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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 – ADASUVE® OBTAINS DRUG REGISTRATION CERTIFICATE**

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 November 2023, the Drug Registration Certificate for Adasuve® (Loxapine for Inhalation) has been obtained from the China National Medical Products Administration (“**NMPA**”). Adasuve® has been approved to acutely treat agitation associated with schizophrenia or bipolar disorder in adults.

The approval is based on the results of several clinicals from the US, Europe and China. In the most recently conducted Phase III clinical trial in China in which 150 patients had been enrolled, the primary endpoint was met with statistical significance, as demonstrated by a statistically significant decrease ( $p < 0.05$ ) from baseline in the Positive and Negative Syndrome Scale Excited Component (also known as PEC) score at 2 hours post dose. Furthermore, Adasuve® provides rapid onset of action, an important feature in treating agitation episodes. Pharmacokinetic (PK) profiles have shown peak plasma levels reached in 2 minutes, demonstrating IV-like kinetics. According to Journal of Affective Disorders 2017 and Journal of Global Health 2015, the pooled life time prevalence of bipolar disorder in the general population of China was 0.09%, while the life time prevalence of schizophrenia was 0.83% in urban China. 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). Agitation episodes often require medical treatment.

#### **ABOUT ADASUVE®**

Adasuve® (Loxapine for Inhalation) is the first and only orally inhaled loxapine powder for the acute treatment of agitation associated with schizophrenia or bipolar disorder in adults. Adasuve® is a handheld, 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<sup>®</sup> 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 Pharmaceuticals, Inc., a California-based company is focused on the research, development and commercialization 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<sup>®</sup> 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 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, pediatrics, 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 of development, commercialization, and manufacturing rights from various United States, European and Japanese companies. In the past two years, the Company has successfully obtained 10 new drug approvals in China. More information is available at [www.leespharm.com](http://www.leespharm.com).

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

Hong Kong, 28 November 2023

*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, and Dr. Chan Yau Ching, Bob, Ms. Cheang Yee Wah, Eva and Dr. Tsim Wah Keung, Karl are independent non-executive Directors of the Company.*