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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
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 OptiTROP-Lung03 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.

OptiTROP-Lung03 is a multi-center, randomized, pivotal clinical study that evaluates 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 epidermal growth factor receptor (EGFR)-mutant non-small cell lung cancer (NSCLC) who failed after treatment with EGFR-tyrosine kinase inhibitor (TKI) therapy and platinum-based chemotherapy. At a pre-specified analysis, sac-TMT monotherapy demonstrated a statistically significant and clinically meaningful improvement in objective response rate (ORR) and progression-free survival (PFS) compared with docetaxel.

The Company has filed the Application for sac-TMT in adult patients with locally advanced or metastatic EGFR-mutant NSCLC who experience progression following treatment with an EGFR-TKI and platinum-based chemotherapy.

The Application is the second NDA for sac-TMT that has been accepted by the NMPA. On August 14, 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, an NDA 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) was accepted by the NMPA.

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, August 19, 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.