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 COMPANY HAS SUCCESSFULLY COMPLETED THREE CLINICAL STUDIES FOR LY03004 IN THE U.S.

The board of directors of Luye Pharma Group Ltd. (the "**Company**") is pleased to announce that the Company has completed the following three clinical studies involving a total of 172 patients in the United States (the "**U.S.**") for an investigational drug product of risperidone ("**LY03004**"), formulated as extended release microspheres for intramuscular injection for the treatment of schizophrenia and/or schizoaffective disorders:

- In the pivotal clinical study, 108 patients with schizophrenia and/or schizoaffective disorders were enrolled at ten study sites with significant experiences in the U.S., each of whom received five consecutive injections (once every two weeks) of either LY03004 or another marketed product (the "**Marketed Drug**") at 25.0 mg. The results indicated stable plasma drug level was reached about two weeks after the first injection of LY03004 compared to four weeks after the first injection of the Marketed Drug. Furthermore, this pivotal study demonstrated pharmacokinetic bioequivalence of LY03004 compared to the Marketed Drug at steady state, based on the U.S. Food and Drug Administration (the "**FDA**") standard method to assess bioequivalence, i.e., the 90% confidence interval for the ratio of total plasma drug level (AUC) and peak plasma drug level (Cmax) between LY03004 (the test drug) and the Marketed Drug (the reference drug) after the fifth injection is within 80% to 125%. Similar safety profiles were also observed between LY03004 and the Marketed Drug after received five consecutive injections.

- In the single dosage study, 32 patients with schizophrenia and/or schizoaffective disorders in the U.S. received an injection of either LY03004 or the Marketed Drug at 25.0 mg or 50.0 mg. The results showed that LY03004 commenced releasing drug on the first day after injection and reached peak plasma drug level in about 14 days, while the Marketed Drug only released a small amount of drug following a single injection with very limited drug release in the subsequent 21 days, reaching peak plasma drug level in about 32 days. This result indicated that unlike the

Marketed Drug, LY03004 does not need the administration of oral drugs three weeks after the first injection. However, LY03004 and the Marketed Drug showed similar safety profiles after a single administration at either 25.0 mg or 50.0 mg.

- In the single ascending dose study, 32 patients with schizophrenia and/or schizoaffective disorders in the U.S. received a single ascending injection of LY03004 at one of the four doses (12.5 mg, 25.0 mg, 37.5 mg and 50.0 mg). The results of this study demonstrated a good safety profile and dose proportionality of 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 the 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 also be reached much faster with LY03004 compared to the 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 (WHO), schizophrenia affects more than 21 million people worldwide, and one in two people living with schizophrenia does not receive care for the condition. According to the U.S. National Institutes of Health (NIH) 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. The Company plans to discuss with the FDA about the possibility of a New Drug Application (NDA) submission based on the results of these three studies. In addition, the Company is also targeting to obtain regulatory approval for LY03004 in Europe and Japan. Besides LY03004, the Company is currently developing several new pharmaceutical products in the U.S.

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

Hong Kong, 14 May 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.