

*Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.*



**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**

### **ACCEPTANCE OF BLA IN CHINA FOR AFLIBERCEPT INTRAVITREOUS INJECTION (BA9101)**

The board of directors (the “**Board**”) of Shandong Boan Biotechnology Co., Ltd. (the “**Company**”) announces that the biologics license application (“**BLA**”) for Aflibercept Intravitreal Injection (“**BA9101**”) developed by the Company has been accepted by the Centre for Drug Evaluation of the National Medical Products Administration (“**CDE**”) of the People’s Republic of China (“**China**”). BA9101 is a biosimilar of EYLEA® for the treatment of Neovascular (Wet) Age-Related Macular Degeneration (“**nAMD**”) and Diabetic Macular Edema (“**DME**”) in adults.

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 inhibiting endogenous VEGF receptor binding and activation of VEGF-A and PlGF, so it can be used as the treatment for pathological neovascular ophthalmopathy of retina and choroid.

EYLEA® was approved in the United States in 2011 and the European Union in 2012, respectively. It is currently approved for the treatment of nAMD, DME, Macular Edema Following Retinal Vein Occlusion (“**RVO**”), 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. Following *the Guideline of Similarity Evaluation and Extrapolation of Biosimilar Medicinal Product* issued by the CDE of China, BA9101 is eligible to apply for and obtain all the indications that were approved for EYLEA® in China.

BA9101 has been developed following the relevant research guidelines of biosimilars. The results of the Phase 1 clinical trial (safety and tolerability comparison study) of BA9101 showed that the safety and tolerability of BA9101 group were consistent and comparable with those of the reference product group. A Phase 3 clinical trial of BA9101 comparing its efficacy and safety versus reference product met all the endpoints. The results showed that the Best Corrected Visual Acuity (BCVA) based on the Early Treatment of Diabetic Retinopathy Study (ETDRS) visual acuity test in both treatment groups improved significantly from the baseline at Weeks 4, 8, 12, 16, 20, and 24, indicating the high similarity of BA9101 to the reference product in terms of efficacy. BA9101 also demonstrated a rapid onset and sustained efficacy in the study.

Various retinal diseases such as nAMD and DME are the leading causes of visual impairment and blindness, resulting in tremendous physical and mental sufferings of patients. Due to the ageing population and various other factors, the number of patients with such diseases is increasing constantly, 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, mCNV and ROP worldwide, and its future market is promising driven by the demand in the clinical practice. According to the data from IQVIA, the sales of anti-angiogenic ophthalmic drugs in China were approximately RMB3,868 million, representing an increase of 24.5% compared to 2022. Among these, the sales of EYLEA® in China were approximately RMB838 million, representing an increase of 30.1% compared to 2022. In addition, the global sales of EYLEA® reached USD9.21 billion in 2023 according to publicly available data.

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 China.

The Company believes that the collaboration with Ocumension Therapeutics, being 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, 16 July 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.*