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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 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 28 April 2020, Lee’s Pharmaceutical (HK) Limited (“**LPHK**”), a wholly-owned subsidiary of the Company, its New Drug Application (“**NDA**”) of Natulan® for the treatment of advanced Hodgkin’s lymphoma (“**HL**”) has been accepted for review by China’s National Medical Products Administration (“**NMPA**”). The Group is expected to submit the Priority Review application of NDA by end of May 2020.

The confirmatory study (NCT02800447) was an open label, randomised, controlled, multicentre study which was led by more than 13 trial sites in China. It was designed to observe and compare the objective response rate (ORR) of baseline BEACOPP (chemotherapy combination that includes bleomycin, etoposide, doxorubicin hydrochloride (Adriamycin), cyclophosphamide, vincristine (Oncovin), procarbazine and prednisone) and ABVD (chemotherapy combination that includes doxorubicin hydrochloride (Adriamycin), bleomycin, vinblastine and dacarbazine) regimens for patients with advanced HL and evaluate the safety of Natulan® in Chinese patients with advanced HL. A total of 93 advanced HL patients were enrolled and the study not only met the primary endpoint showing non-inferior ORR in baseline BEACOPP group compared with ABVD group, but also achieved significantly higher complete remission rate 16.22% (6/37) in baseline BEACOPP group (21 days per cycle) after 4 cycles of treatment vs 2.17% (1/46) in ABVD group (28 days per cycle).

HL is a cancer of the lymphatic system, which can affect the lymph nodes, spleen, bone marrow, and other internal organs. HL is one of two common types of cancers of the lymphatic system. According to GLOBOCAN database, there were about 5,007 new cases of HL in China in 2018.

LPHK signed an distribution agreement with Leadiant Biosciences Ltd in May 2018, to exclusively commercialise Natulan® for Greater China.

ABOUT Natulan®

Natulan® (Procarbazine Hydrochloride Capsule) in combination chemotherapy is suitable for the treatment of HL and certain brain cancers (such as glioblastoma multiforme). It is a member of a group of medicines called alkylating agents. It has originally been developed by Hoffmann-La Roche, which first filed a patent claiming its preparation process and its use. The drug (Matulane®) gained FDA approval in the US in July 1969.

ABOUT LEADIANT BIOSCIENCES

Leadiant Biosciences, formerly known as Sigma-Tau Rare Disease, is a research-based global pharmaceutical company dedicated to the development, registration and commercialisation of novel and effective therapies that address the needs and improve the quality of life of patients suffering from rare and ultra-rare disease. Leadiant Biosciences operates as Leadiant Biosciences, Ltd. in the UK, acting as a distribution network in Europe and the rest of the world. Additional information on Leadiant Biosciences is available at www.leadiantbiosciences.com.

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, 8 May 2020

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

* For identification purpose only