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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
CORE PRODUCT SACITUZUMAB TIRUMOTECAN (sac-TMT)
APPROVED FOR MARKETING FOR SECOND INDICATION
BY THE NATIONAL MEDICAL PRODUCTS
ADMINISTRATION IN EGFR^m NSCLC

The board (the “**Board**”) of directors (“**Directors**”) of Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (the “**Company**”) is pleased to announce that the Company’s trophoblast cell-surface antigen 2 (TROP2)-directed antibody-drug conjugate (ADC) sacituzumab tirumotecan (sac-TMT, formerly SKB264/MK-2870) (佳泰莱®) was approved for marketing by the National Medical Products Administration (NMPA) for the second indication which is for the treatment of adult patients with epidermal growth factor receptor (EGFR) mutant-positive locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) following progression on EGFR-tyrosine kinase inhibitor (TKI) therapy and platinum-based chemotherapy. This is the first TROP2 ADC drug approved for marketing in lung cancer globally. Compared with current standard of care, sac-TMT significantly extends the overall survival benefits of these patients.

The approval is based on a multi-center, randomized, controlled, pivotal study (OptiTROP-Lung03) that evaluates the efficacy and safety profile of sac-TMT monotherapy 5mg/kg every other week (Q2W) as an intravenous injection versus docetaxel for the treatment of patients with locally advanced or metastatic EGFR-mutant NSCLC who have failed after treatment with an EGFR-TKI and platinum-based chemotherapy (used sequentially or in combination). As demonstrated in a pre-specified interim analysis, sac-TMT monotherapy demonstrated a statistically significant and clinically meaningful improvement in objective response rate (ORR), progression-free survival (PFS) and overall survival (OS) compared with docetaxel.

Previously, the NMPA has approved the marketing of sac-TMT in China 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) and accepted a supplemental new drug application (sNDA) seeking the approval of sac-TMT monotherapy for patients with EGFR-mutant NSCLC who have failed after EGFR-TKI therapy.

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, March 10, 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, 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.