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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

APPROVAL OBTAINED FOR INITIATING CLINICAL TRIAL FOR THE INNOVATIVE ADC CANDIDATE BA1301 FOR INJECTION IN CHINA

The board of directors (the “**Board**”) of Shandong Boan Biotechnology Co., Ltd. (the “**Company**”, together with its subsidiaries, the “**Group**”) announces that BA1301 for injection, an antibody-drug conjugate (“**ADC**”) candidate developed by the Group, has obtained the approval from the Centre for Drug Evaluation (“**CDE**”) of the National Medical Products Administration in the People’s Republic of China (“**China**”) to initiate clinical trials for the treatment of advanced solid tumors with Claudin 18.2 expression.

BA1301 for injection is the Group’s first novel ADC candidate that targets Claudin 18.2. It employs a site-specific conjugation technology to connect the cytotoxic payload with a monoclonal antibody that targets Claudin 18.2. This enables the cytotoxic payload to be directed to the tumor site through the targeting characteristics of the antibody. Such design reduces the toxic side effects of the cytotoxic payload, thus improving the therapeutic window, while retaining its tumor-killing effect.

The completed preclinical efficacy studies show that BA1301 for injection has excellent internalization activity and bystander killing effect, and demonstrates significant inhibitory effect on tumor growth in tumor models with different expression levels of Claudin 18.2 *in vitro* and *in vivo*. The completed preclinical pharmacokinetic and toxicological studies show that BA1301 for injection has a good safety profile, tolerability and stability in animals with no significant free cytotoxic payload released in plasma.

Based on the data from the World Health Organization's International Agency for Research on Cancer, the incidence of gastrointestinal tumors was more serious among the new cancer cases in China during 2020. Among them, gastric cancer is the third prevalent malignant cancer in China. The number of new cases and deaths of gastric cancer in China was around 480,000 and 370,000 respectively in 2020, accounting for nearly half of the new cases and deaths of this disease worldwide; pancreatic cancer is said to be one of the deadliest cancers because of its highly invasive biological characteristics, which is another difficult problem in clinical diagnosis and treatment. The number of new cases and deaths of pancreatic cancer in China was both over 120,000 in 2020. Due to the insidious early symptoms of gastric and pancreatic cancer, most patients are already in the middle or late stages when they are diagnosed. The prognosis of advanced gastric cancer and pancreatic cancer is very poor and palliative systemic chemotherapy of low efficacy is generally the main therapy for such cancers, but the overall treatment effect is still not satisfactory, and it has limited options for back-line treatment. In addition, systemic chemotherapy has low specificity, which often causes serious toxic side effects, making it impossible to obtain satisfactory clinical benefits. Therefore, new targeted therapeutics are needed to improve the outcomes. Claudin 18.2 protein is a transmembrane protein involved in the regulation of tight junctions between cells, and can be consistently and stably expressed to a high degree in gastrointestinal tumors. It was reported that 70% of gastric cancer patients, 50% of pancreatic cancer patients, and 30% of esophageal cancer patients express Claudin 18.2; at the same time, Claudin 18.2 protein is mainly expressed in the human epithelial cells and has high tissue specificity. Therefore, the drug candidate targeting Claudin 18.2 has high anti-tumor potential.

BA1301 for injection is expected to improve the treatment effects of gastric adenocarcinoma/gastroesophageal junction adenocarcinoma, pancreatic cancer and other tumors with Claudin 18.2 expression, providing patients with new treatment options. The Company believes that BA1301 for injection will have broad market prospects based on the huge clinical demand of patients with gastric cancer and pancreatic cancer.

Warning under Rule 18A.05 of the Rules Governing the Listing of Securities on the Stock Exchange of Hong Kong Limited: There is no assurance that BA1301 for injection will ultimately be successfully marketed by the Company. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the shares of the Company.

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, 9 January 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 Dr. Li Youxin, Mr. Liu Yuanhong, 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.