

# FOR IMMEDIATE RELEASE

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# EMERGENT BIOSOLUTIONS ADVANCES PROGRAM SUPPORTING LICENSURE OF A POST-EXPOSURE PROPHYLAXIS INDICATION FOR BIOTHRAX

- Pivotal clinical study to support licensure of a post-exposure prophylaxis (PEP) indication for BioThrax meets primary and key secondary endpoints; Data to be presented at Bacillus ACT meeting
- Final clinical study report submitted to BARDA and FDA
- Data from preliminary non-clinical and clinical PEP studies published in Clinical and Vaccine Immunology journal

**ROCKVILLE, MD, July 10, 2013** — Emergent BioSolutions Inc. (NYSE: EBS) today announced that its pivotal Phase 3 clinical study evaluating the immunogenicity and safety of a three-dose BioThrax<sup>®</sup> (Anthrax Vaccine Adsorbed) regimen for post-exposure prophylaxis (PEP) has been completed and has met its primary and key secondary endpoints. The company has submitted the final clinical study report to the Biomedical Advanced Research and Development Authority (BARDA) and the U.S. Food and Drug Administration (FDA) and these results will be used to support an eventual supplemental Biologics License Application (sBLA) seeking licensure of a PEP indication for BioThrax. BioThrax is the only FDA-licensed vaccine for the prevention of anthrax disease. BioThrax is not licensed for use in a post-exposure setting.

"Emergent's on-time completion of this study and submission of our clinical study report represents a key milestone in our BioThrax PEP development program," said Adam Havey, executive vice president and president of Emergent's biodefense division. "These data represent the culmination of a multi-year effort aimed at evaluating the use of BioThrax for PEP. This work is an excellent example of the partnership between industry and the U.S. Government agencies including BARDA, FDA, the National Institute of Allergy and Infectious Diseases, and the Centers for Disease Control and Prevention."

The Phase 3 open-label clinical study enrolled 200 healthy adult volunteers and was conducted at four sites within the U.S. Data from this study will be presented at the International Conference on *Bacillus anthracis, B. cereus, and B. thuringiensis* (Bacillus ACT) in September 2013. This study is fully funded under contract number HHSO100200700037C provided by BARDA within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services.





Additionally, data from non-clinical and clinical PEP studies that preceded the Phase 3 study have been published in the July issue of *Clinical and Vaccine Immunology*. The publication describes preexposure and post-exposure vaccine efficacy study data in animal models of anthrax disease, as well as exploratory clinical vaccine immunogenicity study data. This is the first comprehensive report of animal and clinical studies evaluating efficacy and immunogenicity of a vaccine that will utilize the FDA "Animal Rule" as a pathway to licensure by demonstrating efficacy in adequate and wellcontrolled animal models.

## **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. BioThrax is not licensed for use in a post-exposure setting. The safety and efficacy of BioThrax have not been established in pediatric or geriatric populations. 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 11 million doses have been administered to more than 2.9 million military personnel. For full prescribing information, please visit

http://www.biothrax.com/prescribinginformation biothrax us.pdf.

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### **About Emergent BioSolutions**

Emergent BioSolutions is a specialty pharmaceutical 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 may be found at <u>www.emergentbiosolutions.com</u>. Follow us on twitter: <u>@emergentbiosolu</u>.

### 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; our commercialization, marketing and manufacturing capabilities and strategy; and our estimates regarding expenses, future revenue, capital requirements and needs for additional financing. 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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