Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.

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
UPDATE ON AN INVESTIGATIONAL EAR DRUG PRODUCT

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 as the "**Group**") on a voluntary basis.

The Board of the Company is pleased to announce that, Zhaoke Pharmaceutical (Hefei) Company Limited, a wholly-owned subsidiary of the Company, successfully recruited its first patient dosed with Cetraxal® Plus an ear drops product licensed from Laboratorios Salvat S.A. ("**Salvat**") targeting acute otitis externa ("**AOE**"), and acute otitis media with tympanostomy tubes ("**AOMT**"), in a Phase III clinical trial in China on 4 January 2021.

The trial is designed to be conducted in 44 clinical centers with Doctor Yasheng Yuan from Eye & ENT Hospital of Fudan University as the leading principal investigator. The purpose of this Phase III, multicenter, randomised, evaluator-blinded, parallel-group, active-controlled clinical trial is to evaluate the efficacy and safety of ciprofloxacin 0.3% plus fluocinolone acetonide 0.025% (CIPRO+FLUO) otic solution in the treatment of AOE.

The clinical trial is designed to enrol a total of 600 subjects (300 in the Cetraxal® Plus group and 300 in the positive reference drug group). The primary endpoint of this trial is to assess the efficacy of CIPRO+FLUO otic solution vs ciprofloxacin 0.3% otic solution in the treatment of AOE. The key secondary endpoints are to assess the safety of CIPRO+FLUO otic solution vs ciprofloxacin 0.3% otic solution in the treatment of AOE and to assess the plasma concentration of ciprofloxacin and fluocinolone acetonide after multiple doses of CIPRO+FLUO otic solution in 12 adult subjects, and evaluate the pharmacokinetic parameters.

* *For identification purposes only*

ABOUT Cetraxal® Plus

Since its first approval in Spain in 2002 (Cetraxal® Plus, developed by Laboratorios Salvat, S.A.), ciprofloxacin 0.3% plus fluocinolone acetonide 0.025% (CIPRO+FLUO) otic solution has been approved in over 50 countries as the multiple-dose formulation presented in 10 ml bottles. The CIPRO+FLUO otic solution presented in single-dose containers and subject of this submission is also approved in the United States since April 2016, in Canada since December 2016, and in several European countries since January 2018, and is intended for the treatment of infections caused by susceptible isolates of the designated microorganisms in the AOE due to Staphylococcus aureus, and Pseudomonas aeruginosa and in the AOMT due to Staphylococcus aureus, Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis and Pseudomonas aeruginosa in patients aged 6 months and older. The single-use formulation of this CIPRO+FLUO otic solution was developed as a convenient to use, preservative-free ear drops preparation. Each single-dose container (0.25 ml) delivers 0.75 mg of ciprofloxacin and 0.0625 mg of fluocinolone acetonide. The compound formulation is the first topical ear drops in China, containing quinolone antibiotics and corticosteroids. It is classified as a category 5.1 product under the Requirement for Registration Classification and Application Dossier of Chemical Products released by the China's National Medical Products Administration.

ABOUT LABORATORIOS SALVAT, S.A.

Laboratorios Salvat S.A. is a privately owned pharmaceutical group, that develops and manufactures products, closely identified with technological innovation and strongly committed to R&D. Founded in 1955, headquartered in Barcelona (Spain) and its US subsidiary, Salvat USA, is located in Miami, FL. Salvat is present in over 60 countries and keeps strengthening its international presence through the licensing of its own developments. Additional information regarding Salvat is available at https://www.svt.com.

ABOUT LEE'S PHARM

Lee's Pharm is a research-driven and market-oriented biopharmaceutical company with more than 25 years of operation 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 over 20 international companies and currently markets 23 proprietary, generic and licensed-in pharmaceutical products in Mainland China, Hong Kong, Macau and Taiwan. The Company focuses on several key disease areas such as cardiovascular, woman health, paediatrics, rare diseases, oncology, dermatology, obstetrics and urology, and has more than 40 products under different development stages

stemming from both internal research and development as well as from the licensing and development, commercialisation, and manufacturing rights from various United States, European and Japanese companies. Lee's Pharm has also involved in the business in ophthalmology through its investment in Zhaoke Ophthalmology Limited, an associated company of the Group.

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

Hong Kong, 13 January 2021

As at the date of this announcement, Ms. Lee Siu Fong (Chairman), Ms. Leelalertsuphakun Wanee and Dr. Li Xiaoyi are executive directors of the Company, Mr. Simon Miles Ball is a non-executive director of the Company, Dr. Chan Yau Ching, Bob, Mr. Lam Yat Cheong and Dr. Tsim Wah Keung, Karl are independent non-executive directors of the Company.