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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

NEW DRUG APPLICATION FOR CORE PRODUCT SKB264 (MK-2870) ACCEPTED BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION

Reference is made to the announcement of Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (the “**Company**”) dated August 13, 2023, announcing that the Company planned 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 of the Company’s core product SKB264 (also known as MK-2870).

The board (the “**Board**”) of directors (“**Directors**”) of the Company is pleased to announce that the new drug application (the “**Application**”) for SKB264 (MK-2870) 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) was accepted by the CDE of the NMPA on December 8, 2023. The Application is based on a multi-center, randomized, controlled phase 3 clinical study of SKB264 (MK-2870) monotherapy as second line or above treatment for locally advanced or metastatic TNBC (OptiTROP-Breast01). The relevant information is announced as follows:

Drug name:	SKB264 for injection
Brand name:	佳泰萊
Form of dosage:	Injection
Strength:	200 mg/vial
Application matter:	Registration of domestic production of pharmaceutical product
Registration classification:	Classification 1 of therapeutic biological products
Applicant:	Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd.
Acceptance number:	CXSS2300093
Proposed indication:	This product is used 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).

The updated efficacy and safety results from a phase 2 expansion cohort in patients with previously treated metastatic TNBC for SKB264 (MK-2870) have been presented at the 2023 San Antonio Breast Cancer Symposium (SABCS), details of which may be found in the Company's prospectus dated June 29, 2023 and announcement dated November 30, 2023.

SKB264 (MK-2870) was granted Breakthrough Therapy Designation by the CDE of the NMPA of China for locally advanced or metastatic TNBC in July 2022. On November 9, 2023, it was announced on the official website of the CDE that the Application was officially included in the priority review and approval process of the CDE.

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 SKB264 (MK-2870) in all territories outside of Greater China (includes Mainland China, Hong Kong, Macao, and Taiwan).

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, December 11, 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.