XBiotech Announces Expansion of Global Phase 3 Registration Study in Europe using Xilonix(TM) for Treatment of Metastatic Colorectal Cancer

August 7, 2015

First Patients Screened in Europe to Mark Worldwide Expansion of U.S. FDA Colorectal Cancer Study

AUSTIN, Texas, Aug. 7, 2015 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ:XBIT), the world's leading developer of next-generation True Human™ therapeutic antibodies, announced today it has expanded its "XCITE" cancer study into Europe. XCITE is an FDA Fast Tracked, Pivotal Phase 3 study of its cancer drug Xilonix™ for treatment of metastatic colorectal cancer. Screening has now begun at the Marii Skłodowskiej-Curie Oncology Center in Warsaw, Poland, marking the first patient recruitment site outside the U.S. and the commencement in earnest of the global phase of the FDA study.

Xilonix™ Colorectal cancer Immunotherapy Treatment Evaluation ("XCITE"), is designed to assess improvement in overall survival of patients in response to monotherapy with XBiotech's True Human™ monoclonal antibody. The double-blinded, placebo controlled study currently has about 98 sites in the United States and with this launch in Poland, will bring on line more than 80 sites across Eastern and Western Europe. The XCITE trial will continue to expand to include nearly 200 clinical sites across 20 countries worldwide including Australia, Canada and South America. As previously disclosed, XBiotech expects to complete enrollment of this study by the end of 2016.

Dr. Michael Stecher, XBiotech's Medical Director, stated, "Our on-time launch of XCITE into Europe marks an important milestone in our oncology program and signifies we are moving as planned toward completing enrollment by the end of 2016. Since we have been operating another Phase III oncology program in colorectal cancer in Europe, it was important to time the launch of the U.S. FDA study into Europe so as not to compete for patient enrollment. Our clinical operations team has managed to dovetail this important study with impeccable timing to coincide almost precisely with the completion of the European Phase III program. We expect the rapidly escalating engagement we have seen with our European study will now spill over to this new program, which gives us good confidence that we will achieve our enrollment objectives in 2016 as well as report interim survival data around the time of enrollment completion."

Total enrollment in the XCITE study will consist of 600 patients. The primary objective of the trial is to assess the ability of Xilonix to improve overall survival in patients with metastatic colorectal cancer who have failed standard therapies. The study will also assess progression free survival, tumor response, change in muscle mass and improvements in quality of life. Earlier observations of Xilonix therapy in advanced cancer patients revealed physical recovery that strongly correlated with significant improvements in survival. The results were published in April 2014 in *Lancet Oncology.* Based on these results, XBiotech received Fast Track designation from the FDA in October 2012 to develop Xilonix as a treatment in the setting of metastatic colorectal cancer.

To learn more about the XCITE study please visit: www.xcitecolontrial.com

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 is 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 disclosure set forth in "Risk Factors" in 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