



## National Institutes of Health to Sponsor Clinical Trial for Emergent BioSolutions' Group B Streptococcus Vaccine Candidate

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Clinical Trial Follows Promising Phase I Results of a Single Component in the GBS Vaccine

GAITHERSBURG, Md.--(BUSINESS WIRE)--Dec. 21, 2006--Emergent BioSolutions Inc. (NYSE: EBS) today announced that it has signed a clinical trial agreement with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), under which NIAID will fund, manage and conduct a clinical study on EBS-C12, as well as EBS-C12 in combination with EBS-A42. Both EBS-C12 and EBS-A42 are novel recombinant proteins that have been selected for use in the company's group B streptococcus (GBS) vaccine candidate. This proposed clinical study follows promising results from a first quarter 2006 open-label, dose escalating Phase I clinical trial in the United Kingdom of EBS-A42 in which the protein elicited a statistically significant immune response at all dose levels and was well tolerated by participants with no subjects withdrawing due to an adverse event.

"A vaccine protective against GBS has been a high public health priority as it remains a leading cause of neonatal mortality despite the use of antibiotics in pregnancy," said Steven N. Chatfield, Ph.D., the company's chief scientific officer. "We are very pleased that the NIH has agreed to support this clinical trial to evaluate our GBS vaccine candidate, which has been designed as a combination of novel, recombinant, purified proteins to provide broad coverage protection against GBS infection."

Under the agreement, NIAID will conduct a Phase I, open-label, dose escalating study to evaluate the safety, tolerability and immunogenicity of both EBS-C12, which is a single protein targeting protection against GBS infection, and EBS-C12 in combination with EBS-A42. These recombinant proteins will be administered to healthy adult volunteers on three occasions. The trial will be conducted at an NIAID clinical research site and NIAID will serve as the Investigational New Drug (IND) Application sponsor. It is anticipated that the IND for this clinical trial will be submitted in the fourth quarter of 2007 and the clinical study completed in 2008.

### About Emergent BioSolutions' GBS Vaccine Program

The company is developing a proprietary GBS vaccine to protect against GBS disease. To date, the company has identified three novel recombinant proteins that are being combined to form its GBS vaccine candidate. The three proteins have completed preclinical studies in which it was shown that the proteins are immunogenic, eliciting antibodies that recognized a number of GBS serotypes indicating the potential to generate an immune response with broad coverage. The company is designing its GBS vaccine candidate to be administered by injection with an alum adjuvant in a three dose regimen.

In first quarter 2006, the company completed an open-label, dose escalating Phase I clinical trial of EBS-A42, one of the selected proteins, in the United Kingdom in 47 healthy adult volunteers. The purpose of this trial was to evaluate the safety and immunogenicity of this protein. In this trial, EBS-A42 was adjuvanted with alum and tested at four different strengths, with two doses given 28 days apart. EBS-A42 was immunogenic at all doses tested, the immune response rate was 83% at the lowest dose tested and 100% at the highest dose tested. In addition, EBS-A42 was well tolerated at all dose levels tested, with no serious adverse events reported.

### Overview of GBS Disease

GBS is a bacterium that causes illness in newborn babies, pregnant women, the elderly and adults with other illnesses, such as diabetes or liver disease. GBS is the most common cause of sepsis and meningitis in newborns in the developed world. Currently there is no vaccine approved by the U.S. Food and Drug Administration for the prevention of GBS disease; the NIH has identified prevention of GBS infection in newborns as a major vaccine objective. Approximately 10% to 30% of women are found to be carrying the bacterium, and are offered intravenous antibiotics during their labor as a preventative measure. In the absence of antibiotic treatment, the U.S. Centers for Disease Control and Prevention (CDC) estimates that the risk is one in 200 of delivering a baby with group B streptococcus infection. In spite of antibiotic treatment, the CDC projects that there are approximately 2,750 neonatal infections each year in the United States. In a study of 338 of these cases of neonatal infections, the death rate was approximately 6%.

In the U.S. population over one year of age, approximately 17,500 cases of GBS infection occur each year, with most occurring in those over age 50. According to the CDC, the average death rates for invasive infections are approximately 8% to 10% for adults 18 to 64 years of age and 15% to 25% for adults 65 years of age and over.

### About Emergent BioSolutions Inc.

Emergent BioSolutions Inc. is a biopharmaceutical company focused on the development, manufacture and commercialization of immunobiotics. Immunobiotics are vaccines and immune globulins that induce or assist the body's immune system to prevent or treat disease. The company's biodefense business is focused on developing and commercializing immunobiotics for use against biological agents that are potential weapons of bioterrorism. The company's commercial business is focused on developing immunobiotics for use against infectious diseases with significant unmet or underserved medical needs. More information on the company is available at [www.emergentbiosolutions.com](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 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 our plans for future sales of BioThrax(R); our plans to pursue label expansions and improvements for BioThrax(R); our plans to expand our manufacturing facilities and capabilities; the rate and degree of market acceptance and clinical utility of our products; our ongoing and planned development programs; preclinical studies and clinical trials; our ability to identify and acquire or in license products and product candidates that satisfy our selection criteria; the potential benefits of our existing collaboration agreements and our ability to enter into selective additional collaboration arrangements; the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; our commercialization, marketing and manufacturing capabilities and strategy; our intellectual property portfolio; and our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and other factors identified in the company's Registration Statement on Form S-1 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.

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