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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: 0950)

VOLUNTARY ANNOUNCEMENT – UPDATE ON THE LICENSED-IN AND RESEARCH AND DEVELOPMENT OF A NEEDLE-FREE PERCUTANEOUS INJECTION DRUG DELIVERY SYSTEM PRODUCT

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, in December 2017, Powder Pharmaceuticals, Incorporated (“**PPI**”), an associated company of the Group, has obtained approval for conducting clinical trial of an amide local anesthetic indicated for use on intact skin (lidocaine hydrochloride monohydrate powder) (trade name: Zingo®), which is a needle-free percutaneous injection drug delivery system, by the China Food and Drug Administration (“**CFDA**”). Zingo® has already obtained approval for manufacturing by the United States Food and Drug Administration (“**FDA**”) and obtained product registration certificate of Zingo® from the Department of Health in Hong Kong.

Zingo® is the first FDA-approved needle-free and pain-free powder injection system. It can provide local analgesia prior to venipuncture or peripheral intravenous cannulation in children 3–18 years of age and to provide topical local analgesia prior to venipuncture in adults. The rapid onset of analgesia in 1-3 minutes provides care givers and patients the opportunity for a pain-free and needle-free access procedure. Zingo® has demonstrated its product safety and efficacy with no systemic exposure. Clinical trials have shown a statistical difference in pain scores during needle access procedures when using Zingo® versus a placebo system.

Zingo[®] has been granted by CFDA priority review for its clinical trial application in March 2017. An Investigational New Drug (“**IND**”) meeting was held in August 2017 which provided a communication channel for the Group to clarify the issues that had been raised by the experts from Centre for Drug Evaluation of CFDA (“**CDE**”) and discuss the clinical protocol requirements of Zingo[®]. The meeting completed successfully, the Group not only obtained the clear path of registration, but also reached the agreement with CFDA on the protocol design which allowed the Group to initiate the clinical study rapidly. The clinical study is expected to be completed by October 2018. Meanwhile, the Group is preparing for the construction of a dedicated production facility in the Group’s manufacturing base in Nansha District, Guangzhou so as to transfer the production technology of this product to China and become localised production, so that more children in China could benefit from the use of this product in the future.

On 23 January 2018, The Central Leading Group for Comprehensively Deepening Reforms held the second meeting. “Opinions on Reforming and Improving the Policies Regarding the Security of Supply of Generic Drugs and Use of Generic Drugs” (《關於改革完善仿製藥供應保障及使用政策的若干意見》) (the “**Opinions**”) was reviewed and approved at the meeting. It is mentioned in the Opinions that “the reform and improvement of the policies regarding the security of supply of generic drugs and use of generic drugs has to fulfill the needs of the people, with clinical trial needs, demonstrated efficacy, supply shortage, prevention and control of major infectious diseases and rare diseases, dealing with public health emergencies, medications for children as the focus. It shall also promote the research and development and innovation of generic drugs, improve the quality and efficacy, enhance capabilities of securing drug supply, and provide better protection for the people’s demand for drugs”. Zingo[®] is one of the 30 drugs (medications for children) being regarded by the Center for Drug Evaluation as meeting the above criteria.

PPI is committed to the development of products that utilise a proprietary needle-free, painless, powder delivery technology and other medical devices. PPI intends to supply Zingo® globally through international business partners. PPI has successfully obtained approval from FDA in July 2013 for the manufacturing facilities in Hong Kong to produce Zingo® and market it to U.S.

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

Hong Kong, 26 January 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.