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LUYE PHARMA GROUP LTD.

绿叶制药集团有限公司

(Incorporated in the Bermuda with limited liability)

(Stock Code: 02186)

VOLUNTARY ANNOUNCEMENT

UPDATED PROGRESS IN RELATION TO THE MARKETING REVIEW OF PALIPERIDONE PALMITATE EXTENDED-RELEASE INJECTABLE SUSPENSION (LY03010) IN THE UNITED STATES

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that no patent infringement lawsuit has been filed against the Group's New Drug Application ("**NDA**") for Paliperidone Palmitate Extended-release Injectable Suspension ("**LY03010**") submitted to the U.S. Food and Drug Administration ("**FDA**") through the 505(b)(2) pathway, after the NDA was accepted and within the statutory time limit under the U.S. Federal Food, Drug, and Cosmetic Act. This means that LY03010 has successfully overcome the patent challenge in its NDA review process.

LY03010 is an innovative formulation developed by the Group for the treatment of schizophrenia and schizoaffective disorder. The product was granted a patent in the U.S. in 2023, which will expire in 2039. Following the submission of LY03010's NDA to the FDA, the Group sent a Paragraph IV patent declaration to the Marketing Authorization Holder ("**MAH**") and the patent owner of INVEGA SUSTENNA®. According to the U.S. Federal Food, Drug, and Cosmetic Act, a suit by the MAH and the patent owner of the drug within 45 days from the date of receipt of the Paragraph IV patent declaration triggers a 30-month stay of regulatory approval.

As of the date of this announcement, the period for filing lawsuits that could trigger a 30-month FDA stay period has expired, and no lawsuits have been filed against the Group as such. Therefore, LY03010's NDA review process at the FDA is not subject to patent barriers. According to the Prescription Drug User Fee Act (PDUFA), the target date for the FDA to make a decision on the NDA for LY03010 is 26 July 2024, U.S. time. The Group expects to commence the commercialization of this product as soon as it is approved for marketing in the U.S..

LY03010 is a long-acting injectable formulation of paliperidone, administered once a month. Its NDA submitted in the U.S. is based on a randomized, multiple-dose, open-label, and parallel-group pivotal study evaluating the relative bioavailability of LY03010 versus INVEGA SUSTENNA®. In this study, compared with INVEGA SUSTENNA®, the initial dosing was optimized for LY03010 by omitting the injection on day 8 after the first injection, resulting in comparable total drug exposure. In terms of safety: LY03010 has good safety and tolerability. This study suggests that LY03010 may improve patient compliance by optimizing the initial dosing, while ensuring efficacy and safety.

LY03010 with monthly injection is expected to form a product portfolio that has significant advantages alongside Rykindo® (risperidone) for extended-release injectable suspension (administered once every two weeks), which the Group is already marketing in the U.S. The Group is currently in communication with potential multinational partners about the commercialization of LY03010 in the U.S..

Schizophrenia is a severe mental disorder that affects a population estimated of about 24 million people worldwide. The main challenge in treating schizophrenia as a chronic disease is that it tends to relapse and become protracted, resulting in poor patient compliance. Long-acting injections have become an important formulation for antipsychotics because they can better address clinical needs such as significantly improving patient compliance and reducing relapses. The marketing approval of LY03010 (if granted) will provide a new treatment option for patients. Publicly available information shows that Paliperidone Palmitate Long-acting Injection generated sales of US$4.115 billion in the worldwide market and US$2.897 billion in the U.S. market in 2023.

The Group believes that LY03010 is expected to be the first domestic paliperidone palmitate long-acting injection approved in the U.S. with independent intellectual property rights. At present, the marketing review of the product in the U.S. is progressing as expected, as far as the Company is aware. The Group will actively cooperate with the FDA's review requirements and comprehensively prepare for the subsequent Pre-Approval Inspection (PAI). In addition to the U.S., LY03010 has also entered the marketing review stage in China, and the Group hopes LY03010 to benefit patients around the world as soon as possible to serve the clinical needs.

The Central Nervous System ("**CNS**") therapeutic area, which includes schizophrenia, has long been a strategic focus for the Group. The Group has built a diversified CNS portfolio. Rykindo® (risperidone) for extended-release injectable suspension, 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., as far as the Company is aware. Ruoxinlin (Toludesvenlafaxine Hydrochloride Sustained-release Tablets), approved for marketing in China is the first "Class 1 Chemical Drug" for the treatment of major depression disorder developed by a Chinese company, as far as the Company is aware. Other products in the portfolio, such as Seroquel® (quetiapine fumarate) and its extended-release tablets, as well as Rivastigmine Transdermal Patches (once daily and multi-day), are sold in China and other major markets.

In the Group's pipeline, LY03003 (Rotigotine Extended-Release Microspheres for Injection), which is being developed in China and abroad, has seen its NDA in China granted the priority review designation. 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, clinical, supply chain, 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, 1 February 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.