XBiotech Treats First Patient in Phase 1/2 Clinical Study of Novel True Human(TM) Therapeutic Antibody for Treating Serious Infections Due to Staphylococcus aureus

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AUSTIN, Texas, July 6, 2015 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT), world's leading developer of next-generation True Human™ therapeutic antibodies, announced today treatment of first patient in its Phase 1/2 clinical study. The study is designed to evaluate dosing, safety and efficacy of a novel antibody therapy intended to treat all forms of *Staphylococcus aureus* infections, including Methicillin-resistant *S. aureus* (MRSA). The Company reports that the first patient to enter the study had confirmed MRSA bacteremia that was life threatening. Within 24 hours of receiving a single, low dose of the therapy, the patient had no fever and white blood cell counts began to normalize. These observations suggested rapid control of the infection was achieved upon administration of the antibody. The study is expected to be completed by Q1 2016.

XBiotech's therapy, known as 514G3, was developed from a human donor with natural antibodies effective at neutralizing MRSA and non-MRSA forms of *S. aureus*. 514G3 is expected to treat all strains of MRSA and can be used without consideration for strain-specific resistance to various antibiotics. As a True Human monoclonal antibody, the Company also expects 514G3 to be tolerated without the side effects or risks of antibiotics.

John Simard, the Company's Chief Executive Officer, said, "The ability to treat lethal drug-resistant bacterial infections with a therapy isolated from a human being with natural immunity to the disease is simply a breakthrough approach to creating new medicines. I am thrilled beyond words that our therapy may have helped a patient overcome this dreadful and deadly infection. Our entire team at XBiotech will bring the utmost urgency to providing this therapy to as many patients in as many centers as possible."

Mr. Simard continued, "Entering clinical development with a second True Human therapeutic is a significant achievement for XBiotech. We have been showing the potential for human antibody therapy for the treatment of cancer and other chronic disease conditions. Now with the launch of our first therapy for infectious disease, I think the scope of human-derived antibody therapies really begins to emerge. With our continued success in the clinic, we are set to redefine how drugs are developed and used to treat a range of critical human diseases."

MRSA is a major disease problem worldwide (Grundmann et al. *Lancet*, 2006). When the infection enters the blood (called bacteremia) it is associated with severe morbidity and can quickly become lethal. In addition to methicillin, MRSA have acquired resistance to antibiotics that include erythromycin, clindamycin, ciprofloxacin and tetracycline among others. In 2009, in the U.S. there were an estimated 697,248 hospitalizations related to *S. aureus* infections (Klein et al. *American Journal of Epidemiology*, 2012), while between 1999 and 2005 the cases of hospitalizations due to MRSA more than doubled. Between 2009 and 2010 there were 236,000 cases of MRSA infections related to surgical procedures alone in the U.S. Recent reports from the CDC suggest that the alarming rate of increase in MRSA infections appears to have begun to stabilize in the U.S., but the threat of MRSA remains and the emergence of more aggressive strains continues to be a serious worldwide problem.

The randomized, placebo-controlled, dose escalation study will enroll 52 patients at approximately 16 clinical sites in the United States, Europe and Southeast Asia. Hospitalized patients with *S. aureus* bacteremia will be randomized to receive 514G3 plus standard of care antibiotics or placebo plus antibiotics. The study will be unblinded during the Phase 1 dose escalation stage, where the maximum tolerated dose will be determined, followed by a Phase 2 study designed to assess efficacy against *S. aureus* infection. The primary efficacy endpoint is time to clearance of bacteremia, as measured by blood culture. The study will also evaluate pharmacokinetic parameters as well as duration of fever and length of hospitalization as secondary endpoints. For more information about the study, visit www.clinicaltrials.gov.

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 most advanced product, Xilonix™, is a potential breakthrough antibody therapy that is currently the subject of two pivotal Phase III clinical studies for treating 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 believes that its broad pipeline of True Human antibodies will be 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, XBiotech expects that True Human antibodies will 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.

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