

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 TREPROSTINIL INJECTION OBTAINED APPROVAL FOR DRUG REGISTRATION

This announcement is made by the board of directors (the “**Board**”) 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 18 March 2020, Treprostinil Injection, a drug indicated for the treatment of pulmonary arterial hypertension (“**PAH**”) and developed by Zhaoke Pharmaceutical (Hefei) Company Limited (“**ZKHF**”), a wholly-owned subsidiary of the Company, has obtained approval for manufacturing and marketing from the National Medical Products Administration (the “**NMPA**”) of the People’s Republic of China (the “**PRC**”). The Abbreviated New Drug Application (ANDA) of Treprostinil Injection was submitted in June 2019 and the application had been granted a priority review status. The aforesaid approval by NMPA has made ZKHF’s Treprostinil the first generic available in China.

Treprostinil Injection is a subcutaneously or intravenously administered prostacyclin analogue for the treatment of PAH in patients (PAH; WHO Group 1) to diminish symptoms associated with exercise and improve exercise capacity. It is indicated for severe PAH patients with New York Heart Association Functional (“**NYHA**”) classification II, III, or IV. Studies establishing effectiveness included patients with NYHA Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH, PAH associated with congenital systemic-to-pulmonary shunts, or PAH associated with connective tissue diseases.

* For identification purposes only

The Group had first made Treprostinil available to China patients by registering Remodulin[®], a Treprostinil originally developed and marketed by United Therapeutics of United States in 2014. During the last five years, the Group has built a dedicated team and infrastructure to serve the PAH patients in China and address the unmet medical need. For severe PAH patients, Remodulin[®] has become a treatment of choice and has been well received by physicians and patients alike. However, due to the nature of the product, the cost of the product became prohibitive for some patients to initiate and/or continue the therapy.

According to Southcn.com (南方網), there are only approximately 10,000 to 20,000 PAH patients having been treated out of approximately 5 to 8 million PAH patients in China (including those PAH cases associated with congenital heart disease and other chronic conditions). The Group is expected that an affordable cost of Treprostinil Injection to PAH patients will improve the opportunity to unlock its market potential.

ABOUT LEE'S PHARM

Lee's Pharm is a public biopharmaceutical company with over 25 years of operations in China's pharmaceutical industry. It is fully integrated with solid infrastructures in drug development, clinical development, regulatory, manufacturing, sales and marketing in China with global perspectives and currently markets 17 products in the PRC. The Company focuses on several different areas such as cardiovascular, rare diseases, ophthalmology, oncology, gynecology and dermatology. It has more than 60 products under different development stages stemming from both internal R&D and acquisition of licensing and distribution rights from various U.S., European and Japanese companies.

The Company has committed to the development of pharmaceutical products for rare diseases in China since 2012, and is a founding member of Shanghai Foundation for Rare Disease and a member of China Alliance of Rare Disease. Besides Treprostinil, the Group is also developing other orphan drugs, including but not limited to Sodium Phenylbutyrate, INOmax[®], Surfaxin[®], Tekglutik[®], Neridronate and Anfibatide. In 2016, Anfibatide received orphan drug designation from the U.S. Food and Drug Administration for treatment of thrombotic thrombocytopenic purpura (TTP).

Additional information is available at <https://www.leespharm.com/>.

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

Hong Kong, 19 March 2020

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.