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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 DIRECT ORAL ANTICOAGULANT

This announcement is made by the board (the “**Board**”) of 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 1 March 2021, the Group has been granted the approval of the Investigational New Drug (“**IND**”) application of GCC-4401C from the China’s National Medical Products Administration (“**NMPA**”) to conduct clinical trials investigating GCC-4401C as a potential treatment for cirrhotic patients with non-tumoral portal vein thrombosis (“**PVT**”).

PVT is one of the common complications of liver cirrhosis, particularly in those with advanced cirrhosis. According to the Chinese experts’ consensus, the prevalence of non-tumoral PVT in liver cirrhosis reported varies from 5% to 20%, with higher prevalence in patients with more severe liver disease. It is a challenge to treat patients with cirrhosis using anticoagulants because cirrhotic patients usually have coagulation abnormalities and increased risk for gastrointestinal bleeding. This represents an area of high unmet medical needs as no approved drug is indicated for the treatment of non-tumoral PVT in China.

The Group is expected to conduct three single-center Phase I clinical trials in China, including a single-dose escalation study, a multiple-dose escalation study and a two treatments (fasted vs. fed), two-period, two-sequence crossover study, to evaluate the safety, tolerability and efficacy of GCC-4401C in healthy Chinese subjects, as well as the effect of food on pharmacokinetics (PK) and pharmacodynamics (PD). Following the completion of the Phase I trials, the Group will initiate a single-center Phase Ib clinical trial, followed by a multi-center Phase II trial and a Phase III trial, to evaluate the efficacy and safety of GCC-4401C in Chinese cirrhotic patients with non-tumoral PVT.

* For identification purpose only

The Group has a strong pipeline in the anti-coagulant and anti-thrombosis area, with 2 commercialised assets and 2 assets in developing stage. For the 2 commercialised assets, Livaracine, a low molecular weight heparin, has been marketed in China for over 20 years; and Fondaparinux Sodium Injection, a synthetic anti-thrombotic agent, has been recently approved for drug registration in China. For the 2 assets in developing stage, Tecarfarin, a warfarin like anticoagulant, is currently in Phase I clinical stage; and Anfibatide, an anti-platelet drug, has completed a Phase II trial in the treatment of ST Segment Elevation Myocardial Infarction (STEMI) in China.

ABOUT GCC-4401C

GCC-4401C was licensed by the Group from GC Pharma in December 2017, which is a novel DOAC with structural similarity to rivaroxaban. It directly inhibits the activity of factor Xa, an important validated target in the blood coagulation pathway, to prevent thrombosis. Phase I clinical development of GCC-4401C has been completed in the U.S. for the prevention and treatment of thromboembolic disease. It has the potential to become the best in class of active factor Xa inhibitor available. This research was supported by Korea Drug Development Fund funded by Ministry of Science and ICT, Ministry of Trade, Industry, and Energy, and Ministry of Health and Welfare (KDDF-201210-04, Republic of Korea). GCC-4401C was originated by Legochem Bioscience and licensed to GC Pharma in 2009.

ABOUT LEE'S PHARM

Lee's Pharm is a research-driven and market-oriented biopharmaceutical company with more than 25 years of operation in the pharmaceutical industry in China. The Company is fully integrated with solid infrastructures in drug development, clinical development, regulatory, manufacturing, sales and marketing based in Mainland China with global perspectives. The Company has established extensive partnerships with over 20 international companies and currently markets 23 proprietary, generic and licensed-in pharmaceutical products in Mainland China, Hong Kong, Macau and Taiwan. The Company focuses on several key disease areas such as cardiovascular, woman health, paediatrics, rare diseases, oncology, dermatology, obstetrics and urology, and has more than 40 products under different development stages stemming from both internal research and development as well as from the licensing and development, commercialisation, and manufacturing rights from various United States, European and Japanese companies. Lee's Pharm has also involved in the business in ophthalmology through its investment in Zhaoke Ophthalmology Limited, an associated company of the Group.

ABOUT GC PHARMA

GC Pharma (formerly known as Green Cross Corporation) is a biopharmaceutical company that delivers life-saving and life-sustaining protein therapeutics and vaccines. Headquartered in Yongin, South Korea, GC Pharma is one of the leading plasma protein and vaccine product manufacturers in the world and has been dedicated to quality healthcare solutions for more than half a century. Green Cross Corporation updated its corporate brand to GC Pharma in early 2018. Green Cross Corporation remains the company's legal name.

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

Hong Kong, 11 March 2021

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.