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KELUN-BIOTECH
科伦博泰

Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd.

四川科伦博泰生物制药股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

(Stock Code: 6990)

VOLUNTARY ANNOUNCEMENT
POSITIVE PHASE 2 INTERIM RESULTS AND INITIATION OF
PHASE 3 STUDY OF SKB378/WIN378 IN ASTHMA

The board (the “**Board**”) of directors (“**Directors**”) of Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (the “**Company**”) is pleased to announce that Windward Bio AG (“**Windward Bio**”), the Company’s partner, has reported positive interim results from the Phase 2 portion of the POLARIS-1 clinical trial of SKB378/WIN378, a fully human ultra-long-acting monoclonal antibody targeting thymic stromal lymphopoietin (TSLP), in asthma. The Phase 3 portion of POLARIS-1 has also been initiated.

SKB378/WIN378 is a novel fully human, ultra-long-acting monoclonal antibody with a unique binding mode to inhibit TSLP. It was engineered for improved potency, extended half-life and silenced effector function. It is the only known investigational drug that blocks TSLP signaling by binding to two different sites on TSLP, interfering with the binding of TSLP to both of its co-receptors on the cell surface of epithelial cells.

POLARIS-1 (NCT07120503) is an operationally seamless, global Phase 2/3 study of SKB378/WIN378 in adults with uncontrolled asthma conducted by Windward Bio. The Phase 2 portion of the study is a 48-week, randomised, double-blind study evaluating three dose levels of SKB378/WIN378 administered subcutaneously against placebo, with primary objectives of characterising pharmacokinetics, safety, immunogenicity and pharmacodynamic activity, as well as informing dose selection for Phase 3 development. The study also evaluates the effect of SKB378/WIN378 on lung function and biomarkers of airway inflammation. The Phase 2 portion enrolled a total of 147 patients, exceeding the initial enrolment target of 120 patients, with the interim analysis conducted on the first 98 patients. The Phase 3 portion is evaluating two twice-yearly doses of SKB378/WIN378 against placebo, with a primary endpoint of annualized asthma exacerbation rate in patients with severe asthma.

The interim analysis demonstrated the following at Week 24 after a single dose of SKB378/WIN378:

- (i) Dose-dependent mean increases in forced expiratory volume in one second (FEV₁) of up to 174mL (placebo-adjusted mean increase up to 256mL, p=0.033);
- (ii) Dose-dependent mean reductions in fractional exhaled nitric oxide (FeNO) of up to 24 parts per billion (or a 43% reduction; p=0.006); and
- (iii) Reductions in mean blood eosinophil count (EOS) of up to 200 cells/μL (or a 51% reduction; p<0.0001).

FEV₁ is a key measure of lung function, while FeNO and EOS are key markers of inflammation that correlate with asthma exacerbations. Near-maximal effects were observed as early as Week 2 and sustained through Week 24. The interim analysis demonstrated a half-life of up to 75 days. The interim results and population pharmacokinetic modelling support the potential for twice-yearly dosing of SKB378/WIN378.

SKB378/WIN378 was well tolerated, with favorable safety results, and there were no treatment-related serious adverse events, withdrawals or discontinuations observed as of the data cut-off date. Adverse events were balanced between the active treatment arms and placebo. Less than 1% of participants experienced injection site reactions, and 2% developed anti-drug antibodies, a measure of immunogenicity, which had no impact on the pharmacology of SKB378/WIN378.

Two twice-yearly doses have been selected for the Phase 3 portion of POLARIS-1, which is designed to evaluate the effect of SKB378/WIN378 on annualized asthma exacerbation rate and other key efficacy measures in patients with severe asthma. The Phase 3 portion of the study has been initiated by Windward Bio who plans to begin a second Phase 3 study, POLARIS-2, in the first half of 2027. Data from the Phase 2 portion of POLARIS-1 will be presented at an upcoming medical congress.

SKB378/WIN378 started as a co-development project jointly conducted by the Company and HBM Holdings Limited (the “**Harbour BioMed**”), with both parties equally sharing global rights.

About SKB378/WIN378

SKB378/WIN378 is a novel fully human, ultra-long-acting monoclonal antibody with a unique binding mode to inhibit TSLP. This clinically validated target plays a key role in the development and progression of a wide array of immunological diseases, including asthma, chronic obstructive pulmonary disease (COPD), chronic rhinosinusitis with nasal polyps, and eosinophilic esophagitis. SKB378/WIN378 was engineered for improved potency, extended half-life and silenced effector function. It is the only known investigational drug that blocks TSLP signaling by binding to two different sites on TSLP, interfering with the binding of TSLP to both of its co-receptors on the cell surface of epithelial cells. Phase 2 interim results support the potential of twice-yearly dosing. SKB378/WIN378 produced significant, sustained and dose-dependent increases in FEV₁, a measure of lung function, together with significant and sustained reductions in FeNO and blood eosinophils – key markers that correlate with asthma exacerbations. SKB378/WIN378 is being evaluated in the global Phase 2/3 POLARIS-1 study in asthma and the Phase 2 SIRIUS study in COPD, with a second pivotal Phase 3 asthma trial, POLARIS-2, planned to begin in the first half of 2027. Windward Bio licensed the global rights (excluding Greater China and several Southeast and West Asian countries) for this molecule from the Company (also known as SKB378) and Harbour BioMed (also known as HBM9378).

RISK WARNING

SKB378/WIN378 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 8, 2026

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.