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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

APPROVAL OF THE GROUP'S INNOVATIVE DRUG RUOXINLIN® IN CHINA FOR THE NEW INDICATION OF GENERALIZED ANXIETY DISORDER

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that Ruoxinlin® (toludesvenlafaxine hydrochloride sustained-release tablets), a Class 1 innovative drug independently developed by the Group, has been approved by China's National Medical Products Administration for the treatment of generalized anxiety disorder (the "**GAD**"). To the Company's knowledge, Ruoxinlin® is the first innovative chemical drug for the treatment of anxiety that was independently developed in China and has proprietary intellectual property rights. This approval marks a major breakthrough for China's domestically developed innovative drugs in this therapeutic area.

Ruoxinlin® was first approved for marketing in China in November 2022 for the treatment of major depressive disorder (the "**MDD**"). GAD is the second indication for which Ruoxinlin® has been approved in China. The product is China's first and currently only serotonin (the "**5-HT**"), norepinephrine (the "**NE**") and dopamine (the "**DA**") triple reuptake inhibitor (the "**SNDRI**"). Clinical studies have demonstrated that Ruoxinlin® rapidly and comprehensively improves anxiety symptoms, achieves high response and remission rates, significantly improves patients' overall condition and promotes the recovery of social functioning, and has a favorable overall safety and tolerability profile, offering a differentiated new treatment option for patients with GAD.

Anxiety disorders are among the most prevalent mental disorders in China, with a lifetime prevalence of approximately 7.6% among adults. GAD is one of the most common types of anxiety disorder. It typically follows a prolonged course with a tendency to recur, causes significant impairment to patients' social functioning, occupational functioning and quality of life, and imposes a heavy economic burden on patients, their families and society. In addition, GAD is frequently comorbid with other conditions, most commonly depression. Research indicates that approximately two-thirds of patients with GAD also have a depressive disorder. Compared with patients with a single condition, comorbid patients have more complex clinical presentations, respond less well to pharmacotherapy and have poorer overall functional outcomes, further increasing the difficulty of treatment.

Selective serotonin reuptake inhibitors (the "**SSRIs**") and serotonin–norepinephrine reuptake inhibitors (the "**SNRIs**") are currently first-line treatments for GAD. Their limitations in clinical practice include delayed onset of action, inadequate efficacy and safety concerns. Studies indicate that SSRIs and SNRIs yield an overall response rate of 67.7% and a remission rate of 39.7%, typically begin to show therapeutic effects after two to four weeks of treatment, and are often associated with adverse reactions such as lipid metabolism abnormalities, weight gain, sexual dysfunction, insomnia, fatigue and somnolence. These challenges may compromise treatment benefit and adherence.

SSRIs and SNRIs inhibit 5-HT reuptake, increasing 5-HT levels in the synaptic cleft and helping relieve psychological symptoms of anxiety such as worry, panic and obsessive-compulsive symptoms. SNRIs also inhibit NE reuptake, increasing NE levels in the synaptic cleft, which helps regulate stress-related arousal and relieve somatic symptoms of anxiety such as palpitations, tension and hypervigilance. Compared with SSRIs and SNRIs, Ruoxinlin® additionally inhibits DA reuptake, enabling the synergistic modulation of 5-HT, NE and DA. DA is involved in regulating neural pathways associated with fear extinction, reward and motivation in specific brain regions, as well as cognition-related circuits in brain regions such as the prefrontal cortex. This activity may help restore impaired emotional regulation in patients with anxiety disorders, improve anhedonia and reduced motivation, alleviate cognitive impairment associated with anxiety, and synergistically mitigate the risk of early exacerbation of anxiety associated with elevated NE levels.

Approval of the new indication was based on an eight-week, multicenter, randomized, double-blind, placebo-controlled Phase III clinical study evaluating the efficacy and safety of Ruoxinlin® in the treatment of GAD. The primary endpoint was the change from baseline in the Hamilton Anxiety Rating Scale (HAMA) total score. Results from the trial showed that:

- Ruoxinlin® began to take effect as early as week 1 of treatment. After eight weeks of treatment, the response rate exceeded 80% and the remission rate was approximately 50%, with significant improvements in psychic anxiety, somatic anxiety and core symptoms. In addition, Ruoxinlin® comprehensively promoted the recovery of patients' social functioning, including work, study, social interaction and family life.

- Ruoxinlin® showed a favorable overall safety and tolerability profile, with no significant impact on body weight or glucose and lipid metabolism. The incidence of adverse reactions such as somnolence, insomnia, fatigue and sexual dysfunction was low. The vast majority of adverse reactions were mild to moderate, and most improved or resolved.

In addition, Ruoxinlin® was the first antidepressant independently developed in China to be approved as a Class 1 innovative chemical drug. It is now recommended as a first-line treatment for MDD in both the Chinese Guidelines for the Diagnosis and Treatment of Depressive Disorders (2025 Edition) and the Chinese Guidelines for the Prevention and Treatment of Depression in the Community, and has gained broad acceptance among clinicians and patients.

According to IQVIA, the markets for antidepressants and anti-anxiety drugs in China together totaled RMB9.78 billion in 2025 and RMB5.08 billion in the first half of 2026.

The Group believes that approval of the new indication further broadens the clinical use of Ruoxinlin® and creates new growth opportunities for the product. Drawing on its expertise and established commercial infrastructure in the central nervous system (the "**CNS**") therapeutic area, the Group will accelerate Ruoxinlin®'s market expansion and penetration in the anti-anxiety segment, continue to improve patient access and help realize the product's growth potential. The CNS therapeutic area has long been a strategic focus for the Group. The Group is accelerating the global development of next-generation innovative drugs to address unmet treatment needs for patients with psychiatric and neurological disorders, and to accelerate the translation of clinical value into patient benefit.

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

Hong Kong, 19 November 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.