



AEON Biopharma Presents Positive Clinical and Pre-clinical Data for ABP-450 (prabotulinumtoxinA) in Treating Cervical Dystonia and PTSD, Respectively, at a Leading Neurotoxin Conference

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– Open label extension (OLE) Phase 2 data show peak efficacy for all ABP-450 doses and cycles in treating cervical dystonia (CD) occurred early, within 4 weeks; durability of effect was demonstrated 12 to 16 weeks post treatment –

– Early-phase, original research illustrated successful implementation of image-guided Stellate Ganglion Block (SGB) using ABP-450 both as monotherapy and in conjunction with lidocaine as a preclinical model for treating PTSD –

IRVINE, Calif., Jan. 18, 2024 (GLOBE NEWSWIRE) -- AEON Biopharma, Inc. ("AEON" or the "Company") (NYSE: AEON, AEON WS), a clinical-stage biopharmaceutical company focused on developing a proprietary botulinum toxin complex for the treatment of multiple debilitating medical conditions, today presented new clinical and pre-clinical data for ABP-450 in treating cervical dystonia (CD) and posttraumatic stress disorder (PTSD) at TOXINS 2024, a leading conference held by the International Neurotoxin Association (INA) from January 17th - 20th at the Estrel Berlin in Berlin, Germany.

Cervical Dystonia OLE Phase 2 Data

A poster titled, "Efficacy and Safety of ABP-450 (prabotulinumtoxinA) in Adults with Cervical Dystonia: Results From the Open-label Extension of a Phase 2 Trial," was presented by Chad Oh, M.D., the Company's Chief Medical Officer. Topline data from the recently completed open-label extension (OLE) of the Phase 2 trial demonstrate that ABP-450 was generally safe and well tolerated in CD patients for up to 4 treatment cycles during the 52-week duration of the study. ABP-450 did not appear to increase treatment-related TEAEs at any dose in the study. Peak efficacy for all ABP-450 doses and cycles occurred early, within 4 weeks, and durability of effect was demonstrated from 12 to 16 weeks post treatment. These results support further investigation of ABP-450 as a treatment option for patients with CD and other movement disorders.

The OLE was a 52-week study of ABP-450 in adults with moderate to severe CD, a chronic and debilitating neurologic condition affecting the muscles of the neck, who participated in the placebo-controlled, double-blind Phase 2 (DBP) study and for whom ≥ 8 weeks had elapsed between their single DBP treatment and first OLE treatment. Patients who showed a lack or loss of efficacy at DBP Week 4 or later could transition to the OLE (after 8 weeks had elapsed for patients transitioning prior to Week 8); otherwise, patients entered the OLE at Week 20, providing they met the entry criteria. Patients received up to 4 treatments of ABP-450 during the OLE; patients received a dose range of 115 to 350 units as determined by and at the discretion of the investigator. After the first OLE treatment, patients were eligible for retreatment when their Toronto Western Spasmodic Torticollis rating scale total score (TWSTRS-T) returned to ≥ 20 and ≥ 10 weeks had passed since their last dose of ABP-450.

"We are excited to announce positive data from the 52-week OLE portion of the Phase 2 study of ABP-450 for CD. We believe these results warrant further investigation of ABP-450 as a treatment option for patients with CD and other movement disorders and support advancing our CD program for ABP-450 into a proposed Phase 3 study," commented Marc Forth, AEON's President and Chief Executive Officer. "We look forward to meeting with the FDA to discuss the CD data generated to date, including from the OLE, and solidify the design of a Phase 3 study of ABP-450 to treat CD."

Pre-Clinical PTSD Data Utilizing Stellate Ganglion Block

During TOXINS 2024 conference, Dr. Chad Oh also presented a poster titled, "New Investigations of Stellate Ganglion Block (SGB) with ABP-450 (PrabotulinumtoxinA) in Rats." This poster reports new data from three pre-clinical studies showing right or left SGB, ABP-450 appeared to be safe and well tolerated, with no significant signs of toxicity observed.

"We are excited to present new pre-clinical data supporting our ongoing post-traumatic stress disorder (PTSD) program. We utilize a proprietary injection paradigm in a novel part of the anatomy designed to provide safety and efficacy data to support an IND filing of the PTSD study. This innovative approach has the potential for use of ABP-450 to treat a broad neuropsychiatry portfolio, including PTSD. These early data clearly demonstrate AEON's pioneering role in botulinum toxin research and look forward to keeping you apprised of our progress in advancing this program," continued Dr. Chad Oh.

The stellate ganglion (SG) is formed by the fusion of the sympathetic ganglia in the upper thorax and provides most of the sympathetic innervation to the head and body. The three pre-clinical studies utilized SGB to injected rats with ABP-450 (0.5 or 3 units) both individually and in conjunction with lidocaine (1%-2%) using an ultrasound-guided technique over a duration of 1 to 2 hours. For the SGB procedure, baseline recordings of physiological parameters were assessed (i.e., heart rate, eye appearance, and pupil size) and then the linear ultrasound transducer (FUJIFILM Vevo 3100 micro-ultrasound imaging system) was placed in a short axis view proximal to the clavicle. After identifying the lateral side of the cephalic brachial vein, a 27-gauge needle connected to an insulin syringe (0.5 mL) was advanced from the lateral to medial stellate ganglion (SG) to deliver lidocaine and/or ABP-450.

Both lidocaine and ABP-450 were mixed with Chicago blue dye to confirm SGB targeting.

Based on the results of this study, an appropriate dose for ABP-450 injected into the rat SG appears to be between 1 and 10 U/kg. The primary indicator for SGB (ptosis as a manifestation of the Horner's syndrome) was clearly established and verified parenteral delivery of lidocaine to both the left and right SG, suggesting that left side and/or bilateral dosing is an option for future experiments. This early-phase, original research in a limited dataset illustrated the successful implementation of an imaging-guided SGB model using lidocaine. These results provided pilot data confirming the accurate delivery of combination doses of lidocaine and ABP-450, with evidence of appropriate SGB targeting without significant signs of toxicity, which supports future studies of ABP-450 as a potential treatment of PTSD.

The posters presented by AEON at the TOXINS 2024 conference can be accessed on the Events and Presentations page of the Company's corporate website. ([click here](#)).

About ABP-450 (prabotulinumtoxinA) Injection

ABP-450 contains a 900 kDa botulinum toxin type-A complex produced by the bacterium *Clostridium botulinum*. The active part of the botulinum toxin is the 150 kDa component, and the remaining 750 kDa of the complex is made up of accessory proteins that the Company believes help with the function of the active portion of the botulinum toxin. When injected at therapeutic levels, ABP-450 blocks peripheral acetylcholine release at presynaptic cholinergic nerve terminals by cleaving SNAP-25, a protein integral to the successful docking and release of acetylcholine from vesicles situated within the nerve endings leading to denervation and relaxation of the muscle.

About AEON Biopharma

AEON is a clinical stage biopharmaceutical company focused on developing its proprietary botulinum toxin complex, ABP-450 (prabotulinumtoxinA) injection, or ABP-450, for debilitating medical conditions, with an initial focus on the neurosciences market. AEON recently completed a Phase 2 study of ABP-450 for the treatment of cervical dystonia, released topline data from its Phase 2 study of ABP-450 for the preventive treatment of episodic migraine, and has an ongoing Phase 2 study of ABP-450 for the preventive treatment of chronic migraine. ABP-450 is the same botulinum toxin complex that is currently approved and marketed for cosmetic indications by Evolus under the name Jeuveau. ABP-450 is manufactured by Daewoong in compliance with current Good Manufacturing Practice, or cGMP, in a facility that has been approved by the U.S. Food and Drug Administration, or the FDA, Health Canada and European Medicines Agency, or EMA. 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. The Company has built a highly experienced management team with specific experience in biopharmaceutical and botulinum toxin development and commercialization. To learn more about AEON and the development of its uniquely positioned therapeutic neurotoxin, 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 continued listing on NYSE American, the anticipated timing of clinical results, the impact of current financing arrangements, the competitive environment in which AEON operates, AEON's expected capital resources and liquidity needs and the expected future operating and financial performance and market opportunities of AEON are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "pro forma", "may", "should", "could", "might", "plan", "possible", "project", "strive", "budget", "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 outcome of any legal proceedings that may be instituted against AEON or others; (ii) AEON's future capital requirements, including with respect to potential obligations pursuant to the forward purchase agreements; (iii) AEON's ability to raise financing in the future; (iv) AEON's ability to continue to meet continued stock exchange listing standards; (v) costs related to being a public company; (vi) changes in applicable laws or regulations; (vii) the possibility that AEON may be adversely affected by other economic, business, regulatory, and/or competitive factors; (viii) AEON's estimates of expenses and profitability; (ix) the evolution of the markets in which AEON competes; (x) the ability of AEON to implement its strategic initiatives, including the continued development of ABP-450; (xi) the ability of AEON to defend its intellectual property; (xii) the ability of AEON to satisfy regulatory requirements; (xiii) the impact of adverse geopolitical and macroeconomic developments, such as the COVID-19 pandemic, the Israel-Hamas conflict, the Ukraine-Russia conflict and related sanctions, actual and anticipated changes in interest rates, economic inflation and the responses by central banking authorities to control such inflation on AEON's business; and (xiv) 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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