Emergent BioSolutions IND for Anthrax Monoclonal Antibody Therapeutic Clears FDA Review

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ROCKVILLE, Md., May 17, 2010 (BUSINESS WIRE) --Emergent BioSolutions Inc. (NYSE:EBS) announced today that its Investigational New Drug (IND) application, to commence a Phase I clinical trial for its anthrax monoclonal antibody therapeutic, has cleared U.S. Food and Drug Administration (FDA) review. The Phase I study will evaluate the safety and pharmacokinetics of the company's fully human monoclonal antibody being developed as a parenteral post-exposure therapy for individuals who have symptoms of anthrax disease. In pre-clinical therapeutic studies, Emergent's monoclonal antibody was found to be effective.

"Emergent is committed to advancing its anthrax franchise, which includes both vaccines and therapeutics that address the anthrax threat," said Stephen Lockhart, MRCP, senior vice president product development of Emergent BioSolutions. "The end goal is to strengthen the nation's arsenal of medical countermeasures and provide products that will support the government's biopreparedness efforts."

The Phase I clinical trial is designed as a randomized, double-blind, placebo-controlled, dose-escalation study involving 50 healthy volunteers. Emergent anticipates the overall duration of the trial to be 15 months, with dosing of all subjects expected to be completed within 11 months of initiation of the clinical trial.

Emergent has received $24.3 million in development funding from the United States Government to support the development of its monoclonal antibody as a therapeutic for inhalation anthrax. This study is being funded by the Biomedical Advance Research and Development Authority (BARDA) and the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Department of Health and Human Services (HHS), under contract No. HHSN272200800040C.

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 March 31, 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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