Lee's Pharmaceutical Holdings Limited
李氏大藥廠控股有限公司*

(incorporated in the Cayman Islands with limited liability)

(Stock Code: 950)

VOLUNTARY ANNOUNCEMENT
FDA APPROVAL OF SUPPLEMENTAL NEW DRUG APPLICATION FOR ADASUVE®

This announcement is made by the board (the "**Board**") of directors (the "**Directors**") of Lee's Pharmaceutical Holdings Limited (the "**Company**" or "**Lee's Pharm**", together with its subsidiaries, the "**Group**") on a voluntary basis.

The Board of the Company is pleased to announce that the supplemental new drug application ("**sNDA**") for ADASUVE® (loxapine) Inhalation Powder, a single-dose, single-use drug-device combination product, has been approved by the U.S. Food and Drug Administration ("**FDA**") on 29 December 2025.

The approved sNDA authorises the relocation of the commercial manufacturing facility for ADASUVE® from Mountain View, California, to Fremont, California, pursuant to Section 505(b)(2) of the U.S. Federal Food, Drug, and Cosmetic Act. The application was submitted to the FDA on 29 August 2025 by the former owner, and the assets were subsequently acquired in December 2025 by Nova Pneuma Incorporated ("**NPI**"), a wholly owned subsidiary of the Company, details of which have been disclosed in the announcement dated 9 December 2025.

Following the FDA approval, the Fremont, California manufacturing facility is authorised for the commercial production of ADASUVE® in the United States.

The FDA approval obtained by NPI represents a key regulatory milestone for the Group and signifies the completion of regulatory requirements associated with the Company's first U.S.-based pharmaceutical facility acquisition. The Board considers that this approval supports the Group's strategic expansion of its portfolio of innovative drug delivery technologies based on the Staccato® platform, with potential applications across multiple therapeutic indications, and is aligned with the Company's global expansion strategy and its ongoing commitment to regulatory compliance and pharmaceutical quality.

ABOUT LEE'S PHARM

The Company is a research-driven and market-oriented biopharmaceutical company with more than over 30 years of operation experience in the pharmaceutical industry in China. The Company is fully integrated with solid infrastructures in drug development, clinical development, regulatory, manufacturing, sales and marketing based in Mainland China with global perspectives. The Company has established extensive partnerships with around 30 international companies and currently markets over 25 proprietary, generic and licensed-in pharmaceutical products in Mainland China, Hong Kong, Macau and Taiwan. The Company focuses on several key disease therapeutic areas such as cardiovascular health, woman's health, paediatrics, rare diseases, oncology, dermatology and obstetrics. In addition, the Company has recently acquired U.S.-based assets in line with its strategy to broaden its portfolio of innovative drug delivery technologies through the Staccato® Platform, covering a wide range of indications and reinforcing the Company's global expansion strategy. More information available at www.leespharm.com.

By order of the Board
Lee's Pharmaceutical Holdings Limited
Lee Siu Fong
Chairman

Hong Kong, 27 January 2026

As at the date of this announcement, Ms. Lee Siu Fong (Chairman) and Ms. Leelalertsuphakun Wanee are executive directors of the Company, Dr. Li Xiaoyi, Mr. James Charles Gale and Mr. Huang Zuie-Chin are non-executive directors of the Company, Dr. Chan Yau Ching, Bob, Ms. Cheang Yee Wah, Eva and Dr. Tsim Wah Keung, Karl are independent non-executive directors of the Company.

* *For identification purpose only*