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

PHASE II CLINICAL TRIAL IN CHINA FOR ANSOFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS (LY03005) SHOWED POSITIVE RESULTS

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") is pleased to announce that the Group's product candidate, ansofaxine hydrochloride extended release tablets ("**LY03005**"), a New Chemical Entity (NCE) and China Class 1.1 New Chemical Drug, has completed a phase II clinical trial (the "**Phase II Trial**") in the People's Republic of China ("**China**" or "**PRC**"). The Phase II Trial showed positive results for the treatment of major depressive disorder ("**MDD**").

The Group will request the End-of-Phase 2 Meeting regarding the Phase II Trial with the China Food and Drug Administration ("**CFDA**") to discuss further clinical development plan for LY03005. The Group has confidence in furthering the project.

ABOUT LY03005

LY03005 is a central nervous system product candidate being developed within new compounds platform. It is a serotonin-norepinephrine-dopamine triple reuptake inhibitor (SNDRI) in extended release tablet form for the treatment of MDD.

Traditional anti-depressants such as selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs) drugs are typically associated with disadvantages such as anhedonia, sexual dysfunction and inability to improve cognitive impairment. LY03005 is expected to help preserve patients' sexual function, have a better safety profile and produce a more rapid onset and better efficacy than traditional anti-depressants.

The Group had obtained patents covering the chemical compound, crystal form and formulation of extended release tablets. The patents of the chemical compound and crystal form had been granted in the target countries such as China, United States, Europe, Japan, Korea, etc.

Those patents of the chemical compound were granted and will be valid until 2026 (or 2029 specifically in U.S.).

The Group plans to register and launch LY03005 in the U.S., Japan, China, Europe and other countries.

ABOUT THE PHASE II TRIAL

Prior to the Phase II Trial, the Group had completed three phase I clinical trials for LY03005 in China. The Phase II Trial was designed as a multicenter, randomized, double-blind, placebo-controlled dose-finding trial conducted in 10 sites. 260 subjects with MDD were randomly assigned into the LY03005 groups or the placebo group.

The preliminary results of the Phase II Trial met the primary efficacy endpoint, the reduction in 17-item Hamilton Rating Scale (HAM-D17) total scores from baseline to week 6 was all statistically greater for three dose groups of LY03005 (40mg, 80mg and 160mg) compared with placebo ($p < 0.05$).

For the key secondary endpoint, the mean change from baseline in Montgomery-Åsberg Depression Rating Scale (MADRS) total scores at week 6, all LY03005 groups were also statistically significantly superior to placebo ($p < 0.05$).

In addition, LY03005 was generally safe and well tolerated and the side effects of LY03005 were mostly mild to moderate, including common adverse events such as nausea, dizziness, etc. These findings preliminarily demonstrated the efficacy and safety of LY03005 in the treatment of MDD.

In most of the phase II clinical trials of other anti-depressants, the primary efficacy endpoint is difficult to reach a statistical difference because of the small sample size in general. In the LY03005 Phase II Trial, despite the small sample size, the experimental groups achieved statistically significant differences compared with the placebo group, which was an encouraging result.

ABOUT DEPRESSION

Depression is a common illness worldwide, with more than 300 million people affected according to data of the World Health Organization, and the illness bring pain and hardship to patients and, in particular, cause patients to suffer in their social life.

According to the data of IQVIA, the market size for anti-depressants in the United States and Europe for the first nine months in 2017 was US$3.70 billion and US$2.23 billion, respectively. While the market size for anti-depressants in the PRC in the first nine months in 2017 was approximately RMB3.45 billion, this market grew at a CAGR of 13.3% from 2015 to the first nine months of 2017.

ABOUT PIPELINE

Besides LY03005, the Group has numerous pipeline regarding central nervous system for the concurrent development of China and overseas markets, with projects such as Risperidone Extended Release Microspheres for injection (LY03004) for Schizophrenia and bipolar disorder, Rotigotine Extended Release Microspheres for injection (LY03003) under research for Parkinson's disease, rivastigmine transdermal patch for mild to moderate Alzheimer's disease. The registration of the above products are progressing well in strategic markets such as China, U.S., Europe and Japan, which will be launched in these countries and further expanded into the global market.

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

Hong Kong, 23 January 2018

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 director of the Company is Mr. SONG Rui Lin; 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.