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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 CDE ACCEPTANCE OF PHASE II CLINICAL TRIAL APPLICATION FOR BA1106 IN COMBINATION WITH BA1104 FOR NSCLC

The board of directors (the “**Board**”) of Shandong Boan Biotechnology Co., Ltd. (the “**Company**”) announces that China’s Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) has accepted the Company’s application for a Phase II clinical trial of its proprietary anti-CD25 antibody (code-named BA1106) in combination with its PD-1 inhibitor (a nivolumab injection code-named BA1104) as first-line or second-line regimens for non-small cell lung cancer (NSCLC).

The Phase II clinical trial is a multicenter, single-arm, open-label study designed to evaluate the efficacy, safety, and pharmacokinetic (PK) profile of BA1106 in combination with BA1104 in patients with driver gene-negative NSCLC.

Lung cancer remains one of the most prevalent malignancies in the world, and NSCLC accounts for 85% to 90% of all cases. Among NSCLC patients, approximately 40% to 50% are driver gene-negative, and their incidence is steadily increasing. Although the advent of immune checkpoint inhibitors (ICIs) has significantly benefitted patients, most patients will eventually develop drug resistance. For them, the lack of effective treatment options following disease progression is a broad unmet need.

Present across various solid tumors, regulatory T cells (Tregs) are critical immunosuppressive components of the tumor microenvironment, where high infiltration typically correlates with poor prognosis. As such, targeting Tregs has become a focal point of next-generation cancer immunotherapy. BA1106 is China’s first investigational non-IL-2 – blocking anti-CD25 (IL-2R α) antibody to undergo a clinical trial for the treatment of solid tumors. With “moderate” ADCC activity and a unique binding epitope design, BA1106 selectively targets CD25-overexpressing Tregs. While depleting Tregs, it expands Teff cell populations and preserves IL-2 signaling, thereby enhancing anti-tumor immune responses and demonstrating potential for the treatment of multiple solid tumors.

In the Phase I clinical trial, the combination of BA1106 and BA1104 showed encouraging efficacy signals in patients with lung adenocarcinoma, squamous cell lung cancer, and gastric cancer, and all of them had previously experienced disease progression on ICIs. Furthermore, BA1106 demonstrated a favorable safety and tolerability profile as a monotherapy or in combination with BA1104. Most treatment-related adverse events were mild (Grades 1–2). During dose escalation, no dose-limiting toxicities (DLTs) were observed, and the maximum tolerated dose (MTD) was not reached at dose level up to 1.2 mg/kg. These results are encouraging for subsequent clinical studies.

BA1106 enables precise Treg modulation and efficacy-safety balance with an enhanced anti-tumor immune response. The Phase I clinical trial already demonstrated the potential of BA1106 used in combination with a PD-1 inhibitor, as encouraging signals were observed across multiple tumor types. The Company will speed up the Phase II clinical trial of the combination therapy for treating NSCLC, targeting both treatment-naïve patients and those who have experienced disease progression following prior immunotherapy. In addition, the Company will also explore this combination therapy in other high-incidence solid tumors, including gastric cancer, in an effort to deliver better outcomes for patients.

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 April 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.