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**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

## APPROVAL OF ZEPZELCA® (LURBINECTEDIN FOR INJECTION) FOR MARKETING IN MAINLAND CHINA

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that the National Medical Products Administration ("**NMPA**") of the People's Republic of China ("**China**") has approved the innovative drug Zepzelca® (lurbinectedin for injection) for marketing through the priority review program. The drug is indicated for the treatment of adult patients with metastatic small cell lung cancer ("**SCLC**") with disease progression on or after platinum-based chemotherapy.

Zepzelca® is a selective inhibitor of oncogenic transcription. Whilst inhibiting oncogenic transcription and induce tumor cell apoptosis, it also modulate the microenvironment for tumors to further exert its anti-tumor effects. The drug was also approved by the U.S. Food and Drug Administration ("**FDA**") through its Accelerated Approval Program in 2020. It has been the only new chemical entity approved by the FDA for the treatment of relapsed SCLC in nearly 27 years since 1997.

Lung cancer has the highest incidence and mortality rates among all cancers in China, with over 1.06 million new cases reported in 2022. SCLC which accounts for 13-17% of lung cancers cases is one of the most aggressive subtypes, with a 5-year overall survival rate of less than 10%. Most patients would relapse or develop drug resistance after initial treatment, and the median overall survival ("**mOS**") after receiving further chemotherapy is only 4-5 months. Relapse and drug resistance are inevitable challenges in the treatment of SCLC. The lack of effective therapies after a relapse leaves SCLC patients in a precarious situation. There is an urgent clinical need for innovative treatment options.

The marketing approval Zepzelca® received from the NMPA was primarily based on the results of two clinical studies. The first study, a pivotal trial conducted overseas (a Phase 2 basket trial), was an open-label, multicenter, and single-arm study of Zepzelca® monotherapy (intravenous infusion once every 3 weeks at a dose of 3.2 mg/m$^2$) in adult patients with SCLC (including both platinum-sensitive and platinum-resistant patients) who experienced disease progression after receiving platinum-based chemotherapy. The study was published in *The Lancet Oncology*, which demonstrated an overall response rate ("**ORR**") of 35.2%, a median duration of response ("**mDoR**") of 5.3 months, a median progression-free survival ("**mPFS**") of 3.5 months, and an mOS of 9.3 months for patients treated with Zepzelca®. The other study was a single-arm, bridging clinical study that included dose escalation and expansion of Zepzelca® to evaluate its safety, tolerability, pharmacokinetics (PK), and preliminary efficacy in Chinese patients with advanced solid tumors, including relapsed SCLC. The study showed that for SCLC patients treated with Zepzelca® through intravenous infusion once every 3 weeks at a dose of 3.2 mg/m$^2$, an ORR of 45.5%, an mDoR of 4.2 months, an mPFS of 5.6 months and an mOS of 11.0 months was recorded.

The two studies above indicate that Zepzelca® demonstrates significant anti-tumor effects and is safe and tolerable as a second-line treatment for SCLC. Notably, the study conducted in the Chinese population demonstrated even better patient outcomes.

Additionally, there are multiple ongoing international clinical trials on Zepzelca®. In a Phase 1/2 study of Zepzelca® in combination with atezolizumab as a second-line treatment for patients with extensive-stage SCLC, it demonstrated an ORR of 66.67%, an mPFS of 4.7 months, and an mOS of 14.5 months. In another Phase 1/2 study, Zepzelca® is combined with pembrolizumab, and it showed an ORR of 46.4%, an mPFS of 5.3 months, and an mOS of 11.1 months. Furthermore, clinical studies involving Zepzelca® in combination with immune checkpoint inhibitor as the first-line maintenance therapy for SCLC, and Zepzelca® in combination with chemotherapy for the treatment of relapsed SCLC and leiomyosarcoma are also progressing smoothly. These studies are designed to continue explore the clinical applications and therapeutic potential of the drug.

Zepzelca® has been recommended by the *NCCN Clinical Practice Guidelines in Oncology for Small Cell Lung Cancer*, the *Small-cell lung cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up*, and the *CSCO Guidelines for the Diagnosis and Treatment of Small Cell Lung Cancer* for monotherapy in the treatment of relapsed SCLC. Furthermore, the *CSCO Guidelines for the Diagnosis and Treatment of Small Cell Lung Cancer* has included for the first time the combination of Zepzelca® with immune checkpoint inhibitors for the treatment of SCLC in its 2024 edition.

To date, Zepzelca® has been approved for marketing in 17 countries or regions worldwide. The Group has been granted the rights to develop and commercialize this drug in mainland China, Hong Kong, and Macao, and has received marketing approval for the drug in these three regions.

The Group believes Zepzelca® addresses the prevailing clinical needs and has significant market potential in China. Zepzelca®, together with other oncology products of the Group, enrich the Group's already comprehensive product portfolio. Synergizing with the Group's existing resources and strengths in the oncology field, the addition of Zepzelca® will help accelerate the Company's coverage and development in this field.

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

Hong Kong, 3 December 2024

*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 Dr. LYU Dong; 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.*