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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)**

### **ANNOUNCEMENT**

#### **CLINICAL STUDY OF LY03004 DEMONSTRATES GENERALLY SIMILAR PHARMACOKINETIC AND SAFETY PROFILES IN U.S. PATIENTS TO A MARKETED PRODUCT IN THE SAME DOSAGE FORM**

The board of directors of Luye Pharma Group Ltd. (the “**Company**”) is pleased to announce that the Company has completed a clinical study for risperidone extended release microspheres for injection, an investigational drug product of risperidone (“**LY03004**”) in the United States (the “**U.S.**”). The purpose of this clinical study is to assess the relative bioavailability of LY03004 compared to a marketed product in the same dosage form (the “**Marketed Drug**”) and to evaluate the safety profile of LY03004. 16 patients with schizophrenia and/or schizoaffective disorders were enrolled for this clinical study at two study sites with significant experiences in the U.S..

The results of this clinical study demonstrated similar pharmacokinetic profiles in terms of peak and total plasma drug levels between LY03004 and the Marketed Drug after a single administration at the same dose (25.0 mg). Past clinical studies of the Marketed Drug showed that the Marketed Drug only released a small amount of drug shortly after a single injection with very limited drug release in the subsequent 21 days, reaching peak plasma drug level in about 32 days; whilst LY03004 commenced releasing drug on the first day after injection and reached peak plasma drug level in about 14 days.

The Company has also completed a single ascending dose study of LY03004 with four doses (12.5 mg, 25.0 mg, 37.5 mg and 50.0 mg) in 32 patients with schizophrenia and/or schizoaffective disorders in the U.S., which demonstrated the good safety profile and dose proportionality of LY03004.

Furthermore, the Company is currently conducting a pivotal study for LY03004 project with multiple injections. The Company expects that after completion of the pivotal study, the Company may submit a new drug Application with the U.S. Food and Drug Administration.

LY03004 is an investigational drug product of risperidone formulated as extended release microspheres for intramuscular injection for the treatment of schizophrenia and/or schizoaffective disorders. The Company believes that LY03004 would simplify the treatment regimen and the switching process from oral antipsychotics to long-acting drugs, as LY03004 releases drug and reaches stable plasma drug level in a much shorter period than the Marketed Drug and therefore dispensing the need to administer oral formulation after the injections. The Company expects that LY03004 could be used to improve medication compliance in the patient population, which represents a significant medical need for patients with schizophrenia and/or schizoaffective disorders and their families as well as the society. The Company is targeting to obtain regulatory approval for LY03004 in the U.S. and Europe and believes that the results of this clinical study represents an important progress in the right direction. The board of directors of the Company believes that LY03004 has promising market prospects in the international market. The Company is also currently developing several novel medications similar to LY03004 in the U.S..

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

Hong Kong, 23 March 2015

*As at the date of this announcement, the Executive Directors of the Company are Mr. LIU Dian Bo, Mr. YUAN Hui Xian, Mr. YANG Rong Bing 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.*