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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 RESEARCH AND DEVELOPMENT OF AN INVESTIGATIONAL ONCOLOGY 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 5 February 2021, China Oncology Focus Limited (“**COF**”), a subsidiary of the Group, has been granted breakthrough therapy designation (“**BTD**”) by the China National Medical Products Administration (“**NMPA**”) for anti-PD-L1 monoclonal antibody, Socazolimab (formerly known as ZKAB001), to treat recurrent or 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**”) which was effective from 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. Products with BTD from the NMPA may be considered for conditional approval and priority review when submitting a New Drug Application (“**NDA**”).

The clinical study of Socazolimab monotherapy in recurrent and metastatic cervical cancer is led by Doctor Lingying Wu as the principal investigator and consists of two phases, a traditional open labeled 3+3 dose escalation phase followed by an expansion phase. In view of the positive clinical progress so far, NDA with conditional approval is expected to be filed with the NMPA in the second quarter of this year.

\* *For identification purposes only*

Socazolimab is an in-licensed product from Sorrento Therapeutics, Inc (“**Sorrento**”) for the People’s Republic of China, Hong Kong, Macau and Taiwan.

## **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.

The antibody has been tested or is being tested in various cancer indications including recurrent or metastatic cervical cancer, maintenance therapy for high-grade osteosarcoma after adjuvant chemotherapy, locally advanced and metastatic urothelial carcinoma, extensive small cell lung cancer in combination with carboplatin and etoposide, advanced urothelial carcinoma in combination with albumin-bound paclitaxel and esophageal carcinoma.

## **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 COVI-GUARD™, COVI-AMG™, COVI-SHIELD™, Gene-MAb™, COVI-MSCTM and COVI-DROPS™; and diagnostic test solutions, including COVI-TRACK™, COVI-STIX™ and COVI-TRACE™.

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 1B trial in

osteoarthritis patients. SEMDEXA is in a pivotal Phase 3 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).

## **ABOUT COF**

COF 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 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 and in Phase Ib/II clinical trial for small cell lung 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 23 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. Lee's Pharm has also involved in the business in ophthalmology through its investment in Zhaoke Ophthalmology Limited, an associated company of the Group.

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

Hong Kong, 9 February 2021

*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.*