

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



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

APPROVAL OBTAINED FOR INITIATING CLINICAL TRIAL FOR THE GROUP'S INNOVATIVE ANTIBODY DRUG BA1201 IN CHINA

The board of directors (the “**Board**”) of Luye Pharma Group Ltd. (the “**Company**”, together with its subsidiaries, the “**Group**”) announces that BA1201, an innovative antibody drug discovered and 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 obtained approval from the Centre for Drug Evaluation of the National Medical Products Administration of the People’s Republic of China (“**China**”) to initiate clinical trials.

BA1201 is an anti-PD-L1/TGF- β bispecific antibody fusion protein for the treatment of advanced solid tumors and other indications. This product is also Boan Biotech’s first new bispecific antibody drug under development that has been approved to initiate clinical trial. The approved clinical trial of BA1201 is a phase I clinical study evaluating the safety, tolerability, pharmacokinetic properties and preliminary efficacy in patients with advanced solid tumors.

Different from the monoclonal antibodies against a single target, bispecific antibodies can bind to two antigens at the same time and regulate two signal pathways related to the treatment of cancer, which has unique advantages in cancer immunotherapy. BA1201 includes an anti-PD-L1 antibody infused with TGF- β Type II Receptor domain at its C terminal. BA1201 can not only inhibit PD-L1/PD-1 signaling pathway but also inhibit TGF- β /TGF- β RII signaling pathway, which can eliminate immunosuppression and restore the immune system to target tumor cells for killing, making it more potent than anti-PD-L1 monoclonal antibodies.

In the tumor microenvironment, programmed cell death ligand-1 (PD-L1) and transforming growth factor- β (TGF- β) are usually highly expressed. By binding to PD-1 on lymphocytes, PD-L1 inhibits the proliferation and activation of lymphocytes, induces their apoptosis, and then leads to the immune evasion of tumor cells. TGF- β not only drives tumorigenesis, but also serves as an important factor for immunosuppression. It mediates the drug resistance of tumor cells against the anti-PD-L1 monoclonal antibody. Blocking the immunosuppressive signals induced through PD-L1 and TGF- β simultaneously can produce a synergistic effect for cancer therapy, which can potentially improve the low response rate of current PD-L1/PD-1 inhibitors.

The results of preclinical studies showed that BA1201 had a high affinity and significant anti-tumor activity in several mouse models. Compared with benchmark, BA1201 had a better binding sensitivity on PD-L1 positive cells (with a three times lower IC₅₀). It had a good stability and longer half-life in mice and cynomolgus monkeys, and had a low risk for cardiotoxicity.

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, autoimmune 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 7 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, 14 December 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.