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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

THE ENROLLMENT FOR PHASE III TRIAL OF THE COMPANY'S NIVOLUMAB INJECTION HAS BEEN COMPLETED IN CHINA

The board of directors (the “**Board**”) of Shandong Boan Biotechnology Co., Ltd. (the “**Company**”) announces that patient enrollment has been completed for a Phase III clinical trial of its nivolumab injection code-named BA1104 in the People's Republic of China (“**China**”). This is China's first biosimilar of Opdivo® to advance into a Phase III clinical trial.

Nivolumab is a humanized monoclonal antibody of the IgG4 subtype targeting the programmed death-1 (“**PD-1**”) receptor. By blocking the interaction between the PD-1 receptor and its two ligands PD-L1 and PD-L2, this antibody enhances T-cell-mediated anti-tumor responses and thereby acts as a broad-spectrum anti-cancer therapy. Since it was approved in 2014 as the world's first PD-1 inhibitor, Opdivo® has been approved for multiple indications in dozens of countries and regions involving different types of cancer. In clinical practice, it has been used across different stages of cancer treatment as neoadjuvant or adjuvant therapy and as first-line as well as later-line treatment for advanced tumors. The drug can be administered as monotherapy or in combination with chemotherapy or other immune checkpoint inhibitors.

BA1104 is developed in accordance with the relevant guidelines for biosimilars. The Phase III clinical trial conducted in China is a randomized, double-blind, multicenter study designed to compare the efficacy, safety, and immunogenicity of BA1104 plus chemotherapy versus Opdivo® plus chemotherapy in patients with advanced or metastatic esophageal squamous cell carcinoma. In accordance with the Guidelines on Similarity Evaluation and Indication Extrapolation of Biosimilars issued by China's Center for Drug Evaluation of the National Medical Products Administration (“**NMPA**”), the Company may submit an application to the NMPA for the approval of BA1104 for all indications that Opdivo® has obtained in China after completing its Phase III clinical trial. The results of a Phase I clinical trial show that BA1104 is highly comparable to Opdivo® in terms of pharmacokinetics, safety, and immunogenicity, meeting all the clinical endpoints. The related results have been published in the international journal BioDrugs.

Immunotherapies represented by PD-1 inhibitors have become one of the mainstays in cancer treatment. With continuous breakthroughs in combination therapy regimens and the synergistic development of diverse immunotherapies, the clinical applications of PD-1 inhibitors continue to expand, demonstrating broad clinical value and market potential. Publicly available data show that the worldwide sales of Opdivo® were approximately USD 9.3 billion in 2024. According to a Frost & Sullivan report, the size of the Chinese market for PD-1 inhibitors and PD-L1 inhibitors is expected to reach RMB59.9 billion by 2030.

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, 30 October 2025

As at the date of this announcement, the executive directors of the Company are Ms. Jiang Hua, Dr. Dou Changlin 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.