LUYE PHARMA GROUP LTD.

绿叶制药集团有限公司

(Incorporated in the Bermuda with limited liability)

(Stock Code: 02186)

VOLUNTARY ANNOUNCEMENT

APPROVAL OBTAINED FOR INITIATING CLINICAL TRIAL IN EUROPE FOR PALIPERIDONE PALMITATE PROLONGED RELEASE SUSPENSION FOR INJECTION (LY03010)

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that it has received the approval by the competent authorities to initiate the first clinical trial in Europe for its Paliperidone Palmitate Prolonged Release Suspension for Injection ("**LY03010**"). LY03010 is a second-generation long-acting injectable (LAI) antipsychotic for the treatment of schizophrenia, being developed under Article 10.3 of Directive 2001/83/EC (hybrid application). It is a pharmaceutical equivalent to the reference drug Xeplion®, with the same route of administration, the same indication and an optimized initial dosing regimen.

This upcoming clinical trial is a randomized, open-label, single-dose, parallel-group study to evaluate the relative bioavailability of LY03010 versus Xeplion®. The key clinical trial for LY03010 in the U.S. has been completed and has achieved its endpoints. The Company intends to submit the New Drug Application (NDA) for this drug to the U.S. Food and Drug Administration (FDA) through the 505(b)(2) pathway. In China, LY03010 is already under review for marketing authorization.

Schizophrenia is a severe mental disorder that tends to recur and become protracted. It is estimated that about half of the patients end up becoming mentally disabled, making it challenging for them to live a normal life, and causing a heavy burden to their families and the society. Globally, 24 million people are estimated to be suffering from this disease, and the number in Europe is estimated to be around 3.7 million. Poor patient compliance with medication is a major cause of relapse. Medication discontinuation, in particular, elevates the risk of relapse. Multiple relapses can lead to a prolonged disease duration, increase the difficulty of treatment, and leave patients with more residual symptoms.

Long-acting injectable antipsychotics are recommended by authoritative treatment guidelines both in China and abroad as an important therapeutic strategy for better patient compliance and relapse prevention. Studies showed that patients who received long-acting injection early in the course of their illness had significantly lower rates of hospitalization and treatment discontinuation than those treated with oral antipsychotics; and that the shorter the time interval between first diagnosis and long-acting injection treatment, the lower the rate of hospitalization and the overall treatment costs over a one-year follow-up period.

Based on the huge demand from patients and verified clinical value of LY03010, the Company believes that LY03010 will have good market potential. According to statistics from IQVIA, the global sales of long-acting injectable antipsychotics and Paliperidone Palmitate long-acting injection were about USD7.1 billion and USD4.2 billion respectively in 2021. In addition to LY03010, Rykindo® (risperidone for extended-release injectable suspension), another long-acting injectable antipsychotic from the Group, has been approved for marketing in China and the U.S.. LY03010 and Rykindo® will constitute a differentiated portfolio in the future, providing new treatment options for patients.

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

Hong Kong, 23 February 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.