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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

APPROVAL OBTAINED FOR INITIATING CLINICAL TRIAL FOR THE INNOVATIVE ANTIBODY DRUG BA1106 IN CHINA

The board of directors (the “**Board**”) of Luye Pharma Group Ltd. (the “**Company**”, together with its subsidiaries, the “**Group**”) announces that BA1106 (“**BA1106**”), an innovative antibody 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 obtained the approval from the Centre for Drug Evaluation (“**CDE**”) of the National Medical Products Administration (“**NMPA**”) in the People’s Republic of China (“**China**”) to initiate clinical trials. BA1106 is the first innovative human anti-CD25 monoclonal antibody approved for initiating clinical trials in China for the treatment of solid tumors.

CD25 is also known as interleukin-2 receptor α (IL-2R α). It is expressed at high levels on regulatory T cells (“**Treg cells**”) and it does not exist or is expressed at low levels on effector T cells. Since Treg cells play an inhibitory role on various immune cells and are also an important factor contributing to the poor prognosis of most solid tumors, eliminating Treg cells in the tumor microenvironment has become one of the important strategies for immuno-oncology.

Anti-CD25 antibody is a broad-spectrum immuno-oncology drug with potential indications for cervical cancer, renal cancer, ovarian cancer, melanoma, pancreatic cancer, hepatocellular carcinoma, gastric cancer and breast cancer. However, the current development of anti-CD25 antibody faces two major challenges: first, the function of Fc as mediators is limited, and as a result, they only work in early-stage tumor models, but not in advanced tumor models; second, the IL-2 signaling pathway is blocked, leading to poor antitumor outcomes.

The main mechanism of action of BA1106 is to deplete Treg cells in the tumor microenvironment through the ADCC (antibody-dependent cellular cytotoxicity) effect and to increase the proportion of effector T cells. Preclinical studies have shown that BA1106 has a good therapeutic effect on early-stage and advanced tumors, and shows a good synergistic effect when combined with anti-PD-1 antibody. Moreover, BA1106 does not block the IL-2 signaling pathway, and depletes Treg cells moderately and specifically. Therefore, the Company believes that BA1106 has potential good market prospects.

In November 2021, research results related to BA1106 have been published in *Scientific Reports*, a journal of *Nature* magazine.

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.

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, 7 September 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.