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

SUCCESSFUL COMPLETION OF A U.S. BRIDGING CLINICAL TRIAL OF THE GROUP'S INNOVATIVE DRUG LY03015 (VMAT2 INHIBITOR/SIGMA-1R AGONIST)

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that the Group has successfully completed a bridging clinical trial in the U.S. of LY03015, a new molecular entity developed in-house by the Group, and the results support the commencement of the upcoming efficacy clinical trial of the investigational drug in the U.S. The results also showed that LY03015 demonstrated a more favorable safety and tolerability profile in Caucasian subjects than in Chinese subjects.

LY03015 is the world's first investigational drug designed to inhibit vesicular monoamine transporter 2 ("**VMAT2**") and activate the sigma-1 receptor ("**Sigma-1R**"). It is intended for the treatment of tardive dyskinesia ("**TD**") and chorea associated with Huntington's disease ("**HD**"). The Group has previously completed a multicenter, randomized, double-blind, placebo-controlled, parallel-group phase II clinical trial in China, in which a total of 121 patients with moderate to severe TD participated. The results showed that, following six consecutive weeks of administration, all three LY03015 dose groups demonstrated robust efficacy, with rapid and significant improvement in TD symptoms and a clear dose-response relationship. In particular, the Abnormal Involuntary Movement Scale ("**AIMS**") response rate in the 20 mg dose group, defined as the proportion of patients achieving an improvement of ≥50% in AIMS items 1-7, reached 76.5%. This response rate exceeded historical treatment benchmarks and was nearly double the response levels reported in publicly available data from double-blind, controlled, registrational clinical trials of current first-line therapeutic drugs.

The U.S. bridging clinical study was an open-label, single-dose, parallel-group study designed to evaluate the pharmacokinetics, safety and tolerability of LY03015 following a single 20 mg oral dose in healthy Chinese and Caucasian subjects. A total of 12 healthy Chinese subjects and 12 healthy Caucasian subjects participated in the study, and the results showed the following:

- no difference in the pharmacokinetics of LY03015 was observed between Caucasian and Chinese subjects;

- overall safety and tolerability were favorable, with all treatment-emergent adverse events ("**TEAEs**") being mild in severity and no serious adverse events ("**SAEs**") being reported; and

- safety and tolerability were notably more favorable in Caucasian subjects than in Chinese subjects, with TEAE incidence rates of 33.3% and 83.3%, respectively.

The study demonstrated that the pharmacokinetics of LY03015 are comparable between Caucasian and Chinese subjects, while its safety and tolerability are more favorable for Caucasian subjects. Based on the results of the phase II clinical trial in China, the Group plans to adopt a simplified dosing regimen for patients enrolled in its planned efficacy clinical trial in the U.S. Compared with the dose-titration regimens commonly adopted in current clinical practice, LY03015 is expected to demonstrate a differentiated market value proposition in terms of efficacy, onset of action and dosing convenience.

The Group has a long-established presence in the central nervous system ("**CNS**") therapeutic area, where it has built a differentiated pipeline of small-molecule class 1 drugs for indications including schizophrenia, depression and Alzheimer's disease. LY03015 is an innovative CNS drug candidate being developed by the Group in both China and the U.S. In addition to LY03015, the pipeline includes two candidates currently undergoing phase II clinical trials in China: LY03017, a next-generation 5-HT_{2A}R inverse agonist and 5-HT_{2C}R antagonist intended to treat Alzheimer's disease-related psychosis, Parkinson's disease psychosis, negative symptoms of schizophrenia, major depressive disorder and bipolar disorder; and LY03020, a next-generation antipsychotic and the world's first agonist of both TAAR1 and 5-HT_{2C}R, intended to treat schizophrenia, Alzheimer's disease-related psychosis and bipolar disorder. The pipeline further includes LY03021, a first-in-class $GABA_A$R PAM and NET/DAT inhibitor currently undergoing phase I clinical development in China for the treatment of major depressive disorder.

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

Hong Kong, 5 August 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.