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 CORE PRODUCT TRASTUZUMAB BOTIDOTIN 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 new drug application (NDA) (the "**Application**") for human epidermal growth factor receptor 2 (HER2)-directed antibody-drug conjugate (ADC) trastuzumab botidotin (formerly A166) was accepted by the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of China for the treatment of adult patients with HER2 positive unresectable or metastatic breast cancer (BC) who have received at least one prior anti-HER2 therapy.

The approval is based on a multi-center, randomized, open-label, controlled, phase III KL166-III-06 study that evaluates the efficacy and safety results of trastuzumab botidotin monotherapy versus T-DM1 in patients with HER2 positive unresectable or metastatic BC who have received prior trastuzumab and Taxane-containing regimens. At a pre-specified interim analysis, trastuzumab botidotin monotherapy demonstrated a statistically significant and clinically meaningful improvement in the primary endpoint of progression-free survival (PFS) as assessed by the blinded independent central review (BICR) compared with T-DM1.

Trastuzumab botidotin is an innovative HER2 ADC developed by the Company, which conjugates a novel, MMAF derivative (a highly cytotoxic tubulin inhibitor, Duo-5) via a stable, enzyme-cleavable linker to a HER2 monoclonal antibody with a drug-to-antibody-ratio (DAR) of 2. Trastuzumab botidotin specifically binds to HER2 on the surface of tumor cells and is internalized by tumor cells, releasing the toxin molecule Duo-5 inside the cell. Duo-5 induces tumor cell cycle arrest in the G2/M phase, leading to tumor cell apoptosis. After targeting HER2, trastuzumab botidotin can also inhibit the HER2 signaling pathway; it has antibody-dependent cell-mediated cytotoxicity (ADCC) activity.

RISK WARNING

TRASTUZUMAB BOTIDOTIN 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, January 7, 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, 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.