Emergent BioSolutions Prepares for Initial Shipments of AV7909 Anthrax Vaccine Candidate into the Strategic National Stockpile

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GAITHERSBURG, Md., May 15, 2019 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE:EBS) announced today that the Biomedical Advanced Research and Development Authority (BARDA) has informed the company that it will begin procuring AV7909 (anthrax vaccine adsorbed with CPG 7909 adjuvant) for delivery into the Strategic National Stockpile (SNS). Subject to the fulfillment of certain contractual obligations, the company plans to deliver AV7909 in the second half of 2019 under the terms of its development and procurement contract with BARDA valued at up to $1.5 billion signed in September 2016.

This milestone and the initiation of the Phase 3 trial of AV7909 in March build upon the application that was submitted in December 2018 to the U.S. Food and Drug Administration (FDA) for the potential emergency use of AV7909 in the event of a public health emergency involving *Bacillus anthracis*. The pre-Emergency Use Authorization submission package was completed under the company's 2016 contract with BARDA that includes a five-year base period of performance to develop AV7909 for post-exposure prophylaxis of anthrax disease and to deliver an initial three million doses to the SNS, as well as options for procurement of additional doses.

"Emergent is pleased to respond to BARDA's procurement of AV7909 for delivery into the Strategic National Stockpile representing the initiation of the planned anthrax vaccine transition from BioThrax to AV7909," said Robert G. Kramer Sr., president and chief executive officer of Emergent BioSolutions. "As discussed during the Q1 earnings call, the timing of this stage of the transition is consistent with our expectations and supports our financial projections and guidance for 2019."

Abbey Jenkins, senior vice president and vaccines and anti-infectives business unit head at Emergent BioSolutions, stated, "Emergent is proud of achieving this important milestone that further enables the government's response capability for a large-scale emergency involving anthrax. Our investigational next generation anthrax vaccine candidate AV7909 is designed to offer a two-dose schedule that elicits a rapid immune response. We are now one step closer to delivering the initial three million doses of AV7909 into the SNS. This event marks an important advancement in our more than a decade-long partnership with BARDA, supporting their efforts to enhance U.S. preparedness against public health threats."

The vaccine candidate AV7909 is being developed for post-exposure prophylaxis of disease resulting from suspected or confirmed *Bacillus anthracis* exposure, in conjunction with the recommended course of antimicrobial therapy. AV7909 is comprised of Anthrax Vaccine Adsorbed (AVA) in combination with an adjuvant, the immunostimulatory oligodeoxynucleotide compound CPG 7909. The addition of CPG 7909 to AVA has been shown to accelerate and enhance the immune response. Several Phase 1 and Phase 2 clinical studies have investigated the safety, efficacy, and stability profile of AV7909. The lot consistency, safety, and immunogenicity of AV7909 are currently being evaluated in a Phase 3 trial, which is expected to complete in late 2020.

Contract HHSO100201600030C for the advanced development and delivery of AV7909 is funded by BARDA, a division within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services.

About Pre-Emergency Use Authorization Review

In accordance with regulatory guidance from the FDA,[1] the review by the FDA of a pre-EUA submission is not an indication of FDA's views on the product's potential to be used under an EUA, or that the sponsor has obtained or submitted all the information necessary for FDA to review a formal request for consideration of an EUA. Pre-EUA activities are not a substitute for sponsor efforts to develop the product toward approval, including submission and, when appropriate, implementation of proposals for clinical trials designed to determine whether the product is safe and effective for its intended use.

About Emergent BioSolutions

Emergent BioSolutions Inc. is a global life sciences company seeking to protect and enhance life by focusing on providing specialty products for civilian and military populations that address accidental, deliberate, and naturally occurring public health threats. We aspire to be a Fortune 500 company recognized for protecting and enhancing life, driving innovation, and living our values. Additional information about the company may be found at www.emergentbiosolutions.com. Find us on LinkedIn and follow us on Twitter @emergentbiosolu and Instagram @life_at_emergent.

Safe Harbor Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including statements regarding whether BARDA will exercise its discretion to procure AV7909 relying on the FDA's review and acceptance of the company's pre-EUA submission, the potential dosing schedule and immune response of AV7909, the total potential realizable value of the BARDA development and procurement contract, the anticipated timing of EUA eligibility, our strategy, future operations, prospects, plans and objectives with respect to AV7909, and any other statements containing the words "believes," "expects," "anticipates," "intends," "plans," "estimates" and similar expressions, are forward-looking statements. These forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. We cannot guarantee that any forward-looking statement will be accurate. Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Investors are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date of this press release, and, except as required by law, we do not undertake to update any forward-looking

statement to reflect new information, events or circumstances.

There are a number of important factors that could cause the company's actual results to differ materially from those indicated by such forward-looking statements, including appropriations for the development and procurement of AV7909 under the contract; whether BARDA has exercised its discretion to procure AV7909 relying on the FDA's review and acceptance of the company's pre-EUA submission, and licensure of AV7909 by FDA within the anticipated timeframe, if at all; BARDA's decisions to exercise options under the contract; and our development and manufacturing capabilities and strategies. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in our periodic reports filed with the SEC, when evaluating our forward-looking statements.

[1] Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders (January 2017), Section III (C). Retrieved at www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm#preeua

Investor Contact:
Robert G. Burrows
Vice President, Investor Relations
240-631-3280
burrowsr@ebsi.com

Media Contact:
Lynn Kieffer
Vice President, Corporate Communications
240-631-3391
KiefferL@ebsi.com

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