XBiotech Announces Positive Results in European Phase III Study for Its Breakthrough Therapy for Colorectal Cancer

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Company Now Seeking Marketing Authorization With EMA & Other Jurisdictions

AUSTIN, Texas, Dec. 7, 2015 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ:XBIT), developer of True Human™ therapeutic antibodies, announced today that it met the primary endpoint in its European Phase III clinical study of Xilonix™, a novel therapy for patients with symptomatic, advanced colorectal cancer. Patients enrolled in the double-blinded, placebo-controlled study had refractory, metastatic colorectal cancer and suffered from cancer-associated symptoms such as fatigue, pain, elevated inflammatory markers, weight loss and reduced physical ability at baseline. Patients were randomized 2:1 to receive either Xilonix therapeutic antibody or placebo, respectively.

Significantly more patients treated with Xilonix were responders compared to those given placebo. One-third (33%) of the 207 patients randomized to Xilonix treatment met responder criteria, compared to less than one-fifth (19%) of the 102 placebo patients (p=0.009). Based on a modified intent to treat analysis plan, patients with missing endpoint data or those who received Xilonix instead of placebo were considered non-responders. In total, there were 333 patients enrolled in the study. As per the prospective analysis plan, 24 patients who failed to receive either Xilonix or placebo were excluded from analysis.

Patients were assessed for anti-tumor activity using a novel co-primary endpoint. X-ray imaging was used to quantify change in lean body mass and health status was assessed based on patient-reported outcomes using the European Organization of Research and Evaluation of Cancer instrument (EORTC-QLQ-C30). The study outcome was based on a responder analysis, such that patients with conserved or improved lean body mass and EORTC-QLQ-C30 performance over the treatment period were considered responders. Responder analysis was determined after 4 cycles of therapy (8 weeks). The Company has been developing the responder analysis as a novel surrogate measure of anti-cancer activity.

The Xilonix therapeutic antibody uniquely blocks the inflammation that is believed to support tumor growth, spread and symptomatic effects of the disease. In the presence of progressive disease, patient condition is known to deteriorate. In the context of an antitumor therapy, the control or reversal of symptoms related to disease is considered to be evidence of anticancer activity and a prognosticator of better survival.

This study, developed in collaboration with the EMA, represents the first use of such a responder analysis in a controlled study for the development of an anticancer agent. Xilonix is thus the first anticancer agent evaluated using surrogate measures based on conservation of patient health status, and is believed to be the first anticancer therapy to demonstrate an ability to conserve or improve patient health status with treatment.

The Company plans to proceed with the marketing authorization process with the EMA and other jurisdictions.

John Simard, CEO of XBiotech, stated, "We are gratified to announce these findings with Xilonix. The ability of Xilonix to help improve the health of patients with cancer has been demonstrated. We look forward to seeking approval to deliver this unprecedented cancer agent to patients."

About XBiotech

XBiotech is pioneering a new era in the discovery and development of targeted antibodies based on its True Human^{TM} technology. The company's mission is to rethink the way antibody medicines are discovered and commercialized by advancing its robust pipeline of *truly* natural human antibodies for treating serious diseases such as cancer, inflammatory conditions and infectious diseases. XBiotech's lead product, Xilonix™, is a potential breakthrough antibody therapy that is currently the subject of two pivotal clinical studies for treating patients with advanced colorectal cancer. Xilonix specifically targets and neutralizes interleukin-1 alpha (IL-1a), a molecule known to promote angiogenesis, growth and spread of tumors, as well as mediate symptoms such as metabolic dysregulation, fatigue and anxiety associated with advanced cancer. XBiotech's broad pipeline of True Human antibodies are able to potentially deliver unmatched safety and efficacy because they are cloned directly from individual donors who possess natural immunity against certain targeted diseases. As such, True Human antibodies retain their natural physiology and tolerance profile, having passed the rigors of immune selection in the body. For more information, visit www.xbiotech.com.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements, including declarations regarding management's beliefs and expectations that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "would," "could," "expects," "plans," "contemplate," "anticipates," "believes," "estimates," "predicts," "projects," "intend" or "continue" or the negative of such terms or other comparable terminology, although not all forward-looking statements contain these identifying words. Forward-looking statements are subject to inherent risks and uncertainties in predicting future results and conditions that could cause the actual results to differ materially from those projected in these forward-looking statements. These risks and uncertainties are subject to the disclosures set forth in the "Risk Factors" section of certain of our SEC filings. Forward-looking statements are not guarantees of future performance, and our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate, may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

CONTACT: Ashley Otero
XBiotech

aotero@xbiotech.com
512.386.2930

Tiberend Strategic Advisors, Inc.:

Joshua Drumm, Ph.D. (investors)
jdrumm@tiberend.com
212.375.2664

Janine McCargo (media)
jmccargo@tiberend.com
646.604.5150

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