XBiotech Presents Findings at Investigator Conference for Staphylococcus Aureus Program

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BIOTECHNOLOGY, Oct. 21, 2015 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ:XBIT), the world's leading developer of next-generation True Human™ therapeutic antibodies, announced that it held an investigator conference on October 14th in Austin, TX for its Phase 1/2 clinical study of a novel True Human monoclonal antibody therapy intended to treat all forms of *Staphylococcus aureus* infections, including methicillin-resistant *S. aureus* (MRSA). The Company says clinical data were presented that it believes provides evidence that the therapy can work in patients to mediate immune clearance of *S. aureus*. XBiotech says it plans to submit these data to the FDA as it refines its Fast-Track development strategy for the therapy.

The Company presented findings that showed a direct correlation with the pharmacokinetics of its antibody therapy and the ability of patient blood to mediate clearance of *S. aureus*.

XBiotech hosted 30 attendees, including doctors, nurses and coordinators from five participating sites and others responsible for the administration of the trial. The conference featured a talk by Dr. Mark E. Rupp, Principal Investigator of the study, on the growing impact of *S. aureus* bacteremia in the United States, the devastating consequences of the disease in terms of mortality and morbidity, and the need for new therapies. Dr. Rupp, a world expert on *S. aureus* infections, is Professor and Chief, Division of Infectious Diseases and Medical Director of the Department of Infection Control & Epidemiology at the University of Nebraska.

Dr. Rupp commented, "Infection due to *Staphylococcus aureus* is a very significant clinical problem that results in a substantial amount of death and suffering on a worldwide basis. The ongoing emergence and spread of multi-drug resistant *S. aureus*, including MRSA, clearly indicates a critical need for novel, non-antibiotic, adjunctive and preventive therapy. The anti-*S. aureus* monoclonal antibody 514G3 shows great promise in laboratory and *in-vivo* experiments and may be just what is needed to combat serious infections due to *S. aureus*. This novel product deserves serious and thorough scrutiny."

John Simard, President and CEO of XBiotech, stated, "Early clinical data has provided compelling evidence that the antibody therapy can play a crucial role to enable elimination of *S. aureus* by the immune system. We were inspired by the keen interest in the therapy that we witnessed among clinical investigators. We are working diligently to build on our findings to advance the clinical program as quickly as possible to address the urgent need for an *S. aureus* therapy."

The randomized, placebo-controlled, Phase 1/2 study is designed to evaluate dosing, safety and efficacy of 514G3 and will enroll 52 patients at approximately 16 clinical sites in the United States, Europe and Asia. Hospitalized patients with *S. aureus* bacteremia will be randomized to receive 514G3 plus standard of care antibiotics or placebo plus standard of care antibiotics. The study will be unblinded during the Phase 1 dose escalation stage, where the maximum tolerated dose will be determined, followed by a double-blinded Phase 2 study designed to further assess safety and efficacy. Efficacy measures include time to clearance of bacteremia, as measured by blood culture, duration of fever and length of hospitalization. For more information about the study, visit www.clinicaltrials.gov.

About XBiotech

XBiotech is pioneering 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 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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