XBiotech Announces Successful Completion of Phase I portion of Pancreatic Cancer Study

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Novel Natrunix Treatment Shows Promise in Combination Chemotherapy for Treatment of Pancreatic Cancer

AUSTIN, Texas, June 20, 2022 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ: XBIT) announced today it successfully completed the Phase I portion of its 1-BETTER study, a Phase I/II randomized, double-blind, placebo-controlled clinical study to evaluate its anti-cancer drug Natrunix in combination with chemotherapy for treating pancreatic cancer. Enrollment in the Phase II portion is commencing immediately.

Thirty leading cancer centers across the United States are involved in the Phase I/II study. Pancreatic cancer is the 4th leading cause of cancer death in the United States and the incidence has been increasing steadily since 2000. In 2022 about 50,000 people will die from pancreatic cancer in the United States. The Natrunix antibody therapy represents a groundbreaking approach to therapy—with the aim to of reducing treatment related toxicity of chemotherapy while also blocking the tumor-associated signals that spurn growth and spread of tumors.

The key is Natrunix's ability to specifically target the body's response to injury. Chemotherapy and tumors both elicit an injury response from the body, and this response may counteract some of the beneficial effects of therapy while at the same time cause substantial morbidity. This injury response plays a crucial role in the growth, spread and morbidity of cancer. Natrunix targets this common pathway activated by cytotoxic therapy and paraneoplastic inflammation. Used in combination with chemotherapy, Natrunix is therefore being assessed for its ability to reduce the side effects of chemotherapy treatment and mediate anti-tumor effects.

The Phase I study enrolled patients in three groups, using escalating dose levels of Natrunix. Subjects received the maximum dosing of Natrunix without a single report of "possibly, probably, or definitely related dose limiting toxicity (DLT)" associated with the investigational agent. Subjects received two 14-day cycles of Natrunix in combination with the chemotherapy drugs Onivyde, 5-fluorouracil and leucovorin. At the discretion of the treating oncologist, after completing the two 14-day cycles, patients were allowed to continue to receive Natrunix if they were deemed to be potentially benefiting from the investigational agent. All patients in the highest dose group have continued to receive Natrunix; at this time a total of 14 additional cycles of therapy have been administered to the Phase I subjects.

Dr. David Park, Medical Director, Hematology, Medical Oncology, St Jude Crosson Cancer Institute, Providence OC Cancer Institute stated, "Natrunix has shown to be well-tolerated when administered concurrently with chemotherapy. We are seeing early encouraging signs that this investigational agent may have a salutary effect in patients via its action in the inflammatory pathway(s)."

The Phase II portion of the study is commencing immediately. Key endpoints in the Phase II portion will be progression-free survival, overall survival and time-to-treatment-failure. The Phase II portion is enrolling 60 subjects that will be randomized on a 1:1 basis to receive either Natrunix in combination with ONIVYDE+LV+5-FU (Arm 1), or placebo plus the chemotherapy combination. Subjects will receive the treatment for up to 12 cycles and will be allowed to continue to receive Natrunix if they were deemed to be potentially benefiting from the investigational agent.

About Natrunix
Natrunix is a True Human™ antibody that was discovered, developed and manufactured by XBiotech. True Human™ antibodies are derived—without modification—from individuals who possess natural immunity to certain diseases. In many individuals, the body naturally produces antibodies to block pathological inflammation associated with interleukin-1, one of the most extensively studied inflammatory pathways in medicine. Other marketed biological drugs attempt to treat diseases by blocking interleukin-1, however none specifically and exclusively target interleukin-1 alpha (IL-1a). There is also no other marketed monoclonal antibody therapy derived unaltered from a natural human immune response.

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 is currently 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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