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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

DENOSUMAB INJECTION (BOLUOJIA®) FOR ONCOLOGY INDICATIONS APPROVED FOR MARKETING BY NMPA

The board of directors (the “**Board**”) of Shandong Boan Biotechnology Co., Ltd. (the “**Company**”) announces that Boluojia®, a denosumab injection (120mg) developed by the Company, has been approved for marketing by the National Medical Products Administration (“**NMPA**”) in the People’s Republic of China (“**China**”) for the treatment of giant cell tumor of bone (“**GCTB**”) that is unresectable or where surgical resection is likely to result in severe morbidity in adults and skeletally mature adolescents (defined as having at least one mature long bone and with body weight≥45 kg).

Boluojia® is a biosimilar to XGEVA®. The development of Boluojia® strictly followed relevant guidelines of biosimilars in China, the U.S., the EU, and Japan, and its overall similarity with the reference product has been proven with comprehensive evidence from step-by-step comparative analytical, non-clinical, human pharmacokinetics and clinical efficacy studies. In particular, Boluojia® is shown to be highly similar to the reference product in terms of quality, safety, and efficacy, with no clinically meaningful differences between the two. Two pivotal clinical studies comparing Boluojia® to XGEVA® head-to-head were completed in China. The results of Phase 1 clinical trial were published in the international journal named *Journal of Bone Oncology*, and the results of Phase 3 clinical trial were presented at the 2023 Annual Meeting of the American Society of Clinical Oncology (ASCO) in the form of a poster. At the same time, the Company is working on the Biologics License Application (“**BLA**”) of Boluojia® in China for the indications of bone metastases from solid tumors and multiple myeloma.

Outside the Chinese market, the Company is actively advancing international clinical trials and registration of Boluojia[®]. The Phase 1 clinical trial conducted in Europe has been completed, while enrollment of all subjects in the international multi-center Phase 3 clinical trial in Europe, the U.S., and Japan has also been completed. Following the completion of these trials, Boan Biotech plans to submit BLA for Boluojia[®] to the European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA), and the Japan's Pharmaceuticals and Medical Devices Agency (PMDA), with the intention of marketing the product in more countries and regions worldwide.

GCTB is a primary borderline bone tumor that accounts for 13.7% to 17.3% of all primary bone tumors in China. GCTB is locally aggressive, and has a propensity for local recurrence and distant metastases, which can be life-threatening in severe cases. For patients whose tumor can be surgically resected, denosumab can help achieve surgical downgrading or even avoid surgery. For patients whose tumor can't be surgically resected, denosumab can effectively control it for prolonged periods and improve their quality of life. In addition to GCTB, XGEVA[®] has also been approved in many countries for the treatment of bone metastases from solid tumors, multiple myeloma, and hypercalcemia of malignancy. Denosumab has been clinically applied for more than 10 years with abundant clinical evidence. It is recommended by multiple authoritative guidelines in China and abroad, including European Society of Medical Oncology (ESMO), National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO), and Chinese Society of Clinical Oncology (CSCO).

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

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.