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

DRUG APPLICATION FOR KEY PRODUCT A140 SOLUTION FOR INFUSION (CETUXIMAB SOLUTION FOR INFUSION) ACCEPTED 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 the drug application (the "**Application**") for the A140 solution for infusion (Cetuximab Solution for Infusion, brand name: 達泰萊), a key product of the Company, was accepted by the Center for Drug Evaluation of the National Medical Products Administration of China on September 8, 2023. The relevant information is announced as follows:

Drug name:	Cetuximab Solution for Infusion
Brand name:	達泰萊
Form of dosage:	Injection
Strength:	100mg (50ml)/vial
Application matter:	Registration of domestic production of pharmaceutical product
Registration classification:	Classification 3.3 of therapeutic biological products – biosimilars
Applicant:	Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd.
Acceptance number:	CXSS2300075
Proposed indications:	This product is used for the treatment of rat sarcoma virus (RAS) wild-type metastatic colorectal cancer (mCRC): used in combination with oxaliplatin (OLFOX) or irinotecan (FOLFIRI) regimens for first-line treatment; used in combination with FOLFIRI in patients who have failed FOLFIRI-containing treatment. This product is used for the treatment of head and neck squamous cell carcinoma (HNSCC): in combination with platinum and fluorouracil-based chemotherapy for first-line treatment of recurrent and/or metastatic disease; in combination with radiotherapy for locally advanced disease.

A140 is a recombinant epidermal growth factor receptor (EGFR) human-mouse chimeric monoclonal antibody (mAb) which inhibits the growth and survival of EGFR-expressing tumor cells. The A140 solution for infusion is firstly developed in China to be filed for production in accordance with the "Guidelines for Design of Clinical Trials of Injectable Cetuximab Biosimilar (for Trial Implementation)" using the original cetuximab as a reference drug, with the same amino acid sequence and mechanism of action as the reference drug cetuximab (brand name: Erbitux®), and has the same proposed indications as Erbitux®. The A140 solution for infusion will provide significantly increased accessibility once the Application is approved.

The application for registration of A140 is based on information from a series of studies, including pharmacologic comparative study, non-clinical comparative study, and clinical comparative study. The Phase III clinical safety and efficacy study of A140 is a randomized, double-blinded, parallel-controlled, multi-centered Phase III clinical study comparing the efficacy, safety and immunogenicity of A140 and the original cetuximab combination chemotherapy regimen (mFOLFOX6 regimen) for first-line treatment of RAS wild-type mCRC.

RISK WARNING

A140 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 10, 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.