

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

**ACCEPTANCE OF APPLICATION FOR
MARKETING AUTHORIZATION IN CHINA FOR
GOSERELIN ACETATE EXTENDED-RELEASE MICROSPHERES FOR
INJECTION (LY01005)**

The board of directors (the “**Board**”) of Luye Pharma Group Ltd. (the “**Company**”, together with its subsidiaries, the “**Group**”) announces that the marketing authorization application for the Group’s innovative formulation product Goserelin Acetate Extended-release Microspheres for Injection (“**LY01005**”) has been accepted by the Centre for Drug Evaluation of the National Medical Products Administration (“**NMPA**”) in the People’s Republic of China (“**China**”). The indication submitted for this marketing authorization application in China is prostate cancer. Concurrently with this application, the Group is also undertaking phase III clinical trials for LY01005 for treatment of breast cancer in China.

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 a first-line drug for the treatment of prostate cancer, the only dosage form of goserelin currently on the market is a subcutaneous implant. LY01005, through innovative microsphere technology, can effectively reduce the adverse reactions at the injection site, improve the patient’s medication experience, reduce the difficulty of nursing, and improve the patient’s tolerance and compliance, which is more beneficial for the therapeutic effect of the drug and has obvious clinical advantages.

According to the 2020 latest global cancer burden data from 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 world's largest high-incidence malignant tumor. 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 2020 was approximately RMB7.45 billion, with a compound annual growth rate of 22.6% for the period from 2018 to 2020.

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. It, together with the other oncology products of the Group, creates a comprehensive portfolio. 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, 29 December 2021

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.