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## **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)

### **FDA APPROVAL OF IND FOR GROUP'S PRODUCT TUL321 CAPSULES**

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 investigational new drug application ("IND") for TUL321 Capsules, a Class 1 new drug self-developed by Zhuhai United Laboratories Co., Ltd., a wholly-owned subsidiary of the Company, was approved by the U.S. Food and Drug Administration ("FDA"), with IND number 180385. In addition, the application for clinical trial registration in China has been submitted simultaneously and has been accepted.

TUL321 Capsules are a new-generation complement factor B (CFB) inhibitor. The complement system, an important component of innate immunity, produces activation products that mediate opsonization and phagocytosis, cell lysis, inflammation, immune response regulation, and clearance of immune complexes. It is primarily activated through three pathways: the classical, lectin and alternative pathways. CFB is a key rate-limiting serine protease zymogen in the alternative pathway of the complement system. Under pathological conditions, its abnormal activation can lead to dysregulation of the alternative pathway, causing tissue damage and thereby contributing to various diseases. Preclinical studies have shown that TUL321 Capsules, with their unique target-binding mode and excellent permeability characteristics, demonstrate superior therapeutic potential compared with similar drugs in the treatment of paroxysmal nocturnal hemoglobinuria (PNH), IgA nephropathy, age-related macular degeneration, multiple sclerosis, and myasthenia gravis.

This approval marks a further advancement in the Company's research and development in the field of autoimmune disease treatment. In the future, the Company will continue to dedicate itself to new product development, continuously enhancing its competitiveness and innovation capabilities in the pharmaceutical industry, and is expected to create more benefits for the Company and its shareholders.

By Order of the Board

**The United Laboratories International Holdings Limited**

**Tsoi Hoi Shan**

*Chairman*

Hong Kong, 28 April 2026

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.