Emergent BioSolutions Initiates U.S. Phase II Trial of Oral Typhoid Vaccine Candidate

June 5, 2008

- Study designed to confirm safety and immunogenicity of vaccine manufactured at the large-scale commercial facility planned for launch
- Phase III trials are expected to begin next year

ROCKVILLE, Md.--(BUSINESS WIRE)--June 5, 2008--Emergent BioSolutions Inc. (NYSE:EBS) announced today that dosing of patients has begun in a U.S. Phase II clinical trial of the company's single-dose oral typhoid vaccine candidate. This randomized, double-blind, placebo-controlled, single-dose, dose-escalation trial is being conducted in healthy adults. The company anticipates that trial results will be available by year end. This US study will evaluate vaccine manufactured at the large-scale facility planned for commercial launch. This trial is designed to confirm the safety and immunogenicity of the vaccine, and Phase III trials are expected to begin in 2009. If approved, this candidate would be the first single-dose, drinkable typhoid vaccine available for adults and children.

"The commencement of this U.S. Phase II study represents an important milestone in the clinical development of our oral typhoid vaccine candidate," said Daniel Abdun-Nabi, president and chief operating officer of Emergent BioSolutions. "In previous clinical studies, this vaccine candidate has demonstrated promising immunogenicity and safety results in both children and adults. We are pleased with our continued progress in the development of this important vaccine candidate, which is a cornerstone in our company's mission of protecting life."

Dr. Stephen Lockhart, senior vice president of product development for Emergent BioSolutions, said, "Typhoid fever continues to be a high disease burden worldwide, claiming over 200,000 lives annually, most notably children living in developing countries where the disease is endemic. In addition, there is increasing incidence of antibiotic resistant strains of the disease which would suggest an even greater need for efficient and effective vaccination. This global health problem affects not only individuals living in endemic regions but also those traveling to typhoid endemic regions. With millions of people traveling globally every year, typhoid fever remains a health concern in industrialized and developing countries. This clinical trial is an important next step in the development of this advanced stage product."

About the Typhoid Vaccine Candidate

The company's typhoid vaccine candidate is a live, attenuated strain of Salmonella typhi engineered to eliminate virulence by deletion of two specific genes. The vaccine is intended to be administered in a single, drinkable dose for adults and children residing in typhoid endemic regions as well as individuals traveling to these endemic regions. Currently available typhoid vaccines have limited efficacy in children less than six years of age. In endemic regions, pre-school aged children have the greatest public health risk for contracting typhoid fever. Emergent's typhoid development program is focused on developing a product that is safe and effective with a patient friendly method of administration, as well as serving a critical unmet need in targeting a product that would be effective in children as young as two.

Previously published studies have shown the vaccine candidate to be immunogenic and well-tolerated in both adults and children as young as 5 years of age. The vaccine candidate has completed various trials, including:

- A randomized, placebo-controlled Phase II clinical study conducted among children in Vietnam. Study results showed that 97% of the children administered a single, oral dose of vaccine developed an immune response, defined as an increase in Salmonella typhi anti-LPS IgG and/or IgA antibody levels in the blood. No serious adverse events were reported.
- An open-label, non-placebo controlled, pilot study conducted in the United Kingdom in healthy adults in which the vaccine candidate was well tolerated and immunogenic, eliciting both cell mediated and humoral responses.
- A double-blind, placebo controlled, single-dose, dose escalating clinical trial conducted in the United States in which 100% of the trial participants in the highest dose group and 56% of the participants in the lowest dose group developed an immune response.
- An open-label, non-placebo controlled, single-dose clinical trial conducted in the United States in healthy adults to evaluate the safety and immunogenicity of two different presentations of the vaccine. The vaccine candidate was similarly immunogenic in both presentations and both were well tolerated.
- A single-blind, placebo controlled clinical trial in Vietnam in healthy adults. The Wellcome Trust provided funding for the trial. The vaccine met the criterion for immunogenicity and was well tolerated, with no serious adverse events reported.

For the current clinical study, approximately 200 patients will be enrolled across three sites in the U.S. Screening of patients for this study began in early May 2008. Further information on this trial is available on www.clinicaltrials.gov and can be referenced under the trial code NCT00679172.

Additional trials are being designed that would address the needs of adults, children and seniors residing in and traveling to typhoid endemic regions. Emergent is working closely with regulatory agencies in the U.S., Europe and endemic regions to design a development program that meets disease prevention needs and builds upon current disease management programs.

About Typhoid

Typhoid, also known as typhoid fever, is caused by infection with the bacterium Salmonella typhi. Typhoid is characterized by fever, headache, constipation, malaise, stomach pains, anorexia and myalgia. Severe cases of typhoid can result in confusion, delirium, intestinal perforation and death. Typhoid is transmitted by consuming contaminated food or drinks. Contamination usually results from poor hygiene and sanitation. Typhoid is often endemic in developing countries in which there is limited access to treated water supplies and sanitation.

An estimated 22 million cases of typhoid occur every year worldwide. The World Health Organization (WHO) recommends that pre-school aged children living in typhoid endemic regions be immunized to control the disease. In addition, typhoid fever vaccination should be considered for all persons traveling to developing countries, with travelers to Asia, Africa and Latin America deemed to be especially at risk. U.S. military personnel deployed in these areas are also at risk of infection.

About Emergent BioSolutions Inc.

Emergent BioSolutions Inc. is a leading biopharmaceutical company dedicated to one simple mission--to protect life. We develop, manufacture and commercialize 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, future financial position, future revenues, projected costs, prospects, plans and objectives of management, including our expected revenue growth and net earnings for 2008, 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 ongoing and planned development programs, preclinical studies and clinical trials; our plans to expand our manufacturing facilities and capabilities; the rate and degree of market acceptance and clinical utility of our products; 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 other 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 current report on Form 10-Q for the quarter ended March 31, 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.

CONTACT: Emergent BioSolutions Inc.
Investors Contact:
Robert G. Burrows
Vice President, Investor Relations
301-795-1877
BurrowsR@ebsi.com
or
Media Contact:
Tracey Schmitt
Director, Corporate Communications
301-795-1800
SchmittT@ebsi.com

SOURCE: Emergent BioSolutions Inc.