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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 ONCOLOGY PRODUCT**

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, on 10 July 2020, China Oncology Focus Limited (“**COF**”), a subsidiary of the Group, submitted the application of breakthrough designation to China National Medical Products Administration (“**NMPA**”) for anti-PD-L1 monoclonal antibody, ZKAB001 in recurrent and metastatic cervical cancer.

The State Administration of Market Regulation of China, the parent agency of the NMPA released a revised Drug Registration Regulation (“**Revised DRR**”) on 30 March 2020 which goes into effect on 1 July 2020. The Revised DRR authorises regulatory pathways for priority review and approval (including for breakthrough therapeutic drugs), conditional approval, and special approval procedures. The Revised DRR expanded priority review to breakthrough therapeutic drugs, which are used for the prevention and treatment of diseases that seriously affect the quality of life or seriously life threatening, for which there are no effective prevention or treatment methods or, compared with existing measures of treatment, there is sufficient evidence to show that they have obvious clinical advantages.

There are over 100,000 new cases of cervical cancer and nearly 30,000 women cervical cancer deaths occurs in China each year. The recurrence rate after the first line treatment is high. There is an urgent medical needs to have a new standard treatment in China and around the world. With the rapid development of immune checkpoint inhibitor, anti-PD-L1 antibody, ZKAB001, can become a new hope to the patients in need.

\* For identification purposes only

## **ABOUT COF**

COF, founded in 2015, is a subsidiary of Lee's Pharm and a clinical development stage company focused in oncology with emphasis in immune oncology. COF is currently developing several assets, including Pexa-vec (oncolytic virus) which is in global Phase Ib clinical trial for renal cell cancer; ZKAB001 (PD-L1 inhibitor) in Phase I clinical trial dose expansion phase in China for solid tumors with highly unmet medical need; Zotiraciclib, an oral multi-kinase inhibitor whose initial focus is in the treatment of glioblastoma and hepatocellular carcinoma and Gimatecan, a topoisomerase I inhibitor in Phase I clinical trial for ovarian cancer and in Phase Ib/II clinical trial for small cell lung cancer in China. COF has built a strong pipeline of 10 assets through internal development and in-licensing. The diversity of its products creates a unique position for the company to use immune oncology as backbone therapy in combination with in-house products and develop potential paradigm-shifting treatment for cancer.

## **ABOUT LEE'S PHARM**

Lee's Pharm is a research-driven and market-oriented biopharmaceutical company with more than 25 years of operation in the pharmaceutical industry in China. The Company is fully integrated with solid infrastructures in drug development, clinical development, regulatory, manufacturing, sales and marketing based in Mainland China with global perspectives. The Company has established extensive partnerships with over 20 international companies and currently markets 23 proprietary and licensed-in pharmaceutical products in Mainland China, Hong Kong, Macau and Taiwan. The Company focuses on several key disease areas such as cardiovascular, woman health, paediatrics, rare diseases, oncology, ophthalmology, dermatology, obstetrics and urology. It has more than 60 products under different development stages stemming from both internal research and development as well as from the licensing and development, commercialisation, and manufacturing rights from various United States, European and Japanese companies.

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

Hong Kong, 16 July 2020

*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.*