XBiotech Reports Additional Positive Data From Phase III European Trial of Xilonix™ in Advanced Colorectal Cancer

January 8, 2016

Conference Call and Live Audio Webcast Scheduled for Today at 8:30 a.m. ET

AUSTIN, Texas, Jan. 08, 2016 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ:XBIT), developer of True Human™ therapeutic antibodies, today announced that it has completed data analysis for its Phase III European study and will hold a conference call to provide additional important information regarding the activity of Xilonix™ in the treatment of advanced, symptomatic colorectal cancer.

In addition to previously announced positive results regarding the primary endpoint of the pivotal study, complete data analysis further demonstrated that key secondary measures of antibody activity were also improved. Inhibition of IL-1 alpha on the surface of platelets may represent an important anti-tumor, disease-modifying activity, due to the mechanism of action of Xilonix. In the study, median platelet counts among placebo patients were found to be increased 5-fold compared to patients who received Xilonix, whose platelet counts remained near baseline levels during the treatment cycle (p=0.003).

Furthermore, while the study was not powered to demonstrate differences in serious adverse events (SAEs) between treatment and placebo groups, there was a 26% reduction in the risk of SAEs in the treatment arm relative to placebo (p=0.062). A treatment-related reduction in SAEs compared to placebo patients is a remarkable and important finding. An SAE is defined as a health-related event that is life-threatening, results in persistent or significant disability, or death. This may be the first report of a placebo controlled, randomized clinical study of an anticancer agent where there was *reduced* incidence of SAEs in a treatment arm. Finally, patients in the treatment arm were found to be 53% more likely to have stable disease compared to placebo at eight weeks (p=0.12).

The trends toward reduced disease progression and a reduction in SAEs is compelling given the small patient population in the study. Together, the Company believes that these secondary findings corroborate the therapeutic value of the antibody in advanced, recalcitrant cancer.

John Simard, CEO of XBiotech, stated, "We believe this study serves as a confirmation that Xilonix is a unique anti-cancer agent for gently treating advanced, even fragile cancer patients. We are also very proud that the study represents a milestone in the development of new clinical endpoints to assess efficacy of novel treatments that help heal patients with advanced disease."

The study included only patients with advanced disease with multiple symptoms that were prognosticators of poor outcome. The study was thus performed on a narrowly defined group of patients living with advanced colorectal cancer. The objective response criteria that constituted the primary endpoint were based on findings of a previous study in advanced cancer patients where antibody therapy was associated with recovery from key disease-related symptoms, including objective findings of increased lean body mass (LBM), and recovery from appetite loss, fatigue and pain. The Company collaborated with the Scientific Advisory Group of the European Medicines Agency (EMA) to use these earlier observations to establish novel objective response criteria to enable evaluation and potential registration of a cancer therapy. Thus the present findings of the Phase III study are believed to provide the first evidence that: (1) new endpoints based on symptom recovery may be used to evaluate an anti-tumor agent in advanced cancer; (2) in patients with advanced cancer, clinical trajectory can be positively altered in the presence of recalcitrant tumor; and (3), Xilonix, a True Human antibody therapeutic, represents a novel treatment for a serious unmet medical need in advanced colorectal cancer.

Conference Call Information:
XBiotech will host a conference call and live audio webcast today at 8:30 a.m. ET to review the strategy and findings from the European Phase 3 Xilonix trial.

Interested participants and investors may access the conference call by dialing:

- 1 (877) 242-7960 (U.S.)
- 1 (330) 863-3267 (International)

An audio webcast will also be accessible via the Investors Relations section of the XBiotech website www.xbiotech.com/about/investors.html. The webcast replay will remain available for 90 days.

About XBiotech
XBiotech is pioneering the discovery and development of targeted antibodies based on its True Human™ technology. The company's mission is to rethink the way antibody medicines are discovered and commercialized by advancing its robust pipeline of human antibodies for treating serious diseases such as cancer, inflammatory conditions and infectious diseases. XBiotech's lead product, Xilonix™, is a potential breakthrough antibody therapy that is currently the subject of two pivotal clinical studies for treating patients with advanced colorectal cancer. Xilonix specifically targets and neutralizes interleukin-1 alpha (IL-1a), a molecule known to promote angiogenesis, growth and spread of tumors, as well as mediate symptoms such as metabolic dysregulation, fatigue and anxiety associated with advanced cancer. XBiotech's True Human antibodies are cloned directly from individual donors who possess natural immunity against certain diseases. 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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