XBiotech Enrolls First Patient Under Revised Protocol for U.S. Phase 3 Registration Study Using Xilonix(TM) for Treatment of Metastatic Colorectal Cancer

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Revised Phase 3 Study Now Open to More Patients With Colorectal Cancer

AUSTIN, Texas, April 29, 2015 (GLOBE NEWSWIRE) -- XBiotech (Nasdaq:XBIT), a leading developer of next-generation True Human™ therapeutic antibodies, announced today that it has enrolled the first patient into its revised U.S. Phase 3 study of Xilonix™ in metastatic colorectal cancer patients. Xilonix, XBiotech's monoclonal True Human antibody therapy, is designed to block chronic inflammation associated with malignant tumor growth.

The U.S. Phase 3 study was initially launched in March 2013, and patients were recruited at more than 60 U.S. cancer centers. The Company previously paused the study to propose to the FDA changes in inclusion criteria to allow broader eligibility for cancer patient enrollment. The newly approved protocol enables recruitment of advanced, refractory colorectal cancer patients that includes those who have failed all standard therapies.

Dr. George Fisher, Principal Investigator of the study and Professor of Medicine, Stanford University School of Medicine, said, "Metastatic colorectal cancer is a devastating disease and one of the leading causes of cancer-related deaths in the world. Patients diagnosed with this disease have limited treatment options, thus new therapies are urgently needed. Xilonix is intended to target the inflammatory environment of tumor cells and in so doing, slow the growth and spread of the cancer while improving the symptoms associated with advanced disease. Preliminary results have been encouraging and the absence of serious side effects would be a welcome change from standard chemotherapy agents."

John Simard, President and CEO of XBiotech, commented, "We are very pleased to have begun enrollment in this global Phase 3 study of Xilonix in metastatic colorectal cancer under the revised protocol. This is an important milestone for our Xilonix pipeline as well as our True Human antibody therapy platform."

At the time of the protocol revision, 40 patients had entered the study with approximately equal numbers in each arm. An analysis of the primary and secondary endpoints of the study was conducted, and though statistical significance was unachievable due to the relatively small number of patients (the statistical model was designed for 656 patients), the trends observed were encouraging and suggested continuation of the study.

About XBiotech

At XBiotech we are rethinking the way medicines are discovered and commercialized. From pioneering ways to create safer drugs that harness our natural immunity to disease, to developing simple but cutting edge technology that enables rapid transition to large-scale manufacturing—at XBiotech we are leading innovation in the biotechnology industry.

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