XBiotech Reports Affirmative Interim Analysis of Global Phase 3 Colorectal Cancer Study

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Unblinded IDMC Review Recommends Continuation of Study

AUSTIN, Texas, Feb. 21, 2017 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT) today announced that an Independent Data Monitoring Committee (IDMC) has performed a prospectively planned, unblinded analysis of the Phase 3 XCITE study for the Company's novel candidate antibody therapy for colorectal cancer. The IDMC reported that the FDA Fast-Tracked study had no safety concerns and that indications of efficacy were sufficient to recommend proceeding with the study without modification.

Dr. George Fisher, Professor of Medicine, Stanford Cancer Center, and global Chair of the XCITE study, commented, "We are grateful to the IDMC members for their diligent review of the Phase 3 data. The go-ahead to continue on with our study after this substantial review of safety and efficacy is encouraging and we look forward to that next analysis as the data mature."

These findings also lend support to the Company's recently completed Phase 3 study in Europe, which used a novel primary endpoint to evaluate efficacy for the same antibody therapy for the treatment of advanced colorectal cancer. The Chair of the European study and Professor of Medicine, Bournemouth University, UK, Dr. Tamas Hickish stated, "I am not surprised with these findings since we have seen such a strong connection with survival in patients that achieved the primary outcome in the European study."

According to the IDMC charter, this was the first of two interim efficacy analyses planned prior to the final analysis for overall survival. As determined based on alpha spending function of O'Brien and Fleming sequential group design (O'Brien PC, Fleming TR, 1979), survival analyses are to be performed after 276 (50%), 414 (75%) and 552 (100%) events at the respective stages. The criteria for early termination for efficacy (rejection of null hypothesis) or to accept the null hypothesis is based on the group sequential design. If the test statistics crosses the pre-specified boundaries for type I error (alpha cut-off 0.0029, 0.0121, and 0.025 at the first, second interim or final analysis, respectively) the trial will stop for efficacy. Otherwise the trial continues to the next stage.

The cumulative p value for the acceptance boundary (beta) will be 0.25 and 0.08 at the first and second interim, respectively. If efficacy is established at an interim analysis, enrollment will be stopped and the control group will be allowed to crossover. All subjects will be followed up until death, loss to follow-up, or termination of the study. The decision rule with interim monitoring was planned as follows: If type I error probability (alpha) ≤ the above specified cumulative alpha level at the given stage, trial will stop for efficacy; if the p value ≥ the above specified beta levels, the trial will stop for accepting null hypothesis; if neither of these occurs, the trial will continue to the next stage. At final analysis, if alpha is ≤0.025 then efficacy will be declared, otherwise the null hypothesis will be accepted.

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 are required to have previous failed regimens that included flouropyrimidines, oxaliplatin, irinotecan, and Cetuximab (or Panitumumab for patients with KRAS mutation). Patients are expected to continue in the study until there is evidence of radiographic progression. The study may be stopped for efficacy or futility at the second remaining interim analysis, and patients are otherwise followed for up to 18 months in order to determine overall survival. The study is powered for 552 events at conclusion.

The primary endpoint of this study is 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
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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