XBiotech Announces Discontinuation of Phase III Study for Colorectal Cancer Based on Second Interim Analysis

June 9, 2017

AUSTIN, Texas, June 09, 2017 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT) announced today that an Independent Data Monitoring Committee (IDMC) has performed its second prospectively planned, unblinded analysis of the Phase 3 XCITE study for the Company's novel candidate antibody therapy for the treatment of colorectal cancer. The IDMC had no safety concerns from the unblinded analysis. However, the committee recommended the early termination of the study since the findings were not sufficient to meet efficacy or the threshold for continuation, which involved a prospectively defined acceptance boundary for the interim analysis of less than or equal to p = 0.08.

John Simard, XBiotech President & CEO stated, "We are obviously disappointed with these findings. In the coming weeks, the Company plans to analyze the data extensively to further understand the primary and secondary endpoint data, as well as to identify populations that may have benefited from the therapy. These findings today will not affect our efforts to pursue approval of the therapy based on the successful completion of the European study, which demonstrated control of debilitating symptoms in colorectal cancer."

Patients enrolled in the XCITE study were randomized 2:1 to receive Xilonix or placebo plus, in each case, best supportive care. Advanced colorectal cancer patients were required to have previous failed regimens that included flouropyrimidines, oxaliplatin, irinotecan, and Cetuximab (or Panitumumab for patients with KRAS mutation). Patients were expected to continue in the study until there was evidence of radiographic progression. The patients were to be followed for up to 18 months in order to determine overall survival. The primary endpoint of this study was overall survival, with secondary endpoints including objective response rate, progression free survival, change in lean body mass and patient reported quality of life measures.

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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