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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

BOLUOJIA® (DENOSUMAB INJECTION) NEWLY APPROVED IN CHINA FOR TREATING BONE METASTASES FROM SOLID TUMORS AND MULTIPLE MYELOMA

The board of directors (the “**Board**”) of Shandong Boan Biotechnology Co., Ltd. (the “**Company**”) announces that China’s National Medical Products Administration (NMPA) has approved the supplemental application for Boluojia® (denosumab injection 120 mg) for the treatment of patients with bone metastases from solid tumors or multiple myeloma, to delay or reduce the risk of skeletal-related events (SREs), which include pathological fractures, spinal cord compression, and bone-directed radiation or surgery.

Boluojia® is a biosimilar of Xgeva®, developed independently by the Company as part of its global strategy. The product was first approved in China in May 2024 for the treatment of giant cell tumor of bone (GCTB). The Company is also accelerating the launch of Boluojia® in more countries and regions worldwide.

Bone metastasis is one of the most common sites for the metastasis of malignancies. Over 80% of bone metastases originate from breast, prostate, lung, thyroid, and kidney tumors. SREs such as pathological fractures and spinal cord compression are common complications of bone metastasis that significantly reduce patients’ quality of life and compromise their clinical prognosis. Furthermore, over 80% of patients with multiple myeloma, the second most common and currently incurable hematologic malignancy, will develop myeloma bone disease, which significantly undermines patient survival and quality of life.

The active ingredient of Boluojia® is denosumab, a fully human IgG2 anti-RANKL monoclonal antibody. Denosumab inhibits osteoclast formation, function, and survival by blocking the RANKL-RANK interaction, thereby effectively preventing and reducing the risk of SREs. As the drug is not subject to renal clearance, no dose adjustment is required for patients with renal impairment. Furthermore, it can be conveniently administered via subcutaneous injection. Supported by robust clinical evidence, denosumab is recommended as a first-line therapy for reducing or delaying SREs by multiple authoritative guidelines, including the European Society for Medical Oncology (ESMO), the National Comprehensive Cancer Network (NCCN), and the Chinese Society of Clinical Oncology (CSCO).

The Company developed Boluojia[®] strictly in accordance with the relevant biosimilar guidelines of China, the U.S., the EU, and Japan. Its similarity to the reference product Xgeva[®] has been demonstrated through a series of studies, including pharmaceutical, non-clinical, human pharmacokinetic, and clinical studies. In particular, Boluojia[®] has been shown to be highly similar to the reference product in terms of quality, efficacy, safety, and immunogenicity, with no clinically meaningful differences. The results of two pivotal clinical studies in China comparing Boluojia[®] with the reference product were published in the Journal of Bone Oncology, and the results of a Phase III clinical trial were presented as a poster at the 2023 Annual Meeting of the American Society of Clinical Oncology (ASCO).

Given the strong patient demand for denosumab and its well-established value in clinical practice, denosumab demonstrates broad and promising market prospects worldwide. Publicly available data show that global sales of Xgeva[®] in 2025 were approximately USD2.084 billion, of which approximately USD306 million was generated in China, representing a year-on-year increase of 36.4% from 2024.

An International multicenter Phase III clinical trial has been completed for Boluojia[®] in Europe, the U.S., and Japan, and the marketing authorization application (MAA) for the drug in the U.K. is under review. The Company further plans to submit relevant marketing applications for this drug in the U.S., the EU, Japan, and other high-potential international markets.

The Company adopts a two-pronged approach to commercialize Boluojia[®]: in-house sales & marketing + partnership building. In the Chinese mainland, the Company has an experienced sales & marketing team and a robust sales network spanning over 3,000 hospitals and other medical facilities. With the approval of this new indication, Boluojia[®] will complement the oncology portfolio of the Company, which includes Boyounuo[®] (bevacizumab injection), and strengthen the Company's presence in this therapeutic area. In Hong Kong and Macao, the Company has partnered with Kexing Biopharm Co., Ltd. (Kexing Biopharm) to commercialize Boluojia[®]. Overseas, the Company is expanding the footprint of the drug through partnerships. Specifically, the Company has granted Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd. (NKF) exclusive rights to commercialize Boluojia[®] in the U.S., and has partnered with Shanghai Pharmaceutical Co., Ltd. (Shaphar) to promote the drug in certain Southeast Asian countries and with PHARMACARE to promote the drugs in certain Latin American countries.

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, 26 May 2026

As at the date of this announcement, the executive directors of the Company are Ms. Jiang Hua and Mr. Wang Shenghan; the non-executive directors of the Company are Mr. Liu Yuanchong, Ms. Li Li and Mr. Li Shixu; and the independent non-executive directors of the Company are Professor Shi Luwen, Mr. Dai Jixiong and Dr. Yu Jialin.