LUYE PHARMA GROUP LTD.

绿叶制药集团有限公司

(incorporated in Bermuda with limited liability)

(Stock Code: 02186)

ANNOUNCEMENT

COMPLETION OF PHASE 1 CLINICAL STUDIES OF ANSOFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS (LY03005) IN CHINA

The board of directors of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") is pleased to announce that the Group has officially completed three phase 1 clinical studies for ansofaxine hydrochloride extended release tablets ("**LY03005**") in China. The objective of these clinical studies was to evaluate the safety and pharmacokinetic profiles of LY03005 following single or multiple doses of oral administration. A total of 132 healthy subjects were enrolled for these clinical studies at a study site with significant experience in China, including 72 subjects in the single ascending dose ("**SAD**") study, 12 subjects in the food-effect study and 48 subjects in the multiple ascending dose ("**MAD**") study.

The SAD study showed that concentrations of the main active metabolite of LY03005 were dose-proportional for the dose range of LY03005 from 20 to 200 mg in healthy subjects. The result of the food-effect study indicated that food did not affect the bioavailability in healthy subjects. The MAD study showed that the steady-state of the main active metabolite of LY03005 could be achieved on the third day following multiple dosing, and concentrations of the main active metabolite were dose-proportional at the steady state for the dose range of LY03005 from 40 to 160mg/day. In addition, these three clinical studies demonstrated a good safety and tolerability profile of LY03005, and provided a clear reference and basis for future study. The Group has submitted the application to commence phase 2 and phase 3 clinical trials for LY03005 to the China Food and Drug Administration.

LY03005 is the Group's exclusive ansofaxine hydrochloride, a serotonin-norepinephrine-dopamine triple reuptake inhibitor (SNDRI), in extended release tablet form. LY03005 is expected to be approved as a Class I New Chemical Drug for the treatment of major depressive disorder. The Group believes LY03005, a new SNDRI investigational drug, will have higher efficacy and fewer side effects than traditional anti-depressants. Traditional anti-depressants such as selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs) drugs are typically associated with disadvantages such as slow onset of action, anhedonia, sexual dysfunction and inability to improve cognitive impairment. The Group holds fourteen patents in China and internationally over the chemical compound, crystal form and formulation of LY03005. LY03005 is a key central nervous system product candidate being concurrently developed for the PRC and international market, and is currently undergoing phase I clinical trials in the United States.

According to IMS Health Incorporated, the market size for anti-depressants in the PRC in 2014 was approximately RMB3.4 billion, and grew at a compound annual growth rate of 21% from 2011 to 2014. The board of directors of the Company believes that LY03005 has promising market prospects and will enrich the Group's future product portfolio.

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

Hong Kong, 27 March 2015

As at the date of this announcement, the Executive Directors of the Company are Mr. LIU Dian Bo, Mr. YUAN Hui Xian, Mr. YANG Rong Bing 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.