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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

**NEW DRUG APPLICATION FOR NEW INDICATION OF GOSERELIN
ACETATE EXTENDED-RELEASE MICROSPHERES FOR INJECTION (LY01005)
FOR BREAST CANCER HAS BEEN ACCEPTED IN CHINA**

The board of directors (the “**Board**”) of Luye Pharma Group Ltd. (the “**Company**”, together with its subsidiaries, the “**Group**”) announces that the new drug application for the Group’s new drug Goserelin Acetate Extended-release Microspheres for Injection (“**LY01005**”) for the treatment of breast cancer has been accepted by the Centre for Drug Evaluation of the National Medical Products Administration in the People’s Republic of China (“**China**”). Currently, the new drug application for LY01005 for prostate cancer indication is under review in China.

LY01005 is the Group’s monthly extended release microspheres for intramuscular formulation of goserelin acetate, a gonadotropin-releasing hormone agonist, developed under 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 patient experience for its usage, reduce nursing difficulty and improve the patient’s tolerance and compliance.

The new drug application of LY01005 for breast cancer is based on the results of its phase III clinical trial. The study showed that, when LY01005 was administered intramuscularly at a dose of 3.6 mg once every 28 days, blood estradiol could be effectively controlled to the postmenopausal levels, making LY1005 comparable to the reference drug in terms of efficacy. LY01005 was also similar to the reference drug in terms of safety. Besides, there was no adverse reaction to LY01005 around the injection site, resulting in better patient compliance. Overall, LY01005 was found to be safe and well tolerated in the study.

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. Such data revealed that 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, 15 August 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.