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

ENROLLMENT OF SUBJECTS COMPLETED FOR INTERNATIONAL MULTI-CENTER COMPARATIVE CLINICAL (PHASE 3) STUDY OF DENOSUMAB INJECTION

The board of directors (the "**Board**") of Shandong Boan Biotechnology Co., Ltd. (the "**Company**") announces that it has completed the enrollment of subjects for an international multi-center comparative clinical (Phase 3) study in Europe, the United States, and Japan for the Company's in-house developed Denosumab Injection (BA6101 and BA1102).

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; (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; and (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 multiple myeloma and 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; and (3) treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

This international multi-center comparative clinical (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 Prolia®. 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 the European Medicines Agency ("**EMA**") and the *Guideline for the*

Quality, Safety, and Efficacy Assurance of Follow-on Biologics issued by the Japanese Pharmaceuticals and Medical Devices Agency ("**PMDA**") and based on the Company's discussions with the FDA, EMA and PMDA, after completion of the Phase 3 clinical study, the Company can submit Biologics License Applications ("**BLAs**") for BA6101 and BA1102 for all the approved indications as Prolia® and Xgeva® in the United States, Europe, and Japan, respectively.

In addition, a 3-arm pharmacokinetic similarity clinical (Phase 1) study recently completed in Europe compared among BA6101, original products from the European Union and the United States. The results demonstrate that BA6101 has similar pharmacokinetics, pharmacodynamic, safety and immunogenicity to Prolia® supplied from the European Union and the United States, and that the study met all its clinical endpoints.

Previously, BA6101 (Boyoubei®) was approved for marketing in China in November 2022, as the first Prolia® biosimilar to receive approval in China. The results of the two pharmacokinetic similarity (Phase 1) studies of Boyoubei® in China and one comparative clinical (Phase 3) study were published in *Expert Opinion on Investigational Drugs*, *Frontiers in Pharmacology* and *Journal of Orthopaedic Translation*, respectively. BA1102's BLA 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 US$3.63 billion and US$2.01 billion, respectively, in 2022.

The Company believes that BA6101 and BA1102 have broad market prospects on a global scale, driven by a combination of factors such as large clinical demand, good clinical value and the Company's leading development progress.

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, 4 January 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.