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

APPROVAL OBTAINED FOR INITIATING CLINICAL TRIAL IN CHINA FOR THE 3-MONTH DOSING FORM OF GOSERELIN ACETATE EXTENDED-RELEASE MICROSPHERES FOR INJECTION (LY01022)

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that the long-acting 3-month dosing form of Goserelin Acetate Extended-release Microspheres for Injection ("**LY01022**"), an innovative anti-tumor formulation developed by the Group, has obtained the approval from the Centre for Drug Evaluation of the National Medical Products Administration in the People's Republic of China ("**China**") to initiate clinical trials.

Goserelin is a gonadotropin-releasing hormone ("**GnRH**") agonist for the treatment of a variety of indications including breast cancer, prostate cancer and endometriosis. In terms of clinical application, the drug needs to be in an extended-release form for releasing in a sustained manner in order to provide therapeutic effects. As far as the Company is aware, the only dosage form of goserelin currently on the market is a subcutaneous implant.

The new drug application for the Group's Goserelin Acetate Extended-release Microspheres for Injection ("**LY01005**") administered monthly for the treatment of prostate cancer and breast cancer developed under the Group's innovative microspheres technology platform is being reviewed in China. Compared with a subcutaneous implant, LY01005 can effectively reduce the adverse reactions at the injection site by applying the innovative microsphere technology, improve patient's usage experience, reduce nursing difficulty and improve the patient's tolerance and compliance. LY01022, which has been approved for clinical trial, is a 3-month long-acting dosage form of Goserelin Extended-release Microspheres for Injection. Compared with formulations administered monthly, LY01022 prolongs the dosing cycle and reduces the frequency of injections, which can further improve the patient's compliance.

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. 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. 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 of GnRH 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 LY01022 addresses the prevailing clinical demands, forms a differentiated product portfolio with LY01005, 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 LY01022 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, 30 January 2023

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.