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

APPROVAL FROM FDA FOR CLINICAL TRIAL FOR LY03010

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries "**Group**") is pleased to announce that the clinical trial application (application number: IND 136324) for the Group's new product candidate, Paliperidone Palmitate injectable suspension, for intramuscular use ("**LY03010**"), has obtained the approval from the United States (the "**U.S.**") Food and Drug Administration (the "**FDA**") to initiate clinical trials for the treatment of schizophrenia and schizoaffective disorder in the U.S..

LY03010 is an extended release injectable suspension which is used for the treatment of schizophrenia and schizoaffective disorders by intramuscular injection, monthly dose. LY03010 can improve the common medication compliance issue of oral antipsychotic drugs in the patients with schizophrenia. Compared to another similar drug on the market, LY03010 optimizes the initial dosing regimen, therefore may bring greater convenience to patients and hence increase patient compliance. The FDA has confirmed that it is acceptable to demonstrate bioequivalence at steady state after multiple doses to support the 505(b)(2) NDA submission for LY03010 in the Pre-IND meeting minutes.

Schizophrenia is a severe mental disorder, characterized by profound disruptions in thinking and affecting the language, perception, and self-cognition of patients. According to the World Health Organization, schizophrenia affects more than 21 million people worldwide, and one in two people living with schizophrenia does not receive treatment for the condition. Approximately 2.4 million American adults, or about 1.1 percent of the population age 18 and older, have schizophrenia according to the 2005 National Comorbidity Survey-Replication in the U.S.. The Group expects that LY03010 could be used to improve medication compliance in the patients with schizophrenia and/or schizoaffective disorders, which represents a significant medical need for those patients and their families as well as the society.

The Group believes that LY03010 has good marketing potential and will enrich the Group's product pipeline. Apart from LY03010, the Group has numerous pipeline projects regarding the central nervous system for the concurrent development in China and overseas markets, with projects such as Risperidone Extended Release Microspheres for injection (LY03004) for schizophrenia and bipolar disorder, rotigotine Extended Release Microspheres for injection (LY03003) for Parkinson's disease, ansofaxine hydrochloride extended release tablets (LY03005) under research for depression, and rivastigmine transdermal patch for mild to moderate Alzheimer's disease. The registrations of the above pipeline products are progressing in strategic markets such as China, the U.S., Europe and Japan, and the products are expected to be launched in these countries or regions and further expanded into the global market.

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

Hong Kong, 26 September 2018

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.