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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 ANAESTHESIA PRODUCT**

This announcement is made by the board of directors (the “**Board**”) of Lee’s Pharmaceutical Holdings Limited (the “**Company**” or “**Lee’s Pharm**”, together with its subsidiaries as the “**Group**”) on a voluntary basis.

Reference is made to the announcement of the Company dated 31 August 2020 in relation to the Investigational New Drug (“**IND**”) application of Staccato<sup>®</sup> fentanyl for inhalation for the treatment of cancer breakthrough pain made by Lee’s Pharmaceutical (HK) Limited (“**LPHK**”), a wholly-owned subsidiary of the Company. The Board of the Company is pleased to announce that LPHK has been granted the approval for conducting clinical trials therefor by China’s National Medical Products Administration (“**NMPA**”) on 2 November 2020.

Staccato<sup>®</sup> fentanyl for inhalation system was licensed in by the Group from Alexza Pharmaceuticals, Inc. (“**Alexza**”) in March 2018. A previous Phase I clinical study conducted in the U.S. demonstrated that the pharmacokinetic (“**PK**”) profile of single doses of inhaled fentanyl is comparable to that of intravenous administration. Staccato<sup>®</sup> fentanyl for inhalation system is a combination drug-device delivery product designed for rapid, systemic delivery of aerosolised fentanyl via the lung. The product integrates the latest technology with a unique drug delivery technology, ensuring efficacy while deterring abuse and preventing overdose.

The Group had erected a new manufacturing facility in the Nansha premise for Staccato<sup>®</sup> fentanyl. The Staccato<sup>®</sup> fentanyl facility involves sophisticated thin coating process with precision control. The stainless steel substrate is cut and welded in situ and the drug fentanyl is coated on the substrate to complete the assembly of the drug cassette. As Staccato<sup>®</sup> fentanyl is a drug-device combination, the device part is assembled and tested in house. The device will enable Staccato<sup>®</sup> fentanyl to be the only opioid drug with true abuse-deterrent and overdose-prevention features built in.

\* For identification purposes only

The coming phase I/IIa multi-center study in China is designed to evaluate the efficacy and safety of Staccato® fentanyl in treating breakthrough pain in patients with cancer. The study will be comprised two stages: Stage one study is designed to determine the recommended dosage; and stage two study will be a PK study based on the recommended dosage which can get the patients relieved from the pain in stage one. The Group is expected to commence this phase I/IIa clinical trial of Staccato® fentanyl in early 2021.

According to GLOBOCAN database, there were an estimated 4.3 million new cancer cases in China in 2018, creating a significant unmet medical need for the management of cancer breakthrough pain. A fast acting form of fentanyl is needed to best manage episodes of cancer breakthrough pain and address this unmet need in China.

## **ABOUT ALEXZA**

Alexza Pharmaceuticals, Inc., Mountain View, California based company is focused on the research, development and commercialisation of novel, proprietary products for the acute treatment of underserved medical needs. Alexza is focused on finding new therapeutic solutions for conditions that would benefit from rapid, precise and non-invasive treatment. The Staccato® platform has the potential to address these needs and to provide flexibility to deliver the most important pharmaceutical benefits of therapeutics in an innovative way.

## **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, dermatology, obstetrics and urology, 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. Lee's Pharm has also involved in the business in ophthalmology through its investment in Zhaoke Ophthalmology Limited, an associated company of the Group.

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

Hong Kong, 6 November 2020

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