# 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

## RYKINDO® APPROVED BY THE FDA FOR THE TREATMENT OF SCHIZOPHRENIA AND BIPOLAR I DISORDER

The board of directors (the "Board") of Luye Pharma Group Ltd. (the "Company", together with its subsidiaries, the "Group") announces that the Rykindo® (risperidone for extended-release injectable suspension) (also known as, LY03004) has received marketing approval from U.S. Food and Drug Administration (the "FDA") as a treatment for schizophrenia in adults and as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder in adults.

The Group developed Rykindo® on its proprietary microsphere technology platform. The drug is administered bi-weekly by intramuscular injection and delivers the active ingredient, risperidone, via long-acting and extended-release microsphere technology. As far as the Company is aware, Rykindo® is the first FDA approved complex dosage form product developed by a pharmaceutical company in mainland China in accordance with 505(b)(2) of the Federal Food, Drug and Cosmetic Act.

In addition to the U.S. market, Rykindo® was approved for marketing in China in 2021. The development of Rykindo® in Europe is also progressing well, with a plan to be marketed in the global market.

Schizophrenia and bipolar disorder are both severe mental disorders, and according to recent figures, affect an estimated 24 million and 40 million people worldwide, respectively. In the U.S., the estimated prevalence of schizophrenia and related psychotic disorders ranges between 0.25% and 0.64%, while an estimated 4.4% of U.S. adults experience bipolar disorder at some point in their lives. The two diseases both have high relapse rates, with poor treatment adherence known to be one of the key associated risk factors.

Data from IQVIA has shown that long-acting antipsychotics generated sales of approximately US$7.1 billion in the global market and US$4.4 billion in the U.S. market in 2021.

In addition to Rykindo®, the Group has commercialized several products for the central nervous system ("CNS") therapeutic area, including Toludesvenlafaxine Hydrochloride Extended-Release Tablets (Ruoxinlin®), Quetiapine Fumarate Tablets (Seroquel®), Quetiapine Fumarate Extended-release Tablets (Seroquel XR®), Rivastigmine Transdermal Patch, Rivastigmine Twice Weekly Transdermal Patch, Fentanyl Transdermal Patch and Buprenorphine Transdermal Patch, in 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. Moreover, the Group is developing a number of new drugs for the global markets in CNS and oncology.

The Company believes that Rykindo® 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 create synergy with the Group's existing resources and advantages in CNS to accelerate the Company's layout and development in this field.

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

Hong Kong, 15 January 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.*