AEON Biopharma Designates Former FDA Neuroscience Leader Paul Lee, M.D., Ph.D. as Acting Chief Regulatory Officer

August 24, 2026

- Former Deputy Director of the FDA's Office of Neuroscience

- Dr. Lee has previously advised AEON through Clintrex Research LLC (Clintrex), an affiliate of BlueRidge Life Sciences, on the regulatory strategy for ABP-450

ALISO VIEJO, Calif., Aug. 24, 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 designation of Paul Lee, M.D., Ph.D. as the Company's acting Chief Regulatory Officer, through Clintrex, strengthening the Company's regulatory leadership.

Dr. Lee and Clintrex currently advise AEON on the regulatory and clinical development strategy for ABP-450, providing strategic guidance as the Company advances its biosimilar development program. In his acting Chief Regulatory Officer role, Dr. Lee will lead AEON's regulatory strategy, help guide the Company's interactions with the FDA and work closely with AEON's analytical, CMC and clinical teams as it advances ABP-450 under the 351(k) biosimilar pathway.

"Dr. Lee's expanded role reflects our continued focus on strengthening the regulatory capabilities needed to successfully advance the ABP-450 biosimilar development program," commented Rob Bancroft, President and Chief Executive Officer of AEON. "His senior FDA neuroscience leadership experience, direct experience with biosimilar science and detailed understanding of ABP-450 through his work with AEON and Clintrex, make him exceptionally well positioned to guide our regulatory strategy."

Dr. Lee spent more than seven years at the FDA's Office of New Drugs, most recently serving as Deputy Director of the Office of Neuroscience from May 2024 to June 2025 and as Director of the Division of Neurology 2 from March 2023 to May 2025. In these roles, he oversaw the review and regulation of drug and biologic programs across a broad range of neurological and psychiatric conditions, including migraine, epilepsy, stroke, multiple sclerosis and neurodegenerative diseases. Dr. Lee also recently co-authored a publication describing the FDA review and approval of Tyruko® (natalizumab-sztn), the first FDA-approved biosimilar to natalizumab. Before joining the FDA, Dr. Lee was a staff clinician at the National Human Genome Research Institute, where he served as an investigator in rare-disease clinical trials and as a reviewing physician for the Undiagnosed Diseases Network. Dr. Lee earned his M.D. and Ph.D. in Neuroscience from the University of Maryland and is board certified in neurology with special qualification in child neurology.

Dr. Lee said, "I am pleased to take on this expanded role and work even more closely with the AEON team to advance a scientifically rigorous biosimilar development program. I look forward to bringing my regulatory, neuroscience and biosimilar experience to that work."

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 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 European Medicines Agency for the manufacture of 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 anticipated benefits of Dr. Lee's appointment and his expected contributions to the Company; the timing, objectives and potential outcomes of the Company's anticipated interactions with the U.S. Food and Drug Administration ("FDA"); the Company's ability to obtain FDA feedback on, or alignment regarding, the remaining clinical and regulatory development program for ABP-450; the timing and advancement of the Company's planned clinical development activities; the Company's plans to advance ABP-450 as a proposed biosimilar to BOTOX® (onabotulinumtoxinA) under the Section 351(k) biosimilar pathway; and the Company's product development and business prospects. Forward-looking statements can be identified by the use of words such as "may," "will," "expect," "project," "estimate," "anticipate," "plan," "believe," "potential," "should," "continue," "seek," 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) whether the anticipated benefits of Dr. Lee's designation are realized and whether he is able to contribute to the Company's regulatory and development activities as anticipated; (ii) the Company's ability to obtain additional and sufficient financing; (iii) the Company's anticipated financial performance, including its cash and cash equivalents; (iv) the timing and outcome of the Company's interactions with the FDA, including whether the FDA agrees with the Company's proposed regulatory, analytical, clinical development and extrapolation strategies for ABP-450; (v) the possibility that the FDA may require additional analytical, nonclinical or clinical studies or otherwise modify the Company's anticipated development plans; and (vi) 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.

Contacts

Investor Contact:
Hershel Berry
Blueprint Life Science Group
hberry@Bplifescience.com

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