AEON Biopharma Announces FDA BPD Type 2a Meeting for ABP-450 on November 19

October 1, 2025

- Meeting date aligns with prior guidance -

- FDA to review AEON's analytical development plan and initial data -

IRVINE, Calif., Oct. 01, 2025 (GLOBE NEWSWIRE) -- AEON Biopharma, Inc. ("AEON" or the "Company") (NYSE: AEON), a biopharmaceutical company developing ABP-450 (prabotulinumtoxinA) as a BOTOX® (onabotulinumtoxinA) biosimilar, today announced that the U.S. Food and Drug Administration (FDA) has scheduled a Biosimilar Biological Product Development (BPD) Type 2a meeting for ABP-450 on November 19, 2025, in line with prior guidance.

The meeting will focus on AEON's analytical development plan under the 351(k) biosimilar pathway, including its framework for assessing key quality attributes and its initial similarity data. The objective of the discussion is to establish alignment with FDA on the scope and approach of the remainder of AEON's analytical analysis - a foundational step in advancing ABP-450's biosimilar development.

"The FDA's scheduling of our BPD Type 2a meeting represents an important milestone in the development of ABP-450," said Rob Bancroft, President and Chief Executive Officer of AEON. "Alignment with FDA on the analytical framework is essential in the biosimilar pathway, and we look forward to constructive dialogue on our proposed plan and early results as we advance ABP-450 as a potential biosimilar to BOTOX®."

AEON expects to provide an update on the outcome of the meeting following its completion and receipt of official FDA minutes.

Upcoming Milestones

- 4Q 2025: FDA BPD Type 2a meeting expected to provide alignment on analytical development plan for ABP-450.

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 injection 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, the timing of completion of, or outcome of results from, analytical studies, 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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