XBiotech Completes Enrollment in Global Phase III Study using Xilonix Monotherapy to Treat Advanced Colorectal Cancer

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Enrollment Completed on Schedule in Global Phase III Study Under US FDA Fast Track Program

AUSTIN, Texas, Dec. 07, 2016 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT), developer of True Human™ therapeutic antibodies, today announced that enrollment has been completed in its randomized, double-blind, placebo-controlled Phase III study evaluating Xilonix as a treatment for advanced colorectal cancer. The Phase III study is being conducted under Fast Track designation from the FDA and involves over 600 advanced cancer patients from 18 countries world-wide. The Company reports that the first interim analysis allowing an assessment by the Data Monitoring Committee (DMC) of both safety and efficacy is expected as early as first quarter 2017.

"We have achieved another significant milestone in our oncology program," stated John Simard, President & CEO of XBiotech. "Our team has remained on schedule with this complex project and we now look forward to an interim analysis early next year."

The double-blind, placebo-controlled Phase III study is randomized 2:1 with patients receiving Xilonix or placebo plus best supportive care. Patients are required to have metastatic colorectal cancer, and are required to have failed regimens that include flouropyrimidines, oxaliplatin, irinotecan, and Cetuximab or Panitumumab for patients with KRAS mutation. Patients continue on study until there is evidence of radiographic progression. The primary endpoint of this study is overall survival, with secondary endpoints including objective response rate, progression free survival, change in lean body mass as measured by dual energy X-ray absorptiometry (DEXA), and patient reported quality of life using the validated EORTC QLQ C30 questionnaire. There are two scheduled interim analyses and a final analysis. The study may be stopped for efficacy at either interim analysis, which would potentially enable an early submission of a request for marketing authorization. Patients are otherwise followed for up to 18 months in order to determine overall survival and the study is powered for 552 events at study conclusion.

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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