LUYE PHARMA GROUP LTD.

绿叶制药集团有限公司

(Incorporated in the Bermuda with limited liability)

(Stock Code: 02186)

CLINICAL TRIAL APPLICATION OF HYDROCHLORIDE IRINOTECAN FLOXURUDINE LIPOSOME INJECTION (LY01616) WAS FORMALLY ACCEPTED BY CDE

The board of directors of Luye Pharma Group Ltd. ("**the Company**", together with its subsidiaries, the "**Group**") is pleased to announce that the clinical trial application of the Group's innovative products, Hydrochloride Irinotecan FloxurudineLiposome Injection("**LY01616**") has received formal acceptance from the Centre for Drug Evaluation ("**CDE**") of the People's Republic of China ("**China**").

Irinotecan combined with fluorouracil is one of the first choices for the chemotherapy treatment of advanced colorectal cancer. LY01616 is an innovative combinational liposome formulation loaded with irinotecan and floxurudine, indicated for the treatment of colorectal cancer. Currently there is no same drug product launched globally.

This is the first combinational liposome drug applied for Investigational New Drug ("**IND**") in China. The requirements of its preparation technology are complicated and the production process is difficult. It means that the Group has made new breakthroughs in the field of combinational liposome research and development as well as manufacturing, and has the critical technical ability to encapsulate two drugs in a single liposome.

Compared with single drug chemotherapy, combined chemotherapy can take advantage of different drug mechanisms to achieve a synergistic effect, thereby reducing the occurrence of drug resistance and improving the effect of chemotherapy, which has become the standard for clinical treatment of tumors globally. The ratio of drug combination affects the effect of combined chemotherapy; only specific synergistic ratio can achieve the best therapeutic effect. For traditional combined chemotherapy, due to the differences in drug properties, metabolic pathways in vivo, individual metabolic rate and distribution behavior, it is difficult to maintain the ratio after the combined chemotherapy drugs enter into the body, thus affecting the actual effect. The Group's combinational liposome formulations are

developed to solve these clinical problems. Wrapping the chemotherapeutic drugs into a single liposome at a certain synergistic ratio could maintain the specific synergistic ratio between these two drugs in vivo for a long time, avoiding the mismatch of the ratio of the combined drugs due to the metabolism differences. This has the following advantages compared with traditional combined chemotherapy: (1) loading drugs at specific ratio and delivering drugs to target tissues could better achieve the synergistic effect of combined chemotherapy; (2) reducing the number and frequency of administration and shortening the administration time; (3) reducing the dosage of certain chemotherapy drugs so as to reduce adverse reactions.

Nowadays, colorectal cancer is one of the malignant tumor types with the highest incidence. It is the third most prevalent type of tumor in China, with over 429,000 new cases and 281,000 deaths in 2018.

The Board believes that LY01616 will enrich the Group's oncology product portfolio. The Group's mature marketing team in the field of oncology will bring synergy to the launch of this product.

ABOUT LIPOSOME PLATFORM

The Group attaches great importance to the research and development as well as production of liposome formulation. It has built a variety of new technology platforms such as new liposome platforms, advanced carrier material platforms, and industrialized research platforms. The Group's liposome research and development platform was included in the State Key Laboratory of Long-acting and Targeting Drug Delivery System. The Group has built a highly intelligent liposome production line with continuous improvement in production capacity.

The Group's liposome platform has made a number of significant achievements. The Group's Paclitaxel Liposome for Injection is currently the first and only paclitaxel liposome products approved globally, indicating for non-small cell lung cancer, ovarian cancer, breast cancer. Doxorubicin Hydrochloride Liposome for Injection is currently undergoing Bioequivalency test, and Irinotecan Hydrochloride Liposome for Injection has completed Phase I clinical trials. In addition, there are many other liposome products under preclinical research stages.

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

Hong Kong, 11 June 2020

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 director of the Company is Mr. SONG Rui Lin; and the independent non-executive directors of the Company are Mr. ZHANG Hua Qiao, Professor LO Yuk Lam, Mr. LEUNG Man Kit and Mr. CHOY Sze Chung Jojo.