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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

APPROVAL FOR THE COMMENCEMENT OF PHASE 2 AND PHASE 3 CLINICAL TRIALS FOR ANSOFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS (LY03005) IN CHINA

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 Class 1.1 New Chemical Drug, has obtained the approval from the China Food and Drug Administration (CFDA) to commence phase 2 and phase 3 clinical trials.

The approval for the commencement of phase 2 and phase 3 clinical trials for LY03005 is expected to provide an impetus to the Group's product development in the central nervous system (CNS) therapeutic area and to further enrich the Group's product portfolio in the future.

LY03005

LY03005 is an exclusive ansofaxine hydrochloride product of the Group. It is a serotonin-norepinephrine-dopamine triple reuptake inhibitor (SNDRI) in extended release tablet form for the treatment of major depressive disorder. The Group believes that 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 has completed three phase 1 clinical studies for LY03005 in People's Republic of China ("**China**" or "**PRC**"). The single ascending dose 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 multiple ascending dose 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 160 mg/day. In addition, these three clinical studies demonstrated a good safety and tolerability profile of LY03005, and provided a clear reference and basis for phases 2 and 3 clinical studies.

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 CNS product candidate, which is being concurrently developed for the PRC and international markets and is currently undergoing phase I clinical trials in the United States.

According to World Health Organization (WHO), there are around 400 million people of all ages worldwide suffer from depression. 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 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, 2 July 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.