XBiotech Announces Successful Completion of EMA GMP Inspection

October 12, 2016

Manufacturing Operations Found to be in Compliance with GMP Guidelines

AUSTIN, Texas, Oct. 12, 2016 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT), developer of next-generation True Human™ therapeutic antibodies, today announced a successful GMP (Good Manufacturing Practices) inspection by the European Medicines Agency (EMA). The EMA's Competent Authorities of France [The French Agency for the Safety of Health Products], conducted the inspection in connection with the Xilonix Marketing Authorization Application. XBiotech's production operations were deemed to be in general compliance with the principles and guidelines of good manufacturing practice as laid down in Commission Directive 2003/94/EC. The findings allow the French Agency to recommend to the EMA XBiotech's current facility for the commercial manufacture of Xilonix.

XBiotech is pioneering a new manufacturing process using disposable bioreactor technologies. These manufacturing technologies reduce capital costs and operating complexity while improving flexibility of biological manufacturing compared to existing clean-in-place technologies. XBiotech CEO, John Simard, commented, "The confirmation of GMP compliance is an important step for our manufacturing platform and commercialization capabilities."

The GMP inspection was performed as part of the evaluation of the Company's Marketing Authorization Application for Xilonix for the treatment of advanced colorectal cancer. The Company expects EMA decision on the Marketing Application as early as the end of 2016.

About True Human™ Therapeutic Antibodies
Unlike previous generations of antibody therapies, 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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