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

FIRST SUBJECT ENROLLED IN INTERNATIONAL MULTI-CENTER PHASE 3 CLINICAL STUDY OF DENOSUMAB

The board of directors (the "**Board**") of Shandong Boan Biotechnology Co., Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that it has initiated an international multi-center phase 3 clinical study in Europe, the United States, and Japan for the Company's in-house developed Denosumab Injection (BA6101 and BA1102), and recently the first patient in (FPI) has been enrolled.

BA6101 and BA1102 are biosimilar products to Prolia® and Xgeva®, respectively. Prolia® has been approved worldwide for the following indications: (1) Treatment of postmenopausal women with osteoporosis at high risk for fracture. In postmenopausal women, Prolia® significantly reduces the risk of vertebral, non-vertebral, and hip fractures; (2) Treatment to increase bone mass in men with osteoporosis at high risk for fracture; (3) Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture; (4) Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer; (5) Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. Xgeva® has been approved worldwide for the following indications: (1) Prevention of skeletal-related events in patients with bone metastases from solid tumors; (2) Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity; (3) Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

This international multi-center Phase 3 study is a randomized, double-blind, parallel-group, reference-controlled comparative study to evaluate the efficacy, safety, pharmacokinetics, and immunogenicity of the Company's biosimilar product compared with the reference product. According to the *Guidance for Industry Scientific Considerations in Demonstrating Biosimilarity to a Reference Product* issued by the United States Food and Drug Administration ("**FDA**"), the *Guideline on similar biological medicinal products* issued by European Medicines Agency ("**EMA**"), the *Guideline for the Quality, Safety, and Efficacy Assurance of Follow-on Biologics* issued by Japanese Pharmaceuticals and Medical Devices Agency ("**PMDA**") and based on the discussions with FDA, EMA and PMDA, after completion of the Phase 3 clinical study, BA6101 and BA1102 can apply for approval for all same indications as Prolia® and Xgeva® in Europe, the United States, and Japan.

Previously, BA6101 ("**Boyoubei®**") was approved for marketing in China in November 2022, as the first approved Prolia® biosimilar in the world as far as the Company is aware. The results of the two Phase 1 clinical studies of Boyoubei® were published in *Expert Opinion on Investigational Drugs and Frontiers in Pharmacology*, respectively. Additionally, Boyoubei®'s Phase 3 clinical study was published in *Journal of Orthopaedic Translation*. BA1102's Biologics License Application was also accepted by the Center for Drug Evaluation of the National Medical Products Administration of China in March 2023.

According to publicly available data, Prolia® and Xgeva® had global sales of $3.63 billion and $2.01 billion, respectively, in 2022.

The Company believes that BA6101 and BA1102 will have broad market prospects on a global scale, driven by a combination of factors such as large patient demand and good clinical value.

Cautionary statement under Section 18A.05 of the Listing Rules of the Stock Exchange of Hong Kong Limited: There can be no assurance that we will ultimately be successful in developing and marketing BA6101 and BA1102. 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

The People's Republic of China, Yantai, 4 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.