

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



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 (LY01017) APPROVED FOR
URGENT CLINICAL USE IN HAINAN**

The board of directors (the “**Board**”) of Luye Pharma Group Ltd. (the “**Company**”, together with its subsidiaries, the “**Group**”) announces that Lurbinectedin Injectable (LY01017) (“**Lurbinectedin**”), a drug the Group licensed from Pharma Mar, S.A. (“**PharmaMar**”), has been approved by the Hainan Medical Products Administration for import to specific medical institutions in Hainan Boao Lecheng International Medical Tourism Pilot Zone (“**Boao Lecheng Pilot Zone**”) for urgent clinical use.

Lurbinectedin is a selective inhibitor of oncogenic transcription. It was granted accelerated approval in 2020 by the 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. In addition to the U.S., Lurbinectedin has received provisional marketing approval in Australia, the United Arab Emirates, Canada, Singapore and Qatar for the treatment of adult patients with metastatic SCLC whose disease has progressed during or after receiving platinum-based chemotherapy.

Lung cancer is a malignant tumor with high morbidity and mortality rates in China and worldwide, and small cell lung cancer (“**SCLC**”) is a high-grade neuroendocrine carcinoma that accounts for 13%–17% of all lung cancer cases. According to the International Agency for Research on Cancer (“**IARC**”), lung cancer had higher morbidity and mortality rates than other malignant tumors in China in 2020 with 815,000 new lung cancer cases and 714,000 deaths reported that year. IARC also predicted that in 2022 the number of new SCLC cases in China will exceed 110,000. SCLC is highly likely to metastasize to distant sites within the body in early stages, and patients are often already in an advanced stage of SCLC upon diagnosis, resulting in poor prognosis. Meanwhile, the number of effective SCLC drugs in the market is very limited.

The Group believes that Lurbinectedin has good potential in the Chinese market. The approval for Lurbinectedin to be used in the Boao Lecheng Pilot Zone means the Group will be the first to bring a new treatment option to SCLC patients in China who urgently need effective treatments.

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.

ABOUT LURBINECTEDIN'S DEVELOPMENT IN CHINA

In 2019, the Group was exclusively licensed by PharmaMar to develop and commercialize Lurbinectedin in China, covering all indications including SCLC. In addition, the Group holds the right to request for the transfer of the manufacturing technology for Lurbinectedin from PharmaMar within the licence period for the production of the drug by the Group in China. Currently, the Group has submitted a New Drug Application (“NDA”) for Lurbinectedin in Hong Kong, China and it plans to submit an NDA in Mainland China in the near future.

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. 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 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 PM14. Headquartered in Madrid, Spain, PharmaMar has subsidiaries in Germany, France, Italy, Belgium, Austria, Switzerland and the United States. GENOMICA (a molecular diagnostics company) and Sylentis (a company dedicated to researching therapeutic applications of gene silencing (RNAi)) are also wholly-owned subsidiaries of PharmaMar.

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

Hong Kong, 17 July 2022

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.