



AEON Biopharma Announces FDA Feedback Following BPD Type 2a Meeting for the ABP-450 Biosimilar Program

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FDA provided constructive feedback on Company's analytical similarity strategy under the 351(k) biosimilar pathway

Company continues to execute its analytical program and plans to request a BPD Type 2b meeting with the FDA in 2026 to discuss next steps in the development of ABP-450 as a biosimilar to BOTOX®

IRVINE, Calif., March 25, 2026 (GLOBE NEWSWIRE) -- AEON Biopharma, Inc. ("AEON" or the "Company") (NYSE American: AEON), a biopharmaceutical company advancing ABP-450 (prabotulinumtoxinA) as a biosimilar to BOTOX® (onabotulinumtoxinA) to achieve full-label U.S. market entry, today announced feedback from the U.S. Food and Drug Administration ("FDA" or the "Agency") following a successful Biosimilar Biological Product Development (BPD) Type 2a meeting.

During the meeting, held in January 2026, the FDA reviewed the Company's proposed analytical similarity strategy under the 351(k) biosimilar pathway and provided feedback supporting the Company's planned analytical development approach. The Agency acknowledged the scientific challenges associated with characterizing a 900 kDa botulinum neurotoxin complex, provided constructive feedback on the Company's proposed development approach and analytical assessment plan, and noted that AEON's analytical methodologies appeared reasonable to support advancement of the program toward a comprehensive analytical similarity package. The Company believes this feedback provides a

clear framework for the remaining analytical components of its biosimilar development program and plans to complete the majority of its analytical comparability program in 2026.

AEON is currently planning to request a BPD Type 2b meeting in 2026 to discuss the next phase of the development program to support approval of ABP-450 as a biosimilar to BOTOX[®] across all approved therapeutic indications.

“We are highly encouraged by the FDA’s constructive engagement regarding our analytical approach and the data generated to date,” said Rob Bancroft, President and Chief Executive Officer of AEON. “This meeting represents an important regulatory milestone for our ABP-450 biosimilar effort. The Agency’s feedback reinforces our confidence in the strength of our analytical work and our development trajectory as we advance toward full-label therapeutic approval under the 351(k) pathway. We believe this positions AEON to execute efficiently through the most critical phase of biosimilar development—analytical similarity—while maintaining focus on a capital-efficient path toward regulatory approval.”

About the U.S. Biosimilar Pathway

Analytical similarity forms the scientific foundation of the 351(k) pathway and represents the most data-intensive phase of biosimilar development. When analytical comparability across critical quality attributes is robustly demonstrated, the FDA may reduce the scope of required clinical studies under its totality-of-the-evidence framework. Sponsors may also seek extrapolation to additional indications of the reference product when scientifically justified.

About AEON Biopharma

AEON Biopharma is a biopharmaceutical company seeking full-label access to

the U.S. therapeutic neurotoxin market via biosimilarity to BOTOX[®]. The U.S. therapeutic neurotoxin market exceeds \$3.0 billion annually, representing a major opportunity for biosimilar entry. The Company's lead asset is ABP-450 for debilitating medical conditions. ABP-450 is the same botulinum toxin complex currently approved and marketed for cosmetic indications by Evolus, Inc. under the name Jeuveau[®]. ABP-450 is manufactured by Daewoong Pharmaceutical in compliance with current Good Manufacturing Practices, or cGMP, in a facility that has been authorized by the U.S. Food and Drug Administration, Health Canada, and European Medicines Agency for the manufacture of botulinum toxin products. The product is approved as a biosimilar in India, Mexico, and the Philippines. AEON has exclusive development and distribution rights for therapeutic indications of ABP-450 in the United States, Canada, the European Union, the United Kingdom, and certain other international territories. To learn more about AEON, visit www.aeonbiopharma.com.

Forward-Looking Statements

Certain statements in this press release may be considered forward-looking statements. Forward-looking statements generally relate to future events and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied. Risks and uncertainties include, among others, the finalization and interpretation of FDA meeting minutes, the outcome of future FDA interactions, the scope of any required clinical studies, and the Company's ability to complete its analytical program as planned, among other risks described in the Company's filings with the Securities and Exchange Commission.

Contacts

Investor Contact:

Laurence Watts

New Street Investor Relations

+1 619 916 7620

laurence@newstreetir.com

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