XBiotech Completes Dosing of Subjects in PK Study Being Conducted in Connection with European Marketing Application

February 22, 2017

AUSTIN, Texas, Feb. 22, 2017 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT) announced that all subjects have been dosed in its pharmacokinetic (PK) study evaluating MABp1 half-life in healthy volunteers. This Phase I study will provide further PK data and will enable additional characterization of the PK of MABp1 at a 7.5mg/kg IV dose. Safety and tolerability will also be assessed. PK analyses at various time points ranging from pre-infusion to 336 hours post infusion will be collected. The study is on schedule to be completed as planned for the Company's upcoming regulatory submission.

The Company previously reported it had been granted an additional 30 days to submit its responses to the Day 180 List of Outstanding Issues (D180LOI) by the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) in connection with the Company's Marketing Authorization Application for Xilonix. This extension was granted as a result of a clarification meeting held recently between XBiotech and the EMA. The extension was granted in order to allow sufficient time for the Company to complete the PK study in healthy subjects. These new PK data are intended to address relevant technical questions in the D180LOI and will be included in the Company's response submission scheduled for March 22nd.

"We are happy to report the expeditious execution of this study, which will provide further PK data at multiple time points in the first 96 hours after dosing. This will enable additional and accurate characterization of the peak concentration, half-life and clearance, thus confirming PK is consistent with what would be expected from a monoclonal antibody," commented Michael Stecher, XBiotech's Medical Director. He further stated, "With these additional data in hand, we look forward to fully addressing the complete list of day 180 questions in March."

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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