XBiotech Announces European Medicines Agency (EMA) Validates Marketing Authorization Application (MAA) for Xilonix™ in the Treatment of Advanced Colorectal Cancer

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AUSTIN, Texas, March 23, 2016 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT) announced today that the Company's Marketing Authorization Application (MAA) for Xilonix™, which is intended for the treatment of advanced colorectal cancer, has been validated by the European Medicines Agency (EMA). With this validation, the application process is complete and the EMA's Committee for Medicinal Products for Human Use (CHMP) will now begin the assessment of Xilonix through the centralized review procedure. If approved through this procedure, Xilonix will be licensed in all EU member states.

"The MAA for Xilonix is based on a recently completed Phase III double-blind, placebo-controlled clinical study where the antibody therapy met its primary and secondary endpoints in advanced colorectal cancer," said John Simard, CEO of XBiotech. "The acceptance of our application for review by the EMA is a significant milestone in our oncology program and leads us one step closer towards potentially addressing a serious and growing unmet medical need for patients suffering from advanced colorectal cancer in the European Union. We look forward to continuing to work with the EMA during the review process."

The incidence of advanced, symptomatic colorectal cancer is growing globally with economic development and aging demographics. Persons with advanced colorectal cancer are frequently weakened from successive rounds of cytotoxic therapy, and the risk-benefit associated with further therapy is often questionable. Objective response criteria were developed by XBiotech in collaboration with the EMA's Scientific Advice Working Group and used to establish clinical benefit in a Phase III study of Xilonix. Findings showed a significant improvement in overall response rate for Xilonix-treated patients versus placebo. The objective response criteria consisted of controlling key symptoms (pain, fatigue, appetite loss, and muscle loss) associated with disease progression and prognosis for overall survival. The Company believes that these criteria will allow excellent assessment of overall clinical benefit from therapy in advanced cancer patients.

About XBiotech
XBiotech is pioneering the discovery and development of targeted antibodies based on its True Human™ technology. The company's mission is to discover and commercialize new medicines by advancing its robust pipeline of antibodies derived from natural human immunity. Products in development are for treating a variety of diseases such as cancer, inflammatory and infectious disease. 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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