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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 – UPDATE ON AN INVESTIGATIONAL ANAESTHESIA PRODUCT

The Board of the Company is pleased to announce that, on 30 May 2018, the Group obtained the approval to conduct research and development on Staccato® Fentanyl for inhalation in China from the China Food and Drug Administration ("CFDA") for treatment of cancer breakthrough pain.

Cancer breakthrough pain is a severe and debilitating morbidity of late stage cancer patients. According to Fan et al (Journal of Clinical Oncology 2017), the overall prevalence of breakthrough pain in cancer patients is high (approximately 65%). Fentanyl is an opioid-like substance and a powerful analgesic. Different forms of Fentanyl have been developed as an effective treatment for cancer breakthrough pain outside of China since 1998. US FDA and EMEA have approved several forms of Fentanyl for this indication with different delivery methods such as transmucosal, intranasal and transdermal. Although shown to be safe and effective, Fentanyl has the potential of abuse when used outside of its approved therapeutic indication which has been the overwhelming concern of the China CDA. Consequently, there have not been any Fentanyl product approvals in China for the last twenty five years. Meanwhile, the number of diagnosed cancer patients in China increased rapidly from 2.1 million in 2000 to 4.3 million in 2015 (Yu et al, Journal of Global Oncology 2017), creating a significant and increasing unmet medical need for the management of cancer breakthrough pain in China. A fast acting form of fentanyl is needed to best manage episodes of cancer breakthrough pain and address this growing unmet need.

Staccato® Fentanyl for Inhalation is a combination drug–device delivery product designed for rapid, systemic delivery of aerosolized fentanyl via the lung. Another advantage of this product are its safety features inherent to the device design. Several abuse deterrent and overdose prevention features such as finger print activation, GPS tracking, Cloud data collection and dose limitation have been, or can readily be, incorporated into the device, effectively addressing the abuse and overdose concerns. Since any development work carried out on Fentanyl must be pre-approved by China CDA, Staccato® Fentanyl for Inhalation as a solution for the unmet medical need and abuse and overdose prevention had been presented to the regulatory agency and subjected to review by expert panel. It has been concluded by the agency that this unique drug-device system provides an excellent opportunity to address a highly unmet medical need while drastically improving the control over potential abuse and overdose. As a result, for the first time in last 25 years, an approval has been granted to the Group to develop this fast-acting fentanyl product in China for cancer breakthrough pain.

Staccato® Fentanyl for inhalation system was licensed in by the Group from Alexza Pharmaceuticals, Inc. ("Alexza") in March 2018. A previous Phase I clinical study conducted in the U.S. demonstrated that the PK profile of single doses of inhaled fentanyl is comparable to that of IV administration. The Group is aiming to further advance the development of Staccato® Fentanyl for Inhalation for cancer breakthrough pain by setting up a manufacturing facility in the Group's Nansha site and initiating a clinical development program based on data obtained from the previous study in the US. It is the Group's intention to accelerate the development of this program.

Alexza, Mountain View, 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® 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.

The Group is fully integrated with solid infrastructures in drug development, clinic, perspectives and the Group has established extensive partnerships with over 20 international companies and currently markets 17 proprietary and licensed-in pharmaceutical products in Mainland China, Hong Kong and Macau. The Group focuses on several different areas such as cardiovascular and infectious diseases, dermatology, oncology, gynecology, ophthalmology and others. The Group has more than 50 products under different development stages stemming from both internal research and development as well as from the recent acquisition of licensing and distribution rights from various United States, European and Japanese companies.

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

Hong Kong, 9 July 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.