News Release



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EMERGENT BIOSOLUTIONS ANNOUNCES SUBMISSION TO FDA OF APPLICATION COVERING EMERGENCY USE AUTHORIZATION FOR NUTHRAX™

GAITHERSBURG, Md.—**December 28, 2018**—Emergent BioSolutions Inc. (NYSE:EBS) announced today the submission of an application to the U.S. Food and Drug Administration (FDA) for potential emergency use of NuThrax $^{\text{TM}}$ (anthrax vaccine adsorbed with CPG 7909 adjuvant) in the event of a public health emergency involving *Bacillus anthracis*. NuThrax, also known as AV7909, is being developed as a next generation anthrax vaccine for post-exposure prophylaxis of disease resulting from suspected or confirmed *Bacillus anthracis* exposure, in conjunction with the recommended course of antimicrobial therapy. This submission is anticipated to undergo review by FDA through the first half of 2019.

"We are pleased with engaging in early discussions with the FDA regarding this EUA package submission for NuThrax, which has been identified as a potential critical component of the nation's anthrax preparedness strategy," said Abbey Jenkins, senior vice president and vaccines and anti-infectives business unit head at Emergent BioSolutions. "NuThrax is designed to have attractive features, including the potential to have a shorter dosing schedule and to elicit a faster immune response, that may make it a more appropriate candidate for an effective response to a large-scale public health emergency involving anthrax. We look forward to NuThrax being an EUA-eligible product to enable deliveries to the Strategic National Stockpile in 2019."

NuThrax is comprised of Anthrax Vaccine Adsorbed in combination with the immunostimulatory oligodeoxynucleotide compound CPG 7909. NuThrax was designed to have a two-dose schedule and may elicit a faster immune response than currently available anthrax vaccines. Several Phase 1 and Phase 2 clinical studies have investigated the safety, efficacy, and stability profile of NuThrax.

The FDA submission package was completed under the company's 2016 contract with the Biomedical Advanced Research and Development Authority (BARDA) that includes a five-year base period of performance valued at approximately \$200 million to develop NuThrax for post-exposure prophylaxis of anthrax disease and to deliver to the Strategic National Stockpile an initial three million doses following EUA pre-approval by FDA.

Contract HHSO100201600030C for the advanced development and delivery of NuThrax 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 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. Any statements, other than statements of historical fact, including statements regarding the potential dosing schedule and immune response of NuThrax, 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 NuThrax, 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 NuThrax under the contract; our ability to secure EUA preauthorization approval and licensure of NuThrax 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.

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