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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 COMPLETION OF PATIENT ENROLMENT FOR A PHASE III CLINICAL TRIAL OF INTRAROSA**

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 21 October 2022, Zhaoke Pharmaceutical (Hefei) Company Limited (“**Zhaoke Hefei**”), a wholly-owned subsidiary of the Company, has completed the patient enrolment for a Phase III, multicenter, randomised, double blinded, parallel-group clinical trial of Intrarosa, a product licensed from Endoceutics, Inc. (“**Endoceutics**”), in the treatment of vulvovaginal atrophy (“**VVA**”).

The clinical trial approval was granted to Zhaoke Hefei by the China’s National Medical Products Administration on 5 January 2021. The study is led by Professor Long Sui from the Obstetrics and Gynecology Hospital of Fudan University. Total of 418 patients has been enrolled by 28 study sites and the topline data is expected to be obtained by March 2023.

#### **ABOUT INTRAROSA**

Intrarosa is the only FDA and EMA approved, locally administered, daily non-estrogen steroid for the treatment of moderate to severe dyspareunia (pain during intercourse), a symptom 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 over 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. The Group has obtained market approval of 11 products since 2021 and has completed the patient enrolment for two Phase III clinical studies in the indication of small cell lung cancer (498 patients enrolled) and VVA (418 patients enrolled). More information available at [www.leespharm.com](http://www.leespharm.com).

## **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 US FDA 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, 26 October 2022

*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 and Mr. James Charles Gale are non-executive directors 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.*