Emergent BioSolutions' Investigational Anthrax Vaccine, NuThrax, Granted Fast Track Designation

June 9, 2011

ROCKVILLE, Md., Jun 09, 2011 (BUSINESS WIRE) -- Emergent BioSolutions Inc. (NYSE:EBS) announced today that its investigational anthrax vaccine, NuThrax^{TM} (Anthrax Vaccine Adsorbed with CPG 7909 Adjuvant), has been granted Fast Track Designation by the U.S. Food and Drug Administration (FDA). The vaccine candidate, also known as AV7909, consists of BioThrax$^{(R)}$ (Anthrax Vaccine Adsorbed) in combination with a novel immunostimulatory oligodeoxynucleotide compound, CPG 7909, and is currently being evaluated in a Phase 1b clinical trial for safety, tolerability, and immunogenicity. The FDA's Fast Track Development Program provides for expedited regulatory review of drugs and biologics that treat serious or life threatening diseases and that demonstrate the potential to address unmet medical needs.

"Emergent is pleased to receive Fast Track Designation for NuThrax," said Daniel J. Abdun-Nabi, president and chief operating officer of Emergent BioSolutions. "Expedited regulatory review could mean more frequent communications with FDA, priority review of Biologics License Applications (BLA) for our vaccine, and a rolling BLA submission, which allows FDA to review sections of the BLA in advance of receiving the complete submission."

The Phase 1b trial for NuThrax is being conducted with support from a development contract that is jointly administered under contract number HHSN272200800051C by the National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH), and the Office of 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 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 2011, and any other statements containing the words "believes", "expects", "anticipates", "plans", "estimates", "may", "would", "will", 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 preclinical studies and clinical trials of our product candidates and post-approval clinical utility of our products; the rate and degree of market acceptance 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 plans to pursue label expansions and improvements for BioThrax; 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, 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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