

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

UPDATE ON AN INVESTIGATIONAL GYNECOLOGY 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 13 September 2021, Zhaoke Pharmaceutical (Hefei) Company Limited, a wholly-owned subsidiary of the Company, has enrolled the first patient in China in a pivotal Phase III, multicenter, randomised, double blinded, parallel-group clinical trial of Intrarosa, a product licensed from Endoceutics, Inc., in the treatment of vulvovaginal atrophy (“**VVA**”).

Intrarosa has been marketed in the U.S., Canada and Europe. The purpose of the current Phase III trial in China is to compare the safety and efficacy of Intrarosa to placebo in Chinese population. The primary endpoint is to compare the changes in the dyspareunia (dyspareunia) severity score (by VASQ) at Day 85 with Day 1 in the two groups of subjects. A total of 418 patients will be enrolled. The study is led by Professor Sui Long (隋龍) from the Obstetrics & Gynecology Hospital of Fudan University (復旦大學附屬婦產科醫院) and a total of 28 centers will be participated in this study. The expected enrollment completion time will be in the third quarter of 2022.

ABOUT INTRAROSA

Intrarosa is the only FDA and EMA approved, locally administered, daily non-estrogen steroid for the treatment of VVA due to menopause. Intrarosa’s product information does not have any boxed (safety) warnings, contrary to all other FDA approved drugs for the treatment of VVA, which have boxed warnings. Intrarosa contains prasterone, also known as dehydroepiandrosterone (DHEA). Prasterone is an inactive endogenous steroid, which is converted locally into androgens and estrogens to help restore the vaginal tissue as indicated by improvements in the percentage of superficial and parabasal cells, and pH.

* *For identification purpose only*

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 ENDOCEUTICS, INC.

Endoceutics is a private Canadian pharmaceutical company operating in the field of women's health and hormone-sensitive cancer prevention and treatment. Following approval of Intrarosa by the U.S. Food and Drug Administration in November 2016 for the treatment of moderate to severe dyspareunia, a symptom of VVA due to menopause as well as by the European Medicines Agency in January 2018 and by Health Canada in November 2019 for the treatment of VVA in postmenopausal women, Endoceutics now focuses its efforts on supporting the worldwide commercialisation of this innovative product through partners of choice, and on the advancement of its pipeline.

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

Hong Kong, 13 September 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.