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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

APPROVAL OBTAINED FOR INITIATING CLINICAL TRIAL FOR THE NOVEL BISPECIFIC ANTIBODY BA1202 IN CHINA

The board of directors (the “**Board**”) of Shandong Boan Biotechnology Co., Ltd. (the “**Company**”, together with its subsidiaries, the “**Group**”) announces that BA1202 (“**BA1202**”), a novel bi-specific antibody (“**bispecific antibody**”) drug for injection developed independently by the Group, has been approved for clinical trials by the Center for Drug Evaluation (“**CDE**”) of the National Medical Products Administration of the People’s Republic of China (“**China**”) for the treatment of solid tumors, including CEA-positive tumors such as advanced/metastatic colorectal cancer, non-small cell lung cancer (“**NSCLC**”), pancreatic cancer, and gastric cancer.

CD3 bispecific antibodies are an important direction for the development of innovative cancer immunotherapies. They function by recruiting CD3+ T cells to target tumors. As a bispecific T-cell engager (BiTE), they can bind to both CD3 antigens on the T cell surface and tumor-associated antigens. This enables them to bring T cells to tumor cells and stimulate the release of granzymes and perforin from T cells, which in turn lead to the killing of tumor cells. In addition, CD3 bispecific antibodies can enhance the sensitivity of immunotherapy as they can help turn cold tumors into hot ones by increasing immune cells infiltration into tumor tissues. This characteristic indicates their potential for use in combination with immune checkpoint inhibitors such as PD-L1 antibodies for enhanced efficacy. CEACAM5 (“**CEA**”) is widely expressed on the cell surface of many epithelial tumors, such as colorectal cancer, NSCLC, pancreatic cancer, and gastric cancer, but is expressed less in normal tissues, making it a potential target for tumor-targeted therapy.

BA1202 is a CEA/CD3 bispecific antibody that binds to both CD3 on T cells and CEA on tumor cells, enabling the linking of T cells with tumor cells to facilitate tumor killing.

BA1202 adopts a new butterfly-shaped antibody structure, with one end binding bivalently with high affinity to CEA on tumor cells, and the other end binding monovalently with relatively low affinity to CD3 on T cells, while retaining the Fc region. Such a design enables it to reduce the risk of cytokine release syndrome (“CRS”) while retaining good efficacy through activating endogenous T cells to eliminate CEA-positive tumor cells.

Pre-clinical studies showed that BA1202 exhibited excellent killing activity against CEA-positive tumor cells. In the colorectal cancer model in mouse, it completely eradicated tumors, and showed a good dose-effect relationship which demonstrated the anti-tumor effect even at a low dose of 0.1 mg/kg. BA1202 also demonstrated good safety in a repeat-dose toxicity study in transgenic mice. Compared to other CEA/CD3 antibodies being developed abroad, BA1202 demonstrated more potent anti-tumor activity both *in vivo* and *in vitro*. Moreover, compared to single agent use, BA1202 demonstrated enhanced *in vivo* anti-tumor effects when used in combination with PD-L1 antibodies. The results of the study have been published in *Antibody Therapeutics*.

BA1202 is used for the treatment of malignant tumors such as colorectal cancer in which CEA is widely expressed. The Company believes that BA1202, if successfully developed, will provide an effective treatment regimen for these patients.

Cautionary statement under Section 18A.05 of the Rules Governing the listing of Securities on The Stock Exchange of Hong Kong Limited: There can be no assurance that we will ultimately be successful in developing and marketing BA1202. Shareholders and potential investors of the Company are advised to exercise caution when dealing in shares of the Company.

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, 16 May 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.