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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 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 first patient dosed with ZKY001, a potential first-in-class eye drop targeting corneal epithelial defects (“**CED**”), through anti-inflammatory effects plus stimulation of epithelial cell migration, in a Phase II clinical trial in China on 24 December 2020.

The purpose of the Phase II, Multicenter, Randomised, Double-Masked, Placebo-controlled Study of ZKY001 is to evaluate its efficacy and safety for the treatment of CED after endothelial keratoplasty, a cornea transplant surgery to restore vision when the inner cell layer of the cornea stops working properly. Such surgery inevitably damages the corneal epithelium. This trial also aims to assess the dosage of ZKY001 for future development.

The clinical trial is designed to enroll a total of 105 subjects, who will receive 0.002% ZKY001 (n=35), 0.004% ZKY001 (n=35) or placebo (n=35) four times daily for a 14±2-day dosing period. The administration will begin on day 1 after surgery. The primary endpoint of this trial is the average area of repaired cornea on day 3. The key secondary endpoints include improvement of signs and symptoms of CED from baseline on day 3, 6 and 15, and the average area of repaired cornea on day 2, 4 and 5.

* For identification purposes only

Compared to widely prescribed growth factor therapies, such as rh-EGF and rb-bFGF drugs, which stimulate angiogenesis and may cause edema and inflammation, ZKY001 showed better in vivo efficacy in reducing corneal swelling and suppressing abnormal ocular vessel growth in preclinical animal models. ZKY001 also has a favourable safety profile, well tolerated at all concentrations in one of its Phase I clinical trials. It is believed that ZKY001 has the potential to be a foundational therapy for a broad range of corneal epithelial diseases.

ABOUT ZKY001

ZKY001, one of the core products of ZKO, is a potential first-in-class eye drop targeting CED, the partial or complete loss of the epithelial cells in the cornea. ZKY001 is a seven amino acid peptide, LKKTETQ, resembling part of thymosin β 4 that plays a central role in cell structure and movement. Through its regulation of actin, ZKY001 is able to accelerate corneal epithelial wound repair and enhance epithelial cell migration.

CED is the partial or complete loss of the epithelial cells in the cornea, which could lead to inflammatory responses on the ocular surface, or even stromal keratopathy, a serious corneal condition that may cause permanent vision loss. CED may be caused by mechanical traumas, infections and inflammation on the ocular surface due to diseases such as diabetes and dry eye disease. CED may also be caused by neurotrophic abnormalities that lead to decreased production of tears, post-surgery corneal damages and side effects from preservatives in ophthalmic drugs. It is usually associated with pain, tearing and foreign body sensation of the affected eye, and patients may also experience blurry vision, redness, photophobia, pain with blinking and eye movement.

Currently ZKY001 is the only clinical-stage CED drug candidate in China. It is not a growth factor and does not cause angiogenesis. It employs an innovative mechanism for CED treatment through anti-inflammatory effects plus stimulation of epithelial cell migration. ZKO had completed two preclinical studies to evaluate ZKY001's efficacy for the treatment of CED and a Phase I clinical trial to evaluate ZKY001's safety, tolerability and systemic pharmacokinetics in healthy subjects. Subsequent to the completion of this Phase I clinical trial, ZKO consulted the Center for Drug Evaluation ("CDE") of National Medical Products Administration ("NMPA") for initiating its Phase II clinical trial. According to the correspondence with the CDE, it is understood that the CDE is of the view that the currently available data (including the preclinical studies and the completed Phase I clinical trial) have provided sufficient support for the safety profile of ZKY001 to proceed to subsequent trials.

ABOUT ZHAOKE OPHTHALMOLOGY LIMITED

ZKO is an associated company of the Group. It finished its Series A fund raising of US\$50 million in June 2019 contributed by reputable investors including Coyote Investment Pte. Ltd., Panacea Venture Healthcare Fund I, L.P., Smart Rocket Ltd., and Vertex Profit International Ltd. ZKO has also finished its Series B fund raising of approximately US\$145 million in November 2020, which were jointly led by Hillhouse COFL and TPG Asia (in alphabetical order), co-led by Loyal Valley Capital and other private equity firms, and the majority of shareholders of Series A Preferred Shares also participated in as well. 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.

ZKO 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 20 proprietary products and difficult to manufacture generics (ranged from preclinical to registration stage) for the Chinese and ASEAN markets.

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, Japan Pharmaceutical and Food Safety Bureau and U.S. Food and Drug Administration (FDA). 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 to wet age-related macular degeneration, diabetic retinopathy to corneal and inflammatory diseases.

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

Hong Kong, 29 December 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.