



XBiotech Secures Approval From Data Safety Monitoring Board to Continue Phase 3 Registration Study in Europe for Its Novel Cancer Immunotherapy

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AUSTIN, Texas, May 18, 2015 (GLOBE NEWSWIRE) -- XBiotech (Nasdaq:XBITE), developer of Xilonix anti-cancer therapy for the treatment of colorectal cancer, announced today that the Data Safety Monitoring Board (DSMB) has recommended continuation of the Company's Phase 3 registration study underway in Europe. The study, launched in March of 2014, is on schedule for completion this year. The DSMB decision follows a pre-scheduled interim review as part of the study plan. The DSMB board consists of an independent panel of medical experts that oversee execution of the study. While a DSMB's primary responsibilities are related to safety, they also generally evaluate study conduct with respect to good clinical practices and make recommendations concerning continuation, modification or termination of the trial.

As part of the only planned DSMB review, the group was tasked with assessing what fraction of patients enrolled had completed all endpoints. Normally, not all patients enrolled make it through all the data endpoints. Based on these findings, the DSMB was to make a recommendation for increasing the patient sample size to maintain statistical power of the study. The DSMB made a recommendation for sample size increase that was within expectations and the Company states enrollment remains on pace to meet the completion timelines.

The primary objective of the double-blinded, placebo-controlled, multi-center study is to assess the effectiveness of Xilonix for treating patients with symptomatic colorectal cancer. Xilonix blocks interleukin-1 alpha (IL-1a), an inflammatory mediator that acts at the site of the tumor to stimulate growth of tumor blood supply and support tumor growth. In addition, IL-1a may aid circulating tumor cells to form new sites of metastasis and also be involved as a messenger in the brain, where it can trigger fatigue, anxiety and metabolic dysregulation seen in advanced cancer. In a previous study at MD Anderson, Xilonix therapy appeared to not only have anti-tumor effects and prolong survival, but also seemed to improve symptoms of muscle loss, fatigue, appetite loss, and pain in patients with advanced cancer.

In the current study, anti-tumor effect will be measured by assessing the change in these symptoms for patients treated with Xilonix versus those treated with placebo. Reversal of muscle loss will be assessed with a novel type of radiology called dual energy X-ray absorptiometry, or DEXA. Improvement in pain, appetite loss, and fatigue will be measured with a well-established and validated questionnaire that reliably assesses patient well being as reported by patients themselves.

John Simard, President and CEO of XBiotech, commented, "The DSMB recommendation is indeed an important milestone for our lead oncology therapy. While the DSMB outcome confirms Xilonix's extraordinary safety profile, this result also demonstrates that our study is being well-executed and proceeding according to plan. We are all looking forward to unblinding this remarkable study later this year."

About XBiotech

XBiotech is pioneering a new era in the discovery and development of targeted antibodies based on its True HumanTM 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, XilonixTM, 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 regulate diverse inflammatory pathways. 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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