XBiotech Announces Agreement With the NCIC Clinical Trials Group to Collaborate on Phase II Study in Non-Small Cell Lung Cancer (NSCLC)

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Company Advances Oncology Program With Plans for Phase II NSCLC Study

AUSTIN, Texas, Dec. 11, 2015 (GLOBE NEWSWIRE) -- **XBiotech Inc.** (NASDAQ:XBIT), developer of True Human™ therapeutic antibodies, announced today a letter of agreement with the NCIC Clinical Trials Group (NCIC CTG) to develop a Phase II study to assess Xilonix™ in combination with Tarceva for treatment of NSCLC. The proposed study, which will enroll approximately 75 patients, is projected to launch in Canada in Q2 2016.

Michael Stecher, M.D., the Company's Medical Director, said, "This program represents the second oncology indication we will be pursuing with the Xilonix antibody. We believe that the potential synergy between IL-1 alpha antagonism and EGFR inhibitors makes this a highly attractive combination therapy in non-small cell lung cancer, where safe and effective therapies are urgently needed."

The NCIC CTG study is a follow up of results from a subset of the NSCLC patients treated in an all comers oncology study of Xilonix conducted at MD Anderson Cancer Center in Houston[1], which were published in *Investigational New Drugs* in March 2015[2]. These results highlighted the potential for combination therapy in NSCLC patients treated with EGFR inhibitors. In the MD Anderson study NSCLC patients had metastatic, refractory disease at baseline and were treated with Xilonix monotherapy until disease progression. Patients that had received prior treatment with Tarceva appeared to have considerably better outcomes than those that had not received Tarceva. In the study, radiographic evidence of tumor response, changes in lean body mass and quality of life were assessed and patients were followed for 24 months for survival analysis. Radiographic evidence of anti-tumor effect was observed, and improvements in lean body mass and quality of life were observed. Furthermore, stratification by prior therapies revealed a median overall survival for patients treated with anti-EGFR therapy of 9.4 months compared to only 4.8 months for non-pretreated patients.

About the NCIC Clinical Trials Group

The NCIC CTG is the only Canadian cooperative cancer trials group conducting the entire range of cancer trials from early phase studies to large international randomized controlled trials across all cancer types. Its primary mission is to assess the effectiveness of interventions to prevent the development of cancer or improve the care of those patients who do develop cancer. NCIC CTG trials have led to improved outcomes for cancer patients. It is a national research program of the Canadian Cancer Society. The NCIC CTG's Central Operations and Statistics Office is located at Queen's University in Kingston, Ontario, Canada.

About XBiotech

XBiotech is pioneering a new era in the discovery and development of targeted antibodies based on its True Human™ 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.

[1] MABp1, a first-in-class true human antibody targeting interleukin-1α in refractory cancers: an open-label, phase 1 dose-escalation and expansion study. Lancet Oncol. 2014 May;15(6):656-66. doi: 10.1016/S1470-2045(14)70155-X. Epub 2014 Apr 17.

[2] Xilonix, a novel true human antibody targeting the inflammatory cytokine interleukin-1 alpha, in non-small cell lung cancer. *Invest New Drugs.* 2015 Jun;33(3):621-31. doi: 10.1007/s10637-015-0226-6. Epub 2015 Mar 31.

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