT04152499). The data cut-off date was November 22, 2023 (the "**Data Cut-off Date**").

As of the Data Cut-off Date, 43 NSCLC patients had been enrolled and the median follow-up was 17.2 months. 21 patients with EGFR wild type had received a median of 3 prior regimens of therapy including anti-PD-1/L1 inhibitors. 22 patients with EGFR mutant had progressed on or after TKI therapy, 50% of whom also failed at least one line of chemotherapy. Updated efficacy results are shown in the following:

	Overall (N=43)	EGFR mutant (N=22)	EGFR wild type		
			Total (N=21)	Non-squamous (N=9)	Squamous (N=12)
ORR*, %	43.6%	60.0%	26.3%	22.2%	30.0%
Median DoR, mo (95% CI)	9.3 (3.7, 10.3)	8.7 (3.7, 10.3)	9.6 (3.5, NE)	/	/
Median PFS, mo (95% CI)	7.2 (5.4, 11.3)	11.5 (5.7, 12.9)	5.3 (3.5, 6.2)	5.8 (1.5, 12.1)	5.1 (1.9, 9.3)
Median OS, mo (95% CI)	22.6 (13.1, NE)	22.7 (19.7, NE)	14.1 (10.7, NE)	16.2 (5.8, NE)	12.8 (3.5, NE)
12-mo OS rate, % (95% CI)	69.0% (52.7, 80.7)	81.0% (56.9, 92.4)	57.1% (33.8, 74.9)	66.7% (28.2, 87.8)	50.0% (20.8, 73.6)
18-mo OS rate, % (95% CI)	56.5% (40.1, 70.0)	76.2% (51.9, 89.3)	35.9% (16.0, 56.4)	44.4% (13.6, 71.9)	30.0% (7.7, 56.9)

* Including confirmed or unconfirmed response. Based on response evaluable patients (≥1 on-study scans) with 4 patients (2 EGFR mutant patients with non-squamous histology and 2 EGFR wild type patients with squamous histology) excluded.

The most common Grade ≥3 treatment-related adverse events (TRAEs) were neutrophil count decreased (34.9%), anemia (30.2%), white blood cell (WBC) count decreased (25.6%), stomatitis (9.3%), and rash (7.0%). No TRAEs leading to treatment discontinuation or deaths occurred. No drug-related interstitial lung disease (ILD)/pneumonitis was reported.

Two Phase 3 global studies of sac-TMT in patients with 3L+ EGFR mutant NSCLC (NCT06074588), and 2L EGFR mutant NSCLC (NCT06305754) and a Phase 3 study of sac-TMT in China in patients with 2L EGFR mutant NSCLC (NCT05870319) are ongoing. Additionally two Phase 3 global studies of sac-TMT plus pembrolizumab in patients with metastatic NSCLC expressing programmed death ligand 1 (PD-L1)≥ 50% (NCT06170788) and resectable NSCLC not achieving pathological complete response (NCT06312137) are ongoing.

Gastric/GEJ cancer

Patients with previously treated inoperable advanced gastric/GEJ adenocarcinoma were enrolled to receive sac-TMT monotherapy at 5 mg/kg Q2W until disease progression or unacceptable toxicity in Phase 2 expansion cohort of KL264-01 study (NCT04152499). Patients with heavily pre-treated gastric/GEJ cancer were enrolled first, and then the cohort was amended to enroll patients with only one prior therapy of chemotherapy and anti-PD-1/L1 therapy. The data cut-off date was November 22, 2023.

As of the Data Cut-off Date, a total of 48 patients were enrolled and followed up for at least 9 weeks. 24 patients (50.0%) had received one prior line of therapy (2L), while 24 patients (50.0%) had received ≥ 2 prior lines of therapy (3L+). 40 patients (83.3%) had received prior anti-PD-1/L1 inhibitors. Of 41 response-evaluable patients (defined as ≥ 1 on-study scans), the objective response rate (ORR) was 22.0% (9 partial responses, 2 pending confirmation) and disease control rate (DCR) was 80.5%. The ORRs in the 2L and 3L+ setting were 27.3% (including 2 pending confirmation) and 15.8%, respectively. Median duration of response (DoR) was 7.5 months. In the subset of 3L+ patients (n=24 including 54.2% of patients with ≥ 4 prior lines of therapy) with more mature follow-up (median follow up of 14.6 months), the median progression free survival (mPFS) was 3.7 months (95% CI: 2.6, 5.4) and median overall survival (mOS) was 7.6 months (95% CI: 5.3, 15.5).

The most common ≥ Grade 3 TRAEs were anemia (20.8%), neutrophil count decreased (18.8%), WBC decreased (12.5%) and neutropenia (6.3%). No TRAEs leading to treatment discontinuation or deaths occurred. No neuropathy or drug-related ILD/pneumonitis was reported.

A Phase 3 global study of sac-TMT monotherapy versus standard of care (SOC) chemotherapy in 3L+ gastric/GEJ adenocarcinoma is being planned.

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, April 8, 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.