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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

BOTH BA1105 AND BA1301 BEING GRANTED ORPHAN DRUG DESIGNATIONS FOR TREATMENT OF GASTRIC CANCER BY FDA

The board of directors (the “**Board**”) of Shandong Boan Biotechnology Co., Ltd. (the “**Company**”) announces that BA1105 and BA1301, two of the Company’s innovative Claudin18.2-targeted investigational drugs, have been granted the Orphan Drug Designations (“**ODD**”) by the U.S. Food and Drug Administration (“**FDA**”) for the treatment of gastric cancer, including cancer of gastroesophageal junction. Previously, BA1105 and BA1301 have also been granted the ODD by 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 granted the ODD, 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.

Gastric cancer is the fifth most common cancer and the fourth leading cause of cancer death worldwide. It is estimated that the global burden of gastric cancer will increase 1.6 times in incidence and 2 times in mortality by 2040. The main treatment for advanced gastric cancer is palliative systemic chemotherapy, which generally has very poor efficacy and prognosis. In addition, available second-line treatments for advanced gastric cancer are limited, systemic chemotherapy is less specific, and the outcomes for patients are not as good as expected.

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 gastric cancer, and the tumor in the mouse can be eliminated with relatively low doses. BA1301 is also effective on tumors with low or medium Claudin18.2 expression. 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 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

Yantai, the People's Republic of China, 24 January 2024

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.