Emergent BioSolutions Initiates Phase 3 Clinical Study to Evaluate AV7909 for Post-Exposure Prophylaxis of Anthrax

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GAITHERSBURG, Md., March 19, 2019 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE:EBS) today announced the initiation of a Phase 3 trial to evaluate the lot consistency, immunogenicity, and safety of AV7909 (anthrax vaccine adsorbed with CPG 7909 adjuvant) following a two-dose schedule administered intramuscularly in healthy adults. AV7909 is being developed for post-exposure prophylaxis of disease resulting from suspected or confirmed *Bacillus anthracis* exposure.

“Emergent is pleased with the advancement of the AV7909 development program,” said Abbey Jenkins, senior vice president and vaccines and anti-infectives business unit head at Emergent BioSolutions. “Dosing the first subject in this large clinical study is a milestone achievement and we look forward to continuing to execute on our development and procurement contract for AV7909.”

AV7909 is designed to elicit a faster immune response than the currently available anthrax vaccine. It 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, in previous Phase 1 and Phase 2 studies, to safely accelerate and enhance the immune response.

In evaluating the lot consistency of AV7909, the study will be using three consecutively manufactured lots of the vaccine candidate. This Phase 3 randomized, double-blind, parallel-group study plans to enroll 3,850 adults across 35 sites within the U.S. with an overall study duration of approximately 20 months. More information on the study is available on https://clinicaltrials.gov/ct2/show/NCT03877926.

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

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, intentional, 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, including statements regarding the potential immune response to AV7909. Any statements, other than statements of historical fact, 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 the ultimate success of the planned development program; our ability to secure EUA pre-authorization approval of AV7909 from the FDA within the anticipated timeframe, if at all; our ability to manufacture the product candidate at desired quantities within the anticipated timeframe; and the results of clinical trials and our commercialization and marketing capabilities. 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.

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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