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

DULAGLUTIDE INJECTION (BA5101) ENTERED INTO PHASE III CLINICAL TRIAL IN CHINA

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that the dulaglutide injection ("**BA5101**") 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 entered into phase III clinical trial (comparative clinical efficacy and safety studies) in the People's Republic of China ("**China**"). As a biosimilar to Trulicity®, BA5101 is indicated for glycemic control in adults with type 2 diabetes mellitus.

The completed pharmaceutical, non-clinical and human phase I clinical studies (pharmacokinetic and/or pharmacodynamic comparison studies) have shown that BA5101 has biological similarity with Trulicity®. The phase III clinical trial of BA5101 is a multi-center, randomized, open, parallel and positive-controlled clinical study in Chinese adult patients with type 2 diabetes to compare the efficacy, safety, immunogenicity and PK characteristics of BA5101 and Trulicity®.

Trulicity® is a new generation of long-acting glucagon-like peptide-1 (GLP-1) receptor agonist developed by Eli Lilly in the United States. It can activate GLP-1 receptor and increase the intracellular cyclic AMP (cAMP) in beta cells leading to glucose-dependent insulin release. It can also decrease glucagon secretion and delays gastric emptying. Compared with other original glucose-reducing drugs, its advantages are that it can improve pancreatic islet beta cells function, effectively reduce glycemia and HbA1c levels, and rarely cause hypoglycemia. It can also reduce weight and reduce the risk of major adverse cardiovascular events. A number of relevant clinical studies have shown that it is a safe and effective long-acting drug for type 2 diabetes medication. Its once-a-week dosing regimen can reduce the inconvenience of patients when taking the drug, improve compliance and improve the quality of life of patients with type 2 diabetes.

Trulicity® was first launched in the United States in 2014, and has subsequently launched in many other countries or regions, such as the European Union, Japan and China. Trulicity® is approved for the following indications: (1) as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus; and (2) used to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors. In February 2019, Trulicity® was approved to launch in China by the National Medical Products Administration in China.

At present, the situation of diabetes prevention and control has been reported to be severe in China and around the world. According to the report of Frost & Sullivan, as of 2020, there were more than 400 million people with type 2 diabetes in the world, and the number of people with type 2 diabetes is expected to rise to 586 million by 2030; the number of people with type 2 diabetes in China in 2020 was estimated to be approximately 1.3 million, and the number is expected to rise to 168 million by 2030. Based on the above-mentioned large unmet needs of patients, dulaglutide injection has a broad market prospect on a global scale. According to public financial reports, Trulicity®'s global sales in 2021 was $6.47 billion representing a year-on-year growth rate of 28%.

In addition to the China market, Boan Biotech also intends to register BA5101 in other countries and regions around the world.

ABOUT BOAN BIOTECH

Boan Biotech is a fully integrated biopharmaceutical company and a subsidiary of the Company. It specialises in the development, manufacturing and commercialization of biologics 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 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, 14 July 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.