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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 INHALED ANTIPSYCHOTIC 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 29 April 2020, Lee’s Pharmaceutical (HK) Limited (“**LPHK**”), a wholly-owned subsidiary of the Company has the first patient enrolled in the pivotal trial of Staccato<sup>®</sup> loxapine for inhalation system (Adasuve<sup>®</sup>) in China.

This pivotal Phase III multi-center, randomised, double-blind, placebo-controlled, parallel group study (NCT04148963) is designed to evaluate the efficacy and safety of Staccato<sup>®</sup> loxapine or placebo in treating acute agitation in patients with schizophrenia or bipolar disorder (manic or mixed episodes) as defined by The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria. Patients may receive up to 3 doses of study drug in a 24-hour period, depending on their clinical status. The primary endpoint is the change from baseline in the Positive and Negative Syndrome Scale Excited Component (also known as PEC) score, performed at 2 hours after the first dose.

The study is being conducted at 19 trial sites in China and about 150 patients are expected to enroll. The completion of patient enrollment is expected in the second half 2020 and new drug application submission is expected during the second half of 2021.

Individuals with bipolar disorder or schizophrenia are vulnerable to episodes of agitation, which can be defined as excessive verbal and motor behavior, especially during exacerbations of their disease (Western Journal of Emergency Medicine 2016).

According to Journal of Affective Disorders 2017 and Journal of Global Health 2015, the pooled life time prevalence of bipolar I disorder in the general population of China was 0.09%, while the life time prevalence of schizophrenia was 0.83% in urban China.

## **ABOUT Adasuve®**

Adasuve® is the first and only orally inhaled loxapine powder for the acute treatment of agitation associated with schizophrenia or bipolar I disorder in adults. Adasuve® is a hand-held, non-invasive and fast-acting alternative to currently used therapies. It was approved in 2012 by the U.S. Food and Drug Administration and in 2013 by European Medicines Agency. Adasuve® was first commercially available in the U.S. in March 2014 and was licensed in by the Group from Alexza Pharmaceuticals, Inc. (“**Alexza**”) in October 2017 for China, Hong Kong SAR and Macau SAR.

## **ABOUT ALEXZA**

Alexza, a 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, 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, 12 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