French National Cancer Institute and XBiotech Join forces to Conduct Innovative Phase II/III Adaptive Multicenter Clinical Study for XBiotech's New Cancer Drug for Colorectal Cancer

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XBiotech to Supply INSERM its New Drug to Use in Combination Therapy for Treating Advanced Colorectal Cancer

AUSTIN, Texas, May 03, 2021 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ: XBIT) announced today that it had reached an agreement to supply its new cancer drug XB20-01 to INSERM, and its Federation of Digestive Oncology group, a French organization which supports world-leading innovation for treating colorectal cancer.

Colorectal is one of the most common forms of cancer in Europe and the United States, with nearly 150,000 new cases and 53,000 deaths expected in the US alone in 2021. The current chemotherapy regimen uses a Trifluridine/Tipiracil combination, drugs that interfere with the genetic material of cells in an effort to kill tumors. However, inflammation and toxicity from the chemotherapy is offset only by modest response rates and less than ideal outcomes. Thus, there is significant unmet medical need for this group of colorectal cancer patients. XBiotech's new drug candidate XB20-01 targets an inflammatory process potentially involved in the growth and spread of colorectal cancer; and the new drug may also block inflammation caused by chemotherapy, potentially reducing side effects and improving the treatment effect of chemotherapy.

The chair and lead investigator of the multicenter clinical study is Dr. François Ghiringhelli M.D. Ph.D, Director of INSERM, and Professor of Oncology at the University of Burgundy, Genetic and Immunotherapy Medical Institute. Dr. Ghiringhelli, a world-leading researcher in colorectal cancer, designed the study which features an innovative interim analysis to assess improvement in overall survival. If patients receiving XB20-01 have a predetermined improvement in survival compared to the placebo treated group, the randomized study will be expanded to enroll a phase III portion with overall survival as the primary outcome.

Professor Ghiringhelli, also a Director at the prestigious INSERM center and Head of a Division specializing in "Cancer and adaptive immune response", commented, "This is a very exiting clinical trial, granted by the French Cancer Institute, for a very frequent and devastating disease. Currently very few drugs give promising results for these patients. In case of success, this trial could be practice changing."

John Simard CEO XBiotech stated, "We are honored to be able to provide our new candidate drug to INSERM, an institution that is setting a global standard for public involvement in the promotion of innovation in medicine. François has developed a brilliant study design that we are very excited to support."

Cytotoxic chemotherapy agents result in systemic toxicity—considered to be 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 is believed to play a key role in pro-tumor and treatment related inflammatory pathways.

XBiotech's new drug XB20-01 is a naturally occurring antibody that potently neutralizes IL-1a and is thus a safe and promising approach to block inflammation that occurs with advanced malignancies and chemotherapy. Unchecked, IL-1a can stimulate angiogenesis, enhancing blood and nutrient supply to the tumor; IL-1a 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-1a can mediate metabolic dysfunction, and cause fatigue, anorexia, and anxiety in cancer patients. IL-1a is thus a unique target for addressing paraneoplastic inflammation—with XBiotech's new drug therapy holding 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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