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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 THE INTRODUCTION AND RESEARCH AND DEVELOPMENT OF AN INVESTIGATIONAL OPHTHALMOLOGY 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, on 30 October 2019, the Company’s indirect non-wholly owned subsidiary, China Ophthalmology Focus Limited (“**COPFL**”) has successfully completed a Phase II trial of Cyclosporine A (CsA) Ophthalmic Gel in China (clinicaltrials.gov registration No.: NCT03676335). Topline data show that the experimental drug has similar or a trend towards better efficacy than that of the marketed CsA Ophthalmic Emulsion.

The recently completed trial is a Phase II, randomised, single-blind, positive controlled, dose-finding study to assess the safety and efficacy of CsA Ophthalmic Gel in subjects with dry eye (Keratoconjunctivitis Sicca). The objective of the study is to explore and compare the efficacy and safety of CsA in a proprietary ophthalmic gel formulation with CsA Emulsion (formulation currently available on western markets) in the treatment of the above indication using different dosages and frequencies of administration, and to preliminarily determine the optimal conditions for the design of follow-up clinical study.

A total of 240 patients were enrolled in this study from 13 centers in China. The experimental drugs were given to three separate groups of subjects as follows: Treatment group A: CsA ophthalmic gel: 0.3 g: 0.15 mg, once daily; Treatment group B: CsA ophthalmic gel: 0.3 g: 0.15 mg, twice daily, with an interval of 12 hours; Treatment group C: CsA ophthalmic gel: 0.3 g: 0.3 mg, once daily. The positive control group received CsA Emulsion: 0.4 ml: 0.2 mg, twice daily, with an interval of 12 hours.

Topline data of the current trial showed the new CsA Ophthalmic Gel formulation, (0.3 g: 0.15 mg, once daily) has similar or a trend towards better efficacy than the emulsion formulation currently on the western market. The Company believes that CsA Ophthalmic Gel is well positioned to address the unmet medical need in the treatment of patients with dry eye in China where ophthalmic CsA is still unavailable. The Company has spent 10 years in the development of the patent-protected proprietary ophthalmic gel formulation of CsA and the topline data validated its commitment to the development of this innovative product.

The Company plans to meet with the Center for Drug Evaluation in China to discuss and agree upon a Phase III protocol of the CsA Ophthalmic Gel trial. The pivotal study is expected to initiate patient recruitment in early 2020.

### **ABOUT CYCLOSPORINE A OPHTHALMIC GEL**

Cyclosporine A is a natural cyclic polypeptide immunosuppressant. It acts as a calcineurin inhibitor and suppresses T lymphocytes from releasing pro-inflammatory cytokines. The Cyclosporine A Ophthalmic Gel is a proprietary product shown to possess superior pharmacokinetics profile than that of the emulsion formulation in preclinical studies. It is under development for the treatment of keratoconjunctivitis sicca (dry eye) in China.

### **ABOUT CHINA OPHTHALMOLOGY FOCUS LIMITED**

COPFL is an indirect non-wholly owned subsidiary of the Company. Its Series A fund raising of USD50 million 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 (AMD), 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, Pharmaceutical Inspection Co-operation Scheme (PIC/S), EMEA, Japan and Food and Drug Administration (FDA).

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

Hong Kong, 30 October 2019

\* *For identification purpose only*

*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.*