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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 AN INVESTIGATIONAL ONCOLOGY DRUG PRODUCT**

This announcement is made by the board (the “**Board**”) of directors (the “**Directors**”) 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, on 15 July 2021, China Oncology Focus Limited (“**COF**”), a subsidiary of the Company, has enrolled the first patient in China in the Phase III, multicenter, randomised, double blinded, placebo control clinical trial of Socazolimab (anti-PD-L1 monoclonal antibody, formerly known as ZKAB001) combined with chemotherapy in the first-line treatment of extensive-stage small-cell lung cancer (“**ES-SCLC**”). The clinical trial approval was granted by China’s National Medical Products Administration (“**NMPA**”) on 1 March 2021.

The initiation of this Phase III trial is based on the results from an earlier Phase Ib trial in which Socazolimab combined with carboplatin and etoposide showed promising efficacy and safety profile in patients with ES-SCLC. This clinical trial involves 56 centers and is led by Prof. Shun Lu (陸舜) from Shanghai Chest Hospital (上海市胸科醫院).

Socazolimab is an in-licensed product from Sorrento Therapeutics, Inc (“**Sorrento**”) for the People’s Republic of China, Hong Kong, Macau and Taiwan. To date, three Phase I clinical trials of Socazolimab monotherapy have been completed: (1) recurrent or metastatic cervical cancer; (2) advanced urothelial carcinoma; and (3) high-grade osteosarcoma after adjuvant chemotherapy for maintenance purpose. For recurrent or metastatic cervical cancer, a pivotal study has been completed and breakthrough therapy designation has been granted by the NMPA in February 2021. Pre-NDA meetings were conducted with the Centre for Drug Evaluation (“**CDE**”) and feedbacks have been provided therefrom. Recently, supplemental data has been requested by the CDE and has been submitted by the Company accordingly. The Company expects to file the New Drug Application (“**NDA**”) for Socazolimab in recurrent

\* *For identification purpose only*

or metastatic cervical cancer in the third quarter of 2021. Apart from monotherapies, several studies of Socazolimab combined with chemotherapy are being conducted in advanced urothelial carcinoma (Phase Ib), ES-SCLC (Phase III), neoadjuvant treatment in esophageal carcinoma (Phase Ib+II) and resected biliary tract cancer (Phase I).

## **ABOUT SOCAZOLIMAB**

Socazolimab is a fully human anti-PD-L1 monoclonal antibody identified by Sorrento using its proprietary G-MAB™ library platform. Socazolimab has the following potential advantages over its competitors:

1. Fully human antibody potentially allows it to have minimal immunogenicity; demonstrated by its negative antigen-derived antibody (ADA) generation in humans in studies to date.
2. Potentially lower dose required to achieve efficacy compared to other anti-PD-L1 antibodies.
3. Dual mechanism of action observed with both immune-checkpoint inhibition and antibody-dependent cellular cytotoxicity (ADCC) effect.

## **ABOUT ES-SCLC AND IMMUNOTHERAPY**

Atezolizumab, a PD-L1 inhibitor, in combination with carboplatin and etoposide, was approved by the NMPA as a first-line treatment for ES-SCLC. The treatment was a major milestone and the first new treatment for the aggressive cancer in decades; it increased the median overall survival by 2 months and reduced the risk of death by 23% compared with chemotherapy alone in this disease setting. The advance was celebrated as a major milestone. Durvalumab, another PD-L1 inhibitor, has been granted the NDA in ES-SCLC in China early this month. No PD-1 inhibitor has been approved in this indication.

## **ABOUT COF**

COF is a subsidiary of Lee's Pharm and a clinical development stage company focused on oncology. COF is currently developing several assets, including Socazolimab (anti-PD-L1 antibody) in pivotal clinical trial stage; Zotiraciclib, an oral multi-kinase inhibitor in Phase I clinical trial for glioblastoma; Gimatecan, a topoisomerase I inhibitor in Phase I clinical trial for ovarian cancer, a Phase Ib/II clinical trial for small cell lung cancer and a Phase I clinical trial for pancreatic cancer in China; Pexa-vec (oncolytic virus) which is in global Phase Ib clinical trial for renal cell cancer. 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 25 proprietary, generic 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, dermatology, obstetrics and urology, and has more than 40 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. More information available at [www.leespharm.com](http://www.leespharm.com).

## **ABOUT SORRENTO**

Sorrento is a clinical stage, antibody-centric, biopharmaceutical company developing new therapies to treat cancers and COVID-19. Sorrento's multimodal, multipronged approach to fighting cancer is made possible by its extensive immuno-oncology platforms, including key assets such as fully human antibodies ("**G-MAB™ library**"), clinical stage immuno-cellular therapies ("**CAR-T**", "**DAR-T™**"), antibody-drug conjugates ("**ADCs**"), and clinical stage oncolytic virus ("**Seprehvir™**"). Sorrento is also developing potential antiviral therapies and vaccines against coronaviruses, including COVIGUARD™, COVI-AMG™, COVISHIELD™, Gene-MAb™, COVI-MSCTM and COVIDROPS™; and diagnostic test solutions, including COVITRACK™, COVISTIX™ and COVITRACE™. Sorrento's commitment to life-enhancing therapies for patients is also demonstrated by its effort to advance a first-in-class (TRPV1 agonist) non-opioid pain management small molecule, resiniferatoxin ("**RTX**"), and SP-102 (10 mg, dexamethasone sodium phosphate viscous gel) (SEMDEXA™), a novel, viscous gel formulation of a widely used corticosteroid for epidural injections to treat lumbosacral radicular pain, or sciatica, and to commercialise ZTlido® (lidocaine topical system) 1.8% for the treatment of post-herpetic neuralgia. RTX has completed a Phase Ib trial for intractable pain associated with cancer and a Phase Ib trial in osteoarthritis patients. SEMDEXA is in a pivotal Phase III trial for the treatment of lumbosacral radicular pain, or sciatica. ZTlido® was approved by the FDA on 28 February 2018. More information available at [www.sorrentotherapeutics.com](http://www.sorrentotherapeutics.com).

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

Hong Kong, 22 July 2021

*As at the date of this announcement, Ms. Lee Siu Fong (Chairman) and Ms. Leelalertsuphakun Wanee are executive Directors, Dr. Li Xiaoyi 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.*