LUYE PHARMA GROUP LTD.

绿叶制药集团有限公司

(Incorporated in Bermuda with limited liability)

(Stock Code: 02186)

VOLUNTARY ANNOUNCEMENT

CLINICAL TRIAL APPLICATION SUBMITTED IN THE U.S. FOR THE GROUP'S NEW DRUG LY03015

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 ("**IND**") application for its new central nervous system ("**CNS**") drug LY03015 to the Food and Drug Administration ("**FDA**") of the U.S.. LY03015 is an innovative small molecule compound product indicated for the treatment of tardive dyskinesia ("**TD**") and Huntington's disease ("**HD**"), developed by the Group.

Vesicular monoamine transporter 2 ("**VMAT2**") inhibitors are the only drugs with validated clinical efficacy and safety for the treatment of TD and HD, but all currently launched VMAT2 inhibitors have a variety of unmet clinical needs.

LY03015 is a new generation VMAT2 inhibitor, and can reduce the symptoms of TD and HD by inhibiting the release of presynaptic dopamine ("**DA**"), preventing the stimulation of supersensitive D2 receptors by DA without blocking D2 receptors in the postsynaptic membrane. The results of preclinical studies indicate that LY03015 is more active, has better pharmacokinetic properties and a longer half-life than commercially available products. These properties are expected to reduce the clinical dosage and thus reduce cardiac safety risks and other adverse effects.

This IND submission in the U.S. is in relation to a phase I clinical study evaluating the safety, tolerability, pharmacokinetics of LY03015. The clinical trial is expected to involve 120 subjects.

According to the public data, originators of three VMAT2 inhibitors approved by the U.S. Food and Drug Administration had combined global sales of approximately USD1.659 billion in 2020, with an increase of 37.9% over 2019, indicating relatively strong market potential. In addition to the U.S., clinical trial of LY03015 will also be carried out simultaneously in China.

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.

ABOUT TD AND HD

TD is an extrapyramidal disorder featuring abnormal involuntary movements such as sedentary inability, myoclonus and convulsions, which occurs late after long-term use of dopamine receptor blockers such as antipsychotics. The disease is irreversible and disabling, with each bout of symptoms persisting for extended periods. HD is a hereditary neurodegenerative disease with clinical manifestations of movement disorders, psychiatric symptoms and cognitive impairment. As HD progresses, the advanced stages of the disease are characterized by stiffness and low-activity Parkinson's-like symptoms, which may be accompanied by focal dystonia, severely affecting patients' quality of life and life expectancy.

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

Hong Kong, 2 August 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.