Emergent BioSolutions Receives FDA Approval for BioThrax Supplemental Biologics License Application

December 19, 2008

Reduced Dosage and Intramuscular Administration Approved

ROCKVILLE, Md., Dec 19, 2008 (BUSINESS WIRE) -- Emergent BioSolutions Inc. (NYSE:EBS) announced today that the U.S. Food and Drug Administration (FDA) has approved Emergent's supplemental Biologics License Application (sBLA) for Anthrax Vaccine Adsorbed (BioThrax(R)), the only FDA-licensed vaccine to prevent disease caused by Bacillus anthracis. The supplement provides for a change in the route of administration and a reduction in the total number of vaccinations. The new schedule for BioThrax is five intramuscular (IM) doses at 0, 1, 6, 12 and 18 months, compared with the former schedule of six subcutaneous (SC) doses at 0, 2 weeks and 1, 6, 12, 18 months.

The sBLA was based on results from a planned interim analysis of data from a large multicenter study initiated by CDC in 2002. This study is designed to evaluate whether as few as three doses of BioThrax administered over six months, with booster doses up to three years apart, will confer an adequate immune response. CDC will complete further data analysis in 2009, and Emergent may submit a new sBLA to allow for further reduction in the number of required doses if supported by the data.

Daniel Abdun-Nabi, chief operating officer and president of Emergent BioSolutions said, "Today's announcement is an exciting milestone in our continued mission to advance BioThrax. We are pleased that the U.S. Government shares our commitment to enhancing this critical countermeasure. The CDC is to be applauded for their hard work and diligence throughout this important effort."

About BioThrax(R) (Anthrax Vaccine Adsorbed)

BioThrax is the only FDA-licensed vaccine for the prevention of anthrax infection. It is licensed by the FDA as a pre-exposure prophylaxis for use in adults who are at high risk of exposure to anthrax spores. BioThrax is manufactured from a culture filtrate, made from a non-virulent strain of Baccillus anthracis and contains no dead or live bacteria. BioThrax is administered by intramuscular injection in five doses, with an annual booster dose recommended thereafter. Since 1998, the U.S. government has procured nearly 32 million doses of BioThrax. During that time period, nearly 7.9 million doses have been administered to more than two million military personnel. BioThrax cannot cause anthrax infection. Please visit http://www.emergentbiosolutions.com/pdf/emergent_biothrax_us.pdf for full prescribing information.

About Emergent BioSolutions Inc.

Emergent BioSolutions Inc. is a biopharmaceutical company focused on the development, manufacture and commercialization of immune-related biologic products, consisting of vaccines and therapeutics 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 clinical pipeline includes programs focused on anthrax, botulism, typhoid, tuberculosis, hepatitis B and chlamydia.

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, 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 appropriations for BioThrax procurement; our ability to obtain new BioThrax sales contracts with the U.S. government; our plans to pursue label expansions and improvements for BioThrax; our plans to expand our manufacturing facilities and capabilities; the rate and degree of market acceptance and clinical utility of our products; 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 September 30, 2008 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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