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

MIMEIXIN (OXYCODONE HYDROCHLORIDE AND NALOXONE HYDROCHLORIDE SUSTAINED-RELEASE TABLETS) APPROVED FOR MARKETING IN CHINA

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that its new analgesic product Mimeixin (oxycodone hydrochloride and naloxone hydrochloride sustained-release tablets) has been approved for marketing by the National Medical Products Administration ("**NMPA**") of the People's Republic of China ("**China**") on 28 June 2024, to be used for the management of severe pain (cancer pain and non-cancer pain) that can only be effectively controlled by opioids in adults. Mimeixin's advantage is the addition of naloxone, an opioid receptor antagonist, which reduces opioid-induced constipation ("**OIC**") by blocking the binding of oxycodone to opioid receptors in the intestines.

In China, the development and production of anaesthetic and psychotropic drugs are under strict regulations. Companies developing and manufacturing such products have to obtain a special license, and the total number of companies allowed to develop or manufacture these products is set by the government, meaning that the bar is high for companies to enter this industry. Mimeixin is the first oxycodone hydrochloride and naloxone hydrochloride sustained-release tablet approved in China that is locally developed and technically challenging to make. Mimeixin can effectively manage pain and at the same time mitigate bowel dysfunction, like constipation, induced by opioid drugs. Furthermore, a single dose of Mimeixin offers pain relief for up to 12 hours. This medication also employs a unique drug-locking technology to prevent drug abuse.

All types of cancer frequently cause pain, a torturous symptom that significantly compromises patients' quality of life. Data from the World Health Organization's International Agency for Research on Cancer (IARC) shows that nearly 4.82 million new cancer cases were diagnosed in China in 2022 alone. Pain affects 60% to 80% of patients at late stages of cancer and one third of the affected individuals experience severe pain.

Mimexin is an oral sustained-release tablet combined with oxycodone and naloxone, which exerts analgesic effect through the strong opioid receptor agonist oxycodone, and due to the low oral bioavailability of naloxone, it can directly bind to gastrointestinal opioid receptors to combat oxycodone-induced constipation without affecting the analgesic effect. Extensive clinical studies have demonstrated that compared with oxycodone sustained-release monotherapy, the oxycodone-naloxone sustained-release combination therapy offers similar analgesic efficacy at equivalent dosages, while significantly improving bowel dysfunction and reducing the incidence and severity of OIC. Furthermore, both the NCCN Clinical Practice Guidelines in Oncology: Adult Cancer Pain (2024.V2) and the Management of Cancer Pain in Adult Patients: ESMO Clinical Practice Guidelines state that the prolonged-release combination formulation of oxycodone and naloxone can significantly improve OIC in cancer pain patients undergoing long-term opioid therapy.

In addition to its use in cancer pain management, oxycodone hydrochloride and naloxone hydrochloride sustained-release tablets have been proven in multiple clinical trials to be effective analgesics for patients with moderate to severe pain, such as musculoskeletal pain, postoperative pain, and lower back pain. Moreover, it significantly improved constipation in these patients.

Furthermore, the high risk of psychological dependence associated with opioid analgesics contributes significantly to the global public health challenge of opioid abuse. Mimeixin employs proprietary drug-locking technology to prevent the grinding, extraction, and conversion of oxycodone, thereby deterring drug abuse. Additionally, naloxone, by antagonizing the activity of oxycodone, can prevent users from experiencing euphoria and induce precipitated withdrawal, a mechanism of action that allows Mimeixin to further mitigate the risk of abuse.

The Company believes that Mimeixin addresses the prevailing clinical demands and has good market potential in China. It, together with the other oncology products of the Group, creates a comprehensive product portfolio. Leveraging on the Group's existing resources and advantages in the oncology field, the addition of Mimeixin 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, 4 July 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.