News Release



FOR IMMEDIATE RELEASE

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EMERGENT BIOSOLUTIONS INITIATES FINAL PIVOTAL STUDY TO SUPPORT LICENSURE OF BIOTHRAX AT LARGE SCALE

- Large scale manufacturing of BioThrax in Building 55 will increase annual production capacity from 7-9 million doses to a target of 20-25 million doses

ROCKVILLE, Md.—**September 23, 2014**—Emergent BioSolutions Inc. (NYSE: EBS) today announced the initiation of the pivotal non-clinical efficacy study to demonstrate that BioThrax[®] (Anthrax Vaccine Adsorbed) manufactured at large scale in the company's new modern facility, Building 55, is comparable to the BioThrax currently manufactured in its approved facility, Building 12. Data from this study will be used to support licensure of Building 55. BioThrax is the only vaccine licensed by the U.S. Food and Drug Administration (FDA) for the prevention of anthrax disease.

Adam Havey, executive vice president and president biodefense division at Emergent BioSolutions, stated, "We are pleased to have advanced this Comparability Program through an effective partnership with BARDA. This represents an innovative approach to developing medical countermeasures and meeting the U.S. government's requirements for an anthrax vaccine. In collaboration with FDA, and after having received concurrence on pre-established study endpoints, we are moving forward with a high degree of confidence in this study. We have completed manufacturing BioThrax lots for use in this fifth and final study required for licensure of the scaled-up manufacture of BioThrax in Building 55. We are targeting a rolling submission to FDA of the supplemental Biologics License Application, including data from Chemistry, Manufacturing and Controls by early next year, followed by data from this pivotal non-clinical study later in 2015."

The primary objectives of this randomized, observer-blinded study are to demonstrate consistency of three BioThrax vaccine lots manufactured in Building 55 based on lot-to-lot equivalence as well as to demonstrate comparability of the three Building 55 lots with a Building 12 lot based on non-inferiority.

Building 12 produces 7 to 9 million doses of BioThrax annually. Building 55 has the potential to triple manufacturing capacity to an estimated 20 to 25 million doses annually. Both facilities are located on Emergent's Lansing, Michigan campus.

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This program is fully funded, up to \$107 million, under contract number HHSO100201000034C by the Biomedical Advanced Research and Development Authority within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services.

About Emergent BioSolutions

Emergent BioSolutions is a specialty biopharmaceutical company seeking to protect and enhance life by offering specialized products to healthcare providers and governments to address medical needs and emerging health threats. Additional information about the company may be found at <u>www.emergentbiosolutions.com</u>. Follow us @emergentbiosolu.

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, prospects, plans, objectives, and degree of confidence of management, and any other statements containing the words "believes", "expects", "anticipates", "intends", "plans", "estimates" and similar expressions, are forward-looking statements. These forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. We cannot guarantee that any forward-looking statement will be accurate. Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Investors are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date of this press release, and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events or circumstances.

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 or modifications to existing contracts; availability of funding for our U.S. government grants and contracts; the timing of and our ability to obtain and maintain approval for Building 55; and our manufacturing capabilities and strategy. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in our periodic reports filed with the SEC, when evaluating our forward-looking statements.

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