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 – SODIUM PHENYLBUTYRATE GRANULES OBTAINED APPROVAL FOR DRUG REGISTRATION

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 13 May 2021, the Drug Registration Certificate for Sodium Phenylbutyrate Granules (specification: 150g/bottle, containing 0.94g Sodium Phenylbutyrate for every 1g) developed and manufactured by Zhaoke Pharmaceutical (Guangzhou) Company Limited ("**Zhaoke Guangzhou**"), a wholly-owned subsidiary of the Company, has been obtained from the National Medical Products Administration ("**NMPA**") of the People's Republic of China (the "**PRC**"), and completion of first delivery has been taken place as at the date of this announcement.

Sodium Phenylbutyrate is used as an adjuvant for long-term treatment on urea cycle disorders patients resulting from carbamoyl phosphate synthetase deficiency, ornithine transcarbamylase deficiency or argininosuccinate synthetase deficiency. It is applicable to all new-born babies (born less than 28 days) with profound biotinidase deficiency and to patients with a history of late-onset hyperammonemia brain dysfunction (partial biotinidase deficiency, born for more than one month). The Sodium Phenylbutyrate Granules developed and manufactured by Zhaoke Guangzhou is the first generic version in the PRC. Being for the treatment of rare diseases and for children, it has been included in the priority list for evaluation and approval by the Centre for Drug Evaluation of the NMPA.

* *For identification purpose only*

According to the statistics in the United States, the morbidity of the aforementioned rare diseases is approximately 1/35,000. The statistics estimate that there are approximately 300 to 400 new patients in the PRC every year. For this type of patients, liver transplantation is the optimal treatment method. Patients who are not suitable for liver transplantation treatment may rely on long-term intake of nitrogen scavenger and Sodium Phenylbutyrate is currently one of the best pharmaceutical products thereof, and there is no original Sodium Phenylbutyrate available for sale in the PRC and thus, Zhaoke Guangzhou's Sodium Phenylbutyrate Granules would address the unmet medical needs in the PRC. Hyperammonemia is commonly diagnosed in the infant stage and causes enormous damage to the nervous system of the infant, and even death. Therefore, this must be treated properly as early and timely as possible. At the same time, given the compliance and safety issues of clinical prescription for infant patients, choosing a safe and efficacious drug suitable for infant patients has become a matter of vital importance for clinical treatment and with immense clinical needs.

ABOUT ZHAOKE GUANGZHOU

Zhaoke Guangzhou is a wholly owned subsidiary of Lee's Pharmaceutical in Nansha, Guangzhou, a city of the Greater Bay Area. It is located in the Pearl River Industrial Park in Nansha District, Guangzhou City, Guangdong Province. It principally engages in the research and development and production of controlled release solid oral dosage formulations, oral liquid capsule dosage formulations, and aerosol inhalation products, and involves in various therapeutics areas such as cardiovascular, psychoanesthetic pain, anti-allergy, rare diseases, and anti-tumor. In addition to the newly approved Sodium Phenylbutyrate Granules, Abbreviated New Drug Applications for Azilsartan tablets, Epinastine tablets and Apremilast tablets are currently under review by the NMPA.

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 25 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.

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 Sodium Phenylbutyrate, the Group is also developing other orphan drugs, including but not limited to Treprostinil, 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).

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

Hong Kong, 21 May 2021

As at the date of this announcement, Ms. Lee Siu Fong (Chairman) and Ms. Leelalertsuphakun Wanee are executive directors of the Company, Dr. Li Xiaoyi and Mr. Simon Miles Ball are non-executive directors 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.