FDA Gives Go-Ahead for XBiotech's Candidate Therapy for Phase I/II Double-blind Placebo Controlled Study in Pancreatic Cancer

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XBiotech's New Drug to Enter Clinical Studies in Combination Therapy for Pancreatic Cancer

AUSTIN, Texas, April 19, 2021 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ: XBIT) announced today that the FDA has granted permission to commence clinical trials with its novel drug candidate for treating patients with pancreatic cancer. From 1992 to 2018 the death rate from pancreatic cancer steadily increased in the USA. It is now predicted that pancreatic cancer will claim 48,220 lives and be the 3rd leading cause of cancer death in the USA in 2021 (National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) program).

Pancreatic cancer is typically identified at an advanced stage and treatment often includes surgery and aggressive chemotherapy. A current approved treatment involves combination chemotherapy including ONIVYDE and 5-fluorouracil, drugs that have significant toxicities and provide only modest response rates. XBiotech's new drug candidate (XB2001) specifically targets a process potentially involved in the growth and spread of malignant tumors; and the drug also blocks inflammation associated with tissue injury, which may reduce toxicity associated with the chemotherapy and allow these drugs to be better tolerated and more effective.

The Phase I/II clinical study will evaluate XBiotech's new drug candidate when added to the ONIVYDE/5-FU combination therapy. The clinical study is chaired by Dr. Shubham Pant, a leading researcher and oncologist at MD Anderson Cancer Center; and will involve at least 15 other top cancer centers around the United States. The Phase 1 portion of the study will examine increasing doses of XBiotech's new drug and assess tolerability of the combination at escalating doses. Once a safe dose has been determined, the phase 2 portion will begin, enrolling 60 patients, which will be randomized to receive treatment with ONIVYDE/5-FU or ONIVYDE/5-FU combined with XB2001. Clinical endpoints in the study are safety, overall survival, objective response rate, progression free survival, time to treatment failure, clinical benefit response, number of severe adverse advents, as well as biological measures of experimental drug activity.

Dr. Razelle Kurzrock, M.D., Murray Professor of Medicine, Clinical Science Director, Center for Personalized Cancer Therapy, University of California, San Diego commented, "We need more effective treatments for pancreatic cancer and I believe IL-1a, the target of XB2001, represents an important novel target in oncology. This novel drug approach may both antagonize the biology of the tumor and mitigate chemotherapy-related toxicities—offering hope for improved outcomes in cancer, including tumors of the pancreas."

John Simard, Chairman and CEO of XBiotech, stated, "The launch of our new drug into this challenging area of oncology speaks to our strong conviction to the mechanism of this drug and the substantial unmet medical need for patients suffering from pancreatic cancer."

Several classes of therapeutics are undergoing development for pancreatic cancer, such as new cytotoxic chemotherapy, so called PKIs and immunotherapies. However, each of these treatments approaches are expected to provide, at best, modest improvements in survival and are not expected to replace existing current cytotoxic agents. Thus, significant opportunity exists for new drugs that could synergize with existing cytotoxic agents to reduce treatment and disease-related morbidity, and improve treatment outcomes. XBiotech believes its new drug is strongly positioned for this opportunity.

Cytotoxic chemotherapy agents result in systemic toxicity—which is considered a trade-off for potential anti-tumor activity. Toxicity is of acute importance clinically, but consequences of inflammatory responses induced by cytotoxic agents may also have a more profound impact, promoting tumor growth and compromising the efficacy and durability of the therapy itself. Cytotoxic agents upregulate inflammatory pathways, including activation of leukocytes, vascular endothelium and stromal cells of the tumor microenvironment. IL-1a may be a key player in the tumor and treatment related inflammatory pathway.

XBiotech's new drug XB2001 is a naturally occurring antibody that potently neutralizes IL-1 α and is thus a safe and promising

approach to block inflammation that occurs with advanced malignancies and chemotherapy. Unchecked, IL-1α can stimulate angiogenesis, enhancing blood and nutrient supply to the tumor; IL-1α may also act to recruit unwanted leukocytes (such as myeloid suppressor cells) into the tumor, that can suppress the ability of the body's immune system to fight off the tumor; and systemically, IL-1α can mediate metabolic dysfunction, and cause fatigue, anorexia, and anxiety. IL-1α is thus a central player in paraneoplastic inflammation and XBiotech's new drug therapy holds promise for treating a wide array of cancers.

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 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 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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