

# Safety Monitoring Committee Recommends That Emergent BioSolutions Continue Its Hepatitis B Immunotherapy Phase II Trial

## January 9, 2008

ROCKVILLE, Md., Jan 09, 2008 (BUSINESS WIRE) -- Emergent BioSolutions Inc. (NYSE: EBS) announced today that based upon recommendations from an independent Safety Monitoring Committee (SMC) the company is progressing into the next stage of the enrollment of patients in its study of a hepatitis B immunotherapy. In this study, a total of 45 patients with chronic hepatitis B virus (HBV) infection are being randomized within three separate groups to receive immunotherapy or placebo. The immunotherapy utilizes the company's proprietary spi-VEC delivery system to deliver the hepatitis B core antigen, in order to induce an immune response to the hepatitis B virus.

"We are pleased by the Safety Monitoring Committee's recommendation and look forward to advancing this critical study of our hepatitis B candidate. Hepatitis B is the tenth leading cause of death worldwide and our commitment to the development of this therapeutic vaccine is squarely in line with our mission - to protect life," said Daniel Abdun-Nabi, president of Emergent BioSolutions Inc.

The SMC reviewed the safety data from the first group of patients that have completed day 70 in the study. On the basis of the available data, the SMC recommended that the company continue to progress the study into the two remaining groups. The company anticipates preliminary top line safety and efficacy data from this study will be available at the end of 2008 and complete study results will be available in the first half of 2009.

## About The Hepatitis B Therapeutic Vaccine Candidate

Although current treatment options are safe and effective in the majority of patients, the majority of hepatitis B patients are unable to clear the viral infection resulting in the need for long-term therapy. The company's HBV immunotherapeutic is designed to direct the immune system against virus infected cells in the liver. Following oral administration, the hepatitis B core antigen protein is produced by the spi-VEC Salmonella vector, within gut macrophages. The macrophages "present" portions of the HBV core antigen to the immune system, inducing antigen specific T-cells responsible for cell-mediated immunity. Through the targeted immune response, the company's hepatitis B immunotherapy is anticipated to benefit patients by increasing the potential to clear the virus therefore minimizing the risk of liver damage and eliminating the need for long-term antiviral therapy.

## About Hepatitis B

The World Health Organization (WHO) estimates that up to 2 billion people (one-third of the world's population) have been infected with HBV and that between 350 and 400 million people are chronically infected. Globally, chronic HBV is one of the leading causes of advanced liver cancer. During their lifetime, 10-40% of chronic HBV patients will develop serious sequelae, such as hepatocellular carcinoma, cirrhosis and decompensated liver disease. Hepatitis B virus affects all countries and geographic areas throughout the world.

The hepatitis B market size is estimated to be currently valued at \$500 million and is expected to double to over \$1 billion by 2010. The strong market growth is attributed to an increase in the awareness and diagnosis of hepatitis B, as well as the increasing use of drug combination therapy.

## About Emergent BioSolutions Inc.

Emergent BioSolutions Inc. is a profitable, multinational biopharmaceutical company dedicated to one simple mission--to protect life. We develop, manufacture and commercialize immunobiotics, consisting of vaccines and therapeutics, that assist the body's immune system to prevent or treat disease. Our products target infectious diseases and other medical conditions that have resulted in significant unmet or underserved public health needs. Our 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. More information on the company is available at 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, prospects, plans and objectives of management, including clinical trial results and development plans, 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 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; 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, 2007 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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