European Medicines Agency Grants Eligibility for Submission of XBiotech's Marketing Authorization Application (MAA)

March 4, 2016

AUSTIN, Texas, March 04, 2016 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT) announced today that the Company has been granted eligibility by the European Medicines Agency (EMA) to submit a Marketing Authorization Application (MAA) for its candidate therapy Xilonix™ for the treatment of advanced colorectal cancer. An MAA contains all relevant clinical, scientific and manufacturing information that describes how a drug works and is manufactured. The MAA is submitted as the first step in the process of seeking approval to sell the drug in the European Union member nations. XBiotech was granted the ability to submit its MAA through the Centralised Procedure and has been assigned Rapporteurs, the highly specialized project managers that will shepherd the MAA through the review process. The Company expects to submit an MAA shortly.

John Simard, CEO of XBiotech, stated, "We are gratified that our marketing application has been granted eligibility by the European Medicines Agency. We are looking forward to the submission and review process."

In a recently concluded Phase III study in the EU, patients treated with the antibody therapy Xilonix had failed all conventional therapies and had inoperable or metastatic disease. Patients were also required to have multiple symptoms of disease—each of which correlated with poor prognosis. Treatment of these advanced colorectal cancer patients indicated that the Xilonix antibody therapy was able to control tumour-related symptoms associated with morbidity and death. Furthermore, the Phase III study indicated that Xilonix therapy appears to lack the frank toxicity of many other anti-cancer agents, and that the therapy may not cause the negative hematological effects that result in immunosuppression, eliminating a troubling toxicity and life-threatening risk factor of other anti-cancer therapies used to treat advanced disease.

In the advanced cancer patients treated in this recently completed Phase III study for Xilonix, there was a 76% relative improvement in response rate in patients treated with the antibody, as compared to placebo (p=0.0045). Secondary endpoints used in the Phase III study—control of thrombocytosis and systemic inflammation—which are known prognosticators of overall survival, were also significantly improved in the treated patients compared to controls (respectively p=0.003, p=0.004). In addition to these planned analyses, the study revealed a higher incidence of stable disease in the antibody-treated patients, and there were fewer significant adverse events (SAEs) in the treatment arm than in the placebo group.

The Company believes that the recent and earlier clinical findings to be presented in its MAA provide a compelling case for the clinical benefit of the antibody therapy and establish Xilonix as a groundbreaking therapy for advanced colorectal cancer.

Few agents are reliably able to mediate durable responses in metastatic disease; and many agents have significant trade-offs in terms of side effects, such that the overall benefit of therapy may be questionable in patients with advanced cancer. Based on novel objective response (OR) criteria, developed by XBiotech in conjunction with the EMA's Scientific Advice Working Group, XBiotech's Xilonix was evaluated for its ability to control disease-related symptoms that inversely correlate with survival. The Company believes that using this 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^{TM} 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.

Contact:
XBiotech
Ashley Otero
aotero@xbiotech.com

512.386.2930

XBiotech, Inc