



FDA Grants Fast Track Designation to Emergent BioSolutions' BioThrax(R) for Post-Exposure Prophylaxis against Anthrax Infection

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Company Continues Clinical and Non-Clinical Testing in Pursuit of Post-Exposure Indication

ROCKVILLE, Md.--(BUSINESS WIRE)--Feb. 12, 2007--Emergent BioSolutions Inc. (NYSE: EBS) announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for BioThrax(R) (Anthrax Vaccine Adsorbed) as a post-exposure prophylaxis against anthrax infection. BioThrax is the only FDA approved product for pre-exposure prophylaxis of anthrax infection. The company plans to seek FDA approval of BioThrax for use in combination with antibiotics as a post-exposure prophylaxis for anthrax infection. The company is targeting a three dose regimen given two weeks apart for this indication.

"We are extremely pleased that the FDA has taken this step as we continue our efforts to expand the label indication for BioThrax to include, in combination with antibiotics, its use for post-exposure prophylaxis for anthrax infection," said Fuad El-Hibri, chairman and chief executive officer of Emergent BioSolutions. "Our ongoing BioThrax enhancement programs are critically important and are designed to address the U.S. government's requirements in protecting our front-line forces as well as to building a national stockpile of safe and effective countermeasures against the use of anthrax as a weapon of bioterrorism."

Under the FDA Modernization Act of 1997, Fast Track designation expedites the development and review of a drug that is intended for the treatment of a serious life-threatening condition and demonstrates the potential to address an unmet medical need for such a condition.

BioThrax Post-Exposure Development Program

Currently, the company has an ongoing development program to expand the licensed label indications for BioThrax to include post-exposure prophylaxis when used in conjunction with antibiotics. In support of this expanded label indication, the company is conducting clinical trials, as well as non-clinical trials in accordance with the FDA's animal rule. If the results from these studies are favorable, the company would anticipate filing with the FDA a biologics license application (BLA) supplement for marketing approval of BioThrax for this indication.

The scientific information discussed in this press release related to the use of BioThrax in combination with antibiotic therapy as a post-exposure prophylaxis for anthrax infection is preliminary and investigative. BioThrax is not currently approved by the FDA for this purpose, and no conclusions can or should be drawn regarding the safety or effectiveness of BioThrax for this purpose. Only the FDA can determine whether BioThrax is safe and effective for this purpose. Healthcare professionals should refer to and rely upon the FDA-approved labeling for BioThrax, and not the information discussed in this press release.

About Emergent BioSolutions Inc.

Emergent BioSolutions Inc. is a biopharmaceutical company focused on the development, manufacture and commercialization of immunobiotics, such as vaccines and therapeutics that induce or assist the body's immune system to prevent or treat disease. The company's biodefense business is focused on developing and commercializing immunobiotics for use against biological agents that are potential weapons of bioterrorism. The company's commercial business is focused on developing immunobiotics for use against infectious diseases with significant unmet or underserved medical needs. More information on the company is available at www.emergentbiosolutions.com.

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 pursuit of a label expansion for BioThrax(R) in combination with antibiotics as a post-exposure prophylaxis for anthrax infection, our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management 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 our performance under existing BioThrax(R) sales contracts with the U.S. government, including the timing of deliveries under these contracts; our ability to obtain new BioThrax(R) sales contracts with the U.S. government; our plans for future sales of BioThrax(R); our plans to pursue label expansions and improvements for BioThrax(R); our plans to expand our manufacturing facilities and capabilities; the rate and degree of market acceptance and clinical utility of our products; our ongoing and planned development programs, preclinical studies and clinical trials; our ability to identify and acquire or in license products and product candidates that satisfy our selection criteria; the potential benefits of our existing collaboration agreements and our ability to enter into selective additional collaboration arrangements; the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; our commercialization, marketing and manufacturing capabilities and strategy; our intellectual property portfolio; our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and other factors identified in the company's Registration Statement on Form S-1 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.

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