

*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 – APPROVAL OF A DRUG PRODUCT MANUFACTURED BY ZHAOKE GUANGZHOU TO CONDUCT CLINICAL TRIAL IN THE UNITED STATES**

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 26 October 2022, AU409, an investigational new drug candidate, drug product manufactured by Zhaoke Pharmaceutical (Guangzhou) Limited (“**Zhaoke Guangzhou**”), a wholly-owned subsidiary of the Company, has been approved by the United States Food and Drug Administration (“**US FDA**”) to conduct clinical trial in patients with advanced primary liver cancers or advanced solid tumor with liver predominant metastatic disease in the United States.

AU409 is a novel compound discovered and developed by Auransa Inc. (“**Auransa**”), a private company located in California USA, and its drug product is developed and manufactured by Zhaoke Guangzhou in its facility in Nansha district, Guangzhou in compliance with the Good Manufacturing Practice (“**GMP**”) regulations promulgated by the US FDA. The approved clinical trial will be a first-in-human study.

Lee’s Pharm is also applying to conduct a Phase I clinical trial to use AU409 in patients with advanced hepatocellular carcinoma who have previously failed the standard first line treatments in Hong Kong in collaboration with Dr. Chi-leung Chiang from the University of Hong Kong. A separate clinical trial is being planned in the United States by Auransa.

#### **ABOUT AU409**

AU409 is a first-in-class compound with oral active in models of hepatocellular carcinoma developed by Auransa. The compound is the product of the SMarTR™ Engine, a proprietary artificial intelligence (AI)-driven drug discovery platform of Auransa. It has been shown

\* For identification purpose only

to modulate transcription of certain genes thereby altering the gene expression profile of liver cancer cells. The mechanism of action of AU409 is distinct from that of current drugs approved for HCC including the tyrosine kinase inhibitors (TKIs) such as sorafenib or regorafenib. Non-clinical safety, toxicology and genetic toxicology studies support the first in human clinical studies being proposed.

## **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 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 AURANSA INC.**

Auransa is an AI-driven pharmaceutical company developing precision medicines in areas of significant unmet need. The company is working to redefine medicine, by combining a sophisticated, proprietary, and predictive computational platform with traditional pharmaceutical experience. The company's SMarTR™ Engine has proprietary machine learning, advanced analytics, and mathematics in an AI framework to generate insights from molecular data for a deep understanding of disease biology at subtype resolution. Auransa has successfully generated a broad pipeline of drug candidates focusing on cancer and cancer care. Learn more: [www.auransa.com](http://www.auransa.com).

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

Hong Kong, 9 November 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.*