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

THE MANUFACTURING FACILITY OF PALIPERIDONE PALMITATE EXTENDED-RELEASE INJECTABLE SUSPENSION (LY03010) HAS PASSED PAI BY U.S. FDA WITH NO FDA-483

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that the Group has received the Establishment Inspection Report from the U.S. Food and Drug Administration ("**FDA**") indicating that the manufacturing facility of Paliperidone Palmitate Extended-release Injectable Suspension ("**LY03010**") has successfully passed a Pre-Approval Inspection ("**PAI**") with No Action Indicated (NAI, "**no FDA-483**").

Developed by the Group, LY03010 is a long-acting injectable formulation of paliperidone palmitate for the treatment of schizophrenia and schizoaffective disorder. The Group has submitted a New Drug Application ("**NDA**") for LY03010 to the FDA through the 505(b)(2) pathway. As a crucial step in the NDA review process, the FDA needs to conduct a PAI of the facility producing LY03010.

This is the second time the Group has passed the FDA PAI with no FDA-483, following a no FDA-483 PAI of the Group's production facility for Rykindo® (risperidone) for extended-release injectable suspension in 2019. Passing the PAI again shows the Group's strong capabilities in maintaining a quality system that adheres strictly to the highest international standards, including the FDA's cGMP guidelines. This system provides the quality assurance necessary for the Group to launch more innovative products overseas and enhances its international competitiveness.

Passing the PAI is an important milestone in the NDA review of the product in the U.S., and will significantly advance the NDA review of LY03010 in the U.S. According to the Prescription Drug User Fee Act (PDUFA), the target date for the FDA to make a decision on the NDA of LY03010 is 26 July 2024, U.S. time. The Group is currently in communication with potential multinational partners about the commercialization of LY03010 in the U.S. The Group expects to commence the commercialization of this product as soon as it is approved for marketing in the U.S.

Schizophrenia is a severe mental disorder that affects a population estimated of about 24 million people worldwide. It is a chronic, relapsing, and progressive disease characterized by poor patient compliance, leading to high relapse rates and recurrent symptoms. These challenges have long been central to the difficulties in treating the disease. Long-acting injections have become an important formulation for antipsychotics because they can better address clinical needs such as significantly improving patient compliance and reducing relapses. Publicly available information shows that Paliperidone Palmitate Long-acting Injection generated sales of US$4.115 billion in the worldwide market and US$2.897 billion in the U.S. market in 2023.

The Group believes that LY03010 is expected to be the first domestic paliperidone palmitate long-acting injection approved in the U.S. with independent intellectual property rights. LY03010 is expected to provide patients with new treatment options after being marketed.

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

Hong Kong, 27 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.