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
INNOVATIVE DRUG LURBINECTEDIN APPROVED FOR THE TREATMENT OF RELAPSED SMALL CELL LUNG CANCER IN MACAO, CHINA

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**"), a product of the Group licensed in from PharmaMar, S.A. ("**PharmaMar**") has been approved by the Pharmaceutical Administration Bureau in Macao, China for the treatment of adult patients with metastatic small cell lung cancer ("**SCLC**") with disease progression upon or after receiving platinum-based chemotherapy. Such approval in Macao will allow SCLC patients beyond Macao to benefit from the drug and improve their survival under the relevant policies adopted in the Guangdong-Hong Kong-Macao Greater Bay Area.

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**"). It was the only new chemical entity approved by the FDA for the treatment of metastatic SCLC in more than 20 years.

The approval of Lurbinectedin in Macao is mainly based on data from two clinical studies of the drug conducted in China and overseas. The study conducted overseas was an open-label, multicenter, and single-arm Phase II clinical study of the drug in 105 adult patients with SCLC whose disease progressed after receiving platinum-based chemotherapy. In this study, patients treated with Lurbinectedin demonstrated an overall response rate ("**ORR**") of 35.2%. Among them, the ORR of those who were chemotherapy-sensitive (chemotherapy free interval ("**CTFI**") ≥90 days) was 45%, the median Progression Free Survival ("**mPFS**") was 4.6 months, and the median Overall Survival ("**mOS**") was 11.9 months.

The study conducted in China was a single-arm, dose-escalation, and dose-expansion clinical trial aiming to evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy of Lurbinectedin in Chinese patients with advanced tumors, including relapsed SCLC. In this study, an Independent Review Committee confirmed that the ORR was 45.5% in subjects with relapsed SCLC, the mPFS was 5.6 months, and the mOS was 11.0 months. The study also demonstrated efficacy and a manageable safety profile of the drug as a second-line treatment in Chinese SCLC patients. Besides, its efficacy in Chinese patients was found to be comparable to or even better than that in the SCLC cohort of the Phase II clinical trial conducted overseas.

Lung cancer is the most common and deadly cancer in China, accounting for both the highest incidence and mortality among all cancers. In 2020, about 815,000 new cases of lung cancer and 714,000 deaths from lung cancer were reported in China, of which 13–17% were SCLC. SCLC patients are often already in an advanced stage upon diagnosis, leading to poor prognosis, with a five-year survival rate of only 7% and only 3% for those with extensive SCLC. Although SCLC is very sensitive to the initial treatment, most patients develop drug resistance and experience a relapse after the initial treatment. According to statistics, about 75% of the patients with locally advanced SCLC and more than 90% of those with metastatic SCLC relapse within 2 years of the initial treatment. The high recurrence rate of SCLC poses a huge challenge to its treatment, and an innovative therapy is urgently needed in clinical practice.

In addition to its approval in Macao, Lurbinectedin is also under review for launch in mainland China and Hong Kong, respectively. Moreover, the drug has been granted priority review by the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA). Lurbinectedin has also been recommended by multiple authoritative guidelines in China and abroad. For example, the NCCN Guidelines for Small Cell Lung Cancer (V1. 2024) recommend Lurbinectedin as a preferred treatment for SCLC patients with CTFI shorter than 6 months, and the 2023 Chinese Society of Clinical Oncology Guidelines for Small Cell Lung Cancer recommend it as a second-line treatment for relapsed SCLC after ≤6 months or >6 months.

The Group will continue to promote the registration and commercialization of Lurbinectedin in the China market, 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 sea squirt Ecteinascidia 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.

In 2020, Lurbinectedin received the Accelerated Approval from the U.S. FDA for the treatment of adult patients with metastatic SCLC with disease progression on or after receiving platinum-based chemotherapy. After that, the drug was also approved in several other countries worldwide. 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 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, 4 December 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.