XBiotech Announces Publication of Clinical Results Supporting the Potential of Its True Human(TM) Antibody as a Cardiovascular Therapy

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Results Published in the Journal of Vascular Surgery Suggest Potential to Target Inflammation to Treat Acute Vascular Injury

AUSTIN, Texas, Oct. 2, 2015 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ:XBIT), the world's leading developer of next-generation True Human™ therapeutic antibodies, announced publication of clinical results from a Phase 2 open label, randomized, parallel-group, multicenter study examining SFA restenosis in patients following successful percutaneous revascularization. The results, now available online as an "Article in Press" in the *Journal of Vascular Surgery*, point towards Xilonix's potential as a safe and effective therapy to preserve vessel patency after endovascular intervention. This program has previously been granted Fast Track Designation by the US FDA.

In the article titled, "A Randomized Phase II Study of Xilonix, a Targeted Therapy Against Interleukin 1 alpha, for the Prevention of Superficial Femoral Artery Restenosis After Percutaneous Revascularization," XBiotech reported that researchers observed tendencies toward improved vessel patency and fewer major adverse cardiovascular events following dosing of MABp1 over a 3-month period.

Hosam El Sayed, M.D., Ph.D., associate professor of surgery in the Division of Vascular Diseases and Surgery at The Ohio State University Medical Center and lead author, said, "The cardiovascular field has marked many advancements in recent years, and endovascular interventions to treat peripheral arterial disease have saved and improved many lives, however, the natural history of these lesions after intervention appears to be progression to restenosis. Even as initial reports on newer endovascular technologies have reported lower rates of restenosis of arteries in the lower extremities, a systemic pharmacologic approach to prolong the restenosis free duration would be a major step forward for the treatment of these patients."

John Simard, President and CEO of XBiotech, added, "The pathological role of inflammation in atherosclerosis and acute vascular events is well established. We are excited to provide the first data that a therapeutic antibody may be used as a potentially safe and effective means to reduce restenosis and major adverse cardiovascular events following revascularization."

The study enrolled a total of 43 patients with symptomatic, peripheral vascular disease. Upon successful percutaneous revascularization, patients were randomized to Xilonix or standard of care. Xilonix was administered intravenously immediately following revascularization, and every 2 weeks intravenously for 3 additional doses, with additional subcutaneous doses administered monthly. The major efficacy endpoints were target vessel restenosis and incidence of major adverse cardiovascular events (MACE). At 3-month follow-up, which covers the intravenous dosing period, a trend toward lower incidence of restenosis (0/22 [0%] vs. 2/21 [10%], p=0.14) and MACE (2/22[9%] vs. 5/21 [24%], p=0.22) was observed in the Xilonix cohort. Adverse events were equally distributed in both arms.

About XBiotech

XBiotech is pioneering 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 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 True Human antibodies are cloned directly from individual donors who possess natural immunity against certain diseases. 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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