

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



LUYE PHARMA GROUP LTD.

绿叶制药集团有限公司

(Incorporated in Bermuda with limited liability)

(Stock Code: 02186)

VOLUNTARY ANNOUNCEMENT

**PHASE III CLINICAL TRIAL OF GOSERELIN ACETATE EXTENDED-RELEASE
MICROSPHERES FOR INJECTION (LY01005) FOR TREATMENT OF
BREAST CANCER MET PRIMARY ENDPOINTS IN CHINA**

The board of directors (the “**Board**”) of Luye Pharma Group Ltd. (the “**Company**”, together with its subsidiaries, the “**Group**”) announces that the phase III clinical trial of the Group’s new drug, Goserelin Acetate Extended-release Microspheres for Injection (“**LY01005**”) for the treatment of breast cancer has met expected endpoints in China.

The phase III study is a randomized, open-label, active-controlled, non-inferiority clinical study to evaluate the efficacy and safety of LY01005 after continuous intramuscular injection as compared with reference drug in breast cancer patients. Results of the study showed that, at a dose of 3.6 mg intramuscular injection every 28 days, the serum estradiol (E2) was effectively controlled to postmenopausal levels in the group injected with LY01005, which was similar to the effects of the reference drug, reaching the non-inferiority standard. Generally, the safety profile of LY01005 is also similar to reference drug. Further, the study indicated that there was no adverse reaction of LY01005 on injection site, which improved the patient compliance. Overall, LY01005 was safe and well tolerated.

LY01005 is the Group’s monthly extended release microspheres for intramuscular formulation of goserelin acetate, a gonadotropin-releasing hormone agonist, using the Group’s microspheres technology platform. As far as the Company is aware, the only dosage form of goserelin currently on the market is a subcutaneous implant. LY01005 can effectively reduce the adverse reactions at the injection site by applying the innovative microsphere technology, improve the patient’s medical experience, reduce the difficulty of nursing and improve the patient’s tolerance and compliance, which facilitates the therapeutic effect of the drug and has obvious clinical advantages. Currently, the new

drug application for LY01005 for prostate cancer indication is under review in China. At the same time, the Group will also submit an application for the new indication in China based on the completed phase III clinical results in breast cancer.

According to the latest global cancer burden data released by the International Agency for Research on Cancer (IARC) of the World Health Organization, prostate cancer was the world's second most common malignant tumor among males in 2020. There were approximately 1.41 million new cases of prostate cancer worldwide in 2020, of which approximately 120,000 new cases were in China. Breast cancer was the type of malignant tumor with highest incidence in the world in 2020. There were approximately 2.26 million new cases of breast cancer globally in 2020, of which approximately 420,000 new cases were in China.

According to IQVIA, the market size for gonadotropin-releasing hormone agonist products in China in 2021 was approximately RMB8.97 billion, with a compound annual growth rate of 18.4% for the period from 2019 to 2021.

The Company believes that LY01005 addresses the prevailing clinical demands, provides a new treatment option for prostate cancer and breast cancer patients, and brings benefits to a larger patient pool. At the same time, the product has good market potential in China. Together with the other oncology products of the Group, it is expected to form a comprehensive product portfolio for the Group. Leveraging on the Group's existing resources and advantages in the oncology field, the addition of LY01005 will help accelerate the Company's coverage and development in this field.

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

Hong Kong, 24 July 2022

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 of the Company are Mr. SONG Rui Lin and Mr. SUN Xin; 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.