XBiotech Receives FDA Fast Track Designation for Its Novel True Human(TM) Therapeutic Antibody for Treating Serious Infections Due to Staphylococcus Aureus

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AUSTIN, Texas, Oct. 1, 2015 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ:XBIT), the world's leading developer of next-generation True Human™ therapeutic antibodies, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for its novel True Human monoclonal antibody therapy intended to treat all forms of *Staphylococcus aureus* infections, including Methicillin-resistant *S. aureus* (MRSA).

XBiotech's antibody therapy, known as 514G3, is currently being evaluated in a Phase 1/2 clinical study and 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.

John Simard, the Company's Chief Executive Officer, said, "Receiving FDA Fast Track Designation highlights the importance for this product candidate to treat life-threatening bacterial infections. We look forward to reporting on further developments as this important program continues to generate clinical findings."

About FDA Fast Track Designation

Fast Track designation is awarded to drug developers in order to expedite clinical development and regulatory review. The designation is particularly intended for drugs that are designed to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs.

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

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