Emergent BioSolutions Receives Orphan Drug Designation for Its Investigational Monoclonal Antibody for the Treatment of Inhalation Anthrax

November 4, 2010

ROCKVILLE, Md., Nov 04, 2010 (BUSINESS WIRE) -- Emergent BioSolutions Inc. (NYSE:EBS) announced today that its fully human anthrax monoclonal antibody AVP-21D9, which is in development for the treatment of inhalation anthrax, has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA). 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.

"Receiving FDA Orphan Drug Designation for our investigational monoclonal antibody underscores the unmet medical need in treating inhalation anthrax disease," said Daniel J. Abdun-Nabi, president and chief operating officer of Emergent BioSolutions. "Emergent is committed to advancing product candidates that could help address that need. We also fully support the U.S. government's preparedness efforts against the threat of anthrax as a biological weapon through continuing to manufacture and deliver doses of BioThrax(R), the only vaccine licensed by the FDA for the prevention of anthrax infection, into the strategic national stockpile."

The designation provides for a number of potential incentives related to AVP-21D9, including a seven-year period of marketing exclusivity, reduced regulatory fees, certain tax credits, and additional regulatory support for research and development initiatives.

AVP-21D9 is presently in a randomized, double-blind, placebo-controlled, dose escalation Phase I clinical study involving 50 healthy volunteers designed to evaluate the safety and pharmacokinetics of the product candidate.

The development of AVP-21D9 is being funded by contract no. HHSN272200800040C, which is provided by the Biomedical Advance Research and Development Authority (BARDA) and administered by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), Department of Health and Human Services (HHS).

About Emergent BioSolutions Inc.

Emergent BioSolutions Inc. is a global 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 and investigational products target infectious diseases, oncology, and autoimmune disorders. Additional information about the company may be found at http://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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