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
THE BREAST CANCER INDICATION OF BAITUOWEI (GOSERELIN MICROSPHERES FOR INJECTION) APPROVED IN CHINA

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that the Group's innovative formulation, Goserelin Microspheres for Injection ("**Baituowei**"), has been approved by the National Medical Products Administration ("**NMPA**") of the People's Republic of China ("**China**") for the treatment of breast cancer in premenopausal and perimenopausal women that can be treated with hormones. As far as the Company is aware, this product is the world's first and only formulation of goserelin long-acting microspheres approved for launch. Previously, this product has been approved by NMPA for the treatment of prostate cancer for patients requiring androgen deprivation therapy ("**ADT**") on 30 June 2023. Currently, the Group collaborates with BeiGene, Ltd. ("**BeiGene**") (a company listed on NASDAQ (ticker: BGNE), The Stock Exchange of Hong Kong Limited (stock code: 06160) and the Shanghai Stock Exchange (stock code: 688235)) to commercialize this product in Mainland China.

Breast cancer is the number one malignant tumor threatening women's health worldwide and is also a highly prevalent cancer in the Chinese female population. In 2020, China was reported to have 420,000 new cases of breast cancer, and the incidence was growing in different age groups. In China, breast cancer tends to have an earlier onset than in Europe and the United States, which premenopausal breast cancer patients in China account for approximately half of all the patients. The premenopausal patients also have a higher risk of relapse and a lower overall survival rate compared with the elder ones.

Baituowei is the world's first and only approved microsphere formulation of Goserelin, as far as the Company is aware. With its innovative microsphere formulation, Baituowei is able to ensure efficacy and safety while significantly improving patient experience. In a Phase III clinical trial of Baituowei for the treatment of breast cancer, its efficacy and safety profile were found to be comparable to those of the reference drug. In addition, Baituowei could reduce the incidence and severity of adverse reactions

at the injection site. Its modified needle has a diameter of only 0.8 millimeters to effectively reduce patients' psychological burden associated with the treatment, and to improve patient confidence and compliance. It was found to be clearly superior over the reference drug.

Data from IQVIA shows the total size of the market for gonadotropin-releasing hormone ("**GnRH**") agonists in China was approximately RMB9.5 billion in 2022, with a compound annual growth rate (CAGR) of 17.7% from 2018 to 2022.

The Company believes that Baituowei has the potential to address the prevailing clinical demands and has good market potential in China. The approval of the new indication will further expand the patient groups that can benefit from Baituowei. Meanwhile, the Group and BeiGene intend to continue to expand commercial collaboration to unleash the product's social value and commercial value faster by leveraging its superiority in treating prostate cancer and breast cancer.

ABOUT BREAST CANCER

Breast cancer was reported to be the most common cancer in women worldwide and the number one malignancy threatening women's health worldwide. In 2020, globally it was estimated that more than 2 million patients with breast cancer and nearly 685,000 people died from it. In China, nearly 420,000 women were reported to be diagnosed with breast cancer and 120,000 women died from it in 2020, accounting for approximately 18% of the global breast cancer deaths.

In clinical practice, breast cancer is normally categorized into four subtypes: Luminal A, Luminal B, HER2-positive, and triple-negative. Among them, Luminal A and Luminal B are the hormone receptor-positive subtypes, and their onset and prognosis are highly correlated with estrogen, which account for about 70% of all breast cancer cases. Ovarian function suppression (OFS) is a hormone therapy (Endocrine therapy) to inhibit the generation of estrogen by the ovary through surgery or drug means, which is cornerstone method for treating premenopausal hormone receptor-positive breast cancer. OFS treatments represented by Gonadotropin-releasing hormone analogs (GnRHa) can inhibit the secretion of the follicle-stimulating hormone and the luteinizing hormone, causing the estrogen levels of pre-menopausal women to reach postmenopausal levels. This can inhibit estrogen-related tumor growth while keeping ovarian function in a state of reversible inhibition.

The Chinese Expert Consensus on the Clinical Application of Ovarian Function Suppression in Early-Stage Breast Cancer (2021) recommends GnRH agonists as the OFS treatments of choice for early-stage hormone receptor-positive breast cancer in premenopausal women. Furthermore, the use of OFS drugs to protect ovarian function and reduce fertility impairment is recommended for premenopausal breast cancer patients no matter they are hormone receptor-positive or negative, both before and during chemotherapy.

ABOUT BAITUOWEI

Developed by the Group, Baituowei (Goserelin Microspheres for Injection) is designated as a "Class 2.2 new chemical drug" in China and has been approved for launch to treat prostate cancer patients requiring ADT as well as premenopausal and perimenopausal women with breast cancer that can be treated with hormones. Baituowei is an innovative formulation developed on the microsphere platform of the National Key Laboratory of Advanced Drug Delivery and Release Systems and manufactured following the Company's quality management system that is compliant with the Chinese GMP, the U.S. cGMP and the EU GMP systems.

In December 2022, the Group and BeiGene formed a partnership for the commercialization of Baituowei. In this partnership, the latter has been granted the exclusive research, development and commercialization rights for the product in Mainland China, and the Group as the product's Marketing Authorization Holder (MAH) manufactures and supplies the product based on the demand forecast by BeiGene.

ABOUT BEIGENE

BeiGene is a global biotechnology company that is discovering and developing innovative oncology treatments that are more affordable and accessible to cancer patients worldwide. With a broad portfolio, they are expediting development of their diverse pipeline of novel therapeutics through their internal capabilities and collaborations. They are committed to radically improving access to medicines for far more patients who need them. Their growing global team of more than 10,000 colleagues spans five continents, with administrative offices in Beijing, China; Cambridge, U.S.; and Basel, Switzerland.

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

Hong Kong, 7 September 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, Mr. CHOY Sze Chung Jojo and Ms. XIA Lian.