

XBiotech Enrolls Final Patient in Phase I Portion of Clinical Study of Novel True Human™ Therapeutic Antibody for Treating Serious Infections Due to Staphylococcus aureus

March 9, 2016

AUSTIN, Texas, March 09, 2016 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ:XBIT) announced today completion of enrollment in the Phase I portion of the ongoing clinical study to evaluate its antibody treatment for *Staphylococcus aureus* (*S. aureus*) infections. The Company is developing a True HumanTM antibody to treat serious, blood-borne infections caused by *S. aureus* including methicillin-resistant (MRSA) strains.

The Phase I portion involved dose escalation to establish a safe dose-level to use during the Phase II expansion. The Phase I portion of the study will not be complete until the last patient enrolled is found to be free of dose-related toxicities. The Phase II portion of the trial will then commence and include a larger cohort of patients that will be used to further investigate safety and efficacy of the therapy.

XBiotech's novel antibody 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 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 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.

Michael Stecher, M.D., XBiotech's Medical Director, said, "*S. aureus* is a major disease problem worldwide and we are encouraged by the advancement of 514G3 in the clinic. We are committed to develop this therapy as expeditiously as possible to address the growing unmet need worldwide for a treatment against these deadly infections."

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. 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 <u>www.xbiotech.com</u>.

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 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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