



FOR IMMEDIATE RELEASE

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EMERGENT BIOSOLUTIONS SEEKS EXPANDED BIOTHRAX LABEL; SUBMITS FDA APPLICATION FOR POST-EXPOSURE PROPHYLAXIS

ROCKVILLE, Md.—**November 10, 2014**— Emergent BioSolutions Inc. (NYSE: EBS) today announced that it has submitted a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) seeking to expand the label of BioThrax[®] (Anthrax Vaccine Adsorbed) to include a post-exposure prophylaxis (PEP) indication. BioThrax, the only FDA-licensed vaccine to prevent anthrax disease, is currently licensed for a pre-exposure prophylaxis indication only.

"This sBLA submission reflects years of collaboration between Emergent and the U.S. government to enhance the country's preparedness to meet immediate public health needs in the event of an anthrax attack. To date, these efforts have led to an enhanced route of administration, a streamlined vaccination schedule, and an extended shelf life for BioThrax. The next milestones for this collaboration are an expanded product label to include PEP and an increase in our manufacturing capacity to a target of between 20-25 million doses per year," said Adam Havey, executive vice president and president, biodefense division at Emergent BioSolutions.

The company made a Request for Priority Review Designation to potentially reduce the anticipated approval of this application to six months. The sBLA proposes to expand the BioThrax indication to include a post-exposure prophylaxis of disease resulting from suspected or confirmed *Bacillus anthracis* exposure when combined with the recommended course of antimicrobials in persons 18 through 65 years of age. The vaccination schedule consists of three doses of BioThrax administered at 0, 2, and 4 weeks post-exposure. This indication is supported by data from twelve non-clinical studies, three Phase 2/3 clinical trials, and a 2010 pre-Phase 3 Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting during which the regulatory pathway for licensure of anthrax vaccines for PEP was established.

All studies supporting licensure were fully funded under contract number HHSO100200700037C provided by the Biomedical Advanced Research and Development Authority within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services.

News Release



About Emergent BioSolutions

Emergent BioSolutions is a global specialty biopharmaceutical company seeking to protect and enhance life by offering specialized products to healthcare providers and governments to address medical needs and emerging health threats. Additional information about the company may be found at <u>www.emergentbiosolutions.com</u>. Follow us @emergentbiosolu.

About BioThrax

BioThrax is the only FDA-licensed vaccine for the prevention of anthrax disease. It is indicated for the active immunization of adults who are at high risk of exposure to anthrax. The safety and efficacy of BioThrax in a post-exposure setting have not been established. Individuals are not considered protected until they have completed the three-dose primary immunization series. Vaccination with BioThrax may not protect all individuals.

BioThrax is manufactured from a culture filtrate, made from a non-virulent strain of *Bacillus anthracis.* To date, Emergent has delivered over 66 million doses of BioThrax to the U.S. government and continues to deliver additional doses under active procurement contracts. Since 1998, over 12 million doses have been administered to more than 3 million military personnel. For full prescribing information, please visit http://www.biothrax.com/prescribinginformation biothrax us.pdf.

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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 our strategy, future operations, prospects, plans and objectives of management, 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 the success of our ongoing and planned preclinical studies and clinical trials; the rate and degree of market acceptance and clinical utility of our products; the success of our ongoing and planned development programs; the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; and our commercialization, marketing and manufacturing 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.