LUYE PHARMA GROUP LTD.

绿叶制药集团有限公司

(Incorporated in the Bermuda with limited liability)

(Stock Code: 02186)

ANNOUNCEMENT

THE FDA CONFIRMED NO ADDITIONAL CLINICAL TRIALS ARE NEEDED FOR THE NDA SUBMISSION FOR LY03004 IN THE U.S.

The board of directors of Luye Pharma Group Ltd. (the "**Company**") is pleased to announce that the United States Food and Drug Administration (the "**FDA**") has confirmed the Company's New Drug Application ("**NDA**") submission in the United States (the "**U.S.**") via a pathway under section 505(b)(2) of the United States Federal Food, Drug and Cosmetic Act (the "**505(b)(2) pathway**") for an investigational drug product of Risperidone Extended-release Microspheres for Injection ("**LY03004**") without additional clinical trials.

On 10 September 2015, the Company had a meeting with the FDA on LY03004 ("**Meeting**"), which is formulated as extended release microspheres for intramuscular injection for the treatment of schizophrenia and/or schizoaffective disorders. At the Meeting and as recorded in the Meeting minutes, the FDA confirmed that the results of the completed pivotal study involving a total of 108 patients enrolled in the U.S. can be used to support a NDA submission via the 505(b)(2) pathway for LY03004 without additional clinical trials. This will significantly cut down costs and time required for obtaining FDA approval for LY03004. The Company is currently preparing the NDA report for LY03004.

The Company believes that LY03004 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, LY03004 has several advantages over another marketed drug, for example, there is no need to administer oral formulation during the three weeks after the first injection of LY03004 compared to the marketed drug. The stable plasma drug level can be reached much faster with LY03004 as compared to that marketed drug.

Schizophrenia is a severe mental disorder, characterized by profound disruptions in thinking, affecting language, perception, and the sense of self. According to 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. According to the U.S. National Institutes of Health report, an estimated of 2.4 million Americans have schizophrenia. The Company expects that LY03004 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 Company believes that LY03004 has good marketing potential and will enrich the Company's product pipeline. In addition to obtaining regulatory approval in the U.S., the Company is also targeting to obtain regulatory approval for LY03004 in Europe and Japan. Apart from LY03004, the Company is currently developing several new pharmaceutical products in the U.S., Europe and Japan.

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

Hong Kong, 7 October 2015

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 are Mr. PAN Jian, Mr. LIU Dong and Ms. WANG Xin; and the Independent Non-executive Directors are Mr. ZHANG Hua Qiao, Professor LO Yuk Lam, Mr. LEUNG Man Kit and Mr. CHOY Sze Chung Jojo.