European Medicines Agency Grants Accelerated Assessment of Marketing Authorization Application for Xilonix(TM), XBiotech's True Human(TM) Therapeutic Antibody Treatment for Advanced Colorectal Cancer

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(GLOBE NEWSWIRE via COMTEX) --- Xilonix poised to be a first-in-class, True Human monoclonal (IgG1k) antibody

- First to neutralize biological activity of interleukin-1a (IL-1a), developed specifically to treat advanced cancer

- EMA decision could speed access to Xilonix for EU patients

AUSTIN, Texas, April 04, 2016 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has granted accelerated review for Marketing Authorization of Xilonix, the Company's first-in-class True Human monoclonal (IgG1k) antibody treatment for advanced colorectal cancer. The CHMP grants accelerated review for medicines deemed to be of public health importance and that represent therapeutic innovation. The accelerated review procedure allows the CHMP to grant an opinion two months earlier than the normal 210-day procedure. With this action, a decision on Xilonix's approval could come as early as third quarter 2016.

Xilonix is XBiotech's lead True Human therapeutic antibody and a potential breakthrough for patients with advanced colorectal cancer. Xilonix specifically targets and neutralizes interleukin-1 alpha (IL-1a), a molecule known to promote angiogenesis (the growth and spread of tumors), as well as mediate symptoms such as metabolic dysregulation (e.g., loss of weight and muscle mass), fatigue and anxiety associated with advanced cancer.

XBiotech recently received validation of its Marketing Authorization Application (MAA) for Xilonix based on results of a Phase III study, which showed a 76% relative improvement in response rate in patients treated with the antibody, as compared to placebo (p=0.0045). Patients treated in the Phase III study had colorectal tumors that were metastatic or inoperable, had failed all recommended forms of chemotherapy and most other forms of therapy, and suffered from symptoms including pain, fatigue, anorexia and wasting. The patients treated in the Phase III study were considered to represent a large patient population that is physically and emotionally exhausted from the disease and treatment-related toxicities.

"XBiotech is encouraged by CHMP's action to grant accelerated review of Xilonix," said John Simard, Chairman, Chief Executive and founder of XBiotech. "There is an urgency to provide advanced colorectal cancer patients with access to new treatments that have been developed with their specific needs in mind."

In the U.S., Xilonix has received Fast Track designation by the Food and Drug Administration (FDA) for the treatment of advanced colorectal cancer.

About Colorectal Cancer

Colorectal cancer is the second leading cause of malignancy in the industrialized world.1 The incidence of colorectal cancer increases with economic development and aging, hence incidence is rising worldwide.2 In Europe, approximately 470,000 patients will be diagnosed with colorectal cancer in 2016, and half of this number will progress and ultimately succumb to the disease.3 Disease progression is associated with significant morbidity, functional impairment and failure of multiple therapies often with substantial toxicities. Patients with advanced disease are thus symptomatic and intolerant to further treatment-related morbidity. New anti-cancer options are needed for patients suffering from advanced colorectal cancer.

About XBiotech's True Human(TM) Therapeutic Antibodies

Unlike antibodies found in other therapies, XBiotech's True Human(TM) antibodies are 100 percent human and derived from healthy people with natural immunity to heal and protect others. By rethinking the approach to antibody therapy, XBiotech developed a proprietary technology to identify, isolate and manufacture human antibodies derived from the body that finally work in harmony with it.

About XBiotech

XBiotech is a fully integrated global 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 improve the standards of care in oncology, inflammatory conditions and infectious diseases. Headquartered in Austin, Texas, XBiotech is expanding its state-of-the-art manufacturing with launch of a new commercial-scale facility in 2016. The manufacturing process has been designed to dramatically reduce time and cost while increasing flexibility, representing a new approach to biotech manufacturing. 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 disclosure set forth in "Risk Factors" in 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.

1 Lozano R, et al. Global and regional mortality from 235 causes of death for 20 age groups in 1990 and 2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet 2012;380: 2095e128.

2 United European Gastroenterology (UEG). https://www.ueg.eu/press/releases/ueg-press-release/article/europe-is-falling-behind-america-in-the-fight-against-colorectal-cancer-due-to-low-screening-uptake/. Accessed April, 2016.

3 EuropaColon. http://www.europacolon.com/crcstatistics.php?Action=Crcstatistics. Accessed April, 2016.

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