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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

COMPLETION OF PHASE 3 TRIAL OF BA1104 (NIVOLUMAB) IN CHINA, WITH PRIMARY ENDPOINT MET

The board of directors (the "**Board**") of Shandong Boan Biotechnology Co., Ltd. (the "**Company**") announces that the Phase 3 clinical trial in China of its PD-1 inhibitor BA1104 (nivolumab injection) has been completed and has met its primary endpoint. The Company will shortly submit a marketing authorization application for the product to China's National Medical Products Administration (NMPA). BA1104 is the first biosimilar to Opdivo® to have completed a Phase 3 clinical trial in China. Based on China's Technical Guidelines for Similarity Evaluation and Indication Extrapolation of Biosimilars, the Company intends to seek approval for the indications for which Opdivo® has been approved in China.

Nivolumab is a fully human monoclonal antibody of the IgG4 subtype targeting the programmed death-1 (PD-1) receptor. It blocks PD-1 from binding to its ligands PD-L1 and PD-L2, enhancing T-cell antitumor responses, and is a cornerstone of cancer immunotherapy. Publicly available information shows that Opdivo® has been approved for multiple indications across a range of tumor types in dozens of countries and regions worldwide. Its clinical use extends across all stages of cancer treatment, including preoperative neoadjuvant therapy, postoperative adjuvant therapy, and first-line and later-line treatment of advanced cancer. Treatment regimens include monotherapy, combinations with chemotherapy, and combinations with novel immune checkpoint inhibitors. In 2025, global sales of Opdivo® reached US$10.049 billion, an increase of 8% year over year.

BA1104 has been developed in accordance with relevant biosimilar guidelines in China, the United States, Europe and Japan. The Phase 3 clinical trial was a randomized, double-blind, multicenter study designed to compare the efficacy and safety of BA1104 and Opdivo®, each in combination with chemotherapy, in patients with advanced or metastatic esophageal squamous cell carcinoma.

The Phase 3 clinical study met its prespecified primary endpoint. The results showed that the confidence interval for the objective response rate (ORR) ratio between BA1104 and the reference product fell entirely within the prespecified equivalence margins, demonstrating equivalence between the two. The independent central imaging review results showed good agreement with investigator assessments. Results for secondary efficacy endpoints, including disease control rate (DCR), progression-free survival (PFS), and overall survival (OS), were highly similar between the two groups, with no clinically meaningful differences in efficacy observed. In terms of safety, BA1104 demonstrated a favorable overall safety and tolerability profile, and the two products had highly similar safety profiles. Positivity rates for anti-drug antibodies (ADA) and neutralizing antibodies (NAb) were low and comparable between the two groups, indicating similar immunogenicity.

The Company previously completed comparative analytical and nonclinical studies of BA1104 and Opdivo®, and conducted a randomized, double-blind, single-dose Phase 1 clinical study in healthy Chinese male volunteers to evaluate the pharmacokinetic (PK) profiles, safety, and immunogenicity of the two products. The 90% confidence intervals for the geometric mean ratios of $AUC_{0-\infty}$, AUC_{0-t}, and C_{max} all fell within the prespecified range of 80.00%-125.00%, confirming that their PK profiles were highly similar. The study results have been published in the international journal BioDrugs. In the Phase 1 clinical study, ADA and NAb positivity rates were comparable between the two products, indicating similar immunogenicity.

In addition to China, the Company is actively expanding the overseas presence of BA1104. The Company previously held a Biosimilar Biological Product Development (BPD) Type 2b meeting with the U.S. Food and Drug Administration (FDA), at which the FDA agreed to a "streamlined" clinical development strategy under which only a single PK similarity study (a Phase 1 trial) would be required to support submission of a Biologics License Application (BLA), without the need for a Phase 3 clinical trial. In addition, the Company plans to pursue registration and marketing of BA1104 in more countries and regions.

PD-1 inhibitors are a cornerstone of current cancer immunotherapy. In addition to its BA1104 biosimilar development program, the Company is actively exploring the therapeutic potential of combining it with the Company's proprietary novel antibodies. Through its "immuno-oncology + antibody-drug conjugates (IO + ADC)" development strategy, the Company is building a differentiated pipeline of innovative therapies and exploring new approaches that balance efficacy and safety while addressing drug resistance more effectively, with the aim of achieving new breakthroughs in cancer treatment.

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, 17 November 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.