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**EMERGENT BIOSOLUTIONS PRESENTS POSITIVE INTERIM PHASE 2 DATA EVALUATING OTLERTUZUMAB (TRU-016) IN COMBINATION WITH BENDAMUSTINE IN PEOPLE WITH RELAPSED CHRONIC LYMPHOCYTIC LEUKEMIA**

**ROCKVILLE, Maryland—December 9, 2013**—Emergent BioSolutions Inc. (NYSE: EBS) today announced positive interim results from a Phase 2 study evaluating the combination of otlertuzumab (TRU-016) and bendamustine versus bendamustine alone in people with relapsed chronic lymphocytic leukemia (CLL) (Study 16201). Overall response rate was the primary endpoint of the study. Data show that otlertuzumab in combination with bendamustine produced a higher response rate than bendamustine alone by International Workshop on CLL (IWCLL) and National Cancer Institute (NCI) response criteria. Overall incidence of adverse events, severe and serious adverse events were generally similar in both arms of the study. The Phase 2 data were presented at the American Society of Hematology annual meeting in New Orleans, Louisiana.

Otlertuzumab is a humanized anti-CD37 mono-specific protein therapeutic that targets the CD37 signaling pathway involved in B-cell malignancies such as CLL, non-Hodgkin's lymphoma (NHL), diffuse large B-cell lymphoma (DLBCL) and other cancers of the blood. Otlertuzumab is built on Emergent's ADAPTIR™ (modular protein technology) platform, for the treatment of CLL.

"This is a revolutionary time in the treatment of CLL and we are pleased to present data that demonstrate proof of concept for otlertuzumab, a novel protein therapeutic," said Scott C. Stromatt, M.D., senior vice president and chief medical officer, Emergent BioSolutions. "We believe otlertuzumab has the potential for use in combination with existing or other experimental therapies to expand treatment options for people with CLL."

**About the Phase 2 (16201) Study**

In a Phase 2 multicenter, open-label, randomized, combination study, 65 patients with relapsed CLL who had 1-3 prior treatments were enrolled and randomized into one of two dosing schemes: 1) otlertuzumab (20 mg/kg) plus bendamustine (70mg/m<sup>2</sup>) or 2) bendamustine (70mg/m<sup>2</sup>) alone.

Results reported for subjects evaluable to date based on IWCLL criteria for the combination of otlertuzumab and bendamustine (n=29) showed the overall response rate (ORR) was 69 percent with a complete response (CR) rate of 14 percent. For bendamustine alone (n=31), the ORR was 32 percent with a CR rate of 3 percent. The NCI response rates for the combination of otlertuzumab and bendamustine (n=32) were 81 percent ORR and 22 percent CR compared to 64 percent ORR and 9 percent CR for bendamustine alone (n=33).

Overall incidence of adverse events, severe and serious adverse events were generally similar in both arms of the study. There was a greater incidence of severe neutropenia with the combination, but this did not result in a greater incidence of severe or serious infections. There was no increase in serious adverse events in the otlertuzumab plus bendamustine arm compared to the bendamustine arm.

### **About Chronic Lymphocytic Leukemia (CLL)**

According to the American Cancer Society, CLL is the most common form of blood cancer. There are approximately 94,000 patients currently diagnosed with CLL in the U.S., with over 15,000 new cases diagnosed each year. Most cases of CLL (95 percent) start in white blood cells called B cells, the primary target of otlertuzumab.

### **About Otlertuzumab (TRU-016)**

Otlertuzumab is a CD37-specific therapeutic protein in development for the treatment of B-cell malignancies such as CLL that was built on the ADAPTIR™ (modular protein technology) platform. CD37 is a tetraspanin protein expressed on the surface of normal and transformed B cells and demonstrates death signaling via SHP1.

### **About the ADAPTIR™ Platform**

ADAPTIR monospecific proteins are single chain polypeptides that comprise three components: a binding domain (VL and VH), a hinge domain, and an effector domain (huFc). They have a differentiated structure from monoclonal antibodies and can generate a unique signaling response. In addition, ADAPTIR proteins may mediate complement dependent cytotoxicity and Fc dependent cytotoxicity, similar to monoclonal antibodies.

### **About Emergent BioSolutions**

Emergent BioSolutions is a specialty pharmaceutical company seeking to protect and enhance life by offering specialized products to healthcare providers and governments to address medical needs and emerging health threats. Additional information about the company may be found at [www.emergentbiosolutions.com](http://www.emergentbiosolutions.com). Follow us @emergentbiosolu.

### **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, are forward-looking statements. Forward-looking statements in this press release include statements about the potential and therapeutic opportunity of otlertuzumab. These forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. We cannot guarantee that any forward-looking statement will be accurate. Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Investors are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date of this press release, and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events or circumstances.

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 clinical trials; the rate and degree of market acceptance and clinical utility of our products; the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; and our commercialization, marketing and manufacturing capabilities and strategy. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Investors should consider this

## News Release



cautionary statement, as well as the risk factors identified in our periodic reports filed with the SEC, when evaluating our forward-looking statements.

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