

**FOR IMMEDIATE RELEASE**

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**EMERGENT BIOSOLUTIONS RECEIVES ORPHAN DRUG DESIGNATION FOR BIOTHRAX FOR POST-EXPOSURE PROPHYLAXIS OF ANTHRAX DISEASE**

**ROCKVILLE, MD, April 21, 2014** – Emergent BioSolutions Inc. (NYSE:EBS) announced today that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to BioThrax® (Anthrax Vaccine Adsorbed) for post-exposure prophylaxis (PEP) of anthrax disease resulting from suspected or confirmed exposure to *Bacillus anthracis*. Orphan status is given to drugs and biologics that are being developed to treat rare medical conditions, specifically those affecting fewer than 200,000 persons in the U.S. This designation provides incentives to the BioThrax PEP Program, including the waiver of the Biologics License Application (BLA) supplemental regulatory filing fee and marketing exclusivity of up to seven years.

“Emergent is pleased with FDA’s Orphan Drug Designation of BioThrax for post-exposure prophylaxis,” said Adam Havey, executive vice president and president, biodefense division at Emergent BioSolutions. “This designation will help streamline discussions around regulatory requirements at our pre-BLA meeting with FDA next month. We look forward to discussing our supplemental application for the expanded indication of post-exposure prophylaxis and the role of BioThrax in the treatment of inhalation anthrax.”

BioThrax, the only FDA-licensed vaccine to prevent anthrax disease, is currently licensed for a pre-exposure prophylaxis indication. Emergent recently announced completion of a non-interference study, results from which will be used to support a supplemental BLA seeking licensure of a PEP indication for BioThrax to be used in combination with antibiotics in people with suspected or confirmed exposure to anthrax spores. This study is fully funded under contract number HHSO100200700037C provided 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**

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 [www.emergentbiosolutions.com](http://www.emergentbiosolutions.com). Follow us on twitter: [@emergentbiosolu](https://twitter.com/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](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; 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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