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 COMPANY SUBMITTED NDA FOR PALIPERIDONE PALMITATE EXTENDED-RELEASE INJECTABLE SUSPENSION (LY03010) TO THE FDA

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that the Group submitted its New Drug Application ("**NDA**") to the U.S. Food and Drug Administration ("**FDA**") through the 505(b)(2) pathway for Paliperidone Palmitate Extended-release Injectable Suspension ("**LY03010**") for the treatment of schizophrenia and schizoaffective disorder. LY03010 is developed on the Group's platform for long-acting and extended-release drug delivery systems. It is expected to become China's first long-acting paliperidone palmitate injectable suspension to be approved in the U.S. Currently, LY03010 is also under review for its marketing authorization application in China.

Paliperidone is a first-line treatment for schizophrenia. It can relieve the positive symptoms of psychosis and improve the cognitive-affective symptoms in schizophrenia patients. Paliperidone is available in both oral tablets and long-acting injections. Compared with oral tablets, long-acting injections require less frequent administration and are able to maintain a stable and effective concentration of the active ingredient in the blood for an extended period of time. This allows them to improve patient compliance, to significantly lower the risk of relapse during long-term treatments, and to improve the long-term outcomes for patients.

LY03010 is a long-acting injectable formulation of paliperidone, administered once a month. Its NDA submitted in the U.S. is based on a randomized, multiple-dose, open-label, and parallel-group pivotal study evaluating the relative bioavailability of LY03010 versus INVEGA SUSTENNA®. In this study, LY03010 was demonstrated to be bioequivalent to INVEGA SUSTENNA® at steady state after multiple administrations. Furthermore, compared with INVEGA SUSTENNA®, the initial dosing was optimized for LY03010 by omitting the injection on day 8 after the first injection, resulting in comparable total

drug exposure. In terms of safety: LY03010 has good safety and tolerability. This study suggests that LY03010 may improve patient compliance by optimizing the initial dosing, while ensuring efficacy and safety.

Schizophrenia is a severe mental disorder that affects a population estimated of about 24 million people worldwide. The main challenge in treating schizophrenia as a chronic disease is that it tends to relapse and become protracted, resulting in poor patient compliance. 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. The marketing approval of LY03010 (if granted) will provide a new treatment option for patients. Publicly available information shows that Paliperidone Palmitate Long-acting Injection generated global sales of US$4.14 billion in 2022 and US$2.075 billion in the first half of 2023, respectively.

The Central Nervous System ("**CNS**") therapeutic area, which includes schizophrenia, has long been a strategic focus for the Group. With breakthroughs in new drug development, the Group's product matrix in the field of CNS is increasingly rich.

The Group has built a diversified CNS portfolio. In January 2023, Rykindo® (risperidone) for extended-release injectable suspension was approved for marketing in the U.S., making it the first new CNS drug developed by a Chinese pharmaceutical company approved for use in the U.S., as far as the Company is aware. In November 2022, Ruoxinlin (Toludesvenlafaxine Hydrochloride Sustained-release Tablets) was approved for marketing in China as the first "Class 1 Chemical Drug" for the treatment of Major Depression Disorder developed by a Chinese company, as far as the Company is aware. Other products in the portfolio such as Seroquel® (quetiapine fumarate) and its extended-release tablets, as well as Rivastigmine Transdermal Patches (once daily and multi-day), are sold in China and other major markets.

In the Group's pipeline, LY03003 (Rotigotine Extended-Release Microspheres for Injection), which is being developed in China and abroad, has seen its NDA accepted in China and granted the priority review designation. Several other new products, such as LY03015, a VMAT2 inhibitor, are undergoing clinical trials in China and abroad. The Company has built competitive capabilities in conducting R&D, regulatory, clinical, supply chain, and commercial activities internationally, laying a solid foundation for commercializing new products around the world in the future.

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

Hong Kong, 9 October 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, Mr. CHOY Sze Chung Jojo and Ms. Xia Lian.