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

CLASS 1 INNOVATIVE ANTIDEPRESSANT RUOXINLIN® APPROVED FOR MARKETING IN MACAO

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that Ruoxinlin® (Toludesvenlafaxine Hydrochloride Extended-Release Tablets), the Group's innovative drug for treating Major Depressive Disorder ("**MDD**"), has been approved for marketing in Macao by the Pharmaceutical Administration Bureau of the Macao SAR Government.

Ruoxinlin® is China's first independently developed and patented Class 1 innovative chemical drug for the treatment of MDD. Preclinical studies have shown that it acts as a serotonin (5-HT)-norepinephrine (NE)-dopamine ("**DA**") reuptake inhibitor (SNDRI). In addition, a PET/CT study has confirmed that the drug can bind to DA transporters in the brains of both rats and healthy human subjects, further strengthening the evidence for its triple reuptake inhibitory effects.

The results of the Phase 3 clinical study of Ruoxinlin® demonstrated that it is able to treat MDD in a comprehensive and stable manner. Specifically, it significantly reduces anxiety, retardation, fatigue, and anhedonia, improves cognitive abilities, promotes the recovery of social functions, and is safe and well-tolerated. It does not cause somnolence or negatively affect sexual function, body weight, and lipid metabolism.

MDD has always been accompanied by high recurrence, suicide, and disability rates. Although past antidepressants have been generally effective, there are still significant unmet clinical treatment needs. Most patients still experience residual symptoms after receiving medication treatment, including anxiety, cognitive impairment, fatigue, anhedonia, etc., which severely impair social functioning and significantly accelerate the recurrence of MDD. Additionally, these medications can easily cause adverse reactions such as sexual dysfunction, weight gain, emotional blunting, and drowsiness, which affect patient compliance with treatment and become important factors leading to poor prognosis.

Since its approval and launch in mainland China in November 2022, Ruoxinlin® has gained growing clinical recognition for its efficacy and safety, becoming one of the fastest-growing new antidepressants in mainland China in recent years. More than 30,000 patients have benefited from the drug to date. At the end of 2024, following successful negotiations, Ruoxinlin® was included in the China's National Reimbursement Drug List for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (2024 Version) for the first time. This helps to improve the drug's accessibility and availability, allowing it to benefit more patients. In addition, a Phase 3 clinical trial of the drug for treating Generalized Anxiety Disorder is currently underway.

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

Hong Kong, 7 April 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.