# 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 is pleased to announce that China Ophthalmology Focus Limited ("**COPFL**"), a subsidiary of the Company, has successfully completed its pivotal Phase III trial of Adapalene-Clindamycin Combination Gel ("**ACCG**") in China for the treatment of moderate acne vulgaris. The top-line results from the pivotal Phase III trial show that the study has met its primary endpoint, demonstrating ACCG's superiority over either the Adapalene Gel or Clindamycin Phosphate Gel alone with highly significant statistic difference (P<0.0001). New Drug Application submission and marketing approval is expected in the second half of 2020 and in 2021, respectively.

The objective 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 thus chosen as the experimental group in this Phase III study. The combination gel creates synergy by combining two drugs with different mechanisms of action and increases the absorption of Clindamycin, thus reducing the use of the antibiotic to avoid development of bacterial resistance.

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

* *For identification purposes only*

or (iii) 1% Clindamycin Phosphate Gel twice daily. The treatment duration was 12 weeks and both efficacy and safety parameters were measured during the study. The primary endpoint was a composite of percentage change in lesion counts from baseline and reduction of 2 points on Investigator's Global Assessment (IGA) scale at the end of treatment (Day 85±3). Sample size was calculated to detect superiority in efficacy of the combination gel over both individual components.

ACCG demonstrated significant improvement in the primary endpoint when compared to that of the two individual components alone: the percentage change from baseline in total lesion counts was 68.5% for the ACCG group versus 52.8% (P<0.0001) and 59.5% (P<0.0001) for the Adapalene Gel group and Clindamycin Phosphate Gel group, respectively.

According to Chinese Guidelines for the Management of Acne Vulgaris: 2019 Update, the prevalence of acne vulgaris in Chinese population in a cross-sectional study was 8.1%, and over 90% among adolescents. The condition could 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 a retinoic acid receptor (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 has now been shown to be more efficacious than each component 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, 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, 22 June 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.*