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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

FIRST SUBJECT ENROLLED IN THE CHINA PHASE II CLINICAL TRIAL OF THE GROUP'S INNOVATIVE DRUG LY03017 FOR TREATING ALZHEIMER'S DISEASE-RELATED PSYCHOSIS

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 innovative drug LY03017 has completed the enrollment of its first subject in a Phase II clinical trial in China for the treatment Alzheimer’s Disease-related Psychosis (ADP). LY03017 is a next-generation serotonin 2A receptor (5-HT_{2A}R) inverse agonist and a serotonin 2C receptor (5-HT_{2C}R) antagonist. The drug is intended for treating ADP, Parkinson’s Disease Psychosis (PDP), and Negative Symptoms of Schizophrenia.

The Group maintains a long-standing commitment to the central nervous system (CNS) therapeutic area, with LY03017 representing another new molecular entity under development in both China and the U.S. The Phase II clinical trial in China is a randomized, double-blind, parallel-group, and placebo-controlled trial to evaluate the preliminary efficacy and safety of LY03017 in the treatment of hallucinations and delusions associated with psychosis in Alzheimer’s disease (AD). LY03017 has also been cleared to initiate clinical trials in the U.S.

AD is one of the most prevalent neurodegenerative diseases and the leading cause of dementia. According to the World Health Organization, more than 57 million people worldwide are living with dementia, and approximately 60% to 70% of them are AD patients. As the disease progresses, approximately 25% to 50% of the patients will develop psychotic symptoms, primarily delusions and hallucinations. Such symptoms are associated with greater cognitive and functional impairments, dementia severity, and caregiver burden. Currently, no therapies have been approved worldwide for the treatment of ADP, representing a significant unmet medical need.

LY03017 is a next-generation dual-target investigational drug which acts as a 5-HT_{2A}R inverse agonist and a 5-HT_{2C}R antagonist to modulate dopamine-related neural pathways. It is designed to reduce abnormal neural activities associated with hallucinations and delusions, having the potential to improve key symptoms of ADP and PDP. In addition, the drug also has the potential to improve cognitive impairments associated with insufficient dopaminergic signaling in the prefrontal cortex and alleviate negative symptoms such as apathy.

Results from a Phase I clinical trial conducted in China showed that LY03017 was generally safe and well tolerated in both healthy adults and seniors. All observed adverse events were mild to moderate, and no serious treatment-emergent adverse events were observed. Based on its human pharmacokinetics (PK), LY03017 was rapidly absorbed following oral administration, exhibited a linear PK profile, and reached steady state after approximately three days of repeated dosing.

The Group will accelerate the Phase II clinical trial of LY03017 to further validate its therapeutic advantages, with the goal of addressing the extensive unmet needs of patients as early as possible.

The CNS therapeutic area is a strategic focus for the Group. The Group has built a differentiated product portfolio targeting multiple conditions such as major depressive disorder, schizophrenia, bipolar disorder, and AD. This portfolio includes Erzofri[®] (paliperidone palmitate) extended-release injectable suspension and Rykindo[®] (risperidone) for extended-release injectable suspension, both approved for marketing in the U.S.; the Rivastigmine Twice Weekly Transdermal Patch, which was approved for marketing in Japan, China, and several European countries; and Ruoxinlin[®] (Toludesvenlafaxine Hydrochloride Sustained-Release Tablets), which was approved for marketing in China. The Group is also conducting clinical trials for several other investigational drugs, including LY03015 which targets VMAT2/Sigma-1R, LY03020 which targets TAAR1/5-HT_{2C}R, and LY03021 which targets GABA_AR/NET/DAT.

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

Hong Kong, 15 April 2026

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.