XBiotech Announces Submission of Marketing Authorization Application (MAA) for Candidate Colorectal Cancer Therapy to European Medicines Agency (EMA)

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AUSTIN, Texas, March 08, 2016 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT) announced today that the Company has now submitted its Marketing Authorization Application (MAA) for its candidate therapy (Xilonix™) for advanced colorectal cancer to the European Medicines Agency (EMA). Submission of the MAA for Xilonix is necessary for the Company to gain approval to sell the drug in European Union member nations. The Company, which only recently was granted eligibility to submit its MAA through the Centralised Procedure, has made a remarkably quick turnaround for delivery of the extensive MAA documentation needed for the EMA review.

John Simard, CEO of XBiotech, commented, "With submission of the Marketing Authorization Application, we now look forward to the review process."

Few agents are reliably able to mediate durable responses in metastatic disease. And many agents have significant trade-offs in terms of side effects. In patients with advanced disease, often weakened from successive rounds of cytotoxic therapy, the risk-benefit associated with further therapy is often questionable. Based on novel objective response (OR) criteria, developed by XBiotech in conjunction with the EMA's Scientific Advice Working Group, the candidate therapy subject of the MAA was recently evaluated in a Phase III clinical study for the ability to control disease-related symptoms that inversely correlate with survival. The Company believes using the symptom-based objective response criteria will allow better assessment of overall benefit from therapy in advanced cancer patients.

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 most advanced product, Xilonix™, is a potential breakthrough antibody therapy that is currently the subject of two pivotal Phase III clinical studies for treating 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 believes that its broad pipeline of True Human antibodies will be 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, XBiotech expects that True Human antibodies will retain their natural physiology and tolerance profile, having passed the rigors of immune selection in the body. 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 disclosure set forth in "Risk Factors" in 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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