AEON Biopharma Submits IND for Comparative Pharmacodynamic Study of ABP-450

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Submission advances ABP-450 biosimilar development program following recent FDA Type 2b meeting

Planned CMAP study designed to generate clinical evidence comparing the neuromuscular activity of ABP-450 and BOTOX®; study initiation expected in Q1'2027

ALISO VIEJO, Calif., Nov. 09, 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 the submission of an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for a comparative pharmacodynamic study utilizing compound muscle action potential (CMAP) measurements.

The submission follows AEON's recently completed Biosimilar Biological Product Development (BPD) Type 2b meeting with the FDA and represents continued progress in advancing the Company's strategy to develop an integrated totality-of-evidence package under the 351(k) biosimilar regulatory pathway.

"With the further clarity provided during our recent Type 2b meeting with the FDA, we are moving decisively into the next phase of development for ABP-450," said Robert Bancroft, President and Chief Executive Officer of AEON. "Our strategy emphasizes rigorous, sensitive scientific assessments capable of detecting even small differences, should they exist, thereby providing greater confidence in the assessment of biosimilarity between ABP-450 and BOTOX®. The planned CMAP study is designed to generate objective pharmacodynamic evidence that can be integrated with our comparative analytical work and other human evidence to support our proposed biosimilar BLA."

The planned CMAP study is designed to compare the pharmacodynamic activity of ABP-450 and BOTOX® using an objective, quantitative measure of neuromuscular response, with an emphasis on sensitivity to detect potential differences between the products, should they exist. By providing a sensitive assessment of the products' biological activity in humans, the study is intended to bridge the comparative analytical evidence with clinical pharmacology data, further strengthening the scientific foundation for establishing biosimilarity.

AEON's development strategy emphasizes scientifically rigorous and sensitive comparative assessments capable of identifying meaningful differences between ABP-450 and BOTOX® to address residual uncertainty regarding biosimilarity. AEON believes this approach is consistent with the FDA's evolving perspective on biosimilar development, including the recognition that comparative clinical efficacy studies may be less sensitive than other methods for detecting differences between products.

As previously announced, feedback from the FDA's Type 2b meeting provided greater clarity regarding the Company's development pathway, including the potential role of comparative clinical pharmacology evidence in supporting a streamlined regulatory approach. AEON is pursuing a totality-of-evidence strategy that may support a biosimilar BLA without a standalone comparative clinical efficacy study, subject to the adequacy of the supporting evidence and further FDA review.

Following IND submission, AEON intends to advance preparations for study initiation, subject to applicable regulatory requirements, with expected study initiation in the first quarter of 2027.

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, among other things, 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 $3.5 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 initiate the CMAP pharmacodynamic study; (ii) the Company's ability to obtain any required regulatory and institutional approvals, activate clinical sites and enroll, conduct and complete the planned CMAP study; (iii) the design, execution and potential evidentiary value of that study; (iv) the Company's ability to complete its comparative analytical assessment and the scientific bridging necessary to support consideration of previously completed comparative studies; (v) the potential for analytical, pharmacodynamic and existing comparative human evidence, individually or collectively, to support a determination of biosimilarity or reduce or eliminate the need for a standalone comparative efficacy study; (vi) the nature and scope of any additional clinical studies that may be required; 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," "achieve," "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, including any required additional studies; and (xiv) 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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Source: AEON Biopharma