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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 AUTHORIZATION APPLICATION FOR
DENOSUMAB INJECTION (LY06006/BA6101) 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 marketing authorization application for Denosumab injection (LY06006/BA6101) developed by Shandong Boan Biotechnology Co. Ltd. 山東博安生物技術股份有限公司 (“**Boan Biotech**”, a subsidiary of the Company) has been accepted by the Centre for Drug Evaluation of the National Medical Products Administration (“**NMPA**”) in the People’s Republic of China (“**China**”).

LY06006/BA6101 is the biosimilar to Prolia[®] (Denosumab injection). Denosumab is a fully human IgG2 monoclonal antibody. Denosumab prevents RANKL from activating its receptor, RANK. Prevention of the RANKL/RANK interaction inhibits osteoclast formation, function, and survival, thereby decreasing bone resorption and increasing bone mass and strength in both cortical and trabecular bone.

In 2010, Prolia[®] was firstly launched in the United States, and it was subsequently launched in more than 80 other countries or regions around the world. Prolia[®] has been approved around the world for the following indications: (1) treatment of postmenopausal women with osteoporosis at high risk for fracture; (2) treatment to increase bone mass in men with osteoporosis at high risk for fracture; (3) treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture; (4) treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer; and (5) treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

According to public financial reports, sales of Prolia[®] amounted to US\$2.76 billion in 2020 globally. In June 2020, Prolia[®] was approved by NMPA to launch in China.

In addition to the China market, Boan Biotech also intends to carry out the registration of LY06006/BA6101 in other countries and regions around the world.

ABOUT BOAN BIOTECH

Boan Biotech is a fully integrated biopharmaceutical company as a subsidiary of the Company. It specialises in therapeutic antibody development, manufacturing and commercialization with a focus on oncology, autoimmune, pain and endocrine diseases. Boan Biotech's antibody discovery activities are organized around three platforms, namely Human Antibody Transgenic Mouse and Phage Display Technology, Bispecific T-cell Engager Technology and ADC Technology Platform. Boan Biotech has developed more than 10 innovative antibody products with international intellectual property protection and 8 biosimilar products.

Boan Biotech has developed extensive experience in areas of antibody discovery, cell line development, upstream and downstream process development, analytical development, technology transfer, pilot and commercial scale production. Boan Biotech is also actively exploring other cutting-edge technologies. Its cell therapy products use non-viral vectors for CAR-T for late stage solid tumors. Boan Biotech is also developing new generation of universal CAR-T and switchable CAR-T, to develop safer, effective and affordable products for patients.

In addition to China, Boan Biotech is also engaged in biopharmaceutical products development in markets in the United States and the European Union.

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

Hong Kong, 13 October 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.