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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) GRANTED ORPHAN DRUG DESIGNATION 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, a small molecule rearranged during transfection (RET) kinase inhibitor program (also known as KL590586 or EP0031), has been granted Orphan Drug Designation by the United States Food and Drug Administration (FDA) for the treatment of RET fusion-positive solid tumors.

A400 (EP0031) is a next-generation selective RET inhibitor (SRI) with broad activity against common RET fusions and mutations. Therefore, A400 (EP0031) may overcome resistance mechanisms to first generation SRIs. In preclinical studies, A400 (EP0031) demonstrated favourable 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. At present, the Company is conducting A400 (EP0031) pivotal clinical study in China for RET-positive non-small cell lung cancer.

In March 2021, the Company granted Ellipses Pharma Limited, 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.

## **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, November 26, 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.*