XBiotech Completes Enrollment for Xilonix(TM) Phase III Registration Study in Europe

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AUSTIN, Texas, Aug. 17, 2015 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ:XBIT), the world's leading developer of next-generation True Human™ therapeutic antibodies, announced today it has completed enrollment of the Company's pivotal, randomized double-blinded placebo controlled Phase III study in Europe of Xilonix™ for the treatment of advanced colorectal cancer. Xilonix, a novel anti-cancer agent, is being developed via a ground-breaking regulatory path that XBiotech established in collaboration with the scientific advisory committee of the European Medicines Agency (EMA). The Phase III program has now met the enrollment objective for study completion and the Company remains on track to announce results by year end.

Dr. Tamas Hickish, lead investigator of the European program, said, "I believe this study of a completely novel drug will give new insight into how to treat advanced bowel cancer. The innovative approach to target IL-1a is a fascinating concept in the treatment of advanced cancer. The strong enrollment is a reflection of the need for anti-cancer therapies that maintain patient health while treating the disease."

John Simard, President and CEO, stated, "To get to this point, we brought together a novel manufacturing program, distributed drug across Western and Eastern Europe, and executed a first-of-its-kind multinational clinical study—so I am especially pleased to say that we have completed enrollment of the Phase III study on schedule for a 2015 readout."

Mr. Simard further stated, "Robust enrollment speaks to the support Xilonix gained among caregivers and patients. Keep in mind that XBiotech has spent less than $9 million for execution of this study."

The Company's Xilonix therapeutic monoclonal antibody targets the molecular signaling known to stimulate growth of blood vessels and breakdown of connective tissue. The same signals may be involved in metastasis and messaging to the brain to cause pain, fatigue, anxiety, appetite suppression and hypermetabolic syndrome seen in advanced cancer. Earlier observations of Xilonix therapy in advanced cancer patients suggested physical recovery that strongly correlated with significant improvement in survival in colorectal cancer (Hong et al. *Lancet Oncology* 2014). These findings formed the basis for developing this unique regulatory pathway in Europe in collaboration with the EMA.

The Phase III trial is evaluating the efficacy of Xilonix in patients with metastatic colorectal cancer that is refractory to standard therapy. The trial design is double-blind, placebo-controlled and randomizes patients (2:1) to Xilonix plus best supportive care (BSC), or to placebo plus BSC. Eligible patients have metastatic colorectal cancer, have progressed on an oxaliplatin- and irinotecan-based regimen and are experiencing symptoms due to their underlying malignancy. The co-primary endpoint of improvement in lean body mass and improvement in quality of life is assessed after eight weeks of therapy, using whole body DEXA scanning for body composition assessment and the validated EORTC QLQ-C30 questionnaire for life quality assessment. The co-primary endpoints were designed to capture important surrogates for anti-cancer treatment effect, especially those that have been found in the past to correlate independently with improved overall survival. After completing assessment of the primary endpoint at eight weeks, patients are eligible to cross over into an open label extension of Xilonix.

About XBiotech

XBiotech is pioneering the discovery and development of targeted antibodies based on its True Human^{TM} 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.

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