Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.

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 A400/EP0031 ACCEPTED FOR REVIEW 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 a new drug application (NDA) for the Company's small molecule rearranged during transfection (RET) kinase inhibitor A400 (also known as EP0031) was accepted for review by the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of China for the treatment of adult patients with RET-fusion positive locally advanced, or metastatic non-small cell lung cancer (NSCLC). This acceptance for review is based on the positive results from the two pivotal Phase 2 cohorts of the KL400-I/II-01 study for both 1L and 2L+ advanced RET-fusion positive NSCLC.

Cohort 1 and 2, the Phase 2 stage of the KL400-I/II -01 study, evaluate the efficacy and safety of A400/EP0031 90mg orally once daily (QD) for the treatment of patients with pretreated and treatment-naïve RET-fusion positive locally advanced, or metastatic NSCLC, respectively. Primary efficacy endpoints of the two pivotal cohorts were reached, where A400/EP0031 demonstrated favorable efficacy in pretreated and treatment-naïve NSCLC including patients with prior immunotherapy or brain metastases. A400/EP0031 also demonstrated an encouraging, manageable tolerability and safety profile.

ABOUT A400/EP0031

A400/EP0031 is a novel next-generation selective RET inhibitor for NSCLC, medullary thyroid cancer (MTC) and other solid tumors with a high prevalence of RET alterations. The Company is currently conducting a phase 1b/2 clinical study for RET+ MTC and solid tumor in China. The results from the Phase 1 study of A400/EP0031 in patients with advanced RET-mutant MTC were presented at the 2025 ASCO Annual Meeting.

In March 2021, the Company granted Ellipses Pharma Limited, a U.K.-based international oncology drug development company, an exclusive license to develop, manufacture and commercialize this agent outside Greater China and certain Asian countries under the code EP0031.

In March 2024, it was announced that EP0031/A400 was granted Fast Track designation by the Food and Drug Administration (FDA) for the treatment of RET-fusion positive NSCLC. In April 2024, EP0031/A400 was cleared by the FDA to progress into Phase 2 clinical development and is now open in the United States, United Kingdom, Europe and United Arab Emirates.

RISK WARNING

A400 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, September 23, 2025

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, Ms. LIAO Yihong and Mr Zeng Xuebo as non-executive Directors, and Dr. ZHENG Qiang, Dr. TU Wenwei, Dr. JIN Jinping, and Dr. LI Yuedong as independent non-executive Directors.