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## 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 DERMATOLOGY PRODUCT

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

The Board of the Company is pleased to announce that, the Company's indirect non-wholly owned subsidiary, China Ophthalmology Focus Limited ("**COPFL**") has the last of the 1,617 enrolled patients completed the final study visit in its pivotal Phase III clinical trial of Adapalene-Clindamycin Combination Gel ("ACCG") for the treatment of moderate acne vulgaris in China on 7 April 2020. Clinical data collection and analysis are currently underway and top-line results are expected to be announced in May/June 2020, subject to successful database lock and results validation and New Drug Application ("NDA") submission is expected during the second half of 2020.

The purpose of the ACCG's Phase III multi-center, randomised, single-blind, parallel, positive controlled study (clinicaltrials.gov registration No.: NCT03615768) is to evaluate the efficacy and safety of ACCG for the treatment moderate acne vulgaris. The previous Phase II study results indicated that 0.1% Adapalene + 1% Clindamycin was the best combination for the treatment of acne vulgaris and used as the experimental group in this Phase III study. The combination gel creates synergy by combining two drugs with different mechanisms of action and increasing the absorption of Clindamycin.

The design of this Phase III clinical trial is a result of consultation with China Center for Drug Evaluation following the successful completion of Phase II study in 2017. The study involves 28 clinical trial centers and enrolls a total of 1,617 patients in China, including 95 adolescents between the ages of 12 and 18. There are three intervention groups in which patients receive treatment of (i) the combination gel of 0.1% Adapalene and 1% Clindamycin once every night, or (ii) 0.1% Adapalene Gel once every night, or (iii) Clindamycin Phosphate 1% Gel

\* For identification purpose only

twice daily. The treatment duration is 12 weeks and both efficacy and safety parameters are measured during the study. The primary endpoint is a composite of percentage change in lesion counts from baseline and reduction of 2 points on Investigator's Global Assessment scale at the end of treatment (Day  $85\pm3$ ). Sample size is calculated to detect superiority in efficacy of the combination gel over both individual components.

It is so far the largest dermatology study ever conducted in China with 1,617 patients from 28 study sites. The Company believes that the combination of Adapalene (a retinoic acid receptor (RAR) agonist) with Clindamycin (an antibiotic) will be more efficacious than conventional therapies in treating moderate acne vulgaris.

According to "Chinese Guidelines for the Management of Acne Vulgaris: 2019 Update", the prevalence of acne vulgaris in Chinese population in a cross-sectional statistical study is 8.1% and is over 90% among adolescents, some even persist in adulthood.

## ABOUT ADAPALENE-CLINDAMYCIN COMBINATION GEL

Adapalene-Clindamycin Combination Gel is a proprietary product of COPFL under development for the treatment of moderate acne vulgaris. Adapalene is an RAR agonist that stimulates skin growth and Clindamycin is an antibiotic that blocks bacterial protein synthesis. Combination of Adapalene and Clindamycin with different mechanisms of action is believed to be more efficacious than each alone in the treatment of acne vulgaris.

## ABOUT CHINA OPHTHALMOLOGY FOCUS LIMITED

COPFL is an indirect non-wholly owned subsidiary of the Company. Its Series A fund raising of USD50 million completed in June 2019 was contributed by reputable investors including Coyote Investment Pte. Ltd., Panacea Venture Healthcare Fund I, L.P., Smart Rocket Ltd., and Vertex Profit International Ltd. COPFL specialises in the development, manufacturing and marketing of ophthalmic drugs. It has built up a state-of-the-art development and production facility in Nansha, Guangzhou through its 100% subsidiary Zhaoke (Guangzhou) Ophthalmology Pharmaceutical Limited. The facility supports the in-house development and future commercialisation of over 21 proprietary products and difficult to manufacture generics (ranged from pre-clinical to registration stage) for the Chinese and ASEAN markets. Its portfolio is diversified in having both small molecules and biologics, and having both novel and generic medicines, covering different ophthalmic indications from dry eye syndrome, glaucoma, wet age-related macular degeneration, diabetic retinopathy to corneal and inflammatory diseases. It is currently the only modern facility in China that is recognised as being designed and built for ophthalmic drugs according to all applicable standards, namely China National Medical Products Administration, Pharmaceutical Inspection Co-operation Scheme (PIC/S), European Medicines Evaluation Agency (EMEA), Japan Pharmaceutical and Food Safety Bureau and U.S. Food and Drug Administration (FDA).

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

Hong Kong, 14 April 2020

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