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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
BROADLY NEUTRALIZING ANTIBODY AGAINST SARS-COV-2 IN CHINA**

The board of directors (the “Board”) of Luye Pharma Group Ltd. (the “Company”, together with its subsidiaries, the “Group”) announces that BA-CovMab injection, a broad-spectrum neutralizing antibody against severe acute respiratory syndrome coronavirus 2 (“SARS-CoV-2”) 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 National Medical Products Administration (“NMPA”) in the People’s Republic of China (“China”) to initiate clinical trials.

Since the outbreak of the SARS-CoV-2 pandemic, new variants of SARS-CoV-2, such as the Alpha variant, the Beta variant, the Delta variant, and the Omicron variants, have continued to emerge around the world. Among them, Omicron has become the dominant strain worldwide, and it is also the main variant disseminating in China. Although multiple vaccines and therapeutic drugs have been put into use, the continuous mutation in the virus enhances its infectivity and escape ability, which compromised the effects of approved vaccines and impaired the efficacy of the neutralizing antibody treatments. To fight against the continuous mutation of SARS-CoV-2, there is an urgent need for broad-spectrum and effective neutralizing antibody for treatment and prevention of the disease.

With the proprietary Human Antibody Transgenic Mouse and Phage Display Technology platform of Boan Biotech, BA-CovMab identified potent broad-spectrum neutralizing antibody BA-CovMab through the combined sequential immunization and sequential screening strategy. Cryogenic electron microscopy studies have demonstrated that BA-CovMab combines with conserved sites in the receptor-binding domain (“RBD”) of SARS-CoV-2 spike protein and avoids most mutation-sensitive sites in the RBD of SARS-CoV-2 spike protein. As such, it can broadly and effectively neutralize diverse SARS-CoV-2 variants with a lower risk for loss of neutralizing activity against future variants.

Based on the data from studies on the *in vitro* neutralization abilities of BA-CovMab, BA-CovMab maintains high neutralizing potency against the 18 variants such as D614G and Alpha, Beta, Delta, Omicron BA.1-BA.5. In relation to Omicron BA.1, BA.2, BA.2.12.1, BA.2.13, BA.2.75, BA.3, BA.4 and BA.5 variants, the IC₅₀ values were 1.24–5.52 ng/mL. Studies on the neutralization abilities of BA-CovMab on live virus also indicated that BA-CovMab maintains high neutralizing potency against Omicron BA.1 and BA.2. The results of pharmacodynamic studies in mice showed that BA-CovMab is effective in treatment and prevention of Omicron BA.1 and BA.2 infection. BA-CovMab can significantly reduce the titer of live virus in the lungs of animal infection models by 2–3.5 log₁₀ (p<0.005), basically clear the virus in the lungs, and has an excellent protective effect. In addition, preclinical pharmacokinetics and toxicology studies of BA-CovMab also showed a longer half-life and a good safety profile in rats. Neutralizing antibodies could be used for the treatment and prevention of infection by SARS-CoV-2. The specificity and safety of neutralizing antibody BA-CovMab has dual functions of prevention and treatment. It is expected to be a powerful weapon against the continuous mutation of SARS-CoV-2.

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 multiple 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, 12 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.