

## **XBioTech Expanded its XCITE Cancer Study into Europe in Cooperation with KCR** *First Patients Screened in Europe to Mark Worldwide Expansion of U.S. FDA Colorectal Cancer Study*

Berlin, 1 September 2015 – XBioTech, the world's leading developer of next-generation True Human™ therapeutic antibodies, announced that it expanded its "XCITE" cancer study into Europe. This milestone was done in cooperation with KCR, Contract Research Organization (CRO) operating in 19 countries in Europe as well as the U.S.

XCITE is an FDA Fast Tracked, Pivotal Phase 3 study of its cancer drug Xilonix™ for treatment of metastatic colorectal cancer. Screening has recently begun at the Maria Skłodowska-Curie Oncology Center in Warsaw, Poland, marking the first patient recruitment site outside the U.S. and the commencement in earnest of the global phase of the FDA study.

Xilonix™ Colorectal cancer Immunotherapy Treatment Evaluation ("XCITE"), is designed to assess improvement in overall survival of patients in response to monotherapy with XBioTech's True Human (TM) monoclonal antibody. The double-blinded, placebo controlled study currently has about 98 sites in the United States and with this launch in Poland, Europe, with the KCR support, will bring on line more than 80 sites across the whole region.

The XCITE trial will continue to expand to include nearly 200 clinical sites across 20 countries worldwide including Australia, Canada and South America. As previously disclosed, XBioTech expects to complete enrollment of this study by the end of 2016.

Dr. Michael Stecher, XBioTech's Medical Director, stated, "Our on-time launch of XCITE into Europe marks an important milestone in our oncology program and signifies we are moving as planned toward completing enrollment by the end of 2016. Since we have been operating another Phase III oncology program in colorectal cancer in Europe, it was important to time the launch of the U.S. FDA study into Europe so as not to compete for patient enrollment. Our clinical operations team has managed to dovetail this important study with impeccable timing to coincide almost precisely with the completion of the European Phase III program. We expect the rapidly escalating engagement we have seen with our European study will now spill over to this new program, which gives us good confidence that we will achieve our enrollment objectives in 2016 as well as report interim survival data around the time of enrollment completion."

Dr. Anna Baran, KCR's Chief Medical Officer, added: "We are very satisfied for going live with another trial which is a part of the Xilonix development program. The first patient screened in Europe is a significant step for study expansion. From a CRO's perspective, this is a great inspiration to commit to further developing this novel therapy, which is already recognized by the global oncology community."

Total enrollment in the XCITE study will consist of 600 patients. The primary objective of the trial is to assess the ability of Xilonix to improve overall survival in patients with metastatic colorectal cancer who have failed standard therapies. The study will also assess progression free survival, tumor response, change in muscle mass and improvements in quality of life. Earlier observations of Xilonix therapy in advanced cancer patients revealed physical recovery that strongly correlated with significant improvements in survival. Based on these results, XBioTech received Fast Track designation from the FDA in October 2012 to develop Xilonix as a treatment in the setting of metastatic colorectal cancer.

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### **About KCR**

KCR is a Contract Research Organization (CRO) operating across 19 countries in Europe as well as the U.S. The company is a strategic solutions provider for pharmaceutical and biotechnology firms who are looking for a reliable alternative to top tier CROs. Over 300 professionals offer full service capabilities in three main product lines: Trial Execution, Functional Service Provision (FSP) and Late Phase, across a wide range of therapeutic areas. Focusing on knowledge, quality and innovation, KCR and its services supports 12 of the Top 20 Global Pharma companies, as well as biotech firms from Europe, Israel and the U.S. on long standing contracts. For more information please visit: [www.kcrcro.com](http://www.kcrcro.com).

**KCR: We see human behind every number.**

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