LUYE PHARMA GROUP LTD.

绿叶制药集团有限公司

(Incorporated in Bermuda with limited liability)

(Stock Code: 02186)

VOLUNTARY ANNOUNCEMENT

ACCEPTANCE OF THE NDA AND PRIORITY REVIEW GRANTED FOR ROTIGOTINE EXTENDED-RELEASE MICROSPHERES FOR INJECTION (LY03003) BY NMPA IN CHINA

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that the New Drug Application ("**NDA**") of Rotigotine Extended-Release Microspheres for Injection ("**LY03003**") by weekly developed by the Group has been accepted and granted priority review by the Centre for Drug Evaluation ("**CDE**") of the National Medical Products Administration ("**NMPA**") in the People's Republic of China ("**China**") for the treatment of Parkinson's disease ("**PD**").

Developed on the Group's leading microsphere platform, to the best knowledge of the Company, LY03003 is the world's first long-acting extended-release microsphere formulation for the treatment of PD. This drug is also being developed in parallel in the U.S. and Japan. As far as the Company is aware, LY03003 is the world's first weekly dopamine agonist formulation that produces CDS. Unlike other short-acting DAs that are already commercially available, LY03003 does not produce non-physiological, pulsatile stimulation. Injected intramuscularly, it exhibits distinct properties of an extended-release formulation. LY03003 maintains a stable release of rotigotine over seven days, to really produce CDS. It also maintains a stable concentration of the active ingredient in the blood, to produce sustained therapeutic effects over several days in a row and reduce adverse reactions arising from concentration fluctuation. Additionally, the once-a-week dosing frequency improves patient compliance and makes the long-term management of the disease easier.

The NDA for LY03003 is made based on several Phase I clinical trials and one Phase III clinical trial. The results of those trials show that LY03003 is safe and effective in treating PD and can comprehensively improve the patients' motor symptoms in a sustained manner, thereby improving their quality of life.

PD is a neurodegenerative disease common in middle-aged and older people, characterized by clinical manifestations of motor symptoms such as tremor, myotonia, and postural instability as well as non-motor symptoms such as sleep disorder, autonomic dysfunction, cognitive impairment, and mental disorder. At the middle or advanced stage, PD is often accompanied by motor complications, which significantly impact the patients' quality of life. According to statistics, approximately 10 million people worldwide are living with the disease. The number of PD patients in China is expected to increase from 1.99 million in 2005 to nearly 5 million by 2030, which is expected to account for almost half of all the PD patients in the world.

Current treatments for PD, whether medications or surgeries, primarily focus on alleviating the symptoms, but they are unable to prevent the disease from progressing or provide a cure. This means that the ability of the patients to work or engage in everyday activities is impaired, leading to the significant reduction of their quality of life. As the disease progresses, both the motor and non-motor symptoms of the patients will gradually become worse, to impose a long-lasting and huge burden on the public health system. Therefore, early diagnosis, early treatment, and long-term management are encouraged in clinical practice to improve symptoms, slow down progression, and achieve better long-term outcomes. Non-ergot dopamine agonists ("**DAs**") including rotigotine are the preferred medications for patients in the early stage of young-onset PD. Non-ergot DAs that produce continuous dopaminergic stimulation ("**CDS**") can also treat motor complications of PD patients in the middle or advanced stage and slow down their progression.

The Company believes that there are significant unmet needs for the treatment of PD and thus LY03003 has promising market prospects and will enrich the Group's future product portfolio of central nervous system ("**CNS**") therapeutic area.

On its innovative microsphere platform, the Company has developed a series of microsphere formulations with promising clinical applications targeting major therapeutic areas such as the central nervous system and oncology. In addition to LY03003, the Company is also developing LY03009, a monthly rotigotine microsphere formulation. Furthermore, the NDA for the company's in-house developed Goserelin Microspheres for Injection (Baituowei) was just approved in China on June 30, making it the world's first and only microsphere formulation of goserelin approved for launch. In January this year, the Company's long-acting Risperidone Microspheres for Injection (Rykindo®) had its NDA approved in the U.S., making it the first complex formulation developed by a pharmaceutical company from the Chinese mainland to receive approval from the U.S. Food and Drug Administration under the provisions of Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act.

While accelerating the commercialization of innovative formulations from its microsphere platform, the Company is leveraging its leading edge in this field and its existing resources to speed up its strategic expansion in key therapeutic areas around the world.

By Order of the Board
LUYE PHARMA GROUP LTD.
Liu Dian Bo
Chairman

Hong Kong, 1 August 2023

As at the date of this announcement, the executive directors of the Company are Mr. LIU Dian Bo, Mr. YANG Rong Bing, Mr. YUAN Hui Xian and Ms. ZHU Yuan Yuan; the non-executive directors of the Company are Mr. SONG Rui Lin and Mr. SUN Xin; and the independent non-executive directors of the Company are Mr. ZHANG Hua Qiao, Professor LO Yuk Lam, Mr. LEUNG Man Kit and Mr. CHOY Sze Chung Jojo and Ms. XIA Lian.