

*Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.*



## **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 – NEW DRUG APPLICATION OF SOCAZOLIMAB FOR TREATMENT OF RECURRENT OR METASTATIC CERVICAL CANCER SUBMITTED AND ACCEPTED BY NMPA**

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 26 October 2021, the new drug application (“**NDA**”) for Socazolimab to treat recurrent or metastatic cervical cancer, from China Oncology Focus Limited, a subsidiary of the Group, has been successfully submitted and accepted by the Center for Drug Evaluation (the “**CDE**”) of the China’s National Medical Products Administration (the “**NMPA**”) for review. The priority review and conditional approval applications have also been submitted simultaneously with the NDA.

Socazolimab 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. The clinical study of Socazolimab monotherapy in recurrent and metastatic cervical cancer has shown promising safety and efficacy profile.

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

\* *For identification purpose only*

## 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 stage small cell lung cancer in combination with carboplatin and etoposide, advanced urothelial carcinoma in combination with albumin-bound paclitaxel, esophageal carcinoma and metastatic melanoma in combination with oncolytic virus, Pexa-Vec.

## 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 1B 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 on oncology. COF is currently developing several assets, including Socazolimab, an anti-PD-L1 antibody in New Drug Application stage in China; Zotiraciclib, an oral multi-kinase inhibitor in Phase I clinical trial for glioblastoma; Gimatecan, a topoisomerase I inhibitor in Phase II 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 and obstetrics, 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.

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

Hong Kong, 27 October 2021

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