Emergent Announces Initiation of a Phase 1b/2 Study of TRU-016 in Combination with Rituximab and Bendamustine in Subjects with Relapsed - Indolent Lymphoma

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ROCKVILLE, Md., Aug 17, 2011 (BUSINESS WIRE) --

Emergent BioSolutions Inc. (NYSE:EBS) today announced the initiation of a Phase 1b/2 study (16011) of TRU-016 in combination with rituximab and bendamustine for patients with relapsed indolent non-Hodgkin's B-cell lymphomas, including follicular lymphoma, small lymphocytic lymphoma and marginal zone lymphoma. TRU-016 is a CD37-directed Small Modular ImmunoPharmaceutical(TM) protein therapeutic in development for the treatment of B-cell malignancies. TRU-016 is being developed in collaboration with Abbott.

"Although patients show a high rate of clinical response to first line therapies they often relapse and in many cases, develop a resistance to treatment," said Dr. Scott Stromatt, Vice President of Clinical Research and Chief Medical Officer at Emergent BioSolutions. "Our preclinical studies show that when used together, TRU-016 and bendamustine resulted in increased anti-tumor activity beyond results achieved when either drug was administered alone. TRU-016 is also synergistic with rituximab in preclinical models. Based on these data, as well as data from our ongoing clinical studies of TRU-016 for chronic lymphocytic leukemia, we believe that TRU-016 in combination with bendamustine and rituximab could produce meaningful results in patients with indolent NHL."

The Phase 1b portion is a dose escalation study to determine the Phase 2 dose of TRU-016 given in combination with rituximab and bendamustine. In this portion of the trial, up to 12 patients will receive two dose levels of TRU-016 in combination with rituximab and bendamustine administered intravenously. The primary safety endpoint for the Phase 1b portion of the study is the incidence of dose-limiting toxicities (DLTs).

The Phase 2 portion will be an expansion study of approximately 76 additional patients to examine the safety and efficacy of TRU-016 in combination with 375 mg/m^2 of rituximab and 90 mg/m^2 of bendamustine, versus bendamustine and rituximab. The primary efficacy endpoint for the Phase 2 portion of the study is complete response (CR) rate as determined by using the Revised Response Criteria for Malignant Lymphoma. The pharmacokinetics and pharmacodynamics of TRU-016 will be studied in both phases of the study.

The total expected enrollment for both phases of this study is expected to be 88 patients, all of whom have a confirmed diagnosis of relapsed indolent B-cell lymphoma, and who have failed prior treatments. Study enrollment is expected to be completed by the end of 2012. Additional information about this Phase 1b/2 clinical study can be found at www.clinicaltrials.gov (protocol 16011).

About non-Hodgkin's Lymphoma (NHL)

According to the National Cancer Institute, there are approximately 65,980 cases of NHL diagnosed each year, with close to 30% of these cases resulting in death. NHL is a broad range of malignant lymphoid disorders that are categorized on the basis of aggressiveness and cell of origin. Indolent or slow-growing NHL causes few symptoms, particularly early in the natural history of the disease, making early detection difficult. The majority of patients with indolent NHL present with Stage III or IV disease. Most patients with NHL requiring treatment receive rituximab in combination with chemotherapy as initial treatment; however, many patients become refractory to both chemotherapy and rituximab.

About TRU-016

TRU-016 is a CD37-directed protein therapeutic in development for the treatment of B-cell malignancies. TRU-016 is being developed in collaboration with Abbott. 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 immunotherapeutics. TRU-016 is currently in Phase 1b/2 development for chronic lymphocytic leukemia and non-Hodgkin's lymphoma.

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 June 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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