



AEON Biopharma FDA Type 2b Meeting Feedback Clarifies Biosimilar Development Plan for ABP-450

September 30, 2026

FDA indicated previously completed ABP-450 head-to-head studies versus BOTOX® may be submitted as supportive evidence; AEON expects to advance the required scientific bridging work

AEON plans to submit an IND for CMAP pharmacodynamic study in the fourth quarter of 2026

AEON plans to leverage its analytical, pharmacodynamic, and existing comparative human evidence to support a potential streamlined development path

ALISO VIEJO, Calif., Sept. 30, 2026 (GLOBE NEWSWIRE) -- AEON Biopharma, Inc. ("AEON" or the "Company") (NYSE American: AEON), a biopharmaceutical company advancing ABP-450 as a biosimilar to BOTOX® (onabotulinumtoxinA) for therapeutic use to achieve full-label U.S. market entry, today announced receipt of the official minutes from its Biosimilar Biological Product Development ("BPD") Type 2b meeting held with the U.S. Food and Drug Administration ("FDA" or the "Agency") regarding ABP-450's development pathway.

"The Type 2b meeting feedback provides greater clarity on the development pathway for ABP-450 and, consistent with FDA's recent biosimilar guidance, supports a potentially more efficient clinical development program," said Rob Bancroft, President and Chief Executive Officer of AEON. "Our strategy is to bring together the most sensitive, complementary and relevant evidence available, including our analytical program, comparative human pharmacodynamic data and the substantial comparative human experience already generated with ABP-450. Where those lines of evidence converge, we believe they may support proceeding without a standalone comparative efficacy study or narrowing the clinical work required, improving the capital and time efficiency with which we advance ABP-450 toward its potential commercial opportunity. We are excited to embark on this next phase of ABP-450's development and look forward to submitting the IND for the CMAP study later this year."

The Type 2b meeting provided feedback across the following components of AEON's development plan:

Comparative Pharmacodynamic Study

AEON proposed a two-stage design for a comparative pharmacodynamic ("PD") study using Compound Muscle Action Potential ("CMAP") measurement in the extensor digitorum brevis muscle consisting of an initial dose-finding stage followed by a comparative PD evaluation. The FDA agreed in principle with the initial dose-finding stage which will be conducted in healthy volunteers. The FDA also provided recommendations intended to strengthen the study's ability to demonstrate assay sensitivity. AEON intends to incorporate the FDA's feedback and advance the study under an investigational new drug application ("IND"), which the Company expects to submit in the fourth quarter of 2026.

In a biosimilar development program, PD measures are tests that evaluate the biological, molecular, and physiological effects a drug has on the body to confirm that the biosimilar interacts with its intended therapeutic target in a similar way as the original reference biologic. PD evidence is particularly important for a botulinum toxin, which acts locally and is not present at reliably measurable systemic concentrations following therapeutic administration, making conventional comparative pharmacokinetic studies infeasible.

Previously Completed Comparative Studies

The FDA indicated that comparative clinical studies previously conducted by Daewoong Pharmaceutical across several indications including studies in blepharospasm, upper limb spasticity, glabellar lines and lateral canthal lines, can be submitted for consideration as supportive evidence, subject to appropriate scientific bridging to U.S.-licensed BOTOX® and between the ABP-450 drug product used in each study and ABP-450 as currently manufactured. Blepharospasm and upper limb spasticity are therapeutic indications included on the U.S. BOTOX® label, while glabellar lines and lateral canthal lines are included on the BOTOX Cosmetic® label.

These studies evaluated ABP-450 relative to BOTOX® across a range of indications, doses and muscles, with each study meeting its pre-specified non-inferiority endpoint. AEON intends to complete the scientific bridging work necessary to support their consideration within the totality of evidence for ABP-450. If appropriately bridged, AEON believes these studies could complement the analytical and PD programs by providing additional comparative human evidence supportive of biosimilarity.

Comparative Clinical Study Considerations

The FDA's scientific approach to biosimilar development has continued to evolve toward greater reliance on evidence that is most sensitive to detecting meaningful differences between a proposed biosimilar and its reference product. In October 2025, the FDA

issued draft guidance recognizing that traditional comparative efficacy studies (“CES”) generally have limited sensitivity to detect product differences and may not be necessary where more sensitive evidence sufficiently supports a determination of biosimilarity. The guidance reflects the FDA’s growing experience that traditional clinical efficacy endpoints may provide limited additional discriminatory information in biosimilar development.

Consistent with this evolving framework, during the Type 2b meeting, the FDA emphasized that, if additional clinical evidence is ultimately needed, such evidence should be sufficiently sensitive to detect a meaningful difference between the products, if one exists. The FDA also indicated that more sensitive measures of biological activity, rather than traditional clinical efficacy endpoints, could be considered and that the design of any additional clinical study should be guided by the specific residual uncertainty remaining following completion of the comparative analytical assessment (“CAA”). Accordingly, AEON does not intend to initiate a CES at this time and will first evaluate the totality of its analytical, pharmacodynamic and comparative human evidence to determine whether additional clinical evidence is scientifically necessary and, if so, the most appropriate approach to address any remaining residual uncertainty.

Indication-Specific Considerations

The FDA feedback also addressed indication-specific considerations, including chronic migraine. During the meeting, the FDA invited the Company to provide analyses supporting the rationale for the outcome of the previously conducted Phase 2 study for the prevention of migraine headache, which the Company intends to complete and provide to the FDA as part of its 351(k) Biologics License Application (“BLA”) submission.

Comparative Analytical Assessment

The CAA is the scientific foundation of development under the 351(k) pathway and provides a sensitive means of identifying potential structural and functional differences between a proposed biosimilar and its reference product. AEON is conducting a broad CAA of ABP-450 and U.S.-licensed BOTOX® across structural, physicochemical and functional attributes. The Company recently reported progress across multiple dimensions of that program, including expanded primary-sequence characterization, confirmation of critical disulfide-bond architecture, and pilot forced-degradation results demonstrating highly similar degradation behavior between ABP-450 and BOTOX® under thermal and oxidative stress conditions.

Next Steps: Converging Evidence

AEON’s next phase of development will integrate its maturing comparative analytical foundation with multiple independent and complementary lines of evidence, including human PD evidence, existing comparative human evidence scientifically bridged to the biosimilar program, and targeted evidence addressing indication-specific questions. The Company intends to leverage the convergence of these evidence streams to build a scientifically supported case whereby a standalone CES may not further inform a determination of biosimilarity. AEON plans to return to the FDA in 2027 with its integrated evidence package.

Anticipated milestones for ABP-450’s development program include:

- Continued completion of CAA studies in support of biosimilarity between ABP-450 and BOTOX®
- Filing an IND for CMAP PD study in Q4 2026
- CMAP PD study initiation in Q1 2027
- Scientific bridging of ABP-450 and BOTOX® to support previously completed comparative studies

About the U.S. Biosimilar Pathway

The 351(k) biosimilar pathway is grounded in a totality-of-the-evidence approach. The FDA evaluates a proposed biosimilar using the most sensitive and scientifically informative methods available to identify potential differences from its reference product, with comparative analytical assessment providing the scientific foundation. The nature and extent of any additional studies the FDA may require prior to approval are informed by the residual uncertainty remaining after that assessment. Once biosimilarity is established, the FDA has the authority to approve a biosimilar for additional indications of the reference product through scientifically justified extrapolation, without requiring separate clinical studies in each indication.

In October 2025, the FDA issued draft guidance proposing that a comparative efficacy study — a comparative clinical study with efficacy endpoints — may not be necessary where a comparative analytical assessment demonstrates that a proposed product is highly similar to its reference product. The draft guidance reflects the FDA’s view that comparative analytical methods are generally more sensitive than comparative efficacy studies for detecting differences between products.

About AEON Biopharma

AEON Biopharma is a biopharmaceutical company pursuing 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. 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 a facility that has been authorized by the U.S. Food and Drug Administration, Health Canada, and the European Medicines Agency for the manufacture of

certain third-party botulinum toxin products. 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

This press release contains forward-looking statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements reflect the current beliefs and expectations of management. All statements other than statements of historical fact are statements that could be deemed 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. Forward-looking statements in this press release include, among others, (i) statements regarding the Company’s plans and expected timing to submit an IND and initiate the CMAP pharmacodynamic study; (ii) the design, execution and potential evidentiary value of that study; (iii) the Company’s ability to complete its comparative analytical assessment and the scientific bridging necessary to support consideration of previously completed comparative studies; (iv) the potential for analytical, pharmacodynamic and existing comparative human evidence, individually or collectively, to support a determination of biosimilarity or reduce the need for a standalone comparative efficacy study; (v) the nature and scope of any additional clinical studies that may be required; (vi) the timing and outcome of future interactions with the FDA, including the Company’s planned engagement with the FDA in 2027; and (vii) the Company’s ability to advance ABP-450 through the 351(k) pathway toward potential full-label therapeutic approval and commercial entry. In addition, when or if used in this press release, the words “may,” “could,” “should,” “anticipate,” “believe,” “estimate,” “expect,” “intend,” “plan,” “potential,” “will,” “predict” and similar expressions and their variants, as they relate to the Company, may identify forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Although the Company believes the expectations reflected in such forward-looking statements are reasonable, the Company can give no assurance that such expectations will prove to be correct. Risks and uncertainties that could cause actual results to differ materially from those expressed or implied in the Company’s forward-looking statements include, among others, (viii) the FDA’s interpretation of the data and information generated or submitted by the Company; (ix) the possibility that the FDA may require additional analytical, pharmacodynamic, clinical or other studies; (x) the Company’s ability to successfully complete its planned studies and scientific bridging activities; (xi) whether the results of those activities will support the Company’s proposed development approach; (xii) changes in FDA guidance, regulatory requirements or interpretations, including with respect to the role of comparative clinical studies in biosimilar development; (xiii) the Company’s ability to obtain sufficient capital to fund its planned development activities; (xiv) and other risks described in the Company’s filings with the Securities and Exchange Commission. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. Forward-looking statements speak only as of the date of this press release, and the Company undertakes no obligation to update such statements except as required by applicable law.

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