Emergent BioSolutions Announces That the Final Phase II Clinical Study Results for Typhoid Vaccine Reaffirms Clinical Endpoints Met; Immune Response Seen in 97% of Treated Subjects

January 8, 2008

Company plans to initiate Phase IIb clinical trial in 2008

ROCKVILLE, Md.--(BUSINESS WIRE)--Emergent BioSolutions Inc. (NYSE: EBS - News) announced today that the final analysis from a recently completed, randomized, placebo-controlled, blinded Phase II clinical study reaffirmed that its single-dose, drinkable typhoid vaccine candidate was highly immunogenic and well-tolerated with an acceptable safety profile in the population studied. For the study, a total of 151 Vietnamese children between 5 and 14 years of age were enrolled. A total of 101 children received the vaccine candidate and 50 children received placebo. This clinical study is the first trial involving a pediatric population and was performed in collaboration with the Wellcome Trust, Oxford University and the Hospital for Tropical Diseases, Ho Chi Minh City, Vietnam.

Study Results

- 97% of the children dosed developed an immune response, which was defined as an increase in Salmonella typhi LPS-specific IgG antibody levels and/or Salmonella typhi LPS-specific IgA antibody levels in the blood, suggestive of systemic and mucosal protective immunity, respectively. This represented a statistically significant difference from the placebo group.
- 93% of the children developed responses as measured by increases in Salmonella typhi LPS-specific IgG antibody levels suggestive of systemic protective immunity and 94% developed an immune response as measured by increase in Salmonella typhi LPS-specific IgA antibody levels suggestive of mucosal protective immunity.
- There were no safety concerns following administration of a single dose of the drinkable typhoid vaccine candidate. The proportion of subjects reporting adverse events was similar for the vaccinated group (26%) and placebo group (22%); this difference was not statistically significant.
- There were no serious adverse events reported, no deaths and no subjects withdrew due to adverse events. There were small differences in specific adverse events with more gastrointestinal symptoms and headaches reported in the vaccinated group and more respiratory symptoms in the placebo group.

“We are pleased that the full analysis of the data from this Phase II study reaffirms that our typhoid vaccine candidate met the pre-established clinical endpoints. These data are encouraging and indicate great promise regarding both the safety and efficacy of what would be the first single-dose, drinkable typhoid vaccine,” stated Fuad El-Hibri, chairman and chief executive officer of Emergent BioSolutions. “Typhoid is often endemic in developing countries and claims 200,000 lives annually. A Phase II trial in the United States and a Phase IIb trial in an endemic population are both slated to begin by the end of 2008. Both of these trials will use clinical material produced using a scaled-up commercial manufacturing process.”

The trial and development of the vaccine have been made possible by funding from the Wellcome Trust, the largest medical research charity in the United Kingdom.

Dr. Ted Bianco, director of technology transfer at the Wellcome Trust, stated, “We are delighted to have partnered with Emergent BioSolutions to support this trial in Vietnam. The trial will advance the development of a sorely needed vaccine for typhoid fever. The ease of administration of the product is one of its chief attractions from a public health perspective."

About the Typhoid Vaccine Candidate

The company's typhoid vaccine candidate is a live attenuated strain of the Salmonella typhi bacterium designed to eliminate virulence by deletion of two specific genes. The vaccine is intended to be administered in a single, drinkable dose. If approved, this method of administration could provide a competitive advantage compared to currently approved typhoid vaccines.

Previous study results have shown the vaccine candidate to be immunogenic and well-tolerated. In addition to this Phase II clinical study, the following clinical trials have been completed:

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 immunogenicity.

- A double-blind, placebo controlled, single-dose, dose escalating clinical trial conducted in the United States in which 100% of the subjects in the highest dose group and 56% of the subjects in the lowest dose group had an immune response on the scheduled testing days.

- An open-label, 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 candidate met the criterion for immunogenicity and was well tolerated, with no serious adverse events reported.

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 drink. 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 per year worldwide. The Centers for Disease Control and Prevention recommends that all persons from the United States traveling to developing countries consider receiving a typhoid vaccination, with travelers to Asia, Africa and Latin America deemed to be especially at risk. United States military personnel deployed in these areas are also at risk of infection.

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® (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.

About the Wellcome Trust

The Wellcome Trust is the largest charity in the UK. It funds innovative biomedical research, in the UK and internationally, spending around £500 million each year to support the brightest scientists with the best ideas. The Wellcome Trust supports public debate about biomedical research and its impact on health and wellbeing. www.wellcome.ac.uk

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.

Contact:
Emergent BioSolutions Inc.
Investors:
Vice President, Investor Relations
Robert G. Burrows, 301-795-1877
burrowsR@ebsi.com
or
Media:
Director, Corporate Communications
Tracey Schmitt, 301-795-1847
schmittT@ebsi.com