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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**" or "**Lee's Pharm**", together with its subsidiaries as the "**Group**") on a voluntary basis.

The Board of the Company is pleased to announce that, China Oncology Focus Limited ("**COF**"), a subsidiary of the Group, has successfully commenced the patient enrolment and the first patient has been dosed in an osteosarcoma phase III clinical trial using ZKAB001 (anti-PD-L1 monoclonal antibody) on 21 August 2020.

Osteosarcoma is the most common malignant bone tumor in children and young adults. Therapy consisting of surgery and chemotherapy with at least three active agents has improved the probability of long-term survival for patients with localised disease to approximately 70%. However, a significant number of patients who achieve a complete response to upfront therapy develop disease relapse, and the probability of survival after relapse is much lower (approximately 20%).

ZKAB001 is a fully human anti-PD-L1 monoclonal antibody targeting tumor PD-L1 protein. It can release the "brake" causing by the tumor cell to the immune system. A phase I clinical trial in osteosarcoma patients who underwent upfront therapy to evaluate whether ZKAB001 can prevent tumor recurrence was completed early this year and the encouraging results therefrom has led to the initiation of this phase III clinical trial titled "Study of ZKAB001 for Maintenance Therapy in Patients With High-grade Osteosarcoma After Adjuvant Chemotherapy". The study is being conducted at 34 trial sites in China and a total of about 362 patients are expected to be enrolled, including the placebo cohort. The patients will receive ZKAB001 treatment every three weeks for 16 cycles or for one year, whichever comes first. 1-year disease-free survival of the patients will be the primary endpoint of this clinical trial.

## **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 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 Lee's Pharmaceutical Holdings Limited Lee Siu Fong Chairman

Hong Kong, 21 August 2020

\* 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.