XBiotech Completes Enrollment in Global Phase I/II Study for its True Human™ Antibody Treatment for Serious Staphylococcus aureus Infections

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Study for 514G3 Antibody has Fast Track Designation by the FDA

AUSTIN, Texas, Dec. 06, 2016 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT), developer of True Human™ therapeutic antibodies, today announced that enrollment has been completed in its randomized, placebo-controlled Phase I/II study evaluating dosing, safety and efficacy of the Company's novel antibody therapy, 514G3. This proprietary antibody therapy has received Fast Track Designation by the FDA for the treatment of all forms of *Staphylococcus aureus* infections, including Methicillin-resistant *S. aureus* (MRSA). The Company reports that top-line findings from the 514G3 study should be reported in first quarter 2017.

"We are pleased to announce enrollment completion in this study," said Dawn McCollough, Vice President of Clinical Operations at XBiotech. "We are dedicated to developing this novel therapy to treat these life-threatening bacterial infections, which affect millions of people world-wide. This is an important milestone, bringing us one step closer to potentially addressing the urgent need for a safe and effective *S. aureus* therapy. We look forward to presenting findings from this study early next year."

Patients enrolled in the Phase II portion of the study were randomized to receive the highest dose of 514G3, as determined by the Phase I portion of the study, plus standard of care antibiotics vs. placebo plus antibiotics. Patients were treated in hospital settings at sites in the United States, Germany, Taiwan and Korea. In addition to safety and tolerability evaluation, the study includes efficacy measures such as time to clearance of bacteremia (as measured by blood culture), duration of fever, serious adverse events, length of hospitalization and survival. The randomized, blinded Phase II portion has enrolled 36 patients, with 24 of those patients randomized to receive 514G3.

About 514G3
514G3 was developed from a healthy human donor with natural antibodies effective at neutralizing MRSA and non-MRSA forms of *S. aureus*. 514G3 knocks out the principle immune evasion mechanism of the bacteria, allowing white blood cells to detect and destroy the bacteria. 514G3 has potential 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, 514G3 is expected to be well tolerated without the side effects or risks of antibiotics, including the lack of risk of antibiotic resistance.

About *Staphylococcus aureus*
Staphylococcus aureus (*S. aureus*) is a leading cause of bacteremia and is associated with higher morbidity compared with other pathogens. *S. aureus* bloodstream infections are among the most common but also most difficult to treat[1]. The incidence of *S. aureus*, specifically bacteremia caused by methicillin-resistant *S. aureus* (MRSA) strains, has dramatically increased in recent years in the U.S. and parts of Europe[2,3]. This is partly attributable to increased resistance of *S. aureus* strains to available antibiotics. The burden of MRSA bacteremia is high with substantial costs and resources for healthcare systems[4]. Therefore, there remains an urgent need for new treatment approaches.

About True Human™ Therapeutic Antibodies
Unlike previous generations of antibody therapies, XBiotech's True Human™ antibodies are derived without modification from individuals who possess natural immunity to certain diseases. With discovery and clinical programs across multiple disease areas, XBiotech's True Human antibodies have the potential to harness the body's natural immunity to fight disease with increased safety, efficacy and tolerability.

About XBiotech
XBiotech is a fully integrated global biosciences company dedicated to pioneering the discovery, development and commercialization of therapeutic antibodies based on its True Human™ proprietary technologyXBiotech currently is advancing a robust pipeline of antibody therapies to redefine the standards of care in oncology, inflammatory conditions and infectious diseases. Headquartered in Austin, Texas, XBiotech also is leading the development of innovative biotech manufacturing technologies designed to more rapidly, cost-effectively and flexibly produce new therapies urgently needed by patients worldwide. 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] Wisplinghoff H, Bischoff T, Tallent SM, Seifert H, Wenzel RP, Edmond MB. Nosocomial bloodstream infections in US hospitals: analysis of 24,179 cases from a prospective nationwide surveillance study. Clin Infect Dis 2004; 39:309–17.

[2] Steinberg JP, Clark CC, Hackman BO. Nosocomial and community acquired Staphylococcus aureus bacteremias from 1980 to 1993: impact of intravascular devices and methicillin resistance. Clin Infect Dis 1996; 23:255–9.

[3] EARSS management team. European Antimicrobial Resistance Surveillance System annual report 2006. Bilthoven, The Netherlands: National Institute for Public Health and the Environment, 2007.

[4] Shorr AF, Lodise T. Burden of methicillin-resistant Staphylococcus aureus on healthcare cost and resource utilization. ISMR Update 2006; 1:4–11.

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