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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

**PHASE III CLINICAL TRIAL OF ROTIGOTINE EXTENDED-RELEASE
MICROSPHERES FOR INJECTION (LY03003) IN PARKINSON'S DISEASE
MET PRIMARY ENDPOINT IN CHINA**

The board of directors (the “**Board**”) of Luye Pharma Group Ltd. (the “**Company**”, together with its subsidiaries, “**Group**”) announces that the phase III clinical trial of the Group’s new drug, Rotigotine Extended-Release Microspheres for injection (LY03003), in Parkinson’s disease has met expected endpoints in China.

The phase III study was a multi-center, randomized, double-blinded and placebo-controlled study to evaluate the efficacy and safety of LY03003 in early stage of Parkinson’s disease. 294 Chinese patients with early stage of idiopathic Parkinson’s disease were enrolled in the study and randomized into LY03003 group and placebo group in a ratio of 1:1. Results of the study showed that the score of Unified Parkinson’s Disease Rating Scale (UPDRS) Part II + III was significantly improved from baseline in the LY03003 group compared with the placebo group, and the difference between the two groups was statistically significant ($P < 0.001$). Relevant secondary endpoints in both groups were also statistically significant ($P < 0.001$). In terms of safety, generally, LY03003 was safe and well tolerated, and there were no serious adverse events (SAE) related to the investigational medicinal product (IMP). The results indicate that LY03003 is safe and effective in the treatment of early stage of idiopathic Parkinson’s disease and provides a comprehensive improvement in the motor symptoms of Parkinson’s disease.

In line with the more pronounced population aging around the globe, the number of patients suffering from Parkinson’s disease has been on the rise. It is estimated that around 10 million people worldwide are living with such disease. The number of Parkinson’s disease patients in China is expected to increase from 1.99 million in 2005 to nearly 5 million by 2030, almost half of the world’s total number

of Parkinson's disease patients. Currently, pharmacological and surgical treatments can only improve the symptoms, but are not able to cure the disease or prevent its progression, causing it necessary for long-term management of the treatment in the disease.

LY03003 delivers medication by weekly intramuscular injection. This is the first product worldwide to produce long-term Continuous Dopamine Stimulation (CDS). It is expected to improve the patients' symptoms throughout the day and quality of life. The stable release of the drug in the human body can improve the motor and non-motor symptoms in patients with early and advanced stage of Parkinson's disease, reduce the "on-off" phenomenon and motor complications in patients with Parkinson's disease. It is expected that long-term application of the drug will delay the development of motor complications.

LY03003 is one of the Group's key central nervous system (CNS) product candidates developed on a long acting and extended-release formulation platform. The drug is being developed concurrently in the markets of China, the U.S., Europe and Japan. The Group plans to register and launch LY03003 in China, the U.S., Japan, Europe and other countries. The Group is concurrently developing Rotigotine Extended-Release Microspheres for monthly injections.

The Board believes that there are significant unmet needs for the treatment of Parkinson's disease and thus LY03003 has promising market prospects and will enrich the Group's future product portfolio.

The Group has launched several products for the CNS therapeutic area, including Risperidone Microspheres for Injection (II) (瑞欣妥[®]), Seroquel, Seroquel XR, Rivastigmine patches, Rivastigmine multi-day transdermal patch, Fentanyl patches and Buprenorphine patches, covering over 80 countries and regions around the world, including large pharmaceutical markets in China, the U.S., Europe and Japan, as well as fast growing emerging markets.

In addition, the Group currently has a number of new drugs under development, covering a variety of diseases such as depression and Parkinson's disease, forming a rich product portfolio in the CNS therapeutic area.

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

Hong Kong, 19 July 2022

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.