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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 THE FIRST PATIENT IN HONG KONG RECEIVES AU409, A NOVEL DRUG PRODUCT MANUFACTURED BY ZHAOKE GUANGZHOU, IN A PHASE I LIVER CANCER CLINICAL TRIAL**

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 15 July 2024, the first patient has been enrolled in a Phase I clinical trial to receive AU409 at Queen Mary Hospital, Hong Kong. This trial focuses on patients with advanced hepatocellular carcinoma who have previously failed standard first-line treatment.

AU409 is a novel drug discovered and owned by Auransa Inc. (“**Auransa**”), and is manufactured by Zhaoke Pharmaceutical (Guangzhou) Limited (兆科藥業(廣州)有限公司), a wholly owned subsidiary of the Group, in compliance with the Good Manufacturing Practice regulations set by the U.S. Food and Drug Administration. This Phase I clinical trial marks the first-in-human study in Asia and is expected to conclude by the second quarter of 2025. The results of this study will be used for China’s new drug registration purpose.

The study, AU409-LEES-2021-03, titled “A Phase I, Single-arm, Open-label, Dose-escalation, Safety and Pharmacokinetic Study of AU409 Capsule in Advanced Hepatocellular Carcinoma Patients Who Failed Standard Treatment” is led by Principal Investigator Dr. Chi Leung Chiang, MD. The primary objectives are to determine the maximum tolerated dose and recommended Phase II dose, as well as to characterise the safety and tolerability of AU409. Secondary objectives include assessing the pharmacokinetics and preliminary anti-tumor activity of AU409.

For more information, view the Phase I trial on ClinicalTrials.gov at <https://www.clinicaltrials.gov/study/NCT06374485?intr=AU409&rank=1>.

\* For identification purpose only

## **ABOUT AU409**

AU409 is a novel small molecule discovered through Auransa's AI platform, the SMarTR™ Engine. AU409 is developed for hepatocellular carcinoma as its first indication and is administered as a once-daily oral pill. Preclinical studies have shown AU409 modulates the transcription of certain genes, altering the gene expression profile of liver cancer cells. Its mechanism of action is distinct from current liver cancer drugs, including tyrosine kinase inhibitors (TKIs) like sorafenib or regorafenib. Non-clinical safety, toxicology, and genetic toxicology studies support the initiation of this first-in-human clinical trial in Asia and the ongoing first-in-human clinical trial in the U.S..

## **ABOUT AURANSA**

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

## **ABOUT LEE'S PHARM**

Lee's Pharm is a research-driven and market-oriented biopharmaceutical company with 30 years' experience in the pharmaceutical industry in China. With solid infrastructures in drug development, clinical development, regulatory, manufacturing, sales, and marketing, the Company has established extensive partnerships with around 30 international companies and currently markets over 25 proprietary, generic, and licensed-in pharmaceutical products in Mainland China, Hong Kong, Macau, and Taiwan. Lee's Pharm focuses on cardiovascular, women's health, pediatrics, rare diseases, oncology, dermatology, and obstetrics, with products in different development stages. In the past two years, Lee's Pharm has successfully obtained 13 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, 1 August 2024

*As at the date of this announcement, Ms. Lee Siu Fong (Chairman) and Ms. Leelalertsuphakun Wanee are executive Directors; Dr. Li Xiaoyi, Mr. James Charles Gale and Mr. Huang Zuie Chin are non-executive Directors; and Dr. Chan Yau Ching, Bob, Ms. Cheang Yee Wah, Eva and Dr. Tsim Wah Keung, Karl are independent non-executive Directors.*