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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

ACCEPTANCE OF BLA IN CHINA FOR DULAGLUTIDE INJECTION (BA5101)

The board of directors (the “**Board**”) of Shandong Boan Biotechnology Co., Ltd. (the “**Company**”) announces that the biologics license application (“**BLA**”) for Dulaglutide Injection (“**BA5101**”) developed by the Company has been accepted by the Centre for Drug Evaluation of the National Medical Products Administration in the People’s Republic of China (“**China**”).

BA5101 is a biosimilar of Trulicity® for glycemic control in adults with type 2 diabetes. As far as the Company is aware, BA5101 is the first biosimilar of Trulicity® to have a BLA filed in China and the first biosimilar of Trulicity® in the world to have completed Phase 3 clinical trial and leading in development progress. In addition to China, the Company is also preparing to register the drug and conduct clinical trials overseas.

Dulaglutide is a long-acting glucagon-like peptide-1 (GLP-1) receptor agonist to be 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 is not prone to causing lower rate of hypoglycemia and can reduce weight gain, hyperlipidemia/blood lipids and long-term cardiovascular disease risks. It can also protect the kidney. Moreover, several clinical studies have shown that the once a week administration of Dulaglutide can reduce the inconvenience experienced by patients when taking medication, thereby improving adherence to the treatment plan.

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 clinical efficacy and safety of BA5101 with Trulicity® among Chinese adult patients 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 the Phase 1 clinical trial has shown that BA5101 is highly similar to Trulicity® in terms of 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.

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, 27 May 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.