**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

## APPROVAL OBTAINED FOR THE GROUP'S NEW DRUG LY03017 FOR CLINICAL TRIALS 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 its in-house developed next-generation serotonin 2A receptor (5-$HT_{2A}$R) inverse agonist and serotonin 2C receptor (5-$HT_{2C}$R) antagonist, LY03017, has received the U.S. Food and Drug Administration (FDA) clearance of its Investigational New Drug (IND) application to initiate clinical trials in the U.S. LY03017 is intended to treat Alzheimer's disease psychosis (ADP), Parkinson's disease psychosis (PDP), and the negative symptoms of schizophrenia (NSS). The FDA has waived the requirement for a single ascending dose (SAD) trial in the Phase I clinical trial of LY03017, and the drug may proceed directly to the multiple ascending dose (MAD) trial and subsequent clinical trials.

Developed simultaneously in China and the U.S. on the Group's New Chemical Entity/New Therapeutic Entity (NCE/NTE) platform, LY03017 is another innovative drug of the Group for treating central nervous system (CNS) diseases. The drug is undergoing a Phase I clinical trial in China.

Globally, there are large numbers of patients with ADP, PDP, and NSS. Specifically, there are about 45 million people with Alzheimer's disease worldwide, of which 25-50% will develop psychotic symptoms at some point during the course of their illness; Parkinson's disease affects more than 8.5 million individuals globally, and the lifetime prevalence of psychosis among them is approximately 60%; and schizophrenia affects approximately 23 million people, with an estimated 60% of them experiencing NSS.

Currently, there is only one drug approved by the FDA for the treatment of PDP, and it is not yet approved in China; globally there are no drugs approved for treating ADP; and only a few drugs show effectiveness in treating NSS, with efficacy that remains unsatisfactory. There is an urgent need to develop new therapies targeting the three indications above.

LY03017 is a next-generation, dual-targeted investigational drug that acts as a 5-$HT_{2A}$R inverse agonist and a 5-$HT_{2C}$R antagonist. By inhibiting dopamine release in the ventral striatum and enhancing dopamine release in the prefrontal cortex, LY03017 has the potential to address hallucinations and delusions in patients with PDP and ADP while also improving NSS. In preclinical studies, LY03017 demonstrated higher pharmacological activity, better tissue distribution, and higher level of cardiac safety both in vitro and in vivo than existing commercially available or investigational therapies for the same indications.

CNS is a key strategic focus for the Group. The Group has built a differentiated portfolio of innovative therapies for multiple CNS diseases, such as major depressive disorder, schizophrenia, bipolar disorder, and Alzheimer's disease, including Erzofri® (paliperidone palmitate) extended-release injectable suspension and Rykindo® (risperidone) for extended-release injectable suspension, both approved for marketing in the U.S.; Rivastigmine Twice Weekly Transdermal Patch, which has been approved for marketing in multiple European countries, Japan, and China; and Ruoxinlin® (toludesvenlafaxine hydrochloride sustained-release tablets) and Jinyouping® (rotigotine microspheres for injection), both approved for marketing in China. In addition, the Group is conducting clinical studies for several other next-generation innovative drugs, including LY03015, which targets VMAT2/Sigma-1R; LY03020, which targets TAAR1/5-$HT_{2C}$R; and LY03021, which targets NET/DAT/$GABA_A$R.

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

Hong Kong, 24 November 2025

*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. HUANG Liming; 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.*