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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

THE MANUFACTURING FACILITY OF RYKINDO® HAS SUCCESSFULLY PASSED USFDA FIRST PAI

The board of directors (the "Board") of Luye Pharma Group Ltd. (the "Company", together with its subsidiaries, the "Group") is pleased to announce that the Group has received the Establishment Inspection Report ("EIR") from the United States Food and Drug Administration ("USFDA") indicating that the manufacturing facility of the Group located in Yantai, China has successfully passed a Pre-Approval Inspection ("PAI") with no FDA-483, Inspection Observation. This seven-day PAI was the Group's first onsite inspection by USFDA, that was triggered by the Company's New Drug Application ("NDA") filing of Rykindo® (LY03004), an Extended-Release Microspheres for Injection administered bi-weekly developed by the Group for the treatment of schizophrenia and bipolar I disorder.

Passing its first USFDA's PAI with zero observation demonstrates the Group's strong commitment and extensive expertise in ensuring compliance with the highest global quality standards, including USFDA cGMP regulations. The Group will continue to strengthen its quality standards to ensure that the Group's products are manufactured at the highest quality for patients worldwide.

Successfully passing the PAI is an important milestone, which brings the Group closer to obtaining its first market approval in the United States and offering another treatment option for patients in the U.S. with schizophrenia and bipolar I disorder.

The Company believes that Rykindo® as a long-acting injectable drug, that is injected only once every two weeks, can improve medication compliance in patients with schizophrenia. Compliance is a common issue with oral antipsychotic drugs and Rykindo® would simplify the treatment regimen. Furthermore, Rykindo® has several advantages over the reference drug, for example, Rykindo® has a shorter period for oral supplementation after the first injection than the reference drug and the steady plasma drug level of Rykindo® can be reached much faster than the reference product.

Schizophrenia is a severe mental disorder, characterized by profound disruptions in thinking, affecting language, perception and the sense of self. According to the World Health Organization (WHO), schizophrenia affects more than 21 million people worldwide, and one in every two persons suffering from schizophrenia does not receive care for the condition.

Bipolar I disorder, also known as manic-depressive illness, is a brain disorder that causes unusual shifts in mood, energy, activity levels, and the ability to carry out day-to-day tasks.

The Group has launched several products for the Central Nervous System therapeutic area, including Seroquel, Seroquel XR, Rivastigmine patches, Fentanyl patches and Buprenorphine patches, 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 to Rykindo®, the Group has a number of other pipeline projects focusing on the Central Nervous System for the concurrent development of China and overseas markets, with projects such as Rotigotine Extended-Release Microspheres for injection (LY03003) for Parkinson's disease, Ansofaxin Hydrochloride Extended-Release Tablets (LY03005) for depression, Paliperidone Palmitate injectable suspension (LY03010) for schizophrenia and schizoaffective disorder and multi-day rivastigmine transdermal patch for mild to moderate Alzheimer's disease. The registrations of the above pipeline products are progressing well in strategic markets such as China, the U.S., Europe and Japan, and the products are expected to be launched in these countries and further expanded into the global markets.

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

Hong Kong, 4 November 2019

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 director of the Company is Mr. SONG Rui Lin; 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.