AEON Reports Expanded Structural Data Supporting Molecular Similarity of ABP-450 to BOTOX®

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- Complementary peptide-mapping methods increased coverage of the active botulinum neurotoxin primary sequence from approximately 93% to 98%, with 100% amino acid identity across all regions analyzed

- Preliminary analysis demonstrates preservation of the critical disulfide bond architecture required for toxin activation

- Primary amino acid sequence and disulfide connectivity are foundational to establishing molecular similarity between ABP-450 and BOTOX®

- FDA feedback from planned Biosimilar Biological Product Development (BPD) Type 2b interaction expected to help inform the next phase of ABP-450 development

ALISO VIEJO, Calif., Aug. 19, 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 final, expanded primary structure results and preliminary disulfide bond characterization data that provide complementary evidence supporting the molecular similarity of ABP-450 to BOTOX®. The expanded primary structure analysis achieved 98% sequence coverage of the active botulinum neurotoxin and demonstrated 100% amino acid identity across every region analyzed. Preliminary disulfide characterization identified the same C430-C454 bond connecting the light and heavy chains in both products across all tested lots.

“Primary structure is the molecular blueprint of a protein, and disulfide connectivity helps confirm that critical regions of the molecule are covalently linked in the same manner,” said Rob Bancroft, President and Chief Executive Officer of AEON. “Achieving 98% sequence coverage with complete identity across all analyzed regions, together with preliminary evidence of the same dominant heavy-chain/light-chain disulfide bond in both products, represents meaningful progress in building the foundational molecular identity package for ABP-450. The consistency of these findings across multiple samples and lots increases our confidence as we continue to build the broader analytical evidence supporting the program.”

The expanded primary structure analysis was performed across six drug product samples encompassing both ABP-450 and BOTOX®. Across every region analyzed, the amino acid sequence was identical, including the critical proteolytic activation junction between the light and heavy chains. Because primary sequence is an identity attribute that is not expected to vary between lots, the 98% result reflects combined coverage generated from complementary digestion strategies and samples rather than a per-lot coverage metric.

The 98% amino acid sequence coverage represents a meaningful expansion from the approximately 93% coverage announced in November 2025. The earlier peptide-mapping work analyzed more than 3,400 amino acids across the five-protein complex and demonstrated 100% primary structure identity across all regions analyzed. The expanded work closes most of the remaining coverage gaps within the active neurotoxin and confirms sequence identity at the critical light-chain/heavy-chain activation junction.

Preliminary analysis identified the same single disulfide bond (C430-C454) connecting the light and heavy chains in both ABP-450 and BOTOX® across all tested lots, with this disulfide-linked form representing approximately 99% of total species in each product. The active botulinum neurotoxin is produced as a single-chain precursor that must be proteolytically activated ("nicked") into a two-chain form, in which the catalytic light chain and the binding/translocation heavy chain remain joined by this interchain disulfide bond. Because this covalent connection is essential for the toxin's biological activity, its presence at the same position and comparable abundance in both products is consistent with the highly similar potency previously reported for ABP-450 and BOTOX®.

In March 2026, AEON reported the results of its BPD Type 2a meeting with the U.S. Food and Drug Administration (“FDA” or the “Agency”), which took place in January 2026. During the meeting, the Agency 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 toward a comprehensive analytical similarity package. The Company looks forward to feedback from its planned BPD Type 2b interaction with the FDA in the second half of 2026, which is expected to help inform the next phase of development for ABP-450, including clinical pharmacology and comparative clinical study requirements.

About the U.S. Biosimilar Pathway

The 351(k) biosimilar pathway is grounded in a totality-of-the-evidence approach, with comparative analytical assessment providing the scientific foundation for establishing biosimilarity. The nature and extent of additional studies are informed by the totality of the evidence and any residual uncertainty remaining following comparative analytical assessment. Once biosimilarity is established, FDA may approve a biosimilar for additional indications of the reference product through scientifically justified extrapolation, without requiring separate clinical studies in each indication.

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 are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and are made in reliance on the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements generally relate to future events or AEON's future financial or operating performance. For example, statements regarding the qualification of analytical methods, the completion, timing or results of additional analytical testing, the interpretation of the primary structure and preliminary disulfide bond data described in this press release, meetings or discussions with the FDA, the clinical development plan for ABP-450, the potential determination that ABP-450 is highly similar to the reference product, and the potential for full-label U.S. market access 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, assumptions and other factors, many of which are outside of AEON's control, that 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 AEON's primary structure and preliminary disulfide bond results; (ii) AEON's ability to qualify its disulfide bond method and to reproduce or confirm the preliminary results described in this press release, which remain subject to change upon completion of the full analysis; (iii) the timing and results of additional analytical, functional, stability, nonclinical, or clinical testing; (iv) the timing and outcomes of the Company's BPD Type 2b meeting and other meetings or discussions with regulatory authorities; (v) AEON's ability to demonstrate biosimilarity to BOTOX® and to obtain regulatory approval of ABP-450 for the therapeutic indications for which the reference product is approved and for any additional indications, on an accelerated timeline or at all; (vi) AEON's dependence on Daewoong Pharmaceutical as the sole manufacturer and supplier of ABP-450 and on the continuation of the parties' license and supply arrangements; (vii) AEON's ability to obtain, maintain and protect intellectual property rights and the outcome of any legal proceedings that may be instituted against AEON or others; (viii) AEON's future capital requirements, its ability to raise additional financing and its ability to continue as a going concern; (ix) AEON's ability to continue to meet applicable stock exchange listing standards; (x) the possibility that AEON may be adversely affected by economic, business, regulatory, competitive, or other factors; and (xi) other risks and uncertainties set forth in the sections entitled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" in the Company's filings with the Securities and Exchange Commission, 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, except as required by law.

Contacts Investor

Contact:

Hershel Berry
Blueprint Life Science Group
Hberry@bplifescience.com

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