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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

PATIENT ENROLLMENT COMPLETED FOR THE PHASE III CLINICAL STUDY OF BA5101 IN CHINA

The board of directors (the “**Board**”) of Shandong Boan Biotechnology Co., Ltd. (the “**Company**”, together with its subsidiaries, the “**Group**”) hereby announces that the Group’s in-house developed Dulaglutide Injection (“**BA5101**”) has completed the patient enrollment for its phase 3 clinical trial (a comparative study of efficacy and safety) in China.

BA5101 is a biosimilar of Trulicity® developed by the Group, for the treatment of adults with insufficiently controlled type 2 diabetes mellitus. This phase III clinical trial of BA5101 that has completed the patient enrollment is a randomized, open-label, parallel-group and positive-controlled clinical study that compares the clinical efficacy and safety of BA5101 with Trulicity® in Chinese adult patients with type 2 diabetes. It will further compare the efficacy, safety, immunogenicity and pharmacokinetic (“**PK**”) characteristics of BA5101 with Trulicity® after multiple subcutaneous injections in Chinese adult patients with type 2 diabetes.

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 pancreatic islet beta cells function, stably and effectively reduce blood glucose and HbA1c levels. In addition, due to its unique mechanism of action, Dulaglutide can simultaneously improve multiple risk factors for cardiovascular diseases such as weight gain, hyperlipidemia/ blood lipids and long-term cardiovascular disease risks, and is not prone to causing lower hypoglycemia rate. It also has a protective effect on the kidney. Moreover, several clinical studies have shown that patients taking Dulaglutide once a week have higher compliance because of the convenience of use.

The development of BA5101 follows the guidelines for biosimilars in China, the United States, Europe, etc. The completed preclinical comparative studies show that BA5101 is highly similar to Trulicity® in terms of physicochemical properties and biological activities. As a fusion protein, the development of Dulaglutide biosimilars is difficult in terms of chemistry, manufacturing and control (CMC). The Group has overcome the technical problems such as oxidation, truncation and complex charge heterogeneity of Dulaglutide. The results of the completed phase I clinical trial in China show that BA5101 has highly similar PK characteristics, safety and immunogenicity with Trulicity®, indicating that it has clinical similarity with the reference product. The clinical results have been published in the journal of *Expert Opinion on Biological Therapy* published by Taylor & Francis.

At present, the situation of diabetes prevention and control has been reported to be severe in China and even around the world. According to latest data released by the International Diabetes Federation (IDF), in 2021, there were 537 million adult diabetes patients worldwide (aged 20-79), and this number is expected to grow to 643 million and 784 million in 2030 and 2045, respectively. In 2021, China had around 141 million adult diabetes patients (aged 20-79), and it is estimated that 164 million and 174 million adults in China will have diabetes by 2030 and 2045, respectively.

According to publicly available data, Trulicity® had global sales of USD7.44 billion in 2022, representing an increase of around 15% since 2021.

The Company believes that BA5101 will have broad market prospects on a global scale, driven by a combination of factors such as large clinical unmet need and clear clinical value.

Cautionary statement under Section 18A.05 of the Rules Governing the listing of Securities on The Stock Exchange of Hong Kong Limited: There can be no assurance that we will ultimately be successful in developing and marketing BA5101. Shareholders and potential investors of the Company are advised to exercise caution when dealing in shares of the Company.

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

Hong Kong, 15 May 2023

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, Ms. Li Li and Mr. Chen Jie; and the independent non-executive directors of the Company are Mr. Shi Luwen, Mr. Dai Jixiong and Dr. Yu Jialin.