AEON Announces Positive Pilot Forced Degradation Results Supporting Analytical Comparability of ABP-450 to BOTOX®

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ABP-450 and BOTOX® demonstrated comparable rates of potency loss under thermal stress and similar site-specific oxidation patterns across methionine sites evaluated

Results provide additional analytical evidence supporting comparability and establish the basis for AEON's planned multi-lot comparability study

ALISO VIEJO, Calif., Sept. 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 positive results from a pilot forced degradation study comparing ABP-450 to BOTOX® under thermal and oxidative stress conditions. Under thermal stress, both ABP-450 and BOTOX® lost potency at comparable rates. Under oxidative stress, methionine sites were modified in both molecules in a similar dose-dependent pattern. Together, the results provide an additional line of analytical evidence relevant to structural comparability, ahead of the Company's planned multi-lot comparability study.

Forced degradation testing is widely used in analytical comparability assessments for complex biologics and complements characterization performed on unstressed material. Rather than comparing two molecules only in their native, as-manufactured state, forced degradation deliberately stresses each molecule - through elevated temperature, oxidation, or other stress factors - and compares how each degrades over time. Because degradation pathways are highly sensitive to a protein's underlying structure, matching degradation behavior under stress can provide evidence of structural similarity beyond what standard characterization alone can detect.

In the thermal stress arm, ABP-450 and BOTOX® were incubated under high heat conditions with relative potency measured at multiple time points using an LD50 assay. Both molecules lost potency at comparable rates, each following a similar trajectory of rapid initial loss reaching approximately half of initial observed potency by day 14.

In the oxidative stress arm, both molecules were exposed to two concentrations of hydrogen peroxide, and oxidation was measured at multiple methionine sites using mass spectrometry peptide mapping. The methionine sites in ABP-450 and BOTOX® oxidized to a comparable magnitude at both peroxide concentrations - a pattern consistent with comparable higher-order structural characteristics, giving no indication of differing solvent exposure at those residues.

As a pilot study, this work was not powered for formal statistical comparison. Formal conclusions regarding analytical comparability under forced degradation conditions will depend on the results of the Company's planned multi-lot comparability study.

"A molecule's structure at rest only tells part of the story — how it behaves under stress tells you a great deal more," said Chad Oh, M.D., Chief Medical Officer of AEON. "In this pilot, ABP-450 and BOTOX® did not just look alike at the outset — they degraded along comparable pathways, at comparable rates, and with residues affected to a comparable degree. That's a meaningful, independent line of evidence for our comparability case, and it gives us a strong foundation as we move into the formally powered comparability study that we expect will contribute to the analytical package supporting our planned BLA."

"Forced degradation is one of several analytical dimensions we are working through this year," commented Rob Bancroft, President and Chief Executive Officer of AEON. "Each component we complete adds to the totality of evidence intended to support our planned 351(k) BLA submission for ABP-450."

Pilot Study Establishes the Basis for the Multi-Lot Comparability Study

The pilot study was designed to establish stability-indicating stress conditions and to confirm whether the selected conditions produced measurable degradation across time points. Based on the results, the Company plans to advance to a formal multi-lot comparability study evaluating ABP-450 lots against BOTOX® comparator lots, designed to support formal conclusions regarding comparability under forced degradation conditions. The Company currently expects to initiate that study in the first half of 2027.

AEON also plans to build upon these findings through a broader forced degradation program evaluating ABP-450 and BOTOX® across additional stress conditions and complementary analytical measures. Together, these studies are designed to further characterize whether the two molecules demonstrate comparable degradation behavior across multiple independent dimensions.

These results add another independent dimension to AEON's growing body of analytical evidence supporting the comparability of ABP-450 to BOTOX®, building upon the Company's previously reported potency, primary structure and disulfide bond characterization data. AEON intends to continue expanding this body of evidence as part of its totality-of-the-evidence approach to

demonstrating biosimilarity.

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 that the U.S. Food and Drug Administration ("FDA") may require a sponsor to undertake prior to approving a biosimilar candidate are informed by the totality of the evidence and any residual uncertainty remaining following comparative analytical 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.

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

The foregoing material may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended. Forward-looking statements include all statements that do not relate solely to historical or current facts, including without limitation statements regarding the Company's product development and business prospects, and can be identified by the use of words such as "may," "will," "expect," "project," "estimate," "anticipate," "plan," "intend," "design," "believe," "potential," "could," "should," "continue" or the negative versions of those words or other comparable words. Forward-looking statements are not guarantees of future actions or performance. These forward-looking statements are based on information currently available to the Company and its current plans or expectations and are subject to a number of risks and uncertainties that could significantly affect current plans. Should one or more of these risks or uncertainties materialize, or the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended, or planned. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, the Company cannot guarantee future results, performance, or achievements. Except as required by applicable law, including the securities laws of the United States, the Company does not intend to update any of the forward-looking statements to conform these statements to actual results.

Factors that may cause actual results to differ materially from current expectations include, but are not limited to: (i) the risk that results from a pilot or other non-pivotal study may not be predictive of, or replicated in, later or more extensively powered studies; (ii) the risk that the Company may not initiate or complete its planned multi-lot comparability study, or its broader forced degradation program, on its currently expected timeline or at all; (iii) the risk that the Company's planned multi-lot comparability study may not meet its pre-specified equivalence criteria; (iv) the risk that the FDA may not accept the Company's contemplated analytical package as supporting a demonstration of biosimilarity under its totality-of-the-evidence framework; (v) the risk that the FDA may not approve ABP-450 for all of the therapeutic indications of the reference product, including through extrapolation, or may not do so on the Company's expected timeline; (vi) the risk that additional data or FDA feedback could alter the Company's analytical, pharmacodynamic or clinical development strategy; (vii) the timing and outcome of the Company's interactions with the FDA; (viii) the Company's dependence on Daewoong Pharmaceutical as the manufacturer of ABP-450 and on the Company's rights under its agreements with third parties; (ix) the risk that the size of the U.S. therapeutic neurotoxin market, or the Company's ability to capture a share of that market, may differ materially from current expectations; (x) the Company's ability to obtain additional and sufficient financing to complete its analytical and clinical development program; (xi) AEON's ability to continue to meet stock exchange listing standards; and (xii) 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 SEC, which are available on the SEC's website at www.sec.gov.

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