



## **Emergent BioSolutions Announces Acceptance of Four TRU-016 Abstracts for Presentation at 2011 American Society of Hematology Annual Meeting**

December 5, 2011

ROCKVILLE, Md.--(BUSINESS WIRE)--Dec. 5, 2011-- Emergent BioSolutions Inc. (NYSE: EBS) announced today that four abstracts on TRU-016 have been accepted for presentation at the 53<sup>rd</sup> Annual Meeting of the American Society of Hematology (ASH) on December 10-13, 2011 in San Diego, California. The data accepted for presentation include clinical results from a Phase 1 study evaluating patients with chronic lymphocytic leukemia (CLL) and non-Hodgkin's Lymphoma ( NHL). TRU-016 is a humanized anti-CD37 mono-specific protein therapeutic in development for the treatment of B-cell malignancies. TRU-016 is being developed in collaboration with Abbott.

"The data accepted for presentation at ASH this year continue to provide supporting evidence that TRU-016 could be a viable option for patients suffering from B-cell malignancies," said Scott C. Stromatt, M.D., Senior Vice President and Chief Medical Officer, Emergent BioSolutions. "We believe that differentiated treatments are needed as many patients with CLL and NHL continue to experience disease relapse. We believe 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."

**POSTER: Phase 1 Study of TRU-016, An Anti-CD37 SMIP™ Protein in Naive and Relapsed and/or Refractory CLL Patients**  
*Publication #1792*  
*Saturday, December 10, 2011, 5:30 PM - 7:30 PM*

Patients in the Phase 1 TRU-016 CLL study received 12 doses of either 10, 20 or 30 mg/kg of TRU-016 administered intravenously weekly for two months followed by three monthly doses. Patients treated in the dose escalation portion of the study were eligible for rollover retreatment in the expanded cohort.

Twenty-six patients (7 naive, 16 relapsed/refractory, and 3 rollover) received TRU-016 in the expanded cohort with 12 patients in active follow up at the time of abstract submission. Lymphocyte reduction of  $\geq 50\%$  was observed in 81% (17/21) of naive and relapsed/refractory CLL patients and 33% (1/3) in rollover CLL patients. Lymph node reduction of  $\geq 50\%$  as measured by CT scan was observed in 46% (6/13) of the patients. The overall response rate was 86% (6/7 partial response) in naive CLL patients and 17% (3/17 partial response) in relapsed/refractory CLL patients. Responses in relapsed CLL patients were limited to those with 1-2 prior treatments as previously observed in the dose escalation phase of the study, for a response rate of 33% (3/9).

There were three subjects with dose limiting toxicities; none occurred more than once in a dose cohort. A maximum tolerated dose was not identified. The most frequent Grade 3/4 adverse events were infection (4 patients), neutropenia (3 patients) and febrile neutropenia (2 patients). There were nine serious adverse events reported by four patients, with two patients having events considered possibly related to TRU-016.

**POSTER: Phase 1 Study of TRU-016, An Anti-CD37 SMIP™ Protein in Relapsed and/or Refractory NHL Patients**  
*Publication #1636*  
*Saturday, December 10, 2011, 5:30 PM - 7:30 PM*

Pre-clinical in vitro and in vivo models of NHL have demonstrated significant activity of TRU-016 against multiple cell lines. As an extension of the ongoing Phase 1 CLL study, NHL patients received 20 mg/kg of TRU-016 administered intravenously once a week for 8 weeks followed by 4 monthly doses.

Sixteen highly-refractory and heavily-pretreated NHL patients (8 follicular, 4 mantle cell lymphoma, and 4 Waldenstrom's) received TRU-016 in the expanded cohort with 4 patients in follow up at the time of abstract submission.

Lymphocyte reduction of  $\geq 50\%$  was observed in 25% (4/16) of the patients. Lymph node reduction of  $\geq 50\%$  as measured by CT scan was observed in 18% (2/11) of the patients. One follicular NHL patient had a partial response, 6 had stable disease (SD) and 1 had progressive disease (PD). Two mantle cell lymphoma patients had SD and 2 had PD. One Waldenstrom's patient had a minor response, 2 had SD and 1 had PD.

The most frequent Grade 3/4 adverse events were neutropenia (6 patients) and thrombocytopenia (2 patients). There were no Grade 3/4 infections reported. There were 2 serious adverse events reported by 2 patients, both were considered unrelated to TRU-016 by the investigators.

The single-agent clinical activity of TRU-016, and the synergistic or additive effect of TRU-016 with multiple agents demonstrated in pre-clinical models, warrant a combination trial of TRU-016, which has been initiated with bendamustine and rituximab in relapsed indolent B-cell NHL patients. Updated results from ongoing patient follow-up will be presented at the meeting.

Additional TRU-016 abstracts accepted for presentation at ASH 2011 include:

**ORAL PRESENTATION: Tetraspanin CD37 Directly Mediates Transduction of Survival and Apoptotic Signals**  
*Publication #622*

Monday, December 12, 2011, 3:30 PM

**POSTER:** Pro-Apoptotic Effect of an Anti-CD37 Scfv-Fc Fusion Protein, in Combination with the Anti-CD20 Antibody, Ofatumumab, on Tumor Cells from B-Cell Malignancies

Publication #1662

Saturday, December 10, 2011, 5:30 PM - 7:30 PM

#### **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](http://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.

Source: Emergent BioSolutions Inc.

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