Emergent BioSolutions Receives Fast Track Designation for Its Investigational Monoclonal Antibody for the Treatment of Inhalational Anthrax

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ROCKVILLE, Md., Oct 01, 2010 (BUSINESS WIRE) --

Emergent BioSolutions Inc. (NYSE:EBS) announced today that its anthrax monoclonal antibody development program investigating AVP-21D9 for the treatment of inhalational anthrax has been granted Fast Track Designation by the U.S. Food and Drug Administration (FDA). Emergent recently commenced a Phase I clinical trial for AVP-21D9, which is a fully human monoclonal antibody product candidate being developed as a parenteral post-exposure therapeutic to treat symptoms of inhalational anthrax disease.

"Emergent is pleased to receive FDA Fast Track Designation, which is designed to facilitate the development and review of new drugs and biologics, and could allow the shortest time to approval of our anthrax monoclonal antibody therapeutic," said Daniel J. Abdun-Nabi, president and chief operating officer of Emergent BioSolutions. "We look forward to continuing to work with the FDA to fill this significant unmet medical need and to address the acknowledged threat of inhalational anthrax as a biological weapon."

The FDA's Fast Track Development Program provides for expedited regulatory review of drugs and biologics that treat serious or life threatening diseases and demonstrate the potential to address unmet medical needs. Under the Fast Track Designation, Emergent is now eligible to receive expedited regulatory treatment, including frequent FDA meetings and written correspondence, receive priority review of its Biological License Applications (BLA) for the product, and submit its BLA on a rolling basis, which allows the FDA to review sections of the BLA in advance of receiving the complete submission.

Emergent's Phase I clinical trial, which involves 50 healthy volunteers, is a randomized, double-blind, placebo-controlled, dose escalation study designed to evaluate the safety and pharmacokinetics of the monoclonal antibody candidate.

About Emergent BioSolutions Inc.

Emergent BioSolutions Inc. is a biopharmaceutical company focused on the development, manufacture and commercialization of vaccines and antibody therapies that assist the body's immune system to prevent or treat disease. Emergent's marketed product, BioThrax(R) (Anthrax Vaccine Adsorbed), is the only vaccine approved by the U.S. Food and Drug Administration for the prevention of anthrax infection. Emergent's product pipeline targets infectious diseases and includes programs focused on anthrax, tuberculosis, typhoid, flu and chlamydia. Additional information may be found 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 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 2010, 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 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 other product candidates; our commercialization, marketing and manufacturing capabilities and strategy; our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and other factors identified in the company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010 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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