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FDA APPROVES EMERGENT BIOSOLUTIONS' BIOTHRAX FOR POST-EXPOSURE PROPHYLAXIS

GAITHERSBURG, Md., November 24, 2015—Emergent BioSolutions Inc. (NYSE: EBS) today announced that the U.S. Food and Drug Administration (FDA) approved its supplemental Biologics License Application to expand the label of BioThrax[®] (Anthrax Vaccine Adsorbed) to include post-exposure prophylaxis (PEP) of disease following suspected or confirmed *Bacillus anthracis* exposure when administered in conjunction with recommended antibacterial drugs. The vaccination schedule for this new indication consists of three doses of BioThrax administered at 0, 2, and 4 weeks post-exposure combined with antimicrobial therapy. BioThrax is the only FDA-licensed vaccine to prevent anthrax.

"Our BioThrax enhancement program is evidence of our successful partnership with the U.S. government to support the nation's biosecurity efforts. Over the years, we have enhanced the features of BioThrax to include intra-muscular route of administration, a streamlined vaccination schedule, extended shelf life, and now a post-exposure prophylaxis indication. We are proud of these achievements and look forward to continuing to supply the stockpile with this important medical countermeasure," said Adam Havey, Executive Vice President and President, Biodefense Division at Emergent BioSolutions.

This expanded indication is supported by data from non-clinical studies, three clinical trials, and a 2010 pre-Phase 3 Vaccines and Related Biological Products Advisory Committee meeting, which confirmed the regulatory pathway for licensure of anthrax vaccines for PEP. BioThrax is the only vaccine to be licensed for post-exposure prophylaxis against anthrax, and is the first vaccine to be licensed using the FDA Animal Rule.

Licensure of BioThrax for PEP is the culmination of a 10-year collaborative effort between Emergent, the Biomedical Advanced Research and Development Authority (BARDA) and the National Institute of Allergy and Infectious Diseases. Studies supporting licensure were funded in part under contract number HHSO-100-2007-00037C provided by BARDA 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 global specialty biopharmaceutical company dedicated to one simple mission—to protect and enhance life. We develop, manufacture, and deliver a portfolio of medical countermeasures for biological and chemical threats as well as emerging



infectious diseases. We also develop and commercialize therapeutics and other specialty products for hospitals and clinics in the areas of hematology/oncology, transplantation, infectious diseases and autoimmune disorders. Through our work, we envision protecting and enhancing 50 million lives with our products by 2025. Additional information about the company may be found at <u>www.emergentbiosolutions.com</u>. Follow us @emergentbiosolu.

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