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 COMPANY SUBMITTED NDA FOR RYKINDO® TO THE U.S. FDA

The board of directors (the "Board") of Luye Pharma Group Ltd. (the "Company", together with its subsidiaries, the "Group") are pleased to announce that the company successfully submitted its first New Drug Application (NDA) to the U.S. Food and Drug Administration ("FDA") for Rykindo® (LY03004) in the United States of America (the "U.S.") on 28 March 2019, an Extended-Release Microspheres for Injection administered bi-weekly, for the treatment of schizophrenia and bipolar I disorder in accordance with 505(b)(2) of the Federal Food, Drug and Cosmetic Act and 21 CFR § 314.50. The to-be-marketed dosage strengths of Rykindo® are 12.5 mg, 25 mg, 37.5 mg, and 50 mg of risperidone per vial. To our knowledge, this is the first NDA submission of a new formulation drug to the U.S. FDA by a Chinese pharmaceutical company.

Rykindo® has been developed under Investigational New Drug Application (IND) 116108. FDA agreed with the Initial Pediatric Study Plan (agreed iPSP) by the Group with a full waiver for studies in pediatric patients. FDA also concluded that the proposed name Rykindo® is a conditionally acceptable proprietary name. The NDA application includes the results from one pivotal and two supportive clinical studies involving a total of 172 patients in the U.S. The pivotal study demonstrated no lag period after the first injection and an equivalent pharmacokinetic profile of Rykindo® at steady state compared to the marketed reference product of risperidone long-acting injection. Similar safety profiles were observed between Rykindo® and the reference product in all three studies.

The Company believes that Rykindo® as an injectable drug can improve medication compliance in patients with schizophrenia which is a common issue with oral antipsychotic drugs and would simplify treatment regimen since it needs to be injected only once every two weeks. Furthermore, Rykindo® has several advantages over the reference drug, for example, there is no need to administer an oral

formulation during the three weeks after the first injection of Rykindo® compared to the reference drug. The steady plasma drug level can also be reached much faster with Rykindo® compared to 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 two people living with 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 Central Nervous System therapeutic areas, including Seroquel, Seroquel XR, Rivastigmine patches, Fentanyl patches and Buprenorphine patches, covering over 80 countries and regions around the world, including large pharmaceutical markets — China, the U.S., Europe and Japan, as well as fast growing emerging markets.

Besides RYKINDO®, the Group has a number of other pipeline projects regarding 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, ansofaxine hydrochloride extended release tablets (LY03005) under research 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 market.

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

Hong Kong, 29 March 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.