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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
APPLICATION FOR MARKETING AUTHORISATION OF PALIPERIDONE
PALMITATE INJECTION (LY03010) IN CHINA HAS BEEN ACCEPTED**

The board of directors (the “**Board**”) of Luye Pharma Group Ltd. (the “**Company**”, together with its subsidiaries, the “**Group**”) announces that the marketing application of Paliperidone Palmitate Injection (“**LY03010**”), a long-acting product developed by the Group in the central nervous system (“**CNS**”) therapeutic area, has been accepted by the Centre for Drug Evaluation of the National Medical Products Administration in the People’s Republic of China (“**China**”) for the acute and maintenance treatment of schizophrenia.

LY03010 is a long-acting paliperidone injection, with a monthly dosing regimen, independently developed by the Group’s long-acting and targeted formulation technology platform. Paliperidone is a second-generation antipsychotic that relieves psychotic positive symptoms while improving cognitive and emotional symptoms and is the first-line treatment for schizophrenia. Paliperidone is available in both oral and long-acting injection formulation. Compared with oral formulation, long-acting injections have the characteristics of less frequent administration and long-term stable effective plasma concentration, thereby improving patient compliance, significantly reducing the risk of recurrence in long-term treatment, and improving patients’ long-term benefits.

Schizophrenia is a severe mental disorder that affects approximately 24 million people worldwide. It is estimated that there are approximately 10 million schizophrenic patients in China. As a recurrent chronic protracted disease, the high recurrence rate and partial or non-adherence to the treatment regimen have become the main difficulties in the management of schizophrenia. Data shows that 60% of patients with the first onset of schizophrenia had poor medication adherence, and the recurrence rate within 5 years exceeds 80%. Multiple recurrences lead to prolonged course of the disease, increase the difficulty of treatment, and also greatly increase the cost of treatment.

Due to the considerable volume of unmet patient needs, according to the statistics of the IQVIA China Drug Hospital Channel Database, the sales of antipsychotic drugs in China reached RMB 6.16 billion in 2021. Based on global treatment trends, the share of long-acting injections is also increasing year by year.

In addition to China, the pivotal study of LY03010 in the United States has recently achieved its endpoints, and LY03010 is planned to submit New Drug Application to the U.S. Food and Drug Administration through 505(b)(2) pathway.

The Group has launched several products for the CNS therapeutic area, including Toludesvenlafaxine Hydrochloride Extended-Release Tablets (Ruoxinlin[®]), Risperidone Microspheres for Injection (II) (Rykindo[®]), Quetiapine Fumarate Tablets (Seroquel[®]), Quetiapine Fumarate Extended-release Tablets, Rivastigmine Transdermal Patch, Rivastigmine Twice Weekly Transdermal Patch, Fentanyl Transdermal Patch and Buprenorphine Transdermal Patch, covering over 80 countries and regions around the world, including large pharmaceutical markets in China, the U.S., Europe and Japan, as well as fast growing emerging markets. In addition, the Group has also developed a number of new drugs such as Rotigotine Extended-Release Microspheres for injection (LY03003) and VMAT2 inhibitor (LY03015) in the China and overseas markets.

The Company believes that LY03010 meets the current urgent clinical needs and has good market potential. At the same time, this product will further enrich the Group's product pipelines in the field of CNS, and cooperate with the Group's existing resources and advantages in the field of CNS to 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, 28 December 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.