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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

CDE APPROVAL OF IND APPLICATION IN CHINA FOR BA2201, A TL1A/IL-23 BISPECIFIC ANTIBODY FOR THE TREATMENT OF IBD

The board of directors (the "**Board**") of Shandong Boan Biotechnology Co., Ltd. (the "**Company**") announces that the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) has approved the Investigational New Drug (IND) application for BA2201, a Class 1 innovative drug independently developed by the Company, allowing it to commence clinical trials. BA2201 is a long-acting bispecific antibody targeting TL1A and IL-23 (p19) and is intended for the treatment of inflammatory bowel disease ("**IBD**") and other autoimmune diseases.

IBD is a group of chronic, relapsing, and non-specific inflammatory disorders of the intestinal tract, mainly including ulcerative colitis (UC) and Crohn's disease (CD). Data show that approximately 4.9 million people worldwide are living with IBD, with China accounting for the largest number of cases and experiencing a rapid rise in prevalence. Long-term disease management remains challenging. Despite advances in targeted therapies, approximately one-third of patients do not respond to initial treatment, and about half lose response over time. In addition, persistent inflammation causes cumulative intestinal damage and complications, and is also associated with the development of intestinal fibrosis.

To address these clinical needs, BA2201 is designed to simultaneously target IL-23 (p19) and TL1A, two core pathogenic pathways in IBD. IL-23 (p19) is a clinically validated therapeutic target for IBD. The TL1A/DR3 pathway is involved in both inflammatory responses and processes related to intestinal fibrosis, and anti-TL1A monoclonal antibodies have demonstrated excellent efficacy in IBD clinical trials. This dual-target design aims to achieve synergistic anti-inflammatory effects and to explore the potential to intervene in mechanisms associated with intestinal fibrosis.

With its unique molecular structure, BA2201 has demonstrated potent anti-inflammatory and anti-fibrotic activity while reducing the immunogenicity risk and has the potential to support once-quarterly (Q3M) subcutaneous dosing in humans, offering differentiated advantages in efficacy and long-term dosing convenience.

In terms of molecular design, BA2201 features a novel asymmetric "1+1" bispecific format. Its TL1A-binding arm is derived from BA-huMab®, the Company's proprietary fully human antibody transgenic mouse platform, and has a unique binding epitope and potent blocking activity. Its IL-23-binding arm also demonstrates potent pathway inhibition. BA2201 combines monovalent TL1A binding with an Fc-silencing design to reduce Fc receptor-mediated binding and lower immunogenicity risk. In addition, its long-acting Fc engineering, combined with the development of a high-concentration subcutaneous formulation, has the potential to support longer dosing intervals and more convenient administration, improving long-term treatment convenience.

The therapeutic potential of BA2201 has been preliminarily validated in animal models. In a mouse colitis model, BA2201 showed excellent anti-inflammatory effects, with superior efficacy compared with anti-TL1A or anti-IL-23 monoclonal antibodies. Preclinical assessments also indicated that BA2201 has a low immunogenicity risk and good tolerability. It exhibited a long half-life in cynomolgus monkeys, supporting its long-acting design.

The approved clinical trial is a randomized, double-blind, placebo-controlled, multicenter Phase 1/2a study designed to evaluate the safety, tolerability, pharmacokinetics, and preliminary efficacy of subcutaneous administration of BA2201 injection in healthy participants and patients with moderate to severe active ulcerative colitis. The study aims to assess the safety, tolerability, pharmacokinetics, pharmacodynamics, and immunogenicity of BA2201 injection administered subcutaneously, as well as its preliminary efficacy in patients with moderate to severe active ulcerative colitis who have failed or are intolerant to standard treatments. With BA2201 entering clinical development, the Company will accelerate subsequent studies to validate this therapeutic approach, which combines dual-target intervention with long-term dosing convenience. In addition to BA2201, the Company has built a portfolio of bispecific and multispecific antibody candidates in the field of autoimmune diseases, and will steadily advance the development and clinical translation of these programs, with the aim of providing more innovative treatment options to patients with these diseases.

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, 6 November 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.