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李 氏 大 藥 廠

## **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 THE INTRODUCTION AND RESEARCH AND DEVELOPMENT OF AN INVESTIGATIONAL ANTICOAGULANT**

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

The Board of the Company is pleased to announce that, on 14 June 2018, the Group has been granted approval from the China National Drug Administration (“CNDA”) to conduct clinical trials investigating Tecarfarin as a potential treatment for patients with mechanical heart valves. Tecarfarin will be studied as a possible alternative to Warfarin.

Tecarfarin was licensed by the Group from Espero BioPharma, Inc. (“Espero”) in 2015. The Group has successfully completed the technology transfer for drug substance and product in China. An open-label, Phase I, sequential cohort, single-dose escalation study will be initiated by the end of this year to assess the safety and tolerability of Tecarfarin in healthy Chinese volunteers. Following a Phase I study in China, the Group will initiate a Phase III registration enabling study. Tecarfarin will be manufactured in the manufacturing site of the Group in Nansha, PRC.

Many patients who have undergone heart valve replacement also have indications for anti-coagulation. In the case of patients with prosthetic heart valves, the presence of a foreign material can stimulate a clotting response. Patients with mechanical heart valves require chronic anti-coagulation. There have been more than 200,000 cases of cardiac valve replacement surgeries in China and 98% of patients received mechanical heart valves (Chen, Q., Dong, L., Dong, Y. et al. J Cardiothorac Surg, 2015). These patients are younger and they must adhere to life-long anticoagulation therapy for which Warfarin is widely prescribed. Tecarfarin may be a suitable alternative for these patients

as well, due to the known drug-drug interactions between Warfarin and other atrial fibrillation (AFib) medications. Tecarfarin also provides a potential alternative to patient populations as direct thrombin inhibitors and Factor Xa inhibitors are contraindicated for use in individuals with mechanical heart valves and post myocardial infarction.

Tecarfarin may potentially improve stability in maintaining a therapeutic anti-coagulation level. This investigational therapy may offer potential for treatment in patients with mechanical and prosthetic heart valves, as well as those with renal dysfunction. It may also present advantages over novel oral anti-coagulants that contain direct thrombin inhibitors and Factor Xa inhibitors, because as a Vitamin K Antagonist, Tecarfarin potentially maintains the ability to be counteracted in the event of an emergency.

The Group is currently a market leader in anti-thrombotic area in China, including Livaracine, its proprietary low molecular weight heparin. It has a robust pipeline of anti-thrombotic, such as a Phase III Warfarin like anticoagulant, Tecarfarin, a Phase II anti-platelet drug, Anfibatide, a Phase I oral Factor Xa inhibitor anticoagulant, GCC-4401C and a synthetic anti-thrombotic agent, Fondaparinux.

The Group is fully integrated with solid infrastructures in drug development, clinic, perspectives and currently markets 17 products in the PRC. Lee's Pharm focuses on several different areas such as cardiovascular and infectious diseases, dermatology, oncology, gynecology, ophthalmology and others. It has more than 50 products under different development stages stemming from both internal R&D as well as from the recent acquisition of licensing and distribution rights from various US, European and Japanese companies.

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

Hong Kong, 29 August 2018

*\* For identification purpose only*

*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.*