XBiotech Advances to Phase II Portion of Clinical Study of Novel True Human™ Therapeutic Antibody for Treating Serious Infections Due to Staphylococcus aureus

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Phase I Results Show 514G3 Antibody Demonstrated a Reduction in Serious Adverse Events

AUSTIN, Texas, March 28, 2016 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ:XBIT), developer of True Human™ therapeutic antibodies, announced today that the last patient in the Phase 1 portion of its ongoing clinical study had cleared the safety window for its novel antibody therapy, 514G3, for the treatment of all forms of *Staphylococcus aureus* infections, including Methicillin-resistant *S. aureus* (MRSA). The phase I dose escalation was thus completed with no dose limiting toxicities, and therefore the phase II portion of the trial will be conducted at the maximum administered dose. The Company reports what it believes is a remarkable finding from the Phase I study, noting that the incidence of serious adverse events (SAE) was 50% less in the treatment arm as compared to placebo. A SAE was defined in the study as any event that was life threatening, or resulted in prolongation of hospitalization or death. Therefore, a 50% reduction in SAEs is an extremely good start for the novel anti-infective therapy.

Patients enrolled in the Phase II portion of the study will be randomized to receive the highest dose of 514G3, as determined by the Phase I portion of the study, plus standard of care antibiotics or placebo plus antibiotics. Efficacy measures include time to clearance of bacteremia, as measured by blood culture, duration of fever and length of hospitalization. The randomized, blinded Phase II portion will enroll 36 patients, with 24 of those patients randomized to receive 514G3.

Michael Stecher, M.D., XBiotech's Medical Director, commented, "We did not expect dose limiting toxicities with the 514G3 antibody therapy. However, while the numbers are still small, the observation of a 50% reduction in SAEs in the treatment arm as compared to placebo suggest we are on the right track to an efficacious therapy for treating staph bacteremia. We are excited to further examine the potential efficacy of 514G3 and advance this program as quickly as possible so that we may address the urgent need for safe and effective therapies to clear these life-threatening infections."

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 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, including the lack of risk of antibiotic resistance.

The randomized, placebo-controlled, Phase 1/2 study is designed to evaluate dosing, safety and efficacy of 514G3 and will enroll a total of 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 is rethinking the way antibody medicines are discovered and commercialized and advancing a robust pipeline of human antibodies for treating serious diseases such as cancer, inflammatory conditions and infectious diseases. XBiotech recently announced that its product candidate Xilonix™ had met its primary and secondary endpoints in a phase III study for colorectal cancer, and that the therapy is now the subject of a marketing authorization application in Europe. 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.

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