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LUYE PHARMA GROUP LTD.

绿叶制药集团有限公司

(Incorporated in the Bermuda with limited liability)

(Stock Code: 02186)

VOLUNTARY ANNOUNCEMENT

**MARKETING REGISTRATION OF GOSERELIN MICROSPHERES FOR
INJECTION (BAITUOWEI) APPROVED BY NMPA**

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 (“**LY01005**”, or “**Baituowei**”), has been approved by the National Medical Products Administration (“**NMPA**”) of the People’s Republic of China (“**China**”) for the treatment of prostate cancer for patients requiring androgen deprivation therapy (“**ADT**”) on 30 June 2023. 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. In the meanwhile, the Group and 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)) will also officially commenced their strategic partnership for the commercialization of this product.

Prostate cancer is reported to be the second most commonly diagnosed cancer in men and the fifth leading cause of death among men worldwide. In China, the new cases of prostate cancer are reported to be growing at 7.1% every year on average, the highest among all cancers in men. It poses a serious threat to the health of men and their quality of life. The most common practice in treating prostate cancer is using an ADT, typically a gonadotropin-releasing hormone (“**GnRH**”) agonist. However, patient compliance is an issue for the traditional treatment of using implant formulation, as there are specific requirements on the environment and medical workers (and thus difficulties for patients) for injecting the implant. Besides, the injection is usually a painful experience for patients.

With its innovative microsphere formulation, Baituowei is able to release the active ingredients more steadily within a treatment cycle, achieve better control over testosterone production, avoid testosterone surge caused by re-dosing, and ensure efficacy and safety. The improved needle for this product has a diameter of only 0.8 millimeter. This can significantly improve patient experience. In a Phase III clinical trial of Baituowei for the treatment of prostate cancer, its efficacy was comparable to that of the reference drug, and its safety profile was similar to that of the reference drug. Besides, this product was found to be able to significantly reduce the incidence and severity of adverse reactions at the injection site, so as to improve patient tolerance and compliance, making it clearly superior over the reference drug.

In addition to prostate cancer, Baituowei is also being reviewed for its New Drug Application (NDA) in China for the treatment of breast cancer.

Data from IQVIA shows the total size of the market for 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.

With an aim to expedite the process for bringing this new medicine to more patients in need, the Group and BeiGene formed a partnership for its commercialization. Under this partnership, the latter has been granted the exclusive right to research, develop and commercialize the product in Mainland China, and the Group as the product's Marketing Authorization Holder (MAH) will manufacture and supply it based on the demand for it forecast by 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. In China, BeiGene has built a team of over 3000 employees and its growing commercial portfolio contains 17 products covering solid tumors and hematological malignancies of high incidence.

The Company believes that Baituowei has the potential to address the prevailing clinical demands and has good market potential in China. The Company looks forward to working closely with BeiGene to make this innovative therapy available to as many patients as possible and at a faster speed.

ABOUT PROSTATE CANCER

Prostate cancer is reported to be the second most common cancer in men globally and the fifth leading cause of cancer death among men worldwide. In 2020, there were reported to be approximately 1.4 million new cases and 375,000 deaths. In recent years, the incidence of prostate cancer in China has been increasing at 7.1% a year, the highest among cancers in men. The five-year survival rate for Chinese prostate cancer patients is approximately 66.4%, lower than the 95% or higher five-year survival rate in developed countries. Due to atypical early symptoms and the low coverage of the prostate-specific antigen (PSA) test, around 40% to 70% of China's prostate cancer patients are already found to have regional or distant metastasis upon initial diagnosis. Treating with an ADT, typically a gonadotropin-releasing hormone agonist, is the most common practice for treating prostate cancer patients throughout their treatment journey.

ABOUT BAITUOWEI

Developed by the Group, Baituowei (Goserelin Microspheres for Injection) is designated as a “Class 2.2 new chemical drug” in China. It is an innovative formulation developed on the microsphere platform of the National Key Laboratory of Advanced Drug Delivery and Release Systems and manufactured following Chinese GMP, American cGMP and European GMP.

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 our diverse pipeline of novel therapeutics through our 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 9,400 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, 4 July 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.