



XBiotech Announces Positive Phase II Final Efficacy Results from Investigator-Sponsored TASKIN Trial in Refractory Metastatic Colorectal Cancer

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Investigator-sponsored study funded by the French National Cancer Institute (INCa) meets pre-specified primary efficacy success criterion with 61.3% 12-month overall survival.

Exploratory Subgroup analysis reveals significant survival benefit in right-sided tumors.

AUSTIN, Texas, Oct. 19, 2026 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ: XBIT) today announced positive final efficacy results from the randomized Phase II portion of the multicenter TASKIN clinical trial. The investigator-sponsored study—funded by the French National Cancer Institute (INCa) and coordinated by investigators at the Centre Georges-François Leclerc (CGFL) in Dijon, France—evaluated the addition of XBiotech's anti-IL-1 α monoclonal antibody, XB2001 (Natrunix™, vilamakitug), to standard-of-care trifluridine/tipiracil (TAS-102) with or without bevacizumab in patients with refractory metastatic colorectal cancer (mCRC).

The TASKIN Phase II study met its pre-specified primary efficacy success criterion under a Simon two-stage design. At the 12-month landmark analysis, 49 of 80 evaluable patients (61.3%) in the vilamakitug experimental arm were alive, surpassing the protocol-defined threshold of 42 or more surviving patients required to establish efficacy. In the control arm (placebo plus standard chemotherapy), 44 of 79 evaluable patients (55.7%) were alive at 12 months.

Professor François Ghiringhelli, M.D., Ph.D., Principal Investigator of the TASKIN study and Director of the Oncology Department at Centre Georges-François Leclerc, commented:

"Patients with refractory metastatic colorectal cancer face severe therapeutic limitations and poor survival outcomes. Meeting our pre-specified primary milestone provides compelling evidence that targeting IL-1 α plays a meaningful role in tumor biology. Most striking is the magnitude of benefit observed in right-sided colorectal cancers, which has been a historically aggressive disease subset with high unmet medical need. The alignment between this pronounced clinical survival advantage and elevated basal IL-1 α tumor expression offers a clear biological rationale for this therapy."

Summary of Overall Findings

- **Time to Strategy Failure (TSF):** The 12-month TSF rate, which captured the duration for which the overall treatment strategy remains viable, was 31.2% in the vilamakitug arm compared to 20.3% in the control arm (log-rank $p = 0.17$).
- **Progression-Free Survival (PFS):** Median PFS was 5.9 months for the vilamakitug arm versus 5.6 months for the control arm, with a 12-month PFS rate of 25.0% versus 21.0% (log-rank $p = 0.42$), with survival curves visibly separating after month 7.
- **Safety & Treatment Adherence:** Vilamakitug demonstrated high feasibility in combination with chemotherapy, showing a 96.4% mean compliance rate for trifluridine/tipiracil and only a 1.3% permanent discontinuation rate for vilamakitug/placebo.

Exploratory Endpoint Analysis, Efficacy in Right-Sided Primary Tumors

A prospective exploratory analysis identified a statistically significant benefit in patients with right-sided (proximal) primary tumors ($n = 37$), a subtype characterized by aggressive tumor biology, high unmet medical need, and poor outcomes under standard therapies:

- **Overall Survival (OS):** Vilamakitug demonstrated a statistically significant 62% reduction in the risk of death compared to control (Hazard Ratio [HR] = 0.38; 95% CI: 0.14–0.99; Cox $p = 0.047$, log-rank $p = 0.038$) through 12 months.
- **Time to Strategy Failure (TSF):** Vilamakitug achieved a 61% reduction in the risk of treatment strategy failure compared to control (HR = 0.39; 95% CI: 0.18–0.85; Cox $p = 0.017$, log-rank $p = 0.014$) through 12 months.

Sushma Shivaswamy, Ph.D., Chief Scientific Officer and Interim Chief Executive Officer of XBiotech, stated:

"We are deeply grateful to Professor Ghiringhelli, the team at Centre Georges-François Leclerc, the French National Cancer Institute, and all the participating patients for advancing this important trial. By uncovering a biomarker-anchored patient population in right-sided disease that derives substantial clinical benefit from vilamakitug, TASKIN provides a focused and validated direction as we advance vilamakitug toward registrational clinical development."

About the TASKIN Trial The TASKIN study (NCT05201352) is an investigator-sponsored clinical trial funded by the French National Cancer Institute (INCa) and sponsored by the Centre Georges-François Leclerc (CGFL) in Dijon, conducted across clinical cancer centers in France. The Phase I portion determined the safety and recommended Phase II dose of vilamakitug with trifluridine/tipiracil and bevacizumab. The double-blind Phase II portion enrolled heavily pre-treated refractory mCRC patients randomized 1:1 to receive standard-of-care trifluridine/tipiracil ($\pm$ bevacizumab) in combination with either vilamakitug or placebo until disease progression or unacceptable toxicity.

About vilamakitug (Natrunix™, XB2001) A True Human™ therapeutic monoclonal antibody developed solely by XBiotech. Vilamakitug is derived from a human donor that had a natural human immune response against interleukin1alpha (IL-1 α). IL-1 α is an apex mediator that creates the environment to support growth and emergence of malignant cells. IL-1 α stimulates angiogenesis, cellular dysregulation, tissue matrix remodeling, tumor migration, adhesion, and invasion, hallmark physiological features of cancer. Remarkably, vilamakitug has been shown clinically to simultaneously reduce levels of each of VEGF-A, ErbB2/HER2, PDGF, and EGF in cancer patients. Rather than a simple cytotoxic agent that kills all growing tissue, vilamakitug therefore can target multiple aspects of the malignant disease process, facilitating anti-tumor effects while controlling the disease process and reducing disease morbidity. Dramatic reduction in incidence of cancer-related morbidity, reduced hospitalization, reduced duration of hospitalization, reduced symptoms such as diarrhea, fatigue and pain, reduced tumor burden, and longer progression free survival and overall survival have been observed in another study in advanced cancer.

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™ discovery platform. XBiotech currently is advancing 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.

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