XBiotech Provides First Quarter 2016 Corporate and Clinical Update

May 18, 2016

Conference Call and Webcast today, May 18 at 8:30 a.m. ET

RECENT HIGHLIGHTS

- *European Medicines Agency accepts Marketing Authorization Application for Xilonix™ in colorectal cancer and grants accelerated review*
- *Xilonix Phase III U.S. trial enrollment on schedule*
- *Novel antibody to treat all forms of S. aureus infections, including MRSA, advances to Phase II, Phase I completed*
- *New manufacturing facility nearing completion*
- *Key additions to leadership team*

AUSTIN, Texas, May 18, 2016 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT), developer of next-generation True Human™ therapeutic antibodies, today provided a business update for the first quarter ended March 31, 2016. Company Founder and Chief Executive Officer John Simard, along with XBiotech's senior leadership and management team, reviewed first-quarter clinical developments and provided updates on the company's pipeline, research and development operations and new manufacturing facility during this morning's conference call and audio webcast at 8:30 a.m. ET.

Simard said XBiotech made significant progress during the quarter, including advancing its lead candidate Xilonix™, a True Human therapeutic antibody in development for the treatment of advanced colorectal cancer, toward regulatory approval. "Just a month after submitting our Marketing Authorization Application to the European Medicines Agency, the Agency granted Xilonix accelerated review," Simard said. "We are rapidly advancing this remarkable candidate therapy through clinical trials and now are poised for our first drug approval, which could come as early as the fourth quarter of 2016." Xilonix also has received Fast Track designation from the U.S. Food and Drug Administration (FDA).

In a pivotal Phase III clinical study, Xilonix was shown to control tumor-related symptoms associated with morbidity and death. These data will be presented for the first time at the 18th European Society of Medical Oncology's World Congress on Gastrointestinal Cancer on July 1 in Barcelona, Spain.

Simard said enrollment is on track for a separate pivotal Phase III trial of Xilonix in advanced colorectal cancer that is part of the FDA's Fast Track program.

Xilonix is specifically designed to target and neutralize interleukin 1-alpha, a protein that has been shown to promote the growth and spread of tumors and is associated with metabolic changes that can cause muscle loss, fatigue, anorexia and anxiety.

"In addition to advanced colorectal cancer, we have seen evidence of activity in other cancer tumor types and firmly believe that anti-IL-1-alpha therapy could be relevant in a broad range of malignancies," Simard said.

The first quarter also saw important developments in the company's infectious disease program. "We completed a Phase I dose-escalation study of our rapidly advancing antibody 514G3, which targets serious, often life-threatening forms of staphylococcus aureus bacteremia infections, including methicillin resistant strains (MRSA)," Simard said, "and we rapidly moved to enrolling patients in the Phase II portion of the study." In this trial, patients are being randomized to receive either the highest dose of 514G3, as determined by the Phase I study, plus standard-of-care antibiotics, or placebo plus antibiotics. The Phase II study will measure efficacy in terms of time to clearance of bacteremia as measured by blood culture, duration of fever, length of hospitalization and incidence of mortality.

"We are excited about moving this program forward as quickly as possible to address the urgent need for safe and effective therapies for clearing these dreadful, life-threatening infections," Simard said.

XBiotech continues to develop its pipeline of True Human antibody therapies. "We have initiated 10 clinical programs across a range of diseases and medical conditions. We continue to see that our ability to rapidly and cost-effectively transition from discovery to potential breakthrough therapies is unprecedented," Simard said. "In breadth and depth, XBiotech's pipeline rivals those of far larger and longer-established pharmaceutical companies."

In anticipation of the approval and commercialization of Xilonix, XBiotech is enhancing its manufacturing capacity and quality programs. "We are looking forward to the completion of the new facility that will house our expanded manufacturing operations on our Austin campus," Simard said. The company plans to move in during the third quarter of 2016.

As part of its overall growth strategy, XBiotech continues to build the senior leadership team. Amgen veteran Scott Whitehurst was appointed Chief Financial Officer and will oversee the Company's financial operations, capital requirements and investor relations function. In addition, former head of medical research at Biogen Inc. Dawn McCollough was named Vice President of Clinical Operations, bringing to XBiotech more than two decades of oversight in all phases of drug development.

SIGNIFICANT UPCOMING MILESTONES

- *Results of the accelerated Assessment of Marketing Authorization Application for Xilonix™ in Europe, 3Q16*
- *Pivotal Xilonix Phase III data presented at the 18th European Society of Medical Oncology's World Congress on Gastrointestinal Cancer, July 2016*
- *Pre-clinical data release for Staphylococcus aureus antibody 514G3 at the Americas Antibody Congress, May 2016*
- *Complete 514G3 Phase II study*
- *Opening of new Austin manufacturing facility, 3Q16*

Financial results for the quarter can be found in the investor section of XBiotech's website (www.xbiotech.com).

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

- 1 (844) 249-9385 (U.S.)
- 1 (270) 823-1533 (international)
- Conference ID: 7241703

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

About True Human™ Therapeutic Antibodies
Unlike previous generations of antibody therapies, XBiotech's True Human™ antibodies are 100 percent human, derived 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.

The first of these therapies, Xilonix™, for advanced colorectal cancer, is in Phase III clinical trials in the United States with a Fast Track designation by the U.S. Food and Drug Administration (FDA). In Europe, Xilonix Phase III clinical trials have been completed, and the therapy is under accelerated review following the validation of its Market Authorization Application by the European Medicines Agency (EMA).

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 technology. XBiotech currently is advancing a robust pipeline of antibody therapies to exceed 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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