XBiotech Announces Enrollment Completion of Phase II, Placebo Controlled, Multicenter Study for Natrunix in Pancreatic Cancer

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AUSTIN, Texas, Aug. 30, 2023 (GLOBE NEWSWIRE) -- XBiotech Inc. announced today completion of enrollment of the Phase II portion of its 1-BETTER study—a Phase I/II randomized, double-blind, placebo-controlled clinical study for Natrunix in combination with chemotherapy for treating pancreatic cancer.

Natrunix is indistinguishable from a naturally occurring antibody present in a healthy human. Natrunix binds and neutralizes a potent substance, a so called cytokine known as interleukin-1a (IL-1a), that causes connective tissue breakdown, growth of new blood vessels, and recruitment of white blood cells. Malignant tumors, like pancreatic cancer, stimulate the body's production of IL-1a that induce tumor neovascularization, growth and spread. Additionally, IL-1a acts as an alarm signal when there is body injury (such as when tumors grow), enhancing pain perception, metabolism, appetite, fatigue, and anxiety. The insult from chemotherapy also induces IL-1a production. Adding Natrunix to your chemotherapy regimen may therefore provide numerous benefits, including anti-tumor activity, reduction in chemotherapy side effects, improvement in chemotherapy activity—including increasing the number of cycles of therapy that can be tolerated while improving quality of life.

Twenty-two leading cancer centers across the United States have been 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, an estimated 50,000 people died from pancreatic cancer in the United States. The Natrunix antibody therapy represents a groundbreaking approach to therapy.

The Phase II portion enrolled 65 subjects using the maximum dose studied from the Phase I study that were 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. Key endpoints in the Phase II portion are safety and tolerability, progression-free survival, overall survival and time-to-treatment-failure.

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.

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