The United Laboratories International Holdings Limited
聯邦制藥國際控股有限公司
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 3933)

PROGRESS IN CLINICAL TRIAL OF THE GROUP'S PRODUCT TUL01101 TABLETS

This announcement is made by The United Laboratories International Holdings Limited (the "Company") on a voluntary basis.

The board of directors (the "Board") of the Company is pleased to announce that the Phase II clinical trial of TUL01101 Tablets, a Class 1 new drug independently developed by Zhuhai United Laboratories Co., Ltd., a wholly-owned subsidiary of the Company, in adult patients with moderate-to-severe atopic dermatitis has been completed in China.

This multicenter, randomized, double-blind, parallel, placebo-controlled trial enrolled 201 subjects who were randomly assigned to receive TUL01101 Tablets in three dose groups (20 mg, 40 mg, and 60 mg) and placebo once daily for 12 consecutive weeks. The trial aimed to evaluate the efficacy, safety, tolerability and pharmacokinetic characteristics of TUL01101 Tablets in adult patients with moderate-to-severe atopic dermatitis.

The primary efficacy endpoint of this trial was the percentage change from baseline in the Eczema Area and Severity Index (EASI) score at Week 12. The key secondary efficacy endpoints included the proportion of subjects achieving an improvement of≥75% from baseline in EASI score (EASI-75 response rate) at different time points, and the proportion of subjects achieving an Investigator's Global Assessment (IGA) score of 0/1 with a reduction of≥2 points from baseline (IGA response rate).

The trial results demonstrated that all TUL01101 Tablets dose groups showed significant efficacy, effectively clearing skin lesions, relieving pruritus, and improving subjects' quality of life. A marked reduction in EASI score was observed as early as Week 1, and all TUL01101 Tablets dose groups were significantly superior to the placebo group. During the treatment period, both EASI-75 and IGA response rates showed a continuous increasing trend. At Week 12, the percentage changes from baseline in EASI score for the TUL01101 20 mg, 40 mg, and 60 mg groups were -81.98%, -79.87%, and -87.85%, respectively; the EASI-75 response rates were 78.0%, 80.0%, and 84.0%, respectively; and the IGA response rates were 46.0%, 52.0%, and 68.0%, respectively.

During the trial, TUL01101 Tablets demonstrated an overall positive safety and tolerability profile. The most common adverse event was upper respiratory tract infection, and the vast majority of adverse events were mild to moderate in severity. No new safety signals beyond those previously reported for similar products were observed.

The Phase II clinical trial of TUL01101 Tablets in adult patients with moderate-to-severe atopic dermatitis achieved its expected objectives, supporting its progression to the next stage of clinical trial. Recently, the Company has conducted the communication with regulatory authorities regarding the EOP2 (End of Phase II/Pre-Phase III) of TUL01101 Tablets and is now initiating a Phase III clinical trial in adult patients with moderate-to-severe atopic dermatitis in China.

ABOUT TUL01101 TABLETS

TUL01101 Tablets is a highly selective JAK1 inhibitor. To date, it has been approved to conduct clinical trials in China for indications of atopic dermatitis and rheumatoid arthritis. Going forward, the Company will continue to expand the clinical research of TUL01101 Tablets in the field of autoimmune diseases.

By Order of the Board
The United Laboratories International Holdings Limited
Tsoi Hoi Shan
Chairman

Hong Kong, 10 November 2025

As at the date of this announcement, the Board comprises Mr. Tsoi Hoi Shan, Mr. Leung Wing Hon, Ms. Choy Siu Chit, Mr. Fang Yu Ping, Ms. Zou Xian Hong and Ms. Zhu Su Yan as executive directors; and Mr. Chong Peng Oon, Prof. Song Ming and Dr. Fu Qiushi as independent non-executive directors.