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

NEW DRUG APPLICATION FOR CLASS 1 INNOVATIVE DRUG RUOXINLIN® FOR THE NEW INDICATION OF GENERALIZED ANXIETY DISORDER ACCEPTED IN CHINA

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that the Centre for Drug Evaluation of the National Medical Products Administration in the People's Republic of China ("**China**") has accepted the New Drug Application ("**NDA**") of a new indication for Ruoxinlin® (Toludesvenlafaxine Hydrochloride Sustained-Release Tablets), a Class 1 innovative drug in China, for the treatment of Generalized Anxiety Disorder ("**GAD**"). This marks another milestone for Ruoxinlin® after it was approved in November 2022 for the treatment of Major Depressive Disorder. Upon approval of the new indication, this drug will have the potential to become the first serotonin, norepinephrine, dopamine reuptake inhibitor ("**SNDRI**") for treating GAD in China, bringing a novel therapeutic option to a broader patient population.

The NDA submission for the new indication of Ruoxinlin® is supported by results from an 8-week, multicenter, randomized, double-blind, placebo-controlled Phase III clinical study involving 555 patients. The study evaluated the efficacy and safety of the drug for GAD patients, with the change from baseline in the Hamilton Anxiety Rating Scale (HAM-A) total score as the primary endpoint. The results of this study demonstrated that Ruoxinlin® delivered rapid and comprehensive relief of anxiety symptoms, achieving a response rate of over 80% and a remission rate of approximately 50%. The drug exhibited a favorable safety and tolerability profile, showing no significant impact on body weight or glucose and lipid metabolism, with a low incidence of adverse events such as somnolence, insomnia, fatigue, and sexual dysfunction. Most adverse events were mild to moderate, with the majority of them being resolved or improved over time.

According to the 2023 Global Burden of Disease (GBD) data, anxiety disorders are the most common mental disorders in China, affecting approximately 58.67 million people nationwide. GAD is a common subtype, with a lifetime prevalence of 4.1%–6.6% in adults. However, the disease remains underdiagnosed and undertreated, and its high comorbidity with other conditions imposes a substantial economic and social burden on patients, their family members, and society in general.

In clinical practice, selective serotonin reuptake inhibitors ("**SSRIs**") and serotonin, norepinephrine reuptake inhibitors ("**SNRIs**") are widely used for treating anxiety spectrum disorders and are considered the first-line standard of care for GAD. However, the efficacy of these treatments remains limited. A meta-analysis shows that SSRIs/SNRIs yield an overall response rate of 67.7% and a remission rate of 39.7%. Furthermore, these medications are often associated with adverse effects such as lipid metabolism disturbances, weight gain, somnolence, and sexual dysfunction. These side effects can negatively impact patient adherence and overall clinical benefit, frequently leading to treatment discontinuation.

Despite the substantial disease burden, the availability of innovative therapies for anxiety disorders in China remains very limited. Data from IQVIA shows that the market size for SSRIs and SNRIs was RMB4.83 billion in 2024, and no Class 1 innovative drug for the treatment of anxiety disorders has been approved in China over the past 20 years.

As China's first locally developed proprietary Class 1 chemical antidepressant approved for marketing, Ruoxinlin® has served nearly 190,000 patients since it was approved over three years ago. Its efficacy and safety profile has been widely recognized, making it one of China's fastest-growing antidepressants in recent years. At the end of 2024, Ruoxinlin® was included in China's National Reimbursement Drug List for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance for the first time. In September 2025, it received a Class 1A recommendation as a first-line treatment for depression in the Chinese Guidelines for the Diagnosis and Treatment of Depressive Disorders under the new mechanism category of SNDRI. As the review of this new indication progresses, the accessibility of Ruoxinlin® is expected to be further increased.

The Central Nervous System (CNS) therapeutic area, which includes depression and anxiety, is a strategic focus for the Group. The Group has built a differentiated product portfolio covering multiple conditions such as schizophrenia, bipolar disorder, and Alzheimer's disease. In addition to Ruoxinlin®, this portfolio also includes Erzofri® (paliperidone palmitate) extended-release injectable suspension and Rykindo® (risperidone) for extended-release injectable suspension, both approved for marketing in the U.S., as well as Rivastigmine Twice Weekly Transdermal Patch, which has been approved for marketing in Japan, China, and several European countries. The Group is also developing next-generation innovative drugs and conducting clinical trials for several Class 1 new drugs, including LY03015, which targets VMAT2/Sigma-1R; LY03017, which targets 5-HT_{2A}R/5-HT_{2C}R; 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, 8 January 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.