# XBiotech Announces French National Agency (ANSM) Approval and National Cancer Institute (INSA) funding to Support Phase I/II/III Clinical Study for Natrunix™ in Combination with Trifluridine/Tipiracil (TASKIN) for Treatment of Metastatic Colorectal Cancer

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**ANSM approves NATRUNIX for INSA funded Phase-I-III Study at 20 Leading Medical Centers in France**

AUSTIN, Texas, April 28, 2022 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ: XBIT) announced today that the French National Agency for the Safety of Medicines and Health Products [L'Agence nationale de sécurité du médicament et des produits de santé (ANSM)] approved the launch of a multicenter randomized clinical study for XBiotech's candidate cancer treatment Natrunix in combination with trifluridine/tipiracil for the treatment of colorectal cancer. The French National Cancer Institute (INCA) has also awarded a grant to fund all clinical costs for the study.

Investigators will combine Natrunix and trifluridine/tipiracil as a new candidate therapy for metastatic colorectal cancer in subjects that have failed earlier treatment with oxaliplatin, irinotecan, and fluoropyrimidine. The study will randomize patients to receive the Natrunix plus chemotherapy or placebo plus chemotherapy and is designed to seamlessly proceed to a Phase III study based on achievement of certain early efficacy milestones.

Headed by Dr. François Ghiringhelli and Dr. Come Lepage, the clinical program will include over 20 participating clinical centers and enroll at least 160 subjects. Dr. François Ghiringhelli is Professor in Medical Oncology and Director of the INSERM research team at the Georges-Francois Leclerc Cancer Centre, and Dr. Come Lepage, Prof. Department Gastroenterology and Digestive Oncology, University Hospital Dijon, Dijon, France. The study design was developed by the lead investigators in collaboration with XBiotech.

The first portion of the study will be an open label, dose escalation (3:3). The Phase II portion will be a multicenter, randomized, double blind, placebo-controlled, non-comparative trial that will enroll 160 subjects. The main objective of the phase II study is to evaluate the efficacy of Natrunix + trifluridine/tipiracil in comparison with placebo + trifluridine/tipiracil with respect to 6-month overall survival in patients with refractory metastatic colorectal cancer. Secondary efficacy measures in the phase 2 portion will include progression free survival, median overall survival, tolerance, quality of life, serum markers of inflammatory cytokines, and tumor markers by immunohistochemistry. With successful completion of the primary endpoint in the Phase II portion, the study will continue into a phase III trial with the number of additional patients enrolled based upon results from the Phase II.

Natrunix is a therapeutic monoclonal antibody discovered, manufactured and undergoing clinical development by XBiotech. The antibody blocks the activity of interleukin-1 alpha (IL-1α). Malignant tumors "trick" the body into producing IL-1α, which has multiple roles in supporting tumor growth and spread. IL-1α expression is also induced by cytotoxic chemotherapy. IL-1α is a potent activator of new blood vessel formation (upregulating VEGF and tumor neoangiogenesis); it mediates breakdown of connective tissue through stimulating matrix metalloproteinase production; facilitates metastasis (enhancing adhesion and migration across blood vessels); and mediates systemic illness (fatigue, anorexia, and anxiety) through activating the hypothalamic-pituitary-adrenal axis. Using Natrunix to block IL-1α in combination therapy could inhibit tumor growth and spread, reduce unwanted effects of chemotherapy, and improve outcomes.

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 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.

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