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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

## PHASE 3 CLINICAL TRIAL COMPLETED IN CHINA FOR AFLIBERCEPT INTRAVITREOUS INJECTION (BA9101) AND BLA TO BE FILED

The board of directors (the "**Board**") of Shandong Boan Biotechnology Co., Ltd. (the "**Company**") announces that the Phase 3 clinical trial (a comparative study of efficacy and safety) for Aflibercept Intravitreous Injection ("**BA9101**") developed by the Company has been completed in China. The Company is planning to submit a Biologics License Application ("**BLA**") for the drug.

Aflibercept is a homodimeric fusion protein consisting of portions of human vascular endothelial growth factor receptor (VEGFR) extracellular domains (VEGFR1 Ig2 and VEGFR2 Ig3) fused to the Fc portion of human IgG1. Aflibercept acts as a soluble decoy receptor that binds VEGF-A, VEGF-B and PlGF, and thereby can inhibit the binding and activation of VEGF and PlGF, so it can be used as the treatment for pathological neovascular ophthalmopathy of retina and choroid.

The reference product EYLEA® was approved for marketing in the United States in 2011 and the European Union in 2012, respectively. It is currently approved for the treatment of Neovascular (Wet) Age-Related Macular Degeneration (nAMD), Macular Edema Following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR), Visual Impair due to Myopic Choroidal Neovascularization (mCNV) and Retinopathy of Prematurity (ROP) worldwide. EYLEA® was approved in 2018 in China for the treatment of nAMD and DME.

BA9101 is a biosimilar to EYLEA® developed by the Company following the relevant research guidelines of biosimilars. The analytical and non-clinical comparability studies of BA9101 to EYLEA® showed a high degree of similarity in both physiochemical properties and biological activities. The results of its Phase 1 clinical study showed that BA9101 has a good safety and tolerability profile. The completed Phase 3 clinical study of BA9101 is a randomized, double-blind, parallel-controlled and multicenter clinical study to compare the efficacy and safety of BA9101 to EYLEA® (Aflibercept Intravitreous Injection) in the treatment of Neovascular (wet) age-related macular degeneration (nAMD). The results of the study showed that the Best Corrected Visual Acuity (BCVA) in both groups during the 24 weeks of treatment demonstrated a clinically significant improvement from the baseline as proved by the ETDRS visual acuity test, indicating that BA9101 was equivalent to EYLEA® in terms of efficacy. Following the Guideline of Similarity Evaluation and Extrapolation of Biosimilar Medicinal Product issued by the Center for Drug Evaluation of the National Medical Products Administration of China, BA9101 can apply for and obtain all the indications that was approved for EYLEA® in China.

Various retinal diseases such as nAMD and DME are the leading causes of vision impairment and blindness, resulting in tremendous physical and mental sufferings of patients. Due to population aging and other factors, the number of patients with such diseases is constantly increasing, and the demand for ophthalmic drugs is also growing as a result.

Aflibercept is widely used as a first-line treatment for nAMD, DME, RVO, DR, CNV and ROP worldwide, and its future market is promising driven by the demand in clinical practice. According to data from IQVIA and public information, the sales of EYLEA® in 2023 reached RMB838 million in China and USD 9.22 billion worldwide respectively.

Pursuant to a collaboration and exclusive promotion agreement entered in October 2020, the Company has partnered with Ocumension Therapeutics, a company listed on The Stock Exchange of Hong Kong Limited (stock code: 1477), in conducting the Phase 3 clinical study of BA9101 and has granted Ocumension Therapeutics an exclusive right to promote and commercialize BA9101 in mainland China.

The Company believes that the collaboration with Ocumension Therapeutics, as a well-known ophthalmic pharmaceutical company with a professional team will accelerate the marketing approval process and commercialization of BA9101 to meet the urgent clinical needs of Chinese patients and strengthen the Company's position in the field of biological products.

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, 8 April 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 Professor Shi Luwen, Mr. Dai Jixiong and Dr. Yu Jialin.*