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 RESEARCH AND DEVELOPMENT OF AN INVESTIGATIONAL OPHTHALMOLOGY PRODUCT OF AN ASSOCIATED COMPANY OF THE GROUP

This announcement is made by the board of directors (the "**Board**") 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 Zhaoke Ophthalmology Limited ("**ZKO**"), an associated company of the Group, successfully recruited its last patient dosed with Cyclosporine A (CsA) Ophthalmic Gel, a drug for the treatment of keratoconjunctivitis sicca (dry eye) in a Phase III clinical trial in China on 9 April 2021. This trial involves 41 clinical trial centers and has enrolled a total of 644 patients. ZKO plans to submit a New Drug Application to the National Medical Product Administration ("**NMPA**") in the fourth quarter of 2021.

The purpose of this Phase III, Multi-center, Randomized, Double-Blind, Vehicle-controlled, Efficacy and Safety Study of Cyclosporine A Ophthalmic Gel Compared with Placebo in Subjects with Moderate to Severe Dry Eye Disease ("**DED**") (COSMOS; clinicaltrials.gov registration No.: NCT04541888) is to evaluate the efficacy and safety of CsA Ophthalmic Gel for the treatment of keratoconjunctivitis sicca (dry eye). The previous Phase II study results suggested that 0.05% CsA Ophthalmic Gel (q.d.) had efficacy and safety profiles similar to those of Restasis (0.05% Cs A, b.i.d.).

* *For identification purpose only*

The design of this Phase III clinical trial is a result of consultation with China Center for Drug Evaluation following the successful completion of a Phase II study. Patients with moderate to severe DED are randomized to receive either (i) CsA Ophthalmic Gel once every night or (ii) placebo once every night for 84 days. The primary endpoint is inferior fluorescein corneal staining score (ICSS) at the end of treatment (Day 84±3). Secondary endpoints include both signs and symptoms of DED. Safety parameters will also be monitored in the trial.

CsA Ophthalmic Gel is an innovative hydrogel formulation as opposed to the oil-based emulsion formulation in Restasis. The hydrogel formulation has been shown in preclinical studies to greatly improve the exposure of CsA in the tear and ocular surface tissues as compared to Restasis. CsA Ophthalmic Gel's one dose every night regimen is expected to significantly improve patients' quality of life and treatment compliance compared to Restasis' twice-daily dosing regimen by relieving the patients from having to experience potential drug-related transient discomfort in the eye during the day.

ABOUT CYCLOSPORINE A (CsA) OPHTHALMIC GEL

CsA is a natural cyclic polypeptide immunosuppressant. It acts as a calcineurin inhibitor and suppresses T lymphocytes from releasing pro-inflammatory cytokines. The CsA Ophthalmic Gel developed by ZKO is a proprietary product shown to possess pharmacokinetics profile superior to that of the emulsion formulation (Restasis) in preclinical studies. In a Phase II head-to-head comparative trial, CsA Ophthalmic Gel displayed efficacy and safety profile at least similar to those of Restasis (b.i.d.) with only once a day dosing. It is currently under Phase III development for the treatment of moderate to severe keratoconjunctivitis sicca (dry eye) in China.

ABOUT ZHAOKE OPHTHALMOLOGY LIMITED

ZKO aims to provide a one-stop shop of ophthalmic therapies with its comprehensive portfolio and capabilities. ZKO's 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, myopia, wet age-related macular degeneration, diabetic retinopathy to corneal and inflammatory diseases. It specialises in the development, manufacturing and marketing of ophthalmic drugs. It has established 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 25 proprietary products and difficult to manufacture generics (ranging from pre-clinical to registration stage) for the Chinese and ASEAN markets. It is a modern facility in China designed and built for ophthalmic drugs in compliance with all applicable standards, namely China National Medical Products Administration, Pharmaceutical Inspection Co-operation Scheme (PIC/S), European Medicines Evaluation Agency, Japan Pharmaceutical and Food Safety Bureau and U.S. Food and Drug Administration (FDA).

ZKO closed its Series A fund raising of US$50 million in June 2019 with investors including Coyote Investment Pte. Ltd., Panacea Venture Healthcare Fund I, L.P., Smart Rocket Limited and Vertex Profit International Limited. ZKO closed its Series B fund raising of approximately US$145 million in November 2020, which was jointly led by Hillhouse COFL and TPG Asia, and participated by Loyal Valley Capital and other private equity firms, as well as the majority of Series A investors. ZKO submitted its listing application form to the Stock Exchange of Hong Kong Limited ("**Stock Exchange**") for an application for the listing of, and permission to deal in, its ordinary shares on the main board of the Stock Exchange by way of global offering on 18 December 2020. Its post hearing information pack has been submitted to Stock Exchange for publication on 6 April 2021 and it is now available for viewing and downloading from the Stock Exchange's website at http://www.hkexnews.hk/app/sehkappmainindex.htm.

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

Hong Kong, 12 April 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.