

XBiotech Enrolls First Patient in Phase III European Registration Study Using Xilonix™ for Treatment of Colorectal Cancer

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AUSTIN, Texas, Aug. 1, 2014 /[PRNewswire](#)/ -- XBiotech has enrolled the first patient into its European Phase III study using its novel cancer drug Xilonix™ for the treatment of colorectal cancer. The double-blinded placebo controlled study is evaluating the use of the monoclonal antibody therapy designed to block chronic inflammation associated with malignant tumor growth. The treatment is reportedly aimed at reversing disease symptoms associated with disease progression and survival. The Company says novel surrogate endpoints used in the study were established through close collaboration with the European Medicines Agency (EMA) scientific advice committee. XBiotech claims that compared with traditional oncology study endpoints, these will enable faster and more informative evaluation of anti-cancer therapy in patients with advance disease. The results of the study, if completed successfully, will reportedly allow for full marketing approval for Xilonix among member states of the European Union.

The study, headed by acclaimed oncologist Dr. Tamas Hickish is being simultaneously launched in a number of western and eastern European states. Dr. Hickish remarked, "The enthusiasm of patients and doctors for this study is very encouraging for the success of this trial and indicates Xilonix indeed targets an un-met medical need." XBiotech is executing the study in collaboration with KCR, a contract research organization headed in Eastern Europe. Dr. Anna Baran, Chief Medical Officer at KCR, stated, "The oncology research community, including multiple investigators in this study, are looking forward to the scientific outcome of XBiotech's clinical trial," and added that "the novel approach targeting IL-1 pathway is extremely interesting for all stakeholders, not only in the advanced colorectal cancer population, but also in other advanced cancer settings."

The Company reports there are numerous patients awaiting enrollment. Gary Gonzales, XBiotech's Vice President of Clinical Operations stated, "It is exciting to enter the enrollment phase of the trial with what appears to be a strong momentum. We hope that this will continue as additional countries are activated."

Xilonix is a first-in-class True Human™ antibody. The therapy works to block a number of processes that tumors use to grow and spread, such as potentially inhibiting the formation of tumor blood supply and new metastasis. Blocking tumor-related inflammation may also inhibit or reverse wasting and other illness associated with the malignancy.

About XBiotech

XBiotech is leading the commercialization of biological therapies—including the discovery and development of True Human™ antibodies. XBiotech is developing therapeutics for the treatment of major unmet medical needs in oncology, dermatology, vascular and infectious diseases. The Company's most advanced clinical program is a breakthrough therapy for cancer. XBiotech has also established the manufacturing technology to reduce infrastructure needs, lessen capital requirements and shorten lead times for biological drugs, ushering in a new era for cost efficiency in the biopharmaceutical industry.

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