



AEON Biopharma Reports Positive and Robust Biosimilarity Results: Identical Amino Acid Sequence and Highly Similar Functional Analysis Data

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- 100% match of visible amino acid sequence confirmed between ABP-450 and BOTOX® -

- Functional assays demonstrate strong similarity in potency and composition, with directionally consistent enzymatic activity results -

IRVINE, Calif., Nov. 13, 2025 (GLOBE NEWSWIRE) -- AEON Biopharma, Inc. ("AEON" or the "Company") (NYSE American: AEON), a biopharmaceutical company seeking an accelerated and full-label U.S. market entry by developing ABP-450 (prabotulinumtoxinA) as a BOTOX (onabotulinumtoxinA) biosimilar, today announced positive and robust biosimilarity results demonstrating identical amino acid sequence and highly similar functional analysis data. These findings were included in AEON's analytical package submitted to the U.S. Food and Drug Administration (FDA) in advance of its scheduled Biosimilar Biological product Development (BPD) Type 2a meeting on November 19, 2025.

Highlights of Initial Analytical Results

- Primary Structure: 100% amino acid sequence identity confirmed between ABP-450 and BOTOX®, based on sequence coverage of 93% - 99% for the five proteins that comprise the 900kD botulinum toxin type A complex.
 - More than 3,400 peptides analyzed across three lots of ABP-450 and two lots of BOTOX without a single amino acid difference, confirming data robustness.
 - High analytical sensitivity achieved via liquid chromatography/mass spectrometry (LC/MS), with no minor sequence deviations observed.
 - Primary structural identity is a prerequisite for demonstrating biosimilar functional comparability.
- Functional Analyses: Initial functional assays performed by Daewoong Pharmaceutical demonstrated similarity in potency, enzymatic activity, and composition.
 - Potency: ABP-450 demonstrated highly similar potency to BOTOX® across two distinct assays - LD₅₀ (in vivo biological activity) and CBPA (cell-based potency assay) - supporting clinical dose predictability.
 - Composition: ELISA confirmed comparable vial-to-vial active ingredient content between ABP-450 and BOTOX®, further supporting dose similarity and reliability.
 - Enzymatic activity: ABP-450 demonstrated functional cleavage of SNAP-25, consistent with the expected mechanism of action; observed variability is within the expected analytical range and is anticipated to tighten as additional lots are tested.

"We believe these results mark a major step forward in AEON's 351(k) biosimilar pathway for ABP-450," said Rob Bancroft, the Company's President & Chief Executive Officer. "The confirmation of identical amino acid sequencing, together with strong similarity in potency and composition, provides compelling early evidence of biosimilarity to BOTOX®. We expect the functional dataset to continue to strengthen as additional lots are evaluated. Importantly, these data build upon the extensive global body of evidence for ABP-450, which is already approved in 69 countries and manufactured at commercial scale by our partner Daewoong Pharmaceutical in FDA- and EMA-inspected facilities. Together, we believe these factors substantially de-risk our U.S. program and set the stage for constructive discussion with FDA this month."

Established Asset on Accelerated Pathway

- Global Validation: ABP-450 is the same botulinum toxin complex marketed by Evolus in the U.S. as Jeuveau® for aesthetic indications and approved in 69 countries worldwide.
- Proven Manufacturing: ABP-450 is produced by Daewoong Pharmaceutical in a commercial-scale, cGMP facility previously inspected and approved by the FDA, EMA, and Health Canada.
- Extensive Clinical Experience: Millions of patients treated globally provide a strong safety and efficacy foundation.
- Strategic Implications: Analytical findings reported today underscore ABP-450's potential to become the first full label therapeutic biosimilar to BOTOX® in the U.S., positioning AEON to address a >\$3 billion annual therapeutic neurotoxin market.

Upcoming Milestones

- November 19, 2025: FDA Biosimilar Biological Product Development (BPD) Type 2a meeting to review AEON's analytical package and align on next steps in biosimilar development.

About the U.S. Biosimilar Pathway

The U.S. Food and Drug Administration (FDA) regulates biosimilars under the Public Health Service Act's 351(k) pathway, which

requires developers to demonstrate that a proposed product is highly similar to an approved reference biologic with no clinically meaningful differences in safety, purity, or potency. Analytical similarity is the scientific foundation of this process, representing the most critical and data-intensive phase of development. Once analytical comparability across key quality attributes is established, subsequent FDA interactions focus on confirming whether any residual uncertainty requires limited clinical evaluation.

About AEON Biopharma

AEON Biopharma is a biopharmaceutical company seeking accelerated and 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 Practice, or cGMP, in a facility that has been approved by the U.S. Food and Drug Administration, Health Canada, and European Medicines Agency. 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 or AEON's future financial or operating performance. For example, statements regarding meetings with the FDA or potential determination that ABP-450 is highly similar to the reference product for currently approved and future therapeutic indications are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "plan", "possible", "forecast", "expect", "intend", "will", "estimate", "anticipate", "believe", "predict", "potential" or "continue", or the negatives of these terms or variations of them or similar terminology. Such forward-looking statements are subject to risks, uncertainties, and other factors which could cause actual results to differ materially from those expressed or implied by such forward-looking statements.

These forward-looking statements are based upon estimates and assumptions that, while considered reasonable by AEON and its management, are inherently uncertain. Factors that may cause actual results to differ materially from current expectations include, but are not limited to: (i) the FDA's response to the results of AEON's primary structure analysis; (ii) the FDA's response to the results of the select functional analyses completed by Daewoong Pharmaceutical; (iii) the expected Type 2a meeting with the FDA and potential path forward to biosimilarity designation; (iv) AEON's ability to receive full-label access to the U.S. therapeutic neurotoxin market via biosimilarity to BOTOX on an accelerated timeline or at all; (v) the outcome of any legal proceedings that may be instituted against AEON or others; (vi) AEON's future capital requirements; (vii) AEON's ability to raise financing in the future; (viii) AEON's ability to continue to meet continued stock exchange listing standards; (ix) the possibility that AEON may be adversely affected by other economic, business, regulatory, and/or competitive factors; (x) the outcomes from any meetings or discussions with regulatory authorities; (xi) the timing of, or results from, any testing performed on AEON's product; and (xii) other risks and uncertainties set forth in the section entitled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" in the Company's filings with the Securities and Exchange Commission (the "SEC"), which are available on the SEC's website at www.sec.gov.

Nothing in this press release should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made. AEON does not undertake any duty to update these forward-looking statements.

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