# 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

## Both BA1105 and BA1301 Being Granted Orphan Drug Designations for Treatment of Pancreatic Cancer by the FDA

The board of directors (the "**Board**") of Shandong Boan Biotechnology Co., Ltd. (the "**Company**") announces that BA1105 and BA1301, two of its innovative Claudin18.2-targeted investigational drugs, have both been granted the Orphan Drug Designations ("**ODD**") by the U.S. Food and Drug Administration ("**FDA**") for the treatment of pancreatic cancer.

Orphan drugs, also known as drugs for rare diseases, are drugs that prevent, treat or diagnose rare diseases. By being designated as orphan drugs, BA1105 and BA1301 will benefit from policy support for their development, registration and commercialization in the United States in the future. This will also help to reduce the cost on their development and accelerate their clinical development and launch.

Pancreatic cancer is one of the deadliest cancers, and diagnosing and treating it is a major challenge in clinical practice. According to data from the International Agency for Research on Cancer (IARC), which is part of the World Health Organization (WHO), there were 496,000 new cases of pancreatic cancer and 466,000 deaths from it globally in 2020, and 57,000 new cases and 48,000 deaths in the United States alone. Because the disease does not have clear symptoms early on, most patients are already in the middle and advanced stages when diagnosed. The prognosis of advanced pancreatic cancer is extremely poor. It is mainly treated with palliative chemotherapy, which rarely produces positive outcome or improves prognosis in general. Therefore, targeted drugs are urgently needed in clinical practice to improve the outcomes.

Claudin18.2 is a transmembrane protein involved in the regulation of the tight junctions between cells. It is continuously and stably expressed on tumors of digestive tract. Research shows that Claudin18.2 is expressed in 70% of gastric cancer patients, 50% of pancreatic cancer patients and 30% of esophageal cancer patients. This makes Claudin18.2 a potential molecular target for anticancer drugs.

BA1105 is a human anti-Claudin18.2 recombinant IgG1 monoclonal antibody that treats Claudin18.2-positive advanced solid tumors. It is more potent thanks to the adoption of the ADCC (antibody-dependent cell-mediated cytotoxicity) enhancement technology. The drug is undergoing a Phase I clinical study in China.

Non-clinical studies demonstrated high activity of BA1105 on xenograft mouse models of Claudin18.2-positive human pancreatic cancer and gastric cancer, both when used alone and in combination with chemotherapy. BA1105 shows a 10-fold higher potency than the reference antibody against cancer cells on tumors with varying Claudin18.2 expression levels, and is also effective on tumors with low Claudin18.2 expression.

BA1301, the Company's first Antibody-Drug Conjugate (ADC) candidate to undergo clinical study, is undergoing a Phase I clinical study in China. BA1301 uses a site-specific conjugation technique to conjugate a cytotoxic payload with a monoclonal antibody that targets Claudin18.2. This directs the cytotoxic payload towards tumors by leveraging the targeting capability of the antibody, reducing the side-effects of the cytotoxic payload and improving the therapeutic window.

The results from non-clinical studies show that BA1301 is excellent in internalization and bystander killing, and has demonstrated exceptional anticancer activity on tumor models that express Claudin18.2. It can significantly inhibit the growth of a mouse xenograft of the Claudin18.2-positive human pancreatic cancer, and the tumor of the mouse can be completely eliminated at medium and high doses. BA1301 is safe and well-tolerated in animals. Its small-molecule toxins are stably conjugated with a very low release ratio of no more than 0.05% in human and cynomolgus monkey plasma.

The Company believes that the grant of the ODD by the FDA reflects its recognition of the potential of BA1105 and BA1301 for the treatment of pancreatic cancer. These two products could complement each other as first and second-line treatments for advanced pancreatic cancer. They also have the potential to be used in combination with the Company's Nivolumab Injection (BA1104) to increase efficacy and further improve the certainty of clinical development. The Company will accelerate the clinical development of these two product candidates and look forward to bringing these innovative treatments to patients around the world as soon as possible.

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, 27 December 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 and Ms. Li Li; and the independent non-executive directors of the Company are Mr. Shi Luwen, Mr. Dai Jixiong and Dr. Yu Jialin.*