LUYE PHARMA GROUP LTD.

绿叶制药集团有限公司

(Incorporated in the Bermuda with limited liability)

(Stock Code: 02186)

VOLUNTARY ANNOUNCEMENT

FIRST PATIENT ENROLLED FOR PHASE 3 CLINICAL STUDY OF THE GROUP'S INNOVATIVE FORMULATION LY01610

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that the first patient has been enrolled for a Phase 3 clinical trial of its self-developed investigational anticancer drug Irinotecan Hydrochloride Liposome Injection ("**LY01610**"). This is a multicenter, randomized, open-label, parallel-group study that will compare the efficacy and safety of LY01610 with topotecan in patients with relapsed small cell lung cancer ("**SCLC**").

LY01610 is expected to offer a better treatment for relapsed SCLC. To date, no irinotecan hydrochloride liposome injection has been approved for treating SCLC in China.

Chemotherapy remains the principal strategy to control the progression of relapsed SCLC today, as no therapy has clearly improved outcomes and prognoses for years. "The 2023 Guidelines of the Chinese Society of Clinical Oncology (CSCO) for the Diagnosis and Treatment of SCLC" recommend topotecan as a standard second-line treatment for SCLC patients who relapse within six months after receiving a first-line treatment, irinotecan hydrochloride in combination with a platinum-based therapy as a first-line treatment for extensive stage SCLC, and irinotecan hydrochloride alone as a second-line alternative treatment for SCLC.

However, both topotecan and irinotecan hydrochloride have limitations in clinical practice. Topotecan has modest efficacy (Objective Response Rate ("**ORR**") is less than 25% for sensitive relapsed patients and less than 10% for resistant relapsed patients) and can cause severe myelosuppression, leading to poor tolerability (with Grade 4 neutropenia occurring in up to 70% of patients). Irinotecan hydrochloride exhibits significant toxicity against normal cells and is prone to causing late diarrhea

(with around 30% of Grade 3–4 treatment emergent adverse events ("**TEAEs**")) and neutropenia (with around 25% of Grade 3–4 TEAEs) (Note: in this study, the subjects treated with irinotecan hydrochloride were patients with colorectal cancer, not SCLC).

LY01610 overcomes those limitations by innovatively encapsulating irinotecan hydrochloride in liposomes. The encapsulation preserves the structural integrity of the drug's active ingredient and alters its in vivo pharmacokinetics and distribution. As a result, the blood concentrations of the drug and its active metabolites are significantly increased, leading to a longer half-life. The drug is also concentrated in tumor tissues and reduced in other organs, to enhance efficacy and reduce toxicity.

LY01610 demonstrated promising efficacy and safety during Phase 1 and 2 clinical trials that were completed. In the Phase 2 clinical trial for Chinese patients with relapsed SCLC, LY01610 outperformed topotecan, the standard treatment for relapsed SCLC, in terms of ORR, Duration of Response (DOR), Progression-Free Survival (PFS), and Overall Survival (OS). In terms of safety, LY01610 also had lower hematological toxicity than topotecan and caused fewer gastrointestinal adverse events such as diarrhea, than irinotecan hydrochloride.

Lung cancer is the most common cancer and the leading cause of cancer death in China, with about 1,060,600 new cases and 733,300 deaths in 2022, and SCLC accounted for 13–17% of all lung cancer cases. SCLC is highly malignant and often diagnosed at advanced stages, leading to a poor prognosis. The five-year survival rate for SCLC patients in the extensive stage is only 3%, and approximately 75% of patients with locally advanced SCLC and over 90% of those whose cancer has metastasized would relapse within two years after treatments.

The Group will speed up the Phase 3 clinical trial of LY01610 to further demonstrate its superiority, and expects to address the unmet needs of patients.

In addition to LY01610, the Group has also developed other liposomes and targeted drug delivery systems. For example, its exclusive product Lipusu® (paclitaxel liposome injection), which has been launched, is widely recognized by physicians and patients in clinical practice for its clear efficacy and better safety; and the Group's Irinotecan Hydrochloride and Floxuridine Liposome Injection is the first investigational drug of its kind to apply for and undergo clinical trials in China.

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

Hong Kong, 4 March 2024

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 Dr. LYU Dong; 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.