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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
KEY PRODUCT A400 (EP0031) CLEARED TO START PHASE 2
BY THE US FOOD AND DRUG ADMINISTRATION

The board (the “**Board**”) of directors (the “**Directors**”) of Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (the “**Company**”) is pleased to announce that our key product A400 (EP0031), a small molecule rearranged during transfection (RET) kinase inhibitor program (also known as KL590586 or EP0031), has been cleared by the United States Food and Drug Administration (FDA) to progress into Phase 2 clinical development.

A400 (EP0031) is a second-generation selective RET inhibitor (SRI) with broad activity against common RET fusions and mutations.

In March 2021, the Company granted Ellipses Pharma Limited (“**Ellipses**”), a U.K.-based international drug development company, an exclusive, royalty-bearing, sublicensable license to develop, manufacture and commercialize A400 (EP0031) in all countries excluding Greater China, North Korea, South Korea, Singapore, Malaysia and Thailand. In June 2022, the FDA approved an investigational new drug application for A400 (EP0031), and a phase 1/2 trial is ongoing in patients with malignant tumors with RET gene alteration. In November 2023, A400 (EP0031) was granted Orphan Drug Designation by the FDA for the treatment of RET fusion-positive solid tumors. In March 2024, A400 (EP0031) was granted Fast Track Designation by the FDA for the treatment of RET fusion-positive non-small cell lung cancer (NSCLC).

In preclinical studies, A400 (EP0031) demonstrated favorable inhibitory activity against key RET kinases in-vitro and in-vivo. A400 (EP0031) also demonstrated good penetration of the blood brain barrier in animal models. Data shared at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting on A400 (EP0031) showed promising anti-tumor efficacy in patients with advanced RET+ solid tumors, highlighted by ORR of 80.8% and 69.7% for 1L and 2L+ advanced RET+ NSCLC, respectively, based on results from its ongoing phase 1/2 trial. In both cases, DCR of over 96% were reported.

According to the information published on the website of ASCO, clinical data from the phase 1 dose escalation and expansion study of A400 (EP0031) in patients with SRI-naïve or pretreated advanced RET-altered NSCLC and other tumors will be presented by Ellipses at the 2024 ASCO Annual Meeting on June 3, 2024, local time.

At present, the Company is conducting A400 (EP0031) pivotal clinical study in China for RET-positive NSCLC.

RISK WARNING

A400 (EP0031) 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, May 3, 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 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.