



Emergent BioSolutions Receives Orphan Drug Designation for Its TRU-016 Protein Therapeutic for the Treatment of Chronic Lymphocytic Leukemia

December 1, 2011

ROCKVILLE, Md.--(BUSINESS WIRE)--Dec. 1, 2011-- Emergent BioSolutions Inc. (NYSE: EBS) announced today that its humanized anti-CD37 mono-specific protein therapeutic, TRU-016, in development for the treatment of B-cell malignancies has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of chronic lymphocytic leukemia (CLL) patients. This designation is given to drugs and biologics that are being developed to treat rare medical conditions, specifically those affecting fewer than 200,000 persons in the U.S. TRU-016 is being developed in collaboration with Abbott.

"Receiving FDA Orphan Drug Designation for TRU-016 underscores the medical need in treating B-cell malignancies like CLL," said Scott C. Stromatt, M.D., Senior Vice President and Chief Medical Officer, Emergent BioSolutions. "Emergent is pleased to receive this designation and is committed to advancing product candidates that improve the lives of patients suffering from diseases like CLL."

The FDA Orphan Drug Designation of TRU-016 provides for a number of potential benefits, including a seven-year period of marketing exclusivity in the U.S., reduced or waived regulatory fees, certain tax credits, and additional regulatory assistance and access to specific grants programs for research and development initiatives.

TRU-016 is currently being evaluated in multiple human Phase 1 clinical studies for the treatment of CLL and non-Hodgkin's lymphoma (NHL).

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 <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.

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