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 BA2101 INJECTION, AN INNOVATIVE LONG-ACTING MONOCLONAL ANTIBODY IN CHINA

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that the BA2101 injection ("**BA2101 injection**"), a long-acting monoclonal 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.

BA2101 injection is an innovative, long-acting human monoclonal antibody in IgG4 subtype that targets interleukin-4 receptor subunit α (IL-4Rα). BA2101 injection will be administered subcutaneously with an expected dosing interval of 4 weeks. BA2101 injection can inhibit IL-4 and IL-13 signaling, regulate Th2 inflammatory pathway, reduce eosinophils and circulating IgE level, and treat allergic diseases caused by type 2 inflammation. It is expected to be used to treat atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis, prurigo nodularis, and chronic spontaneous urticarial.

The completed preclinical studies show that BA2101 shows a longer half-life and higher drug exposure in cynomolgus monkeys than the marketed drug with the same target with 2-week dosing interval. It is expected that BA2101 may achieve a dosing interval of 4 weeks in human. In the B-hIL4/hIL-4Rα mouse model with asthma, BA2101 shows similar efficacy compared with the marketed drug, and can

significantly inhibit the enrichment of eosinophils in the lung tissue and the production of OVA-specific IgE in mice; In the B-hIL4/hIL-4Rα mouse model with atopic dermatitis, equal doses of BA2101 and the marketed drug are equivalent inhibitory effects on serum IgE levels, and can significantly inhibit the ear swelling in mice. Toxicology study shows that BA2101 is safe in B-hIL4/hIL-4Rα mice. BA2101 injection is expected to become an important long-acting drug for the treatment of type Th2 inflammatory diseases in the future.

As of the end of September 2022, the first IL-4Rα monoclonal antibody Dupilumab (Dupixent®) has been approved by the US FDA for the treatment of 5 diseases caused by Th2 inflammation: prurigo nodularis (PN, for adult patients), eosinophilic esophagitis (EoE, for patients ≥12-year-old), atopic dermatitis (AD, for patients ≥6-month-old), asthma (Asthma, for patients ≥6-year-old), chronic rhinosinusitis with nasal polyposis (CRSwNP, for adult patients). Dupixent® is the only biologic agent approved in China for the treatment of moderate to severe atopic dermatitis (AD, for patients ≥6-year-old). In addition to the currently approved indications, clinical trials of Dupixent® for the treatment of a variety of diseases caused by Th2 inflammation or other allergies are on-going, including chronic pruritus of unknown etiology, neurodermatitis, atopic hand-foot dermatitis, chronic spontaneous urticaria, cold urticaria, bullous pemphigoid, allergic fungal rhinosinusitis, chronic sinusitis without nasal polyps, chronic obstructive pulmonary disease, and allergic bronchopulmonary aspergillosis.

Based on public information, Dupixent® generated global sales of €5,249 million in 2021, with an annual growth rate of 52.7%. According to the Frost & Sullivan report, the global market size of IL-4Rα targeted therapies is estimated to reach US$28.7 billion in 2030 and the market size of IL-4Rα targeted therapies in China is estimated to reach RMB28.2 billion in 2030 due to the expansion of indications and same target drugs to be approved in future.

The Company believes that BA2101 injection for long-acting administration will have broad market prospects based on the huge clinical demand for diseases caused by Th2 inflammation or other allergies.

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, 27 October 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.