LUYE PHARMA GROUP LTD.

绿叶制药集团有限公司

(Incorporated in the Bermuda with limited liability)

(Stock Code: 02186)

ANNOUNCEMENT

COMPLETION OF TWO PHASE 1 CLINICAL STUDIES OF ROTIGOTINE EXTENDED RELEASE MICROSPHERES FOR INJECTION (LY03003) IN THE U.S.

The Board of Directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") is pleased to announce that the Group has completed two phase 1 clinical studies for rotigotine extended release microspheres for injection ("**LY03003**"), an investigational drug product for the treatment of Parkinson's disease ("**PD**"), in the United States (the "**U.S.**").

Twenty healthy volunteers were enrolled to a randomised, double-blinded and placebo-controlled single ascending dose ("**SAD**") study, where 16 subjects received a single injection of LY03003 of either 7mg or 14mg, and 4 subjects received a matching placebo treatment. The results of the SAD study demonstrated a dose proportional increase in plasma rotigotine concentrations corresponding to the dosage injected. No significant safety concerns were observed in the SAD study.

Thirty nine patients with early-stage PD were enrolled to a randomised, double-blinded and placebo-controlled multiple ascending dose ("**MAD**") study, where 31 patients received once a week injection of LY03003 for five consecutive weeks at one of the four doses at 14mg, 28mg, 42mg or 56mg, and 8 patients received a matching placebo treatment. The results of the MAD study demonstrated a dose proportional increase in plasma rotigotine concentrations corresponding to dosage injected after five consecutive injections of LY03003. Steady state was reached after the fifth injection of LY03003, which lasted for at least 7 days. No significant safety concerns were observed in the MAD study.

The MAD study also involved an open-label panel where 20 patients were enrolled to assess the pharmacokinetic and safety profiles of another marketed drug (the "**Marketed Drug**"), which provided a reliable comparison to select doses of LY03003 for future studies. The Marketed Drug was re-launched in the U.S. in 2012 as a patch for the treatment of PD and restless legs syndrome. It has the issue of unstable plasma drug level among patients and is associated with skin irritation and other side effects.

The two phase 1 clinical studies demonstrated that LY03003 treatment was well tolerated and produced good pharmacokinetic profile after a single injection and multiple injections within a diversified dose range. Furthermore, the results of the MAD study demonstrated that weekly injection of LY03003 can reach a stable plasma drug level, which could lead to improvement in efficacy and/or reduction in side effects.

The drug is now being registered via a 505(b)(2) pathway in the U.S. The 505(b)(2) pathway is defined in the Federal Food, Drug, and Cosmetic Act as an application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. According to Section 505(b)(2) application guidance, a New Drug Application ("**NDA**") approval can be obtained for a new drug without conducting the full complement of safety and efficacy trials.

LY03003 is one of the Group's key central nervous system product candidates developed based on the Group's long acting and extended-release formulation platform. To the best knowledge of the Board, LY03003 is the first product worldwide to produce long term Continuous Dopamine Stimulation (CDS), and it can improve efficacy and/or reduce side effects especially for the "on-off" effect. The drug is being concurrently developed in the U.S., China and other global markets and owns a series of China and international patents over the formulation and manufacturing process.

According to the Journal of Neurology, PD is the most common movement disorder and is the second most common neurodegenerative disease. Approximately 1–2% of the population over 65 years of age suffers from PD. This figure increases to 3% to 5% for people who are over 85 years of age. As PD mainly occurs in elderly population, it is more prevalent in developed countries where people have a longer life expectancy. The Board believes that LY03003 has promising market prospects and will enrich the Group's future product portfolio.

The Group plans to discuss with the Food and Drug Administration ("**FDA**") about further development plan for LY03003 in the U.S..

Besides LY03003, the Group is currently developing several new pharmaceutical products in the U.S.. Among them, an anti-schizophrenia drug, LY03004 (Risperidone Extended-Release Microspheres for Injection) has been confirmed by the FDA that the results of its completed clinical studies can be used to support a NDA submission via a 505(b)(2) pathway without additional clinical trials. This will significantly cut down costs and time required for obtaining FDA approval for LY03004. The Company is currently preparing the NDA report for LY03004.

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

Hong Kong, 15 December 2015

As at the date of this announcement, the Executive Directors of the Company are Mr. LIU Dian Bo, Mr. YANG Rong Bin, Mr. YUAN Hui Xian and Ms. ZHU Yuan Yuan; the Non-executive Directors are Mr. PAN Jian, Mr. LIU Dong and Ms. WANG Xin; and the Independent Non-executive Directors are Mr. ZHANG Hua Qiao, Professor LO Yuk Lam, Mr. LEUNG Man Kit and Mr. CHOY Sze Chung Jojo.