XBiotech Announces Outcome of EMA's Oral Explanation Meeting

April 20, 2017

AUSTIN, Texas, April 20, 2017 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT) announced today that the European Medicines Agency (EMA) rendered a negative "trend" vote after meeting with the Company to discuss the "Day 180 List of Outstanding Issues" related to the Company's marketing authorization application (MAA) for its candidate antibody for the treatment of colorectal cancer. A negative trend vote means it is unlikely that a positive Committee for Medicinal Products for Human Use (CHMP) opinion related to the Company's MAA will be attained at the formal decision vote scheduled in May, and that additional steps would need to be taken to potentially gain marketing approval.

At the Oral Explanation meeting, per EMA protocol, the Company gave a 20 minute presentation and had a Q&A session with CHMP members regarding the MAA for its candidate therapy to treat advanced colorectal cancer (data presented by the Company will be filed with the SEC in a Form 8-K and will be available on the SEC's website at www.sec.gov). The Oral Explanation format is intended to provide an opportunity for the Company to clarify data in support of marketing authorization.

The key outstanding issues are related to clinical relevance of the therapy in the indication and quality assurance related matters. The meeting, however, focused on outstanding clinical relevance issues.

John Simard, President & CEO of the Company, stated, "We are disappointed by the outcome of the meeting. We believe that the data speak in a clear and resounding voice to clinical relevance of a new antibody therapy in advanced colorectal cancer. We believe that findings from our Phase III study show that we have developed an important endpoint and methodology to evaluate anti-cancer therapy in advanced stage disease and that our monoclonal antibody represents a breakthrough treatment in patients with advanced colorectal cancer. The EMA marketing authorization application procedure enables the appeal of negative decisions from the oral explanation. We may seek access to this process at the appropriate time."

About True Human™ Therapeutic Antibodies

XBiotech's True Human™ antibodies are derived without modification from individuals who possess natural immunity to certain diseases. With discovery and clinical programs across multiple disease areas, XBiotech's True Human antibodies have the potential to harness the body's natural immunity to fight disease with increased safety, efficacy and tolerability.

About XBiotech
XBiotech is a fully integrated global biosciences company dedicated to pioneering the discovery, development and commercialization of therapeutic antibodies based on its True Human™ proprietary technologyXBiotech currently is advancing a robust pipeline of antibody therapies to redefine the standards of care in oncology, inflammatory conditions and infectious diseases. Headquartered in Austin, Texas, XBiotech also is leading the development of innovative biotech manufacturing technologies designed to more rapidly, cost-effectively and flexibly produce new therapies urgently needed by patients worldwide. 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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