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

SUBMISSION OF NEW DRUG APPLICATION FOR LURBINECTEDIN BY THE GROUP IN MACAO, CHINA

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that the Group has submitted a New Drug Application ("**NDA**") for Lurbinectedin for injection ("**Lurbinectedin**" or "**LY01017**"), a product of the Group licensed in from PharmaMar, S.A. ("**PharmaMar**") in Macao, China, for the treatment of adult patients with metastatic small cell lung cancer ("**SCLC**") with disease progression on 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 United States ("**U.S.**") Food and Drug Administration ("**FDA**") for the above indication.

The NDA filed in Macao is based on data from two clinical studies of Lurbinectedin conducted in China and overseas. The study conducted overseas is an open-label, multicenter, and single-arm Phase II clinical study of the drug in 105 adult patients with SCLC (including platinum-sensitive and platinum-resistant ones) 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 ("**DoR**") of 5.3 months.

The study conducted in China is a single-arm, dose-escalation, and dose-expansion clinical trial 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 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 confirmed the ORR was 45.5% in subjects with relapsed SCLC.

Lung cancer is a malignant tumor with high morbidity and mortality rates worldwide, and SCLC is estimated to account for 13%–17% of all lung cancer cases. SCLC is highly likely to metastasize to distant sites within the body in early stages, and patients are often already in an advanced stage upon diagnosis, resulting in poor prognosis. Meanwhile, advancements in the treatment of SCLC have been limited. For over 20 years prior to the accelerated approval of Lurbinectedin by the U.S. FDA, the agency approved only one new chemical entity for the treatment of metastatic SCLC in 1996.

Currently, Lurbinectedin is also being reviewed for its NDA in the mainland China and Hong Kong SAR of China. 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.

The Group will continue to promote the registration and commercialization of Lurbinectedin in the market of China, so that the product can serve patients with urgent needs as soon as possible.

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 tumors.

Lurbinectedin has also been approved in 11 other countries or regions, in addition to its accelerated approval by the U.S. 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), the NCCN Guidelines for Small Cell Lung Cancer (2022) and the 2023 Chinese Society of Clinical Oncology Guidelines for Small Cell Lung Cancer. Luye Pharma 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 innovative medicines. PharmaMar 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 by itself developed and commercialized Yondelis® in Europe and in conjunction with business parties, Zepzelca® (Lurbinectedin) in the U.S. and China as well as Aplidin® (Plitidepsin) in Australia. 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: namely, 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, a company dedicated to researches on therapeutic applications of gene silencing (RNAi).

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

Hong Kong, 21 August 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, Mr. CHOY Sze Chung Jojo and Ms. XIA Lian.