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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**

## THE ABSTRACT FOR ORAL PRESENTATION OF THE STUDY RESULTS FROM CORE PRODUCT SKB264 (MK-2870) PUBLISHED ON THE WEBSITE OF THE 2023 ESMO CONGRESS

The board (the "Board") of directors (the "Directors") of Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. ("the Company") is pleased to announce that the Company will present the study results from a phase 1/2 basket study in patients with hormone receptor-positive (HR+) and human epidermal growth factor receptor 2-negative (HER2-) metastatic breast cancer (mBC) of the innovative TROP2-ADC (SKB264, also known as MK-2870) in the form of an oral presentation at the European Society for Medical Oncology (ESMO) Congress 2023 to be held in Madrid, Spain from October 20 to 24, 2023. The oral presentation is scheduled to take place on October 22, 2023, 8:35 a.m. to 8:40 a.m. local time. The abstract has also been published on the official website of the ESMO Congress on October 16, 2023, local time (presentation number: 380MO). The study results are summarized as follows:

This is a phase 1/2, single-arm, basket study in patients with HR+/HER2- (including HER2-low and HER2-zero) mBC who received SKB264 (MK-2870) at a dose of 5 mg/kg Q2W until progression or unacceptable toxicity. Eligibility included progression on endocrine-based therapy and at least one prior chemotherapy for mBC. The data cut-off is April 12, 2023, and the median follow-up was 8.2 months.

Of 38 patients evaluable for response assessment, 47% of patients had primary endocrine resistance; 79% of patients had received ≥2 prior chemotherapy for metastatic disease, and prior treatments included taxane and CDK 4/6 inhibitors. The objective response rate (ORR) was 36.8% and disease control rate (DCR) was 89.5%. Median duration of response (DoR) was 7.4 months and the 6-month DoR rate was 80%. Median progression-free survival (PFS) was 11.1 months, and 6-month PFS rate was 61.2%.

The most common  $\geq$ Grade 3 treatment-related adverse events (TRAEs) ( $\geq$ 5%) were decreased neutrophil count, decreased white blood cell count, anemia, decreased platelet count and Gamma-glutamyl Transferase (GGT) increase. No neuropathy or drug-related interstitial lung disease/pneumonitis were reported. There were no TRAEs leading to treatment discontinuation or death.

The Company has received clearance from the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of China to proceed with a registrational phase 3 study of SKB264 (MK-2870) in HR+/HER2- mBC in China for patients who had failed at least one line of chemotherapy for mBC. The Company also obtained the approval from the CDE of the NMPA of China on September 26, 2023 for the Investigational New Drug (IND) application for SKB264 (MK-2870) with or without KL-A167 (anti-PD-L1 inhibitor) in patients with HR+/HER2- mBC who have progressed on endocrine therapy in the metastatic setting.

HR+/HER2- BC is the most prevalent subtype of breast cancer. In 2022, according to Frost & Sullivan and as disclosed in the Company's prospectus dated June 29, 2023, 1.3 million and 187.6 thousand incidences of HR+/HER2- BC have occurred worldwide and in China, respectively.

#### **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, October 16, 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.