XBiotech Announces First Patient Enrolled in Clinical Trial Evaluating XB2001 for the Treatment of Pancreatic Cancer

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XB2001 Is a Novel Therapy that Interrupts Inflammation to Potentially Block Growth and Spread of Tumors and to Reduce Toxicity of Chemotherapy Treatment

AUSTIN, Texas, June 23, 2021 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ: XBIT) has enrolled the first patient in its 1-BETTER study, a randomized, double-blind, placebo-controlled clinical study to evaluate XB2001 in combination chemotherapy for treatment of Pancreatic Cancer.

XBiotech's novel anti-cancer agent, XB2001, is being assessed in combination with ONIVYDE + 5-FU/LV chemotherapy regimens. Safety and tolerability of the regimen, as well as progression-free survival, overall survival and time-to-treatment-failure will be assessed in the study.

XB2001 blocks inflammation pathways turned on by tumors that help tumors vascularize, spread and cause collateral damage to healthy tissues. By using XB2001 to block inflammation in pancreatic cancer, investigators also hope to see a reduction in serious adverse events and reduced hospitalizations of subjects. Moreover, the anti-inflammatory effects of XB2001 may make the chemotherapy more effective and less toxic.

The study is also investigating a novel clinical endpoint that XBiotech calls the "clinical benefit response", which involves radiological assessment of muscle mass and patient reported measures of pain, fatigue and appetite. In earlier clinical studies in advanced cancer patients, XBiotech discovered that subjects with preserved muscle mass and stabilization or improvement of these symptoms, had dramatically improved overall survival. The Company previously validated this endpoint in a phase III study in colorectal cancer patients and will explore this endpoint now with its new drug in pancreatic cancer.

The current study will commence with a Phase 1 portion to establish safety, tolerability and dosing of XB2001 in combination with ONIVYDE+5-FU/LV. The Phase I portion will serve to establish a recommended Phase 2 dose, which will involve enrollment of 60 patients randomized to receive either placebo+ONIVYDE+5-FU/LV or XB2001+ONIVYDE+5-FU/LV for up to 12 cycles.

Dr. Carl Gray, Principal Investigator at Community Cancer Trials of Utah, site of first patient enrollment, commented, "Pancreatic cancer remains an aggressive and difficult form of cancer to treat. If we can use XB2001 to improve outcomes and increase the tolerability of chemotherapy, this would be an exciting advance."

John Simard, chairman and CEO of XBiotech stated, "Chemotherapy and paraneoplastic-related acute and chronic inflammatory responses play a key role in tumor progression and is a cause of significant morbidity with chemotherapy. Currently there is no approved therapy to specifically target this fundamental aspect of tumor biology or these effects of chemotherapy."

About True Human™ Therapeutic Antibodies
XBiotech's True Human™ antibodies are derived without modification from individuals who possess natural immunity to certain diseases. XBiotech is undertaking discovery and clinical development 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 technology. XBiotech 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 is also leading the development of innovative biotech manufacturing technologies designed to more rapidly, cost-effectively and flexibly produce 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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