Shandong Boan Biotechnology Co., Ltd.
山东博安生物技术股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

(Stock Code: 6955)

VOLUNTARY ANNOUNCEMENT

APPROVAL OBTAINED FOR INITIATING CLINICAL TRIALS FOR DULAGLUTIDE INJECTION (BA5101) IN THE U.S.

The board of directors (the "**Board**") of Shandong Boan Biotechnology Co., Ltd. (the "**Company**") announces that the U.S. Food and Drug Administration ("**FDA**") has approved the initiation of clinical trials in the U.S. for our Dulaglutide Injection ("**BA5101**") independently developed by the Company.

BA5101 is a proposed biosimilar to Trulicity® intended for glycemic control in patients with type 2 diabetes. It is the first dulaglutide biosimilar developed by a Chinese company to be approved for clinical trials in the U.S. It is also the first proposed biosimilar to Trulicity® to submit a Biologics License Application ("**BLA**") in China, which was accepted by the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) in May this year.

Dulaglutide is a long-acting, glucagon-like peptide-1 (GLP-1) receptor agonist to be administered once a week. Compared with other glucose-lowering medications, Dulaglutide can improve β-cell function and achieve stable and effective reductions in blood glucose and HbA1c levels. In addition, due to its unique mechanism of action, the drug is less likely to cause hypoglycemia and can reduce body weight, blood lipids, and the risk of long-term cardiovascular diseases. It also helps to protect the kidneys. Multiple clinical studies have also shown that dulaglutide has a good safety profile with low gastrointestinal adverse reactions, and the weekly administration helps to reduce the patient inconvenience and improve treatment adherence.

Trulicity® is being marketed in several countries and regions including the U.S., EU, Japan, and China. It has been approved worldwide for the following indications: (1) as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus; and (2) 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.

The development of BA5101 strictly followed relevant guidelines for biosimilars in China, the U.S., and the EU. The drug's overall similarity to the reference drug, Trulicity®, has been established by evidence from a series of progressive analytical, non-clinical, comparative human pharmacokinetics, clinical efficiency, safety and immunogenicity studies in China. BA5101 has been shown to be highly similar to the reference drug in terms of quality, efficacy, safety, and immunogenicity. Currently, the BLA of BA5101 has taken the lead in entering the BLA review process in China. The t proposed clinical study approved for initiation in the U.S. will be a randomized, open-label, single-dose, three-arm and parallel-controlled clinical study to evaluate the pharmacokinetics, safety, and immunogenicity of BA5101 against reference drugs in healthy subjects. The Company plans to conduct clinical studies and submit marketing authorization applications in the U.S. and Europe, with plans to market it in other countries and regions as well.

Globally there is a huge number of diabetic patients with significant unmet needs. According to the latest data from the International Diabetes Federation (IDF), there were 537 million people (ages 20-79) living with diabetes worldwide in 2021, and the number is expected to reach 784 million by 2045. Data from the American Diabetes Association (ADA) shows that there were 38.4 million Americans living with diabetes in 2021, accounting for 11.6% of the U.S. population. Publicly available financial information shows that the sales of Trulicity® were approximately $7.13 billion worldwide and $5.43 billion in the U.S.

Driven by multiple factors including the huge unmet needs of diabetic patients and the superiorities of dulaglutide in treating diabetes in terms of efficacy and safety, the Company believes that there is a promising global market for BA5101.

By Order of the Board
Shandong Boan Biotechnology Co., Ltd.
Jiang Hua
Chairlady, Chief Executive Officer and Executive Director

Yantai, the People's Republic of China, 5 August 2024

As at the date of this announcement, the executive directors of the Company are Ms. Jiang Hua and Dr. Dou Changlin; the non-executive directors of the Company are Mr. Liu Yuanchong and Ms. Li Li; and the independent non-executive directors of the Company are Professor Shi Luwen, Mr. Dai Jixiong and Dr. Yu Jialin.