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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)**

### **INSIDE INFORMATION UPDATE ON THE 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**”) pursuant to Rule 13.09 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “**Listing Rules**”) and the Inside Information Provisions (as defined under the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong).

The business partner of the Group, Sillajen, Inc. (KOSDAQ: 215600) (“**Sillajen**”), announced that the Independent Data Monitoring Committee (IDMC) for the PHOCUS study, a Phase 3 clinical trial evaluating the oncolytic immunotherapy Pexa-Vec (formerly JX-594) for advanced liver cancer, has evaluated the results of a formal pre-planned futility analysis for this study, and has recommended discontinuation of the trial. While Pexa-Vec is generally well tolerated by patients, the interim results suggest that the study is unlikely to meet the primary objective by the time of the final analysis. The decision was not related to the safety of the investigational product.

The PHOCUS trial was designed to enroll 600 patients with advanced liver cancer (also called hepatocellular carcinoma, or “**HCC**”), worldwide, who had not received prior systemic treatment for their cancer, and they were randomised to one of two treatment groups: one which received Pexa-Vec followed by sorafenib and one which received sorafenib alone. The randomised study was conducted at approximately 86 sites worldwide including North America, Asia, Australia, New Zealand and Europe. The primary objective of the study was to determine the overall survival of patients treated with Pexa-Vec, followed by sorafenib versus sorafenib alone. Secondary objectives included safety as well as assessments for tumor responses between the two groups as measured by the following endpoints: time to progression, progression-free survival, overall response rate and disease control rate.

Nevertheless, some other Pexa-Vec combination with checkpoint inhibitors studies are currently underway outside China by the business partner of the Group, such as Pexa-Vec+Nivolumab-combination therapy on advanced liver cancer, Pexa-Vec+PD-L1+CTLA4-combination therapy on colorectal cancer and Pexa-Vec+PD1 combination therapy on renal cancer. To date, over 50 patients have been treated with the combination therapy, and no Dose Limiting Toxicity (DLT) and drug safety issue were noted. Synergistic efficacy signal has been observed that warrants further studies.

China Oncology Focus Limited (“COFL”), a 65%-owned subsidiary of the Group, is a drug development company specialised in oncology disease area. COFL has an exclusive license to develop Pexa-Vec for the treatment of cancers in the People’s Republic of China, Hong Kong and Macau, and is also developing Pexa-Vec+PD-L1-combination studies plan on other indications such as second-line therapies on melanoma and sarcoma. COFL is currently developing 9 assets, namely Pexa-Vec, PD-L1, Zotiraciclib (formerly known as TG02), Glufosfamide, Gimatecan, Melphalan, Olaparib, Gliolan and Axitinib.

The Group is currently evaluating the operational and financial impact of the results of the interim analysis of the PHOCUS study. **Shareholders of the Company and investors are advised to exercise caution when dealing in the shares of the Company.**

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

Hong Kong, 5 August 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 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.*