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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 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 21 October 2021, China Oncology Focus Limited ("COF"), a subsidiary of the Group, has enrolled the first patient in China in a Phase Ib/II clinical study of Pexa-Vec (Vaccinia GM CSF/Thymidine Kinase-Deactivated Virus) combined with Socazolimab (anti-PD-L1 monoclonal antibody, formerly known as ZKAB001) in metastatic melanoma.

The study is led by Prof. Jun Guo (郭軍) from Beijing University Cancer Hospital (北京大學腫瘤醫院) and is divided into two Phases: Phase Ib and Phase II. The safety and Phase II recommended dose of the combination therapy in patients with local progression of failed first-line treatment or metastatic melanoma will be evaluated in Phase Ib and maximal 12 patients will be enrolled in this stage. Objective response rate (ORR) and progression-free survival (PFS) of Socazolimab combined with Pexa-Vec or Socazolimab monotherapy in patients with local progression or metastatic melanoma will be evaluated in Phase II. A total of 45 patients will be enrolled in that phase. The recruitment of Phase Ib study is expected to be completed in June 2022.

<sup>\*</sup> For identification purpose only

# ABOUT SOCAZOLIMAB

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. The Company has submitted a New Drug Application for Socazolimab in recurrent or metastatic cervical cancer in October 2021. Apart from monotherapies, several studies of Socazolimab combined with chemotherapy are being conducted in advanced urothelial carcinoma (Phase Ib), extensive-stage small-cell lung cancer (Phase III), neoadjuvant treatment in esophageal carcinoma (Phase Ib+II) and Resected Biliary Tract Cancer (Phase I).

Socazolimab is a fully human anti-PD-L1 monoclonal antibody identified by Sorrento Therapeutics using its proprietary G-MAB<sup>TM</sup> 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 PEXA-VEC

Pexa-Vec is the most advanced product candidate from SillaJen, Inc. ("SillaJen"). The vaccinia strain backbone of Pexa-Vec has been used safely in millions of people as part of a worldwide vaccination program, and over 300 cancer patients have been treated with Pexa-Vec to date. Pexa-Vec was engineered to target common genetic defects in cancer cells by deleting their thymidine kinase (TK) gene, thus making Pexa-Vec dependent on the cellular TK expressed at persistently high levels in cancer cells. Pexa-Vec is also engineered to express granulocyte-macrophage colony stimulating factor (GM-CSF) protein. GM-CSF complements the cancer cell lysis of the product candidate, leading to a cascade of events resulting in tumor necrosis, tumor vasculature shutdown and sustained anti-tumoral immune attack. Pexa-Vec has been shown to be effective when delivered both intratumorally and systemically by intravenous administration.

#### **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.

# 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<sup>TM</sup> library"), clinical stage immuno-cellular therapies ("CAR-T", "DAR-T<sup>TM</sup>"), antibody-drug conjugates ("ADCs"), and clinical stage oncolytic virus ("Seprehvir<sup>TM</sup>"). Sorrento is also developing potential antiviral therapies and vaccines against coronaviruses, including COVIGUARD<sup>TM</sup>, COVI-AMG<sup>TM</sup>, COVISHIELD<sup>TM</sup>, Gene-MAb<sup>TM</sup>, COVI-MSC<sup>TM</sup> and COVIDROPS<sup>TM</sup>; and diagnostic test solutions, including COVITRACK<sup>TM</sup>, COVISTIX<sup>TM</sup> and COVITRACE<sup>TM</sup>. 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<sup>TM</sup>), 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.

# ABOUT SILLAJEN

SillaJen, Inc. is a South Korean based biotechnology company headquartered in Busan South Korea, with satellite offices in Seoul, South Korea and San Francisco, CA. The company is focused on the development and commercialization of oncolytic immunotherapy products using the SOLVE<sup>TM</sup> platform, including its lead product Pexa-Vec. Additional information about SillaJen is available at www.sillajen.com.

By order of the Board

Lee's Pharmaceutical Holdings Limited

Lee Siu Fong

Chairman

Hong Kong, 16 November 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.