# 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
## LY03010 ACHIEVED THE ENDPOINTS OF PIVOTAL STUDY IN THE U.S.

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that the pivotal study conducted in the U.S. in respect of the Group's new product candidate for the treatment of schizophrenia and schizoaffective disorders, Paliperidone Palmitate Extended-release Injectable Suspension ("**LY03010**"), for intramuscular use, has achieved the end points based on the completed data analysis. According to the pre-IND meeting with the U.S. Food and Drug Administration (the "**FDA**"), LY03010 will submit New Drug Application ("**NDA**") to the FDA through 505(b)(2) pathway.

The pivotal study is a randomized, multiple-dose, open-label, parallel-group study to evaluate the pharmacokinetic profiles of LY03010 and the relative bioavailability at steady-state of LY03010 versus INVEGA SUSTENNA® in Patients with Schizophrenia or Schizoaffective Disorder. 281 patients have been randomized in a 1:1 ratio into LY03010 group or INVEGA SUSTENNA® group. The study results show that the bioequivalence of LY03010 using the optimized initial dosing regimen compared to INVEGA SUSTENNA® using its original initial dosing regimen at steady state has been demonstrated. The results also show that after the initial injection of LY03010, the desirable exposure was achieved within 1 week, which was comparable to that of INVEGA SUSTENNA®. LY03010 was well tolerated with no unexpected treatment-emergent adverse events ("**TEAEs**") compared to the INVEGA SUSTENNA®. This study suggest that LY03010 could be further convenient to administer and improve compliance by optimizing the initial dosing regimen, while ensuring the efficacy and safety.

The Group has launched several products for the central nervous system therapeutic area ("**CNS**"), including Toludesvenlafaxine Hydrochloride Extended-Release Tablets (Ruoxinlin®), Risperidone Microspheres for Injection (II) (Rykindo®), Quetiapine Fumarate Tablets (Seroquel), Quetiapine Fumarate Extended-release Tablets, Rivastigmine Transdermal Patch, Rivastigmine Twice Weekly Transdermal Patch, Fentanyl Transdermal Patch and Buprenorphine Transdermal Patch, covering over 80 countries and regions around the world, including large pharmaceutical markets in China, the U.S., Europe and Japan, as well as fast growing emerging markets. In addition, the Group has also developed a number of new drugs such as Rotigotine Extended-Release Microspheres for injection ("**LY03003**") and VMAT2 inhibitor ("**LY03015**") in the China and overseas markets.

The Company believes that LY03010 meets the current urgent clinical needs and has good market potential. At the same time, this product will further enrich the Group's product pipelines in CNS, and cooperate with the Group's existing resources and advantages in CNS to accelerate the company's layout and development in this field.

**ABOUT LY03010**

LY03010 is an extended-release injectable suspension which is indicated for the treatment of schizophrenia and schizoaffective disorders by intramuscular injection, monthly doses. LY03010 can improve the common medication compliance issue of oral antipsychotic drugs in the patients with schizophrenia. Compared to another similar drug (INVEGA SUSTENNA®) on the market, LY03010 optimizes the initial dosing regimen, and may therefore bring greater convenience to patients and hence increase patient compliance. In the pre-IND meeting, the FDA has confirmed that demonstration of bioequivalence at steady state after multiple doses would be acceptable to support the 505(b)(2) NDA submission for LY03010.

**ABOUT SCHIZOPHRENIA**

Schizophrenia is a severe mental disorder, characterized by profound disruptions in thinking and affecting the language, perception, and self-cognition of patients. According to the World Health Organization, schizophrenia affects more than 24 million people worldwide. According to Johns Hopkins data, approximately 3 million Americans are affected by schizophrenia. The incidence of schizophrenia is still growing every year. Schizophrenia has brought a heavy burden to a patient's family and the society due to the low treatment rate, poor compliance, high recurrence rate, high hospitalization rate and high disability rate.

## ABOUT THE LONG-ACTING INJECTION FOR THE TREATMENT OF SCHIZOPHRENIA

The long-acting injection is a new dosage form developed for the treatment of schizophrenia in recent years. Compared with the ordinary oral dosage form, it requires a lower administration frequency and is able to maintain a stable and effective blood concentration for a long time, so as to improve the patient compliance and improve the long-term treatment effect of schizophrenia. Currently several long-acting injections have been marketed worldwide, such as paliperidone palmitate, risperidone, aripiprazole, aripiprazole lauroxil and olanzapine. Among them, it was estimated that the market share of paliperidone palmitate long-acting injection is more than 60%. Based on public information, paliperidone palmitate long-acting injection generated global sales of US$4.022 billion in 2021 and US$3.132 billion in January to September 2022.

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

Hong Kong, 21 November 2022

*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.*