Emergent BioSolutions Announces FDA Acceptance of Biologics License Application for AV7909 Anthrax Vaccine Candidate

June 24, 2022

GAITHERSBURG, Md., June 24, 2022 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE:EBS) announced today that the U.S. Food and Drug Administration (FDA) accepted for review the Biologics License Application (BLA) for AV7909 (Anthrax Vaccine Adsorbed, Adjuvanted). AV7909 is the company's new anthrax vaccine candidate evaluated for post-exposure prophylaxis of disease following suspected or confirmed exposure to *Bacillus anthracis* in persons 18 through 65 years of age when administered in conjunction with recommended antibacterial drugs. The Prescription Drug User Fee Act goal date for a decision by the FDA is in April 2023.

"Over the last 20 years, Emergent has partnered with the U.S. government to lead this program from early- to advanced-stage development," said Kelly Warfield, senior vice president research and development at Emergent BioSolutions. "As we progress toward licensure of AV7909, which is designed to follow a two-dose immunization schedule and to elicit a faster immune response, we redouble our efforts to support the government's overall preparedness and response strategy for large-scale emergencies involving anthrax and other threats to public health."

The rolling BLA submission, completed in April 2022, is based on data from the pivotal phase 3 clinical study of AV7909 that evaluated the lot consistency, immunogenicity, and safety of the vaccine candidate following a two-dose schedule administered intramuscularly in healthy adults. It also included data from the phase 2 study that evaluated non-interference between AV7909 and antibacterial drugs approved for post-exposure prophylaxis of anthrax disease.

The BLA submission was completed under contract HHSO100201600030C for the advanced development and delivery of AV7909, funded by the Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services.

About Emergent BioSolutions
At Emergent, our mission is to protect and enhance life. For over 20 years, we've been at work defending people from things we hope will never happen—so we are prepared, just in case they ever do. We provide solutions for complex and urgent public health threats through a portfolio of vaccines and therapeutics that we develop and manufacture for governments and consumers. We also offer a range of integrated contract development and manufacturing services for pharmaceutical and biotechnology customers. To learn more about how we plan to protect or enhance 1 billion lives by 2030, visit our website and follow us on LinkedIn, Twitter, and Instagram.

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 the potential dosing schedule and immune response of AV7909, the total potential realizable value of the BARDA development and procurement contract, the anticipated timing for a decision by the FDA, 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; our ability to secure 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.

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

Media Contact:
Matt Hartwig
Senior Director, Media Relations
mediarelations@ebsi.com

Source: Emergent BioSolutions