XBiotech Announces First Patient Enrolled into the French National Cancer Institute (INCA) Sponsored Phase I/II/III Clinical Study for Natrunix™ Therapy for Colorectal Cancer

October 13, 2022

INCA funded Phase I/II/III Study for Natrunix in Combination with Trifluridine/Tipiracil, the TASKIN Study, Launches at 20 Leading Medical Centers in France

AUSTIN, Texas, Oct. 13, 2022 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ: XBIT) announced today the enrollment of the first patient in a multicenter, randomized clinical study for Natrunix in combination with trifluridine/tipiracil for the treatment of colorectal cancer. The much anticipated clinical study for XBiotech's candidate cancer treatment is being funded by the French National Cancer Institute (INCA). The study is headed by renown oncologists Dr. François Ghiringhelli and Dr. Come Lepage, Professor in Medical Oncology and Director of the INSERM research team at the Georges-Francois Leclerc Cancer Centre, and Professor at the Department of Gastroenterology and Digestive Oncology, University Hospital Dijon, Dijon, France, respectively.

Investigators are combining XBiotech's Natrunix with trifluridine/tipiracil as a new candidate therapy for metastatic colorectal cancer. Subjects receiving the experimental therapy have failed earlier treatment with oxaliplatin, irinotecan, and fluoropyrimidine. Subjects are randomized to receive Natrunix plus trifluridine/tipiracil chemotherapy or placebo plus the chemotherapy. The study is designed to seamlessly proceed through Phase III development based on achievement of certain efficacy milestones in the Phase I/II portions.

Natrunix is a therapeutic monoclonal antibody discovered, manufactured, and undergoing clinical development by XBiotech. The antibody blocks the activity of substance produced by tumors and inflammatory cells that stimulates new blood vessel formation and breaks down connective tissue at the site of the tumor, allowing tumors to grow and spread. The same substance also activates blood vessels, making them sticky to enhance migration of circulating tumor cells to new sites of metastasis. Natrunix potently blocks the action of the substance, known as IL-1, which is also produced in response to chemotherapy.

Colorectal cancer is one of the most common forms of cancer in Europe and the United States, with the American Cancer Society's estimating over 151,000 new cases and over 52,000 deaths annually in the United States alone.

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 is currently advancing a robust pipeline of antibody therapies to redefine the standards of care in oncology, inflammatory and infectious diseases. Headquartered in Austin, Texas, XBiotech has also developed innovative biotech manufacturing technology designed to produce its True Human Antibodies rapidly and cost-effectively. 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.

Contact

Wenyi Wei
wwei@xbiotech.com
Tel. 737-207-4600