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 RECOMMENDED FOR THE FIRST TIME BY THE 2023 CSCO GUIDELINES FOR 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**"), an innovative anti-tumor drug the Group licensed from PharmaMar, S.A. ("**PharmaMar**"), has been recommended for the first time by the 2023 Chinese Society of Clinical Oncology ("**CSCO**") Guidelines for Small Cell Lung Cancer ("**2023 CSCO SCLC Guidelines**").

The meeting of CSCO in relation to the 2023 CSCO SCLC Guidelines was held recently in Guangzhou, China. In the meeting regarding Small Cell Lung Cancer ("**SCLC**"), the experts announced an update to the Internal Medicine section of the 2023 CSCO SCLC Guidelines. Lurbinectedin has been first recommended as a second-line treatment for relapsed SCLC after ≤6 months or >6 months.

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 United States (**U.S.**) Food and Drug Administration ("**FDA**") for the treatment of adult patients with metastatic SCLC with disease progression on or after receiving platinum-based chemotherapy.

2023 CSCO SCLC Guidelines recommend Lurbinectedin as a second-line treatment for relapsed SCLC ≤6 months or >6 months (Class 2A evidence, Level III recommendation). Lurbinectedin was added to the guidelines based on the results of the Chinese Phase I bridging trial (LY01017/CT-CHN-101) reported at the American Society of Clinical Oncology (ASCO) Annual Meeting in 2022. The results of the study showed 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. An Independent Review Committee ("**IRC**")

confirmed the overall response rate (ORR) was 45.5% in subjects with relapsed SCLC, which showed a significantly better trend than the historical data of Topotecan. The median progression-free survival ("**mPFS**"), median overall survival (OS), and median duration of tumor response (DOR) were 5.6 months, 11.0 months, and 4.2 months, respectively. Compared with the basket trial, Lurbinectedin showed a lengthening trend in mPFS estimates in the Chinese population as assessed by the investigator and the IRC. The adverse reactions were basically alleviated after treatment and were safe and tolerated.

In addition to the 2023 CSCO SCLC Guidelines, Lurbinectedin has been recommended by several domestic and overseas authoritative guidelines. The National Comprehensive Cancer Network ("**NCCN**") guidelines (2020.V4) recommended Lurbinectedin for the first time for patients with recurrent SCLC after ≤6 months or >6 months of previous systemic treatment. The most recent NCCN guidelines (2023.V3) also recommend Lurbinectedin as a follow-up systemic treatment for SCLC. In 2021, the SCLC Clinical Practice Guidelines issued by the European Society for Medical Oncology (ESMO) recommended Lurbinectedin for second-line treatment of platinum-resistant recurrent SCLC and third-line treatment for platinum-sensitive recurrent SCLC. Lurbinectedin was for the first time recommended for the second and third-line treatment of extensive stage SCLC in the Clinical Practice Guideline for Stage Ⅳ Primary Lung Cancer in China (2023 Edition).

At present, Lurbinectedin is in the preparation stage of marketing authorization application in the Chinese mainland, and has been granted priority review by the Center for Drug Evaluation of the National Medical Products Administration. In addition to the Chinese mainland, Lurbinectedin is also being reviewed for its New Drug Application in Hong Kong. Moreover, the drug is 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 has also been approved in 9 other countries, in addition to its accelerated approval by the FDA for the treatment of metastatic SCLC. The Group owns the rights to develop and commercialize Lurbinectedin in China.

ABOUT PHARMAMAR

PharmaMar is a biopharmaceutical company focused on the research and development of new oncology treatments, whose mission is to improve the healthcare outcomes of patients afflicted by serious diseases with our innovative medicines. The Company is inspired by the sea, driven by science, and

motivated by patients with serious diseases to improve their lives by delivering novel medicines to them. PharmaMar intends to continue to be the world leader in marine medicinal discovery, development and innovation.

PharmaMar has developed and now commercializes Yondelis® in Europe by itself, as well as Zepzelca® (Lurbinectedin), in the U.S. and China; and Aplidin® (Plitidepsin), in Australia, with different partners. In addition, it has a pipeline of drug candidates and a robust R&D oncology program. PharmaMar has other clinical-stage programs under development for several types of solid cancers: Lurbinectedin and Ecubectedin. Headquartered in Madrid (Spain), PharmaMar has subsidiaries in Germany, France, Italy, Belgium, Austria, Switzerland and the U.S.. PharmaMar also wholly owns Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi).

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

Hong Kong, 27 April 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.