



XBiotech Launching Phase 1/2 Clinical Study of Novel True Human(TM) Therapeutic Antibody for Treating Serious Infections Due to Staphylococcus Aureus

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FDA Lifts Clinical Hold Enabling Clinical Launch of the Company's First Infectious Disease Target

AUSTIN, Texas, May 28, 2015 (GLOBE NEWSWIRE) -- **XBiotech Inc.** (Nasdaq:XBIO), a leading developer of next-generation True Human™ therapeutic antibodies, announced today that the Food and Drug Administration (FDA) has lifted its clinical hold from the Company's IND, enabling launch of its therapy for *S. aureus* infections. XBiotech was placed on clinical hold while it worked with the agency to prepare its novel therapy and manufacturing process for human studies. XBiotech will now begin enrollment of approximately 52 patients in a Phase 1/2 randomized, placebo-controlled, dose escalation study, which will evaluate safety and efficacy of the therapy to treat serious *S. aureus* infections.

This drug candidate was developed using XBiotech's True Human antibody discovery platform, which involves screening healthy individuals to identify those with natural immunity to specific diseases. The therapy was derived from an individual that harbored natural antibodies capable of neutralizing *S. aureus*, including drug-resistant strains of the disease. The treatment is being developed to treat all forms of staph infections and will first be tested in patients with life-threatening infections that are present in the blood, known as bacteremia. The antibody is capable of blocking the key mechanism that *S. aureus* uses to evade the body's immune system. The therapy can thus at once undermine the bacteria's escape mechanism and facilitate its natural clearance by the body's immune system.

John Simard, the Company's Chief Executive Officer said, "We are grateful to the FDA for working very closely with us to launch the first of our new infectious disease therapies. It would be difficult to overstate the potential impact this new therapy could have on how therapies are developed and used to treat infections. Derived from natural immunity, this true human antibody offers the means to provide safer, more effective treatments that are not susceptible to present forms of drug resistance. Our antibody therapy represents what we foresee as the launch of '21st century antibiotics,' and the coming of age of biotechnology in the area of infectious disease."

About XBiotech

XBiotech is pioneering a new era in 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 *truly* natural 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 broad pipeline of True Human antibodies are able to potentially deliver unmatched safety and efficacy because they are cloned directly from individual donors who possess natural immunity against certain targeted diseases. As such, True Human antibodies retain their natural physiology and tolerance profile, having passed the rigors of immune selection in the body. For more information, visit www.xbiotech.com.

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