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KELUN-BIOTECH
科伦博泰

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

PRIMARY ENDPOINT MET FOR PHASE III CLINICAL TRIAL OF CORE PRODUCT SKB264 (MK-2870) IN PATIENTS WITH UNRESECTABLE LOCALLY ADVANCED, RECURRENT OR METASTATIC TNBC WHO HAVE FAILED SECOND-LINE OR ABOVE PRIOR STANDARD OF CARE

The board (the “**Board**”) of directors (“**Directors**”) of Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (the “**Company**”) is pleased to announce that the Independent Data Monitoring Committee (the “**IDMC**”) concluded that the randomized, controlled, open-label, multi-center phase III clinical trial of SKB264 (also known as MK-2870) for injection versus investigator selected regimens in patients with unresectable locally advanced, recurrent or metastatic triple-negative breast cancer (TNBC) who have failed second-line or above prior standard of care (the “**Trial**”) met the primary endpoint of progression-free survival (PFS) as assessed by the independent review committee (IRC). At a pre-specified interim analysis, SKB264 (MK-2870) demonstrated a statistically significant improvement in PFS, compared with the control group receiving standard chemotherapy.

Based on the results from the interim analysis, the Company plans to communicate with the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of China regarding the submission of a new drug application (NDA) of SKB264 (MK-2870).

SKB264 (MK-2870) is an innovative antibody-drug conjugate (ADC) targeting human trophoblast cell-surface antigen 2 (TROP2), in which the Company owns proprietary intellectual property rights. SKB264 (MK-2870) is a core product of the Company currently studied for treatment of advanced solid tumors including TNBC, non-small-cell lung cancer (NSCLC) and HR+/HER2 – breast cancer (HR+/HER2 – BC).

The Trial is the first registrational phase III study of SKB264 (MK-2870) in China. SKB264 (MK-2870) has been granted breakthrough therapy designation by the CDE of the NMPA of China for locally advanced or metastatic TNBC in July 2022.

In May 2022, the Company granted MSD (the tradename of Merck & Co., Inc, Rahway, NJ, USA) exclusive development and commercialization rights for SKB264 (MK-2870) outside Greater China (which includes Mainland China, Hong Kong, Macao, and Taiwan), with whom the Company is closely collaborating on the global clinical development of SKB264 (MK-2870).

RISK WARNING

SKB264 (MK-2870) 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 13, 2023

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.