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
NEW DRUG APPLICATION FOR CORE PRODUCT SACITUZUMAB TIRUMOTECAN (SAC-TMT) ACCEPTED BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION

The board (the "**Board**") of directors ("**Directors**") of Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (the "**Company**") is pleased to announce that the new drug application (NDA) (the "**Application**") based on the positive results from the pivotal phase III OptiTROP-Lung04 study of sacituzumab tirumotecan (sac-TMT, formerly SKB264/MK-2870) was accepted by the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of China in adult patients with epidermal growth factor receptor (EGFR)-mutant locally advanced or metastatic non-small cell lung cancer (NSCLC) who progressed after treatment with EGFR-tyrosine kinase inhibitor (TKI) therapy.

OptiTROP-Lung04 is a multi-center, randomized, registrational phase III clinical study that evaluates the efficacy and safety results of sac-TMT monotherapy versus pemetrexed plus platinum chemotherapy for the treatment of patients with EGFR-mutant locally advanced or metastatic NSCLC who progressed after treatment with EGFR-TKI therapy. At a pre-specified interim analysis, sac-TMT monotherapy demonstrated a statistically significant and clinically meaningful improvement in the primary endpoint of progression-free survival (PFS) as assessed by the blinded independent review committee (BIRC) compared with pemetrexed plus platinum chemotherapy. Sac-TMT also showed a manageable safety profile, with no unexpected safety signals identified.

The Application is the third NDA for sac-TMT that has been accepted by the NMPA. On October 25, 2024, it was announced on the official website of the CDE that the Application was planned to be included in the priority review and approval process of the CDE.

Previously, two NDAs for sac-TMT in patients with 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) and for sac-TMT monotherapy in adult patients with locally advanced or metastatic EGFR-mutant NSCLC who experience progression following treatment with an EGFR-TKI and platinum-based chemotherapy, respectively, were accepted by the NMPA.

Sac-TMT, a core product of the Company, is a novel human trophoblast cell-surface antigen 2 (TROP2) antibody-drug conjugate (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, Macao, and Taiwan).

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, October 31, 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.