Emergent BioSolutions Presents Positive Data from Its TRU-016 Program at American Society of Hematology Meeting

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ROCKVILLE, Md., Dec 06, 2010 (BUSINESS WIRE) -- Emergent BioSolutions Inc. (NYSE: EBS) today announced the presentation of positive data from a Phase I dose escalation study of TRU-016 (Protocol 16007) at the 52nd Annual Meeting of the American Society of Hematology (ASH) in Orlando, Florida. In an oral presentation given yesterday, results from the study show that TRU-016 demonstrates favorable response rates and is generally well-tolerated in patients with chronic lymphocytic leukemia (CLL). TRU-016 is Emergent's humanized anti-CD37 small modular immunopharmaceutical (SMIP(TM)) candidate in development with Abbott for the treatment of B-cell malignancies such as CLL and non-Hodgkin's lymphoma (NHL). Data were presented during an oral presentation by Richard R. Furman, M.D., Director of the CLL Research Center at Weill Medical College of Cornell University. A copy of the presentation is available at www.truemergent.com/tru-016.

"Despite the many different therapies available for patients with CLL, almost all patients will relapse and die of their disease," said Dr. Furman. "Novel agents that are more effective and better tolerated are needed to help transform CLL into a truly chronic condition. Of the therapeutics currently in development, targeting CD37 with TRU-016 appears to be among the most promising. TRU-016 is a potent inducer of apoptosis and Fc dependent cellular cytotoxicity of CLL cells. TRU-016's favorable toxicity profile and preliminary evidence of efficacy in patients warrants further evaluation in combination with other agents."

The objective of the ongoing open label Phase I study was to establish the maximum tolerated dose, overall safety and clinical activity of TRU-016 in patients with advanced CLL and small lymphocytic leukemia (SLL). Data were presented on 57 patients who had a median of four previous therapies and a median of two prior anti-CD20 therapies. Of the 57 patients, 46% received their last treatment for CLL less than 6 months before entering the study. Genomic data were available for 53 patients, the majority of which (n=35) had high-risk genomic features for CLL, including del(17p) and/or del(11q).

Patients received one of nine intravenous doses ranging from 0.03 mg/kg to 20 mg/kg of TRU-016 once a week for a total of 4 to 12 doses (weekly cohort). A second dosing schedule evaluated treatment with 3 mg, 6 mg or 10 mg on days 1, 3 and 5 during the first week of therapy, followed by 3 to 11 weekly doses (TIW cohort). Dose escalation and de-escalation was based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) toxicity grades.

Pharmacokinetic data demonstrate rapid clearance of TRU-016 in the lower dose cohorts. Accumulation was seen in the 3mg/kg TIW and 6mg/kg weekly and higher cohorts. Patients in the 3 mg/kg TIW cohort (n=8) generally maintained serum concentrations of 10 g/ml during treatment. Partial response was observed in seven patients, including two patients with the del(17p) genomic risk factor. The median reduction in absolute lymphocyte count was 73% in those patients with lymphocytosis at baseline. The responses, all partial responses, were observed in patients who had received 1 - 2 prior therapies (n=16) for an overall response rate of 44% (n=7) with a median reduction in lymphocytes of 80% in this population. No responses were observed in patients who had received prior treatment with three or more therapies (n=41), although a median reduction in lymphocytes of 54% was observed in these patients. The median reduction in lymphocytes regardless of baseline lymphocyte count or the number of prior therapies was 60%.

The most commonly reported adverse events were nausea, fatigue, diarrhea, chills, pyrexia, and neutropenia. Serious adverse events occurring in more than one patient were pneumonia, febrile neutropenia, infusion reaction, pyrexia and dyspnea. A maximum tolerated dose has not yet been reached.

Additional data on Emergent's TRU-016 and TRU-ADhanCe(TM) programs were presented at ASH:

- #3931 TRU-016, An Anti-CD37 SMIP™ Biologic, In Combination with Other Therapeutic Drugs In Models of NHL;
- #3098 CD37 Is a Potential Therapeutic Target for B-Cell Non-Hodgkin Lymphoma; and
- #1847 GlycoVariant Anti-CD37 Small Modular Immuno-Pharmaceutical Exhibits Superior Natural Killer Cell Mediated Cytotoxicity Against Chronic Lymphocytic Leukemia Cells at Low Concentrations and Low Antigen Density.

"Based on favorable results observed to date, Emergent and our development partner Abbott are in the process of initiating additional combination studies of TRU-016 in CLL and NHL," said Dr. W. James Jackson, chief scientific officer at Emergent BioSolutions. "We remain hopeful that TRU-016 could play a meaningful role in improving disease outcomes and quality of life, either on its own or in combination with other therapies."

About the Clinical Trial (Protocol 16007)

The purpose of this study is to evaluate the safety and tolerability of TRU-016 in patients with previously treated chronic lymphocytic leukemia (CLL), and to obtain an estimate of clinical activity in patients with CLL and non-Hodgkin's lymphoma (NHL).

This Phase I/Ib open-label study consists of two parts. The initial portion is a Phase I dose-escalation study evaluating the safety and tolerability of TRU-016 administered over a 4-week period to patients with relapsed CLL. It will identify the maximum tolerated dose and evaluate the pharmacokinetics and immunogenicity of TRU-016. Upon demonstrating satisfactory safety and tolerability in the Phase I portion, a Phase Ib

expansion cohort will be enrolled to further characterize the safety of the selected dose from the first stage of the study and to estimate the clinical activity of TRU-016 in patients with treatment-naive CLL, relapsed CLL and NHL.

About CLL

According to the Leukemia & Lymphoma Society (LLS), there are approximately 85,710 people in the U.S. living with CLL, and more than 15,000 new cases are diagnosed each year. Existing treatments for CLL have shown significant efficacy in treating indolent B-cell cancers. However, research suggests that many patients do not achieve an initial response and most eventually relapse, which suggests an acute need for differentiated treatments.

About Emergent BioSolutions Inc.

Emergent BioSolutions Inc. is a global biopharmaceutical company focused on the development, manufacture and commercialization of vaccines and antibody therapies that assist the body's immune system to prevent or treat disease. Emergent's marketed and investigational products target infectious diseases, oncology, and autoimmune disorders. Additional information about the company may be found 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 any potential future securities offering, our expected revenue growth and net earnings for 2010, 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 success of our ongoing and planned preclinical studies and clinical trials; the rate and degree of market acceptance and clinical utility of our products; the success of our ongoing and planned development programs; 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 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, 2010 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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