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

JINYOUPING (ROTIGOTINE MICROSPHERES FOR INJECTION) APPROVED FOR MARKETING IN CHINA

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that its Jinyouping® (rotigotine microspheres for injection, LY03003) developed by the Group has been approved for marketing by the National Medical Products Administration of the People's Republic of China ("**China**") with a priority review designation for the treatment of Parkinson's disease ("**PD**").

Developed on the Group's leading microsphere platform, to the best knowledge of the Company, Jinyouping® is the world's first long-acting extended-release microsphere formulation for the treatment of PD and is administered in weekly doses. Compared with the currently marketed dopamine receptor agonists ("**DAs**") that require daily administration, Jinyouping® is more aligned with the concept of continuous dopaminergic stimulation ("**CDS**") and overcomes the non-physiological and pulsatile stimulation generated by short-acting dopaminergic drugs, and shows obvious characteristics of extended-release formulation which can maintain a stable release of rotigotine over seven days. It also maintains a stable concentration of the active ingredient in the patient's blood, to produce sustained therapeutic effects over several days in a row to truly achieve CDS 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 marketing approval of Jinyouping® is made based on several Phase 1 clinical trials and one Phase 3 clinical trial. The results of those trials show that this product 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 a middle or advanced stage of the disease, PD is often accompanied by motor complications, which significantly impact the patients' quality of life. According to statistics, there are over 3 million PD patients in China, and this number is expected to reach 5 million by 2030.

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 impairs the ability of the patients to work or engage in everyday activities and significantly reduces their quality of life. As the disease progresses, both the motor and non-motor symptoms of the patients will gradually become worse, imposing a sustained and heavy burden on the public health system. Therefore, early diagnosis, early treatment, and long-term management are encouraged in the clinical practice to improve symptoms, slow down progression, and achieve better long-term outcomes. Non-ergot DAs including rotigotine are the preferred medication for patients in the early stage of young-onset PD. Non-ergot DAs that produce 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 Jinyouping® has promising market prospects and will enrich the Group's future product portfolio in the central nervous system ("**CNS**") therapeutic area.

The CNS therapeutic area, which includes PD, is one of the key strategic areas for the Group. To address clinical demand, the Group has built a differentiated portfolio of innovative CNS drugs and formulations based on its platforms for Novel Drug Delivery Systems ("**NDDS**") that includes microspheres and New Molecular Entities ("**NME**"). This focus gives the Group a strong technical advantage and core competitive edge.

Building on technology platforms which include NDDS and NME, the Group has established a robust CNS product portfolio with business spanning across global markets, including China, the U.S. and Europe. Some products in the portfolio have become major products, including Rykindo® (risperidone) for extended-release injectable suspension, which is China's first new CNS drug approved for marketing in the U.S., and Ruoxinlin® (Toludesvenlafaxine Hydrochloride Sustained-release Tablets), the first proprietary Class 1 innovative chemical drug developed in China for the treatment of Major Depressive Disorder.

With the accelerated conversion from innovative products, the Group is leveraging its leading edge in this field and 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, 20 June 2024

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 Dr. LYU Dong; and the independent non-executive directors of the Company are Mr. ZHANG Hua Qiao, Professor LO Yuk Lam, Mr. LEUNG Man Kit, Mr. CHOY Sze Chung Jojo and Ms. XIA Lian.