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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
MARKETING AUTHORIZATION OF DENOSUMAB INJECTION (BOYOUBEI®)
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 marketing authorization in relation to Denosumab Injection (Boyoubei®, BA6101) (“**Boyoubei**®”) developed by a subsidiary of the Company, namely Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術股份有限公司) (“**Boan Biotech**”) has been approved by the National Medical Products Administration (“**NMPA**”) of the People’s Republic of China (“**China**”) for the treatment of postmenopausal women with osteoporosis at high risk for fracture. This product can significantly reduce the risk of vertebral, non-vertebral and hip fractures in postmenopausal women. Boyoubei® is the first biosimilar to Prolia® (the originator of denosumab) approved for marketing in the world. In addition to China, Boyoubei® is being developed in Europe and the U.S., with a plan to be marketed in the global markets.

The active ingredient of Boyoubei® is a human immunoglobulin G2 monoclonal antibody of the RANK ligand. The drug is administered subcutaneously once every six months. Denosumab is an international first-line anti-osteoporosis drug, providing a convenient, effective and economical treatment plan for postmenopausal women with osteoporosis. Denosumab can block RANKL activating osteoclasts and the receptor RANK on the surface of its precursors. Blocking the RANKL/RANK interaction can inhibit osteoclast formation, function and survival, thereby reducing bone resorption, increasing bone mass and strength in the cortex and trabecula.

Boyoubei® follows the relevant research guidelines of biosimilars, through a series of step-by-step pharmaceutical studies as well as studies on non-clinical, human pharmacokinetics and clinical effectiveness which scientifically, rigorously and completely prove the overall similarity between Boyoubei® and the original reference drug: the quality, safety and efficacy of the two drugs are highly similar, and there are no clinically meaningful differences between them. The results of two completed

phase I clinical studies for Boyoubei[®] were published in *Expert Opinion on Investigational Drugs* and *Frontiers in Pharmacology*, and the results of phase III clinical study were published in *Journal of Orthopaedic Translation*.

Based on public information, Prolia[®] generated global sales of US\$3,248 million in 2021, with an annual growth rate of 18%. According to the Frost & Sullivan report, the market size of Denosumab for osteoporosis in China is estimated to reach RMB7.8 billion in 2030.

The Company believes that Boyoubei[®] will have broad market prospects based on the huge patient base and the high clinical value for Denosumab.

ABOUT BOAN BIOTECH

Boan Biotech is a fully integrated biopharmaceutical company and a subsidiary of the Company. It specialises in therapeutic antibody development, manufacturing and commercialization with a focus on oncology, metabolism, autoimmunity and ophthalmology 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 several innovative antibody products with international intellectual property protection and biosimilar products. Two of these products are already in the commercialization stage.

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. 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, 10 November 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.