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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)**

## **VOLUNTARY ANNOUNCEMENT**

### **CLINICAL TRIAL APPLICATION SUBMITTED IN THE U.S. FOR THE GROUP'S NEW DRUG LY03009**

The board of directors (the “**Board**”) of Luye Pharma Group Ltd. (the “**Company**”, together with its subsidiaries, the “**Group**”) announces that the Group has submitted the investigational new drug application for its new central nervous system (“**CNS**”) drug LY03009 to the Food and Drug Administration of the United States of America (the “**U.S.**”). LY03009 is indicated for the treatment of Parkinson’s disease and restless legs syndrome. It is developed on the Group’s long-acting and extended release technology platform.

LY03009 is a microspheres injection for monthly dosing, and can maintain a stable drug level in plasma during aimed dosing intervals. It possesses the benefit of continuous dopaminergic stimulation, which can delay and treat motor complications and delay introduction of levodopa in the treatment of Parkinson’s disease. The maintaining of effective drug level overnight is expected to improve nocturnal symptoms control and its function on awakening. The targeted dosing interval on a monthly basis can reduce administration frequency, simplify treatment regimen, provide convenience, and ultimately contribute to the improvement of treatment compliance and clinical outcomes.

In addition to the U.S., the drug is also undergoing Phase I clinical trials in Australia, with a plan for clinical trials in China as well.

Currently, about 10 million people around the world are living with Parkinson’s disease. Based on the huge patient population and their needs for treatment, the global market for Parkinson’s disease drugs reached USD4.564 billion in 2020, and is projected to reach USD5.934 billion by 2026, with a compound annual growth rate of 4.68%.

According to the Journal of the National Institutes of Health, the prevalence estimates of restless legs syndrome in Europe and North America are 1.9 – 4.6% of general adult populations.

With ageing population worldwide, the Board believes that LY03009 has promising market prospects and will enrich the Group's future product portfolio.

The Group has launched several products for the CNS therapeutic area, including Risperidone Microspheres for Injection (II) (瑞欣妥®), Seroquel, Seroquel XR, Rivastigmine patches, Rivastigmine multi-day transdermal patch, Fentanyl patches and Buprenorphine patches, covering over 80 countries and regions around the world, including large pharmaceutical markets in China, the U.S., Europe and Japan, as well as fast growing emerging markets.

In addition, the Group currently has a number of new drugs under development, covering a variety of diseases such as depression and Parkinson's disease, forming a rich product portfolio in the CNS therapeutic area.

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

Hong Kong, 15 November 2021

*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 of the Company are Mr. SONG Rui Lin and Mr. SUN Xin; 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.*