Emergent BioSolutions Announces Initiation of Phase Ib/II Study of TRU-016 in Combination with Bendamustine for Chronic Lymphocytic Leukemia

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ROCKVILLE, Md., Jan 25, 2011 (BUSINESS WIRE) -- Emergent BioSolutions Inc. (NYSE: EBS) today announced the initiation of a Phase Ib/II study (16201) of TRU-016 for chronic lymphocytic leukemia (CLL). TRU-016 is a CD37-directed Small Modular ImmunoPharmaceutical (SMIP(TM)) protein therapeutic in development for the treatment of B-cell malignancies. TRU-016 is being developed in collaboration with Abbott.

The open-label, multi-center, active-controlled study is expected to enroll up to 114 bendamustine-naïve patients with a confirmed diagnosis of relapsed CLL and who have failed up to three previous treatments. The Phase Ib portion of the study will determine a safe and tolerable dose of TRU-016 in combination with bendamustine in up to 14 patients with relapsed CLL. The primary endpoint for the Phase Ib portion is the incidence of dose-limiting toxicities.

The Phase II portion of the study will evaluate the safety and efficacy of TRU-016 in combination with bendamustine compared with standalone bendamustine treatment in a total of 100 randomized patients. The primary endpoint for the Phase II portion of the study is an overall response rate as defined by 2008 International Workshop on Chronic Lymphocytic Leukemia (IWCLL) criteria. Secondary endpoints include complete and partial response rates as defined by the 1996 National Cancer Institute (NCI) criteria, progression-free survival, duration of response, and improvement in quality of life and disease symptoms.

The pharmacokinetics and pharmacodynamics of TRU-016 will be studied in both phases of the study.

"Given the strong TRU-016 preclinical combination data, and the positive clinical results from the single agent dose escalation study, we believe human clinical evaluation of TRU-016 in combination with bendamustine could yield meaningful results," said Dr. W. James Jackson, chief scientific officer at Emergent BioSolutions. "The dose escalation study in CLL continues to demonstrate that TRU-016 is well tolerated and clinically active and we look forward to Phase I combination data from this study, as well as the planned Phase I combination study for follicular Non-Hodgkin's Lymphoma."

Additional information about this Phase Ib/II clinical study can be found on www.clinicaltrials.gov (protocol 16201).

In December 2010, data were presented at the 52nd Annual Meeting of the American Society of Hematology (ASH) from a Phase I TRU-016 monotherapy, dose escalation trial involving 57 patients who have 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).

Pharmacokinetic data demonstrated 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 from all TRU-016 ASH presentations can be found at: www.truemergent.com.

About CLL

According to the Leukemia & Lymphoma Society, 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 TRU-016

TRU-016 uses a different mechanism of action than currently marketed CD20-directed therapies. As a result, TRU-016 may provide patients with improved therapeutic options and enhance efficacy when used alone or in combination with chemotherapy and/or other CD20-directed therapeutics.

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, estimates of results for 2010, expected revenue growth and net earnings for 2011, 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 ability to obtain additional development funding for our product candidates; the rate and degree of market acceptance and clinical utility of our products; the success of our ongoing and planned development programs, preclinical studies and clinical trials; the timing of and our ability to obtain and maintain regulatory approvals for our other product candidates; our ability to obtain sales contracts for products; 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.

SOURCE: Emergent BioSolutions Inc.

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