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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

THE GROUP'S FIVE NEW PRODUCTS INCLUDED IN CHINA'S 2025 NATIONAL REIMBURSEMENT DRUG LIST OR COMMERCIAL INSURANCE INNOVATIVE DRUG LIST

The board of directors (the “**Board**”) of Luye Pharma Group Ltd. (the “**Company**”, together with its subsidiaries, the “**Group**”) announces that five new products have been included in the 2025 edition of the National Reimbursement Drug List for Basic Medical Insurance, Maternity Insurance and Work-Related Injury Insurance (the “**2025 National Reimbursement Drug List**”) or in the 2025 edition of the Commercial Insurance Innovative Drug List; both lists were released by the National Healthcare Security Administration of China.

Of these five products, Mimeixin® (oxycodone hydrochloride and naloxone hydrochloride sustained-release tablets) and Ruibailai® (paliperidone palmitate injection (II)) are covered by the National Reimbursement Drug List for the first time; Zepzelca® (lurbinectedin for injection) is included in the Commercial Insurance Innovative Drug List; and Baituowei® (goserelin microspheres for injection) and Rykindo® (risperidone microspheres for injection (II)) have successfully renewed their inclusion in the National Reimbursement Drug List.

Mimeixin® and Ruibailai® are included in the National Reimbursement Drug List for the first time

Mimeixin® (oxycodone hydrochloride and naloxone hydrochloride sustained-release tablets) is indicated for the management of severe pain in adults that can only be effectively controlled with opioids. It contains naloxone, an opioid receptor antagonist, which reduces opioid-induced constipation (OIC) by blocking the binding of oxycodone to opioid receptors in the gut. Oxycodone in combination with naloxone in the dosage form of a sustained-release tablet is China's first analgesic product to contain an oral naloxone formulation and remains the country's only strong analgesic combination with a mechanism to address OIC. It is recommended by multiple authoritative guidelines, including the Chinese Guidelines for Cancer Pain Management in Adults (2025 edition) and the NCCN Clinical Practice Guidelines in Oncology: Adult Cancer Pain (Version 2, 2025).

Ruibailai® (paliperidone palmitate injection (II)) is approved in China for treating patients with schizophrenia in the acute and maintenance phases. It is the world's first and only long-acting injectable (LAI) paliperidone with an initiation regimen of only one injection in the first month. The product has also been approved for marketing in the U.S. Compared with traditional paliperidone LAIs that require two initial injections in the first month (on Day 1 and Day 8), Ruibailai® offers a simpler initiation regimen of a single injection at 351 mg in the first month. This helps improve patient compliance and provides a more convenient and sustainable long-term treatment option.

Zepzelca® is included in the Commercial Insurance Innovative Drug List

Zepzelca® (lurbinectedin for injection) is indicated for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy. It is among the first medications included in China's inaugural Commercial Insurance Innovative Drug List. There has long been a lack of new drugs as second-line treatments for SCLC, and no significant breakthrough in efficacy has been made over the last two decades or more. Zepzelca® has achieved a breakthrough in its mechanism of action. As an RNA polymerase II inhibitor, it not only kills tumor cells, but also regulates the immune microenvironment and enhances the antitumor immune response, thus overcoming the limitations of conventional chemotherapy and filling a long-standing therapeutic gap. Zepzelca® is now a Grade I recommendation for second-line treatment of extensive-stage SCLC in the 2025 CSCO Guidelines for the Diagnosis and Treatment of SCLC. The drug is also endorsed by international guidelines from NCCN, ESMO, and others, making it a new standard second-line treatment of SCLC.

Baituowei® and Rykindo® are renewed in the National Reimbursement Drug List

Baituowei® (goserelin microspheres for injection) is the world's only marketed formulation of long-acting goserelin microspheres. It is indicated for treating prostate cancer in patients requiring androgen deprivation therapy and for treating breast cancer in premenopausal and perimenopausal women who can be treated with hormones. Developed on the Group's leading microsphere platform, the drug boasts an upgraded formulation and an improved injection method that balance efficacy, safety, and patient experience, offering a more convenient option for clinical use.

Rykindo® (risperidone microspheres for injection (II)) is approved in China for the treatment of acute and chronic schizophrenia and significant positive and negative symptoms of various other psychotic states. It is China's first locally developed LAI of a second-generation antipsychotic. The drug is also approved for marketing in the U.S., making it the first new drug developed by a Chinese company in the central nervous system therapeutic area approved for marketing in the U.S. Rykindo® offers the benefits of both a long-acting formulation and an atypical antipsychotic. The drug delivers favorable efficacy and safety across the full course of schizophrenia treatment, supported by its distinctive pharmacokinetic and pharmacodynamic profile.

The Group believes that the synergistic coordination between national health insurance and commercial health insurance is a major state initiative to ensure basic coverage for patients, promote innovation, and drive the high-quality development of innovative drugs. With five new products covered by the multi-tiered health insurance system through various access pathways, this will not only make these drugs more affordable for patients in the relevant disease areas and reduce their treatment burdens, but will also accelerate market penetration and coverage of the drugs, laying a solid foundation for their long-term, high-quality growth.

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

Hong Kong, 7 December 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.