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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
CORE PRODUCT TRASTUZUMAB BOTIDOTIN APPROVED
FOR MARKETING BY THE NATIONAL MEDICAL PRODUCTS
ADMINISTRATION FOR 2L+ HER2+ BC

The board (the “**Board**”) of directors (“**Directors**”) of Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (the “**Company**”) is pleased to announce that the Company’s human epidermal growth factor receptor 2 (HER2)-directed antibody-drug conjugate (ADC) trastuzumab botidotin (also known as A166) (舒泰莱®) was approved for marketing by the National Medical Products Administration (NMPA) for adult patients with unresectable or metastatic HER2 positive breast cancer (BC) who have received one or more prior anti-HER2 therapy.

The approval is based on a multi-center, randomized, open-label, controlled, Phase 3 KL166-III-06 study that evaluates the efficacy and safety profile of trastuzumab botidotin 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; the beneficial trend for overall survival (OS) of trastuzumab botidotin was also observed. Results from this study will be presented as an oral report at the 2025 European Society for Medical Oncology (ESMO) Congress held in Berlin, Germany (Presentation # LBA24, Proffered paper session 1: Breast cancer, metastatic).

The Company has initiated an open, multi-center Phase 2 clinical study of trastuzumab botidotin in the treatment of HER2+ unresectable or metastatic BC that previously received a topoisomerase inhibitor ADC.

ABOUT TRASTUZUMAB BOTIDOTIN (舒泰莱®)

Trastuzumab botidotin is a differentiated HER2 ADC to treat advanced HER2+ solid tumors. As an innovative HER2 ADC developed by the Company, it conjugates a novel, monomethyl auristatin F (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 FOR THE TREATMENT OF OTHER INDICATIONS NOT YET APPROVED MAY NOT ULTIMATELY BE SUCCESSFULLY 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, October 17, 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.