XBiotech Advances to Final Dosing Cohort in Phase 1/2 Clinical Study of Novel True Human™ Therapeutic Antibody for Treating Serious Infections Due to Staphylococcus aureus

January 7, 2016

AUSTIN, Texas, Jan. 07, 2016 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ:XBIT), developer of True Human™ therapeutic antibodies, announced today the completion of the second dose cohort in its Phase 1/2 clinical study of 514G3, its novel True Human monoclonal antibody therapy intended to treat all forms of *Staphylococcus aureus* infections, including Methicillin-resistant *S. aureus* (MRSA). Having met this milestone, XBiotech will advance to the third dose level in the Phase 1 portion of the study. The dose will be increased by a factor of four, and represents the final of three planned dosing cohorts.

514G3 was developed from a 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 is expected to treat all strains of *S. aureus* 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.

John Simard, CEO of XBiotech, said, “Safety data review from the second dose cohort revealed no dose limiting toxicities. We are eager to advance to the final dose cohort and move toward the Phase 2 portion of the study. This program is representative of an exciting franchise XBiotech is building to treat a variety of life-threatening infectious diseases.”

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 Southeast Asia. Hospitalized patients with *S. aureus* bacteremia will be randomized to receive 514G3 plus standard of care antibiotics or placebo plus antibiotics. The Phase 1 portion of the study is a dose escalation, which will determine the maximum tolerated dose, followed by a Phase 2 study designed to assess safety and preliminary efficacy against *S. aureus* infection. 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

XBiotech, Inc