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

LURBINECTEDIN FOR INJECTION (LY01017) GRANTED PRIORITY REVIEW BY CHINA'S CDE FOR TREATING SMALL CELL LUNG CANCER

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that Lurbinectedin for Injection ("**Lurbinectedin**" or "**LY01017**") has been granted priority review by the Center for Drug Evaluation ("**CDE**") of the National Medical Products Administration ("**NMPA**") in China. The drug is intended to treat adult patients with metastatic small cell lung cancer ("**SCLC**") who have disease progression upon or after receiving platinum-based chemotherapy.

Lurbinectedin is a selective inhibitor of oncogenic transcription. Its unique dual-action mechanism allows it to regulate the microenvironment for tumors, while inhibiting oncogenic transcription and leading to the apoptosis of cancer cells. In 2020, Lurbinectedin received the accelerated approval from the U.S. Food and Drug Administration ("**FDA**") for the above indication. As far as the Company is aware, this is the only new chemical entity approved by the FDA in the U.S. for the treatment of relapsed SCLC during the past 26 years since 1997.

The approval of Lurbinectedin by the FDA was based on data from an open-label, multicenter, and single-arm Phase 2 clinical study of the drug in 105 adult patients with SCLC (including platinum-sensitive and platinum-resistant patients) whose disease progressed after receiving platinum-based chemotherapy. In this study, patients treated with Lurbinectedin demonstrated an overall response rate ("**ORR**") of 35% and a median duration of response of 5.3 months.

Lurbinectedin was originally developed by the Company's business partner PharmaMar. The Company was granted the exclusive rights to develop and commercialize the drug in China.

The clinical study conducted in China was a single-arm, dose-escalation, and dose-expansion clinical study designed to evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy of Lurbinectedin in Chinese patients with advanced solid tumors including relapsed SCLC. The results of the study show promising efficacy and a manageable safety profile of the drug as a second-line therapy at a dose of 3.2mg/m^2 in Chinese SCLC patients. It was confirmed by an independent review committee that the ORR was 45.5% in subjects with relapsed SCLC. The study also shows that the efficacy of Lurbinectedin on Chinese patients with relapsed SCLC who had experienced progression after receiving the first-line platinum-based chemotherapy was comparable to its efficacy in the Phase II clinical study conducted overseas, and the response rate was even higher in Chinese patients.

The preliminary results of the Chinese study were presented at the 2022 annual meeting of the American Society of Clinical Oncology ("**ASCO**") as well as the 25th National Clinical Oncology Conference and the 2022 annual meeting of the Chinese Society of Clinical Oncology ("**CSCO**"), attracting extensive attention from both Chinese and overseas experts.

It was reported that lung cancer was China's No.1 cancer in 2020 in terms of morbidity and mortality, with approximately 815,000 new cases and 714,000 deaths for that year. Specifically, SCLC accounted for 13%–17% of all lung cancer cases. Most SCLC patients were already in advanced stage cancer upon diagnosis, resulting in poor prognosis. Their five-year survival rate was only 7% or as low as 3% for those in the extensive stage. Although SCLC is very sensitive to initial treatments, most patients would experience a relapse or develop drug resistance after initial treatments. Statistics have shown that approximately 75% of the patients with locally advanced SCLC and more than 90% of those with metastatic SCLC would relapse within two years after receiving treatments. The high relapse rate of SCLC poses a significant challenge to its treatment, and innovative therapies are urgently needed in clinical practice.

In the near term, the Company plans to submit a New Drug Application ("**NDA**") for Lurbinectedin to the CDE. In addition to the Chinese mainland, the NDA for this drug is also being reviewed in Hong Kong, China. Moreover, Lurbinectedin is already available to Chinese patients for urgent clinical use at designated medical institutions in the Hainan Boao Lecheng International Medical Tourism Pilot Zone and through the Named Patient Program in Hong Kong.

ABOUT LURBINECTEDIN

Lurbinectedin is an analog of the marine compound ET-736 isolated from the sea squirt *Ecteinacidia turbinata* in which a hydrogen atom has been replaced by a methoxy group. It is a selective inhibitor of the oncogenic transcription programs on which many tumors are particularly dependent. Together with its effect on cancer cells, Lurbinectedin inhibits oncogenic transcription in tumor-associated macrophages, downregulating the production of cytokines that are essential for the growth of the tumor.

Lurbinectedin is currently approved in other nine countries, following its accelerated approval by the FDA for the treatment of metastatic SCLC. The drug is recommended by *Small-cell lung cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up (published in 2021)* and the *NCCN Guidelines for Small Cell Lung Cancer (2022)*. The Group owns the rights to develop and commercialize Lurbinectedin in China.

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

Hong Kong, 31 March 2023

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. SUN Xin; and the independent non-executive directors of the Company are Mr. ZHANG Hua Qiao, Professor LO Yuk Lam, Mr. LEUNG Man Kit and Mr. CHOY Sze Chung Jojo.