LUYE PHARMA GROUP LTD.

绿叶制药集团有限公司

(Incorporated in the Bermuda with limited liability)

(Stock Code: 02186)

APPROVAL FOR CLINICAL TRIAL FOR NEW DRUG GOSERELIN ACETATE EXTENDED-RELEASE MICROSPHERES FOR INJECTION (LY01005) 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, Goserelin Acetate Extended Release Microspheres for Injection (LY01005), has obtained the approval from the China Food and Drug Administration (the "**CFDA**") to initiate clinical trials for the treatment of carcinoma of the prostate. This product has also obtained the approval from the United States Food and Drug Administration (the "**FDA**") to initiate clinical trials for the treatment of carcinoma of the prostate in March this year.

LY01005 is the Group's 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 and other indications, including prostate cancer, breast cancer and endometriosis. LY01005 is now being registered via a 505(b)(2) pathway of the United States Federal Food, Drug and Comestic Act in the United States ("**U.S.**"). The Company believes its extended-release microspheres formulation of goserelin acetate may have similar bioavailability as compared to another marketed product (goserelin implant), with better patient compliance and more stable efficacy.

The Company had filed a Patent Cooperation Treaty application for its 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 IMS Health Incorporated, the market size for gonadotropin-releasing hormone agonist products in China in 2015 was approximately RMB2.79 billion, and grew at a compound annual growth rate of 21.6% from 2013 to 2015. 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 China and the U.S., the Company is also targeting to obtain clinical trial approval for this potential new drug in Europe and Japan.

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

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

Hong Kong, 9 August 2016

As at the date of this announcement, the executive directors are Mr. LIU Dian Bo, Mr. YANG Rong Bing, Mr. YUAN Hui Xian and Ms. ZHU Yuan Yuan; 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.