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

MEIBIRUI (PALIPERIDONE PALMITATE INJECTION) 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 second-generation long-acting injectable ("**LAI**") antipsychotic Meibirui (Paliperidone Palmitate Injection) as developed independently by the Company has been approved for marketing by the National Medical Products Administration ("**NMPA**") of the People's Republic of China ("**China**"), to be used for the acute and maintenance treatment of schizophrenia.

Schizophrenia is a chronic, highly recurrent and disabling disease, with about 24 million patients worldwide, of which approximately one-third, around 8 million, are in China. One of the major challenges in treating this disease is that the condition is recurrent because of treatment interruption or reduced dosage by patients themselves, which may lead to refractory schizophrenia.

Compared with oral medications, LAI antipsychotics can significantly improve patient compliance and provide an important treatment strategy for relapse prevention. Meibirui is a long-acting injection of paliperidone palmitate administered once a month. Paliperidone, its active ingredient, is a first-line treatment for schizophrenia, which is effective in improving the positive symptoms, negative symptoms, emotional symptoms and cognitive functions of schizophrenia patients.

Driven by the huge demand of patients, the market prospect for LAI antipsychotics is promising. Data from IQVIA shows that the size of the global market for LAI antipsychotics was about US$8 billion in 2023, of which the worldwide sales of long-acting paliperidone palmitate injections were about US$5 billion during the same year.

The therapeutic area of Central Nervous System ("**CNS**"), which includes schizophrenia, has long been a strategic focus of the Group hence a diversified CNS product portfolio has been built. To the best knowledge of the Company, Rykindo® (risperidone) for extended-release injectable suspension, being approved for marketing in the U.S., is the first new CNS drug developed by a Chinese pharmaceutical company approved for use in the U.S. and Ruoxinlin (Toludesvenlafaxine Hydrochloride Sustained-release Tablets), being approved for marketing in China, is the first "Class 1 Chemical Drug" for the treatment of major depression disorder developed by a Chinese company. Other products in the portfolio, such as Seroquel® (quetiapine fumarate) and its extended-release tablets, along with Rivastigmine Transdermal Patches (single-day or multi-day patches), are sold in China and other major markets abroad.

In the Group's pipeline, Rotigotine Extended-Release Microspheres for Injection (LY03003), which is being developed in China and abroad in parallel, is being granted priority review for its NDA in China. Several other new products, such as LY03015, a VMAT2 inhibitor, are undergoing clinical trials in China and abroad. The Group has built competitive capabilities in conducting R&D, regulatory registrations, clinical trials, supply chain management, and commercial activities internationally, laying a solid foundation for commercializing new products around the world in the future.

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

Hong Kong, 11 June 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.