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**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**

### **APPROVAL FOR THE COMMENCEMENT OF CLINICAL TRIALS FOR LEVETIRACETAM EXTENDED RELEASE TABLET**

The board of directors of Luye Pharma Group Ltd. (the “**Company**”, together with its subsidiaries, the “**Group**”) is pleased to announce that the Group’s product candidate, levetiracetam extended release tablet, has obtained the approval from the China Food and Drug Administration to commence clinical trials. Levetiracetam extended release tablet was developed under a cooperation project between the Group and Lotus Pharmaceutical Co., Ltd. (“**Lotus Pharma**”).

The approval for the commencement of clinical trials for levetiracetam extended release tablet is expected to provide an impetus to the Group’s development in the central nervous system therapeutic area and to further enrich the Group’s product portfolio in the future.

#### **ABOUT LEVETIRACETAM EXTENDED RELEASE TABLET**

In September 2011, the Company entered into an agency and sales agreement with Lotus Pharma pursuant to which the Company obtained an exclusive agency and distribution rights to sell Lotus Pharma’s levetiracetam extended release tablet in Mainland China for a term of ten years and a five-year automatic renewal period. Levetiracetam extended release tablet is applicable to epilepsy patients who are over sixteen as an adjunctive therapy for their partial seizures.

In October 2011, Lotus Pharma obtained regulatory approval for launching levetiracetam extended release tablet in Taiwan. In July 2010, Lotus Pharma submitted an application for regulatory approval for launching levetiracetam extended release tablet in the United States (the “**U.S.**”), which is expected to be obtained in the second half of 2016. Currently, no products of levetiracetam extended release tablet have been launched in Mainland China.

According to “Clinical Practice Guidelines: Epilepsy Volume” (2007), the lifetime prevalence of epilepsy is between 0.4% and 0.7% in China. Active epilepsy prevalence is 0.46% with an annual incidence rate of approximately 30 per 100,000 patients. Accordingly, there are approximately 6 million active epilepsy patients in China with approximately 0.4 million new epilepsy patients each year.

According to IMS Health Incorporated, the market size for epilepsy treatment products in China was approximately RMB1.79 billion in 2014, and grew at a compound annual growth rate of 24.5% from 2011 to 2014.

## **LOTUS PHARMA**

According to Lotus Pharma, Lotus Pharma is a company listed on the Taiwan Stock Exchange (stock code: 1795). Lotus Pharma focuses on the research and development of specialty generics and is the only pharmaceutical company in Taiwan authorized by the U.S. Food and Drug Administration, the European Medicines Agency, the Pharmaceuticals and Medical Devices Agency in Japan and Taiwan Food and Drug Administration. Lotus Pharma became alliance with Alvogen Group, an international pharmaceuticals group, in 2014. Lotus Pharma continuously improves and strengthens its capability of research and development internally and simultaneously leverages cooperation with external partners to reinforce operational efficiency and flexibility with a view to ensure its overall competitive advantage. Lotus Pharma makes continuous effort to develop its existing Asia markets, which include Korea, Taiwan, China, India, and to export to Japan and Southeast Asia countries. In addition, it also actively expands the markets in the U.S., central and east Europe and Pan Asia Pacific.

The approval for clinical trials for levetiracetam extended release tablet does not represent that the Group undertakes that positive results will be obtained in future clinical research or that further research will be conducted. **Accordingly, shareholders and potential investors are advised to exercise caution when dealing in the securities of the Company.**

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

Hong Kong, 3 December 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.*