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

PATIENT ENROLLMENT COMPLETED FOR THE PHASE III CLINICAL STUDY OF RUOXINLIN® IN CHINA FOR TREATING GENERALIZED ANXIETY DISORDER

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that all patients have been enrolled for a Phase 3 clinical trial of its Ruoxinlin® (Toludesvenlafaxine Hydrochloride Sustained-Release Tablets) designated as a Class 1 innovative drug in China for the treatment of Generalized Anxiety Disorder (GAD).

The Phase 3 clinical trial is a multicenter, randomized, double-blind, placebo-controlled study designed to evaluate the safety and efficacy of Ruoxinlin® in patients with GAD. A total of 555 participants have been enrolled for the trial. The primary endpoint is the change from the baseline in the total score on the Hamilton Anxiety Scale (HAM-A) by the end of Week 8. The Group expects to complete the trial and submit the marketing authorization application for this indication in China by the end of this year.

Anxiety disorders are the most common mental disorders in China, characterized by prolonged duration, high relapse rates and significant impact on the quality of daily life of patients. GAD is a common type of anxiety disorder. As of 2021, 53.1 million people were estimated to suffer from anxiety disorders in China.

No innovative drug for treating anxiety has been approved for marketing globally over the past 15 years. Ruoxinlin® has the potential to become the world's first serotonin (5-HT), norepinephrine (NE), dopamine (DA) reuptake inhibitor (SNDRI) approved for marketing for this indication.

Currently, first-line treatment for GAD in clinical use includes selective serotonin reuptake inhibitors (SSRIs) and serotonin, norepinephrine reuptake inhibitors (SNRIs). However, common adverse reactions to SSRIs and SNRIs including sexual dysfunction, somnolence, weight gain, and lipid metabolism disorders which may lead to a low patient adherence, which in turn would compromise the efficacy and become a common cause for treatment disruption.

Ruoxinlin® is China's first locally developed proprietary antidepressant approved for marketing for Class 1 chemical drugs. Since its approval and launch in China in 2022, the drug has been recognized for its efficacy and safety in treating patients with Major Depressive Disorder (MDD). Previous clinical studies of Ruoxinlin® in treating MDD demonstrated comprehensive improvements in depressive symptoms. It was shown to be particularly effective in improving anhedonia, retardation, and cognitive impairment. The drug is able to overcome the shortcomings of existing drugs without causing insomnia or somnolence, nor does not negatively affect sexual function, body weight, and lipid metabolism. In addition, MDD patients treated with Ruoxinlin® also showed significant improvements in their total HAM-A score, their HAM-A Psychic Anxiety Factor score and Somatic Anxiety Factor score, and their 17-item Hamilton Depression Rating Scale (HAM-D17) Anxiety/Somatization Factor scores. This indicates that the drug has the potential to reduce anxiety in addition to reducing depression.

In less than three years since its launch in 2022, over 80,000 patients have benefited from Ruoxinlin®, becoming the fastest growing new antidepressant in terms of sales in China in recent years. At the end of 2024, Ruoxinlin® was included for the first time in China's "National Reimbursement Drug List for Basic Medical Insurance, Work-Related Injury Insurance, and Maternity Insurance (2024)", making it more accessible to patients. Its Phase 3 clinical trial for treating GAD is now progressing smoothly. Once it is also approved for marketing, more patients will be able to benefit from this innovative medication.

There is a huge demand for drugs treating central nervous system (CNS) related diseases such as MDD and anxiety. However, new drug development in this area has been relatively slow. The Group has obtained marketing approvals for a number of internationally competitive innovative drugs and formulations in China, the U.S., Europe, Japan, and other markets, 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 of which have been approved for marketing in China. In addition, the Group is actively developing several other innovative drugs filed through China's Class 1 pathway, such as LY03020, which targets TAAR1 and 5-HT_{2C}R; LY03015, which targets VMAT2 and Sigma-1; and LY03017, which targets 5-HT_{2A}R and 5-HT_{2C}R.

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

Hong Kong, 18 August 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.