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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 THE GROUP'S DENOSUMAB INJECTION (BA1102) FOR THE ONCOLOGY INDICATIONS

The board of directors (the "**Board**") of Shandong Boan Biotechnology Co., Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that the biologics license application ("**BLA**") for the denosumab monoclonal antibody injection ("**BA1102**") developed by the Group has been accepted by the Centre for Drug Evaluation of the National Medical Products Administration in the People's Republic of China ("**China**").

BA1102 is a biosimilar of XGEVA®. Its active ingredient is denosumab, a fully human IgG2 anti-RANKL monoclonal antibody. Denosumab binds to RANKL and it inhibits the activation of OPG/RANKL/RANK signaling pathways, and thus inhibits tumor growth and reduces bone destruction. BA1102 is indicated for the treatment of patients with bone metastases from solid tumors and patients with multiple myeloma, to delay or reduce the risk of skeletal-related events ("**SREs**") (e.g. pathologic fractures, spinal cord compression, bone radiotherapy or bone surgery). The drug is also indicated for the treatment of adults and skeletally mature adolescents (defined as having at least one mature long bone and with body weight of 45 kg or above) with giant cell tumor of bone ("**GCTB**") that is unresectable or where surgical resection is likely to result in severe morbidity.

The development of BA1102 follows the relevant development guidelines for biosimilars, through a series of step-by-step comparative analytical, non-clinical, human pharmacokinetics, and clinical studies which scientifically, rigorously and completely prove the overall similarity between BA1102 and the original reference drug such that the quality, safety and efficacy of the two drugs are highly similar, and there is no clinically meaningful difference between them. Two key clinical studies of BA1102 versus the reference product reached all the endpoints: (1) the study comparing their pharmacokinetics ("**PK**"), pharmacodynamics ("**PD**"), safety, tolerability, and immunogenicity in healthy subjects proved that BA1102 is bioequivalent to the reference product in terms of PK and PD; (2) the study comparing their efficacy and safety in patients with bone metastases from solid tumors proved that BA1102 is highly similar to the reference product in terms of efficacy, safety, and immunogenicity.

There are a large number of patients with bone metastases from solid tumors, and the subsequent SREs such as pathologic fractures and spinal cord compression seriously compromise their quality of life. Patients with multiple myeloma also have a higher risk of SREs. GCTB is locally aggressive, and has a propensity for local recurrence and distant metastases, which can become life-threatening in severe cases. Denosumab injection provides an effective therapy for these diseases.

Denosumab has been clinically applied for more than 10 years with abundant clinical evidence. It has been recommended by multiple guidelines in China and abroad, including those from American Society of Clinical Oncology (ASCO), European Society of Medical Oncology (ESMO), National Comprehensive Cancer Network (NCCN), and Chinese Society of Clinical Oncology (CSCO). In addition to specific chemotherapies and targeted therapies for primary tumors, a number of principal Chinese and foreign guidelines also recommend the use of denosumab as a first-line therapy to prevent or delay the occurrence of SREs in patients with bone metastases from solid tumors and those with multiple myeloma. Furthermore, denosumab is currently a preferred treatment for GCTBs that cannot be resected or the surgical resection of which is likely to result in severe morbidity.

In accordance with Frost & Sullivan industry reports, the market size of XGEVA® and its related biosimilars in China is expected to grow to about RMB2.84 billion by 2030.

The Company believes that BA1102 will have broad market prospects on a global scale, driven by many factors such as patient demand and high clinical value.

Warning under Rule 18A.05 of the Rules Governing the Listing of Securities on the Stock Exchange of Hong Kong Limited: There is no assurance that BA1102 will ultimately be successfully marketed by the Company. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the 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, 21 March 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.