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 CLINICAL TRIAL FOR NEW DRUG GOSERELIN ACETATE EXTENDED-RELEASE MICROSPHERES FOR INJECTION (LY01005) 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's product candidate, Goserelin Acetate Extended Release Microspheres for Injection (LY01005), has obtained the approval from the United States (the "**U.S.**") Food and Drug Administration (the "**FDA**") to initiate clinical trials for the treatment of carcinoma of the prostate.

LY01005 is our monthly extended release microspheres for intramuscular formulation of goserelin acetate, a gonadotropin-releasing hormone agonist, applying our microspheres injection technology. It is an oncology product candidate for the treatment of certain cancers, including prostate cancer, breast cancer and endometriosis. LY01005 is now being registered via a 505(b)(2) pathway in the U.S.

The company believes our extended-release microspheres formulation of goserelin acetate may have similar bioavailablility comparable to another marketed product (goserelin implant), but better patient compliance and more steady efficacy. The Company had filed a Patent Cooperation Treaty (PCT) application for our goserelin microsphere pharmaceutical composition in 2014 and such PCT application entered into the U.S., Europe, Japan and certain other countries in 2015.

According to Cancer Statistics in 2015, prostate cancer ranked the first incidence cancer in males in the U.S. There were total 220,800 new prostate cancer cases diagnosed in 2015 in the U.S., which accounted for 26% of all new cancer cases in men. In 2015, 27,540 men died of prostate cancer, which accounted for 9% of all cancer deaths in men in the U.S.

The Company believes that LY01005 has a good marketing potential and will provide an impetus to the Group's development in the oncology therapeutic area. In addition to the U.S., the Company is also targeting to obtain clinical trial approval for this potential new drug in Europe, Japan and China.

Apart from LY01005, the Company is currently developing several new pharmaceutical products in the U.S., including Risperidone Extended Release Microspheres for Injection (LY03004), which had been confirmed by FDA for New Drug Application (NDA) for submission in the U.S. without additional clinical trials, Ansofaxine Hydrochloride Extended Release Tablets (LY03005) and Rotigotine Extended Release Microspheres for Injection (LY03003), which had completed phase I trials in the U.S.

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

Hong Kong, 14 March 2016

As at the date of this announcement, the Executive Directors of the Company are Mr. LIU Dian Bo, Mr. YANG Rong Bin, 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.