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Boan Biotech
博安生物

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

PHASE 3 CLINICAL TRIAL COMPLETED IN CHINA FOR DULAGLUTIDE INJECTION (BA5101) AND BLA TO BE FILED

The board of directors (the “**Board**”) of Shandong Boan Biotechnology Co., Ltd. (the “**Company**”) announces that the Phase 3 clinical trial (a comparative study of efficacy, safety, and immunogenicity) for Dulaglutide Injection (“**BA5101**”) developed by the Company has been completed in China. The Company is planning to submit a Biologics License Application (“**BLA**”) for the drug. BA5101 is a biosimilar of Trulicity® for glycemic control in adults with type 2 diabetes. BA5101 is the first dulaglutide biosimilar in the world to have completed Phase 3 clinical trial as far as the Company is aware, and leads in development progress.

Dulaglutide is a long-acting glucagon-like peptide-1 (GLP-1) receptor agonist administered once a week. Compared with other glucose-reducing drugs, Dulaglutide can improve the functioning of pancreatic islet beta cells, stably and effectively reduce blood glucose and HbA1c levels. Due to its unique mechanism of action, Dulaglutide can improve multiple risk factors for cardiovascular diseases simultaneously such as weight gain, hyperlipidemia/ blood lipids and long-term cardiovascular disease risks, and is not prone to causing lower rate of hypoglycemia. It can also protect the kidney. Moreover, several clinical studies have shown that taking Dulaglutide once a week can also encourage consumption regularity among patients as a result of such convenience of use.

The development of BA5101 follows the guidelines for biosimilars in jurisdictions including China, the United States and Europe. The completed Phase 3 clinical trial was a randomized, open-label, parallel group and positive control study comparing the efficacy and safety of BA5101 with Trulicity® among Chinese adults with type 2 diabetes. The trial met all endpoints: BA5101 was shown to be able to quickly and stably reduce blood glucose and HbA1c levels which is comparable with Trulicity® in terms of efficacy, safety, and immunogenicity. In addition, the outcome of a Phase 1 clinical trial of BA5101 was also demonstrated to be highly similar to Trulicity® in pharmacokinetics, safety, and immunogenicity. The clinical results have been published in the journal of *Expert Opinion on Biological Therapy* published by *Taylor & Francis*.

The development of Dulaglutide biosimilars as fusion proteins faces significant CMC (Chemistry, Manufacturing and Controls) challenges. The Company has successfully resolved oxidation, truncation, charge heterogeneity and other challenges, and as a result, BA5101 is highly similar to Trulicity® in physicochemical property and bioactivity. This demonstrates the strong CMC capabilities and R&D management skills of the Company.

Preventing and controlling diabetes is challenging in both China and worldwide. Data from the International Diabetes Federation (IDF) shows that globally, 537 million people (aged 20-79) had diabetes in 2021, and the number is expected to reach 784 million by 2045. China had 141 million diabetic patients (aged 20-79) in 2021, more than any other country in the world, accounting for over a quarter of the total globally, which was projected to reach 174 million by 2045, posing an enormous challenge to the healthcare system.

Publicly available financial data shows that the global sales of Trulicity® in 2023 were approximately US\$7.13 billion.

Given 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. To enable patients worldwide to benefit from BA5102, the Company has expedited the submission of its BLA in China and has also started overseas registrations 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, 8 March 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 Mr. Shi Luwen, Mr. Dai Jixiong and Dr. Yu Jialin.