Emergent Initiates Phase 2 Study of TRU-016 in Combination with Bendamustine in Patients with Relapsed Chronic Lymphocytic Leukemia

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ROCKVILLE, Md.--(BUSINESS WIRE)--Dec. 28, 2011-- Emergent BioSolutions Inc. (NYSE:EBS) today announced the initiation of a Phase 2 study (protocol 16201) of TRU-016 in combination with bendamustine for patients with relapsed chronic lymphocytic leukemia (CLL). The initiation of this clinical trial triggers a $6 million milestone payment to Emergent. TRU-016 is a humanized anti-CD37 mono-specific protein therapeutic in development for the treatment of B-cell malignancies.

“Preclinical studies have demonstrated increased anti-tumor activity for the combination of bendamustine and TRU-016 beyond the results achieved when either drug was administered alone,” said Scott C. Stromatt, M.D., Senior Vice President and Chief Medical Officer, Emergent BioSolutions Inc. “The safety data from the Phase 1b portion of the combination trial of TRU-016 with bendamustine in relapsed CLL was recently reviewed by an independent Data Monitoring Committee, and they authorized advancement into Phase 2.”

The open-label, multi-center, active-controlled study is enrolling bendamustine-naïve patients with a confirmed diagnosis of relapsed CLL and who have failed up to three previous treatments. The Phase 1b portion of the study evaluated 12 patients with relapsed CLL to determine a safe and tolerable dose of TRU-016 in combination with bendamustine. The primary endpoint for the Phase 1b portion was the incidence of dose-limiting toxicities.

The Phase 2 portion of the study will evaluate the safety and efficacy of TRU-016 in combination with bendamustine compared with bendamustine alone in a total of approximately 100 randomized patients. TRU-016 will be dosed over six 28-day cycles. The primary endpoint for the Phase 2 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.

Pharmacokinetics and pharmacodynamics of TRU-016 will be studied in both phases of the study. Additional information about this Phase 1b/2 clinical study can be found on www.clinicaltrials.gov (protocol 16201).

About Emergent BioSolutions Inc.

Emergent BioSolutions protects and enhances life by developing and manufacturing vaccines and therapeutics that are supplied to healthcare providers and purchasers for use in preventing and treating 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 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 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, 2011 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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