LUYE PHARMA GROUP LTD.

绿叶制药集团有限公司

(Incorporated in the Bermuda with limited liability)

(Stock Code: 02186)

ANNOUNCEMENT

COMPLETION OF PHASE 1 CLINICAL STUDIES OF ANSOFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS (LY03005) IN THE U.S.

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 has completed two phase 1 clinical studies for ansofaxine hydrochloride extended release tablets ("**LY03005**"), a Class 1.1 New Chemical Drug for the treatment of major depressive disorder, in the United States (the "**U.S.**"). A total of 120 healthy volunteers were enrolled for these clinical studies, including 72 subjects in the randomized and double-blinded single ascending dose ("**SAD**") study and 48 subjects in the randomized and double-blinded multiple ascending dose ("**MAD**") study.

In the SAD study, the subjects received a single oral intake of either LY03005 at one of the six doses (20 mg, 40 mg, 80 mg, 120 mg, 160 mg or 200 mg) or a placebo. The results of the SAD study demonstrated good safety profile of LY03005 treatment and linear dose proportionality on the plasma exposure after a single oral administration. The SAD study also involved a food effect panel conducted in 10 subjects, which showed no obvious food effect on the bioavailability of LY03005.

In the MAD study, the subjects received a single daily oral intake of either LY03005 at one of the four doses (40 mg, 80 mg, 120 mg or 160 mg) or a placebo, for eight consecutive days. The results of the MAD study also demonstrated good safety profile of LY03005 treatment and linear dose proportionality on the plasma exposure after multiple oral administrations. The steady state of plasma exposure was reached after 3rd or 4th oral intake of LY03005.

The results of these two phase 1 clinical studies have demonstrated that LY03005 treatment was well tolerated and produced good pharmacokinetic profile in the subjects after single and multiple oral administrations within a diversify dose range, which provides a solid basis for further clinical development.

According to World Health Organization (WHO), there are around 400 million people of all age worldwide suffering from depression. According to the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), 7.6% Americans aged 12 and over had suffered from depression with moderate or severe depressive symptoms during the period from 2009 to 2012.

Traditional anti-depressants such as selective serotonin reuptake inhibitors and serotonin-norepinephrine dual reuptake inhibitors are usually associated with some disadvantages such as slow onset of action, anhedonia, sexual dysfunction, impaired cognitive function, etc. To overcome these side-effects, several serotonin-norepinephrine-dopamine triple reuptake inhibitors (SNDRI) have been or are currently being studied in patients. LY03005 is a new chemical drug within the SNDRI group formulated as a single daily oral intake tablets. The Group believes that LY03005 will have higher efficacy and fewer side effects than traditional anti-depressants.

The Group holds 14 patents over the chemical compound, crystal form and formulation of LY03005 in China and internationally. LY03005 is the Group's key central nervous system product candidate, which is being concurrently developed for the U.S., China and other global markets. The Board believes that LY03005 has promising market prospects and will enrich the Group's future product portfolio.

The Group plans to discuss with the Food and Drug Administration (FDA) about further development plan for LY03005 in the U.S. Besides LY03005, the Group is currently developing several new pharmaceutical products in the U.S.

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

Hong Kong, 12 August 2015

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 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.