XBiotech Provides Update on Phase III Oncology Study in Europe

November 23, 2015

AUSTIN, Texas, Nov. 23, 2015 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ:XBIT), developer of True Human™ therapeutic antibodies, announced today findings related to enrollment in the study. The Company is reporting that data cleaning has revealed a fewer number of per protocol patients available for primary endpoint evaluation. The Company found 25 patients dropped off study prior to receiving any dosing with drug or placebo. Analysis of patient blood samples also revealed that 14 patients erroneously received either placebo or study drug. In addition, 33 patients completed the study but failed to receive scheduled DEXA scans, properly complete EORTC evaluation, or both. The Company reports that these combined irregularities compromises data from 72 patients in the study.

While the study was oversampled to accommodate loss of patients due to disease progression prior to 8 week evaluation, oversampling was not performed to accommodate data loss as described above. With the loss of an additional patients, the study will have reduced statistical power to demonstrate the proposed effect. All patient samples and data has not yet been received and analyzed by XBiotech. The final number of patients affected is expected to increase or decrease only slightly by the final analysis.

John Simard, President and CEO of XBiotech, stated, "These findings relating to the execution of the study is disappointing. We anticipate approximately another 10 days to complete ongoing analysis of patient samples and data. At such time, we will provide an update on our findings. These findings will not necessarily delay the scheduled unblinding or final analysis of the data."

XBiotech has been conducting two separate Phase III studies in colorectal cancer with different study designs under the Food and Drug Administration (FDA) and European Medicines Agency (EMA) regulatory paths, respectively. This update pertains to the European study, which was developed in collaboration with the EMA. The novel study design is a double-blind, placebo-controlled study that randomizes patients (2:1) to receive Xilonix plus best supportive care, or placebo plus best supportive care. The co-primary endpoints being assessed are change in lean body mass and change in patient reported symptoms from baseline to the 8 week follow up. Improvements in lean body mass are measured using a form of X-ray imaging called DEXA, combined with an assessment of patient well-being with respect to pain, fatigue and/or appetite loss. Specifically, stabilization or a gain in lean body mass at the 8-week follow up combined with improvement or no worsening in two of the latter measures of patient well-being, as measured by the validated EORTC QLQ-C30 questionnaire, enable a patient to be considered a responder for the purposes of the primary endpoint. The co-primary endpoints were designed to capture important surrogates for anti-cancer treatment effect, especially those that have been found in the past to correlate independently with improved overall survival. After completing assessment of the primary endpoint at eight weeks, patients are eligible to cross over into an open label extension of Xilonix.

The Company's second colorectal cancer study is a global Phase 3 study being conducted under a Fast Track designation from the FDA. This study is randomized 2:1 with patients receiving Xilonix or placebo plus best supportive care. Patients are required to have metastatic colorectal cancer, and have failed regimens including flouropyrimidines, oxaliplatin, and irinotecan. Unlike the EMA trial, symptoms at baseline are not required for entry. Patients continue on study until there is evidence of radiographic progression. The primary endpoint of this study is overall survival, with secondary endpoints of objective response rate, progression free survival, change in lean body mass as measured by DEXA, and improvement in patient reported quality of life using the validated EORTC QLQ C30 questionnaire.

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

XBiotech logo

XBiotech