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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)

VOLUNTARY ANNOUNCEMENT

**APPROVAL OBTAINED FOR INITIATING CLINICAL TRIAL FOR
THE GROUP'S NEW DRUG LY03015 IN THE U.S.**

The board of directors (the “**Board**”) of Luye Pharma Group Ltd. (the “**Company**”, together with its subsidiaries, the “**Group**”) announces that the Group’s new central nervous system (“**CNS**”) drug LY03015 (“**LY03015**”) has obtained the approval from the Food and Drug Administration of the U.S. (the “**FDA**”) to initiate clinical trials. LY03015 is an innovative small molecule compound product developed by the Group indicated for the treatment of tardive dyskinesia (“**TD**”) and Huntington’s disease (“**HD**”).

As far as the Company is aware, 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.

As a new generation of VMAT2 inhibitor, LY03015 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 can reduce the risk of depression and suicide caused by off-target effects; it presents a favorable prolonged half-life and tissue distribution characteristics, enabling it to achieve once-a-day oral administration and reduce the risk of cardiac QT interval prolongation compared to commercially available products. Its related research has been published in “European Journal of Medicinal Chemistry”.

This clinical trial approved in the U.S. is in relation to a phase I clinical study which is expected to involve 120 subjects and evaluate the safety, tolerability, pharmacokinetics of LY03015.

Based on data publicly available, originators of three VMAT2 inhibitors approved by the FDA had combined global sales of approximately USD1.929 billion in 2021, representing an increase of 16.3% as compared to 2020, indicating relatively strong market potential. In addition to the U.S., clinical trial of LY03015 has been conducted in China

The Group has launched several products in 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 a number of 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, schizophrenia disorder 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. It is a common pain point of drugs for the treatment of schizophrenia disorder. 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, 13 September 2022

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.