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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

FIRST PATIENT ENROLLED IN PHASE III CLINICAL TRIAL OF NIVOLUMAB INJECTION (BA1104) IN CHINA

The board of directors (the “**Board**”) of Shandong Boan Biotechnology Co., Ltd. (the “**Company**”, together with its subsidiaries, the “**Group**”) announces that the first patient in phase III clinical trial of the Group’s Nivolumab Injection (“**BA1104**”) in China has been enrolled. BA1104 is the first biosimilar to Opdivo® to undergo a Phase III study in China.

Nivolumab is a monoclonal antibody that can enhance the immune response of T cells against tumors by preventing the programmed cell death 1 (PD-1) receptor from binding to its ligands PD-L1 and PD-L2. As a broad-spectrum anticancer medication, Nivolumab has been approved for multiple indications both in China and abroad. These include its use as a neoadjuvant, an adjuvant, or a first-line or later-line therapy for advanced cancers. It can be used as a standalone treatment, in combination with chemotherapy, or alongside novel immune checkpoint inhibitors. Nivolumab has become a product of basic therapy for a variety of solid tumors.

The development of BA1104 follows the relevant guidelines for biosimilars. Pre-clinical studies show that BA1104 is highly similar to Opdivo® in pharmaceutical and non-clinical activities. The results of the completed phase I clinical trial support a demonstration of biosimilarity to Opdivo® in terms of pharmacokinetics (PK), safety, and immunogenicity, and all study endpoints were met. The phase III clinical trial is a randomized, double-blind, multicenter study designed to compare the efficacy, safety, and immunogenicity of BA1104 and Opdivo® combined respectively with chemotherapy in patients with advanced or metastatic esophageal squamous cell carcinoma. According to the *Guidelines on Similarity Evaluations and Indication Extrapolation of Biosimilars*, after the completion of the phase III clinical trial, BA1104 can apply and be approved for all the same indications as Opdivo® in China.

Immunotherapies such as PD-1 inhibitors have become one of the primary treatments for different types of cancer worldwide, and have consistently demonstrated clinical value and potential in the marketplace. Publicly available data shows that Opdivo[®], the first approved PD-1 inhibitor in the world, achieved global sales of approximately USD8.249 billion in 2022. Frost & Sullivan predicts that the market for anti-PD-1/L1 antibodies in China will reach RMB29.8 billion by 2025, with a compound annual growth rate of 63.4% from 2018 to 2025.

The Company believes that BA1104 will have broad market prospects, driven by a combination of factors such as large unmet clinical needs and clear clinical value. In the meantime, the Company will also explore the product's potential to combine with other innovative antibodies in its pipeline such as BA1106 (a novel immune checkpoint inhibitor), BA1301 (an antibody-drug conjugate or ADC), and BA1202 (a CD3/CEA bispecific antibody). The Company believes that this will further enhance the Company's pipeline.

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, 30 October 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.