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
CORE PRODUCT SACITUZUMAB TIRUMOTECAN (sac-TMT) APPROVED FOR MARKETING BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION FOR 2L+ TNBC BASED ON OptiTROP-Breast01 STUDY

The board (the "**Board**") of directors ("**Directors**") of Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (the "**Company**") was pleased to announce that the Company received marketing authorization in China from National Medical Products Administration (NMPA) for the first domestically developed trophoblast cell-surface antigen 2 (TROP2)-directed antibody-drug conjugate (ADC) sacituzumab tirumotecan (sac-TMT, formerly SKB264/MK-2870) (佳泰莱®) for 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).

The approval is based on the positive results from a randomized, controlled, phase 3 OptiTROP-Breast01 study in adult patients with unresectable locally advanced or metastatic TNBC who have received at least two prior systemic therapies (at least one of them for advanced or metastatic setting). Sac-TMT demonstrated statistically significant and clinically meaningful improvement in both progression-free survival (PFS) and overall survival (OS) compared to chemotherapy. The results were presented at the special clinical science symposium for next-generation ADCs at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting in May 2024.

Previously, NMPA has accepted two supplemental new drug applications (sNDA) seeking the approvals of sac-TMT monotherapy for the treatment of patients with locally advanced or metastatic EGFR-mutant non-small cell lung cancer (NSCLC) following progression on EGFR-TKI therapy only, or both EGFR-TKI and platinum-based chemotherapy, respectively.

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, 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 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 (includes Mainland China, Hong Kong, Macau, and Taiwan).

RISK WARNING

SACITUZUMAB TIRUMOTECAN (SAC-TMT) MAY NOT ULTIMATELY BE SUCCESSFULLY 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, November 27, 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 as executive Director, Mr. LIU Sichuan, Mr. LAI Degui, 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.