

# Emergent BioSolutions Initiates Pivotal Clinical Trial Evaluating a Three-Dose BioThrax Regimen for Post-Exposure Prophylaxis

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ROCKVILLE, Md., Nov 17, 2011 (BUSINESS WIRE) --

Emergent BioSolutions Inc. (NYSE:EBS) today announced the initiation of a pivotal immunogenicity and safety study to evaluate a three-dose vaccination schedule of BioThrax<sup>(R)</sup> (Anthrax Vaccine Adsorbed) for administration to individuals exposed to anthrax. Through this pivotal, licensure-enabling clinical study, the company seeks to obtain a post-exposure prophylaxis (PEP) indication for BioThrax.

Approval of the PEP indication would expand use of BioThrax beyond its current pre-exposure prophylaxis indication to add an indication in which the vaccine would be used in combination with antibiotics in people who have potentially been exposed to anthrax spores. Immune protection in this setting is important because of the potential for residual anthrax spores to germinate and cause disease after the currently recommended 60-day course of antibiotic treatment has stopped. BioThrax is the only vaccine licensed by the U.S. Food and Drug Administration for the prevention of anthrax disease.

"Emergent is pleased to be working with BARDA to broaden the clinical utility of BioThrax and to further enhance its features in support of the U.S. government's biodefense needs," said Daniel J. Abdun-Nabi, president and chief operating officer of Emergent BioSolutions.

The clinical study involves 200 healthy adult volunteers and will be conducted in four sites within the U.S. The company anticipates preliminary data to be available in the fourth quarter of 2012.

This study is being funded by contract number HHSO100200700037C, provided by the Biomedical Advanced Research and Development Authority (BARDA) of the Department of Health and Human Services (HHS).

#### About Emergent BioSolutions Inc.

Emergent BioSolutions protects and enhances life by developing and manufacturing vaccines and therapeutics that are supplied to healthcare providers and purchasers for use in preventing and treating disease. Emergent's marketed and investigational products target infectious diseases, oncology and autoimmune disorders. Additional information about the company may be found at <a href="https://www.emergentbiosolutions.com">www.emergentbiosolutions.com</a>.

#### **About BioThrax**

BioThrax is the only FDA-licensed vaccine for the prevention of anthrax infection. It is indicated for the active immunization of adults who are at high risk of exposure to anthrax. BioThrax is manufactured from a culture filtrate, made from a non-virulent strain of *Bacillus anthracis*. To date, Emergent has delivered over 55 million doses of BioThrax to the U.S. government and continues to deliver additional doses under active procurement contracts. Since 1998, over 10 million doses have been administered to more than 2.6 million military personnel. For full prescribing information, please visit <a href="https://www.biothrax.com/prescribinginformation\_biothrax\_us.pdf">www.biothrax.com/prescribinginformation\_biothrax\_us.pdf</a>.

#### 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, future financial position, future revenues, projected costs, prospects, plans and objectives of management, including any potential future securities offering, our expected revenue growth and net earnings for 2011, and any other statements containing the words "believes", "expects", "anticipates", "plans", "estimates" and similar expressions, are forward-looking statements. 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 BioThrax<sup>(R)</sup> procurement; our ability to obtain new BioThrax<sup>(R)</sup> sales contracts or modifications to existing contracts; our plans to pursue label expansions and improvements for BioThrax<sup>(R)</sup>; our plans to expand our manufacturing facilities and capabilities; the rate and degree of market acceptance of our products; the success of preclinical studies and clinical trials of our product candidates and post-approval clinical utility of our products; and other factors identified in the company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011 and subsequent reports filed with the SEC. The company disclaims any intention or obligation to update any forward-looking statements as a result of developments occurring after the date of this press release.

SOURCE: Emergent BioSolutions Inc.

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