

Medical Research Council Funds Phase 2 Multi-Center Study of XBiotech's Bermekimab in Advanced Cancer Patients

July 9, 2019

Medical Research Council (MRC) Grants Funding for Bermekimab as Part of its Support for "Outstanding Clinical Programs in the United Kingdom"

AUSTIN, Texas, July 09, 2019 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ: XBIT) announced today that the Medical Research Council (MRC), part of UK Research and Innovation, has awarded funding to study bermekimab therapy in a Phase 2 multi-center study in advanced cancers. The MRC will provide funding for all clinical costs of the Phase 2 study to treat patients with advanced lung, pancreatic and ovarian cancers. The MRC uses leading medical researchers to evaluate and award grants based on the mission "to improve human health through world-class medical research." [https://mrc.ukri.org/]

The phase 2 study will be conducted at multiple cancer centers across the UK. Patients will receive eight weekly doses of bermekimab and be assessed for tumor-related wasting and other quality of life symptoms (using the EORTC QLQ-C30). The study was developed in conjunction with the National Institute for Health Research (NIHR) Cancer & Nutrition Collaboration and the National Cancer Research Institute (NCRI) Supportive and Palliative Care Group.

Barry J. A. Laird, M.D., Senior Lecturer in Palliative Medicine at the University of Edinburgh's Cancer Research Centre, Institute of Genetics and Molecular Medicine, and Consultant in Palliative Medicine at St Columba's Hospice in Edinburgh will head the study. Dr. Laird commented, "In patients with cancer, loss of weight, decreased activity and impaired quality of life are often regarded as inevitable with limited treatments available. Using immunotherapy to abrogate this disease process is a new approach. We are grateful to the MRC and to XBiotech for supporting this trial."

John Simard, President & CEO of XBiotech, commented, "We are pleased that the medical experts at the MRC have committed resources to the bermekimab program in oncology. We are grateful to Dr. Baird for his work in advancing a novel clinical protocol and for bringing this important immunotherapy to patients in the UK. Bermekimab has proven to significantly benefit patients with advanced cancer. We are eager to provide bermekimab in support of the planned clinical study and to help patients suffering from advanced cancer."

Bermekimab targets the inflammatory cytokine interleukin-1a and has been used in other innovative oncology studies. The Company previously met its primary endpoint in a randomized double-blind, placebo-controlled study with bermekimab for the treatment of advanced colorectal cancer. The primary endpoint in the study was a novel symptom cluster, which assessed a combination of physical symptoms—pain, fatigue, anorexia and muscle wasting—that are key measures of patient quality of life and predictors of survival. Patients treated with bermekimab were significantly more likely to achieve the primary endpoint compared to placebo (33% vs 17%, respectively); moreover, patients who achieved the primary endpoint had one-fifth as many serious adverse events, were twice as likely to have stable disease (according to RECIST criteria), showed significant and clinically relevant improvement in all life quality measures, and had almost three-fold increase in survival compared to failures.

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 technologyXBiotech 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 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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Source: XBiotech Inc.