XBiotech and European Medicines Agency (EMA) Agree on Phase III Registration Study for Treatment of Colorectal Cancer

January 30, 2014 11:50 AM ET

PR Newswire
AUSTIN, Texas
Jan 30, 2014

AUSTIN, Texas, Jan. 30, 2014 /PRNewswire/ -- XBiotech announced today that its collaboration with the European Medicines Agency (EMA) has resulted in establishment of a regulatory path for Xilonix™ registration in the European Union for the treatment of colorectal cancer. XBiotech AG will soon launch its Phase III registration study in Europe to evaluate Xilonix in patients with treatment-resistant colorectal cancer. Cancer treatment centers in at least 6 countries will be involved in the registration study, which is expected to take 12 months to complete.

The agreement with the EMA was the culmination of extensive discussion around the scientific and clinical assessment of Xilonix therapy. XBiotech has sought to establish a novel approach to evaluate treatment responses and efficacy of Xilonix in patients with advanced cancer. The Company is reportedly using a new, less harmful form of radiographic measure to assess patient responses. Using this novel method will also enable evaluation of Xilonix therapy in a short time frame, making the clinical study time and cost efficient.

XBiotech's CEO John Simard said, "Establishing a registration path in Europe based on this innovative study design is an important milestone both for XBiotech and for the development of new therapies for treating advanced cancer. We are grateful for the efforts and input from the EMA to help XBiotech lead innovation for this area of oncology. From all points considered, this study represents a significant advance in the way we evaluate and ultimately treat cancer."

Xilonix works to block a number of processes that tumors use to grow and spread. The pleiotropic activity of the drug is unique in that Xilonix inhibits the formation of tumor blood supply, relieves tumor-mediated suppression of natural immune responses, prevents the spread of tumor cells and reduces the negative metabolic effects of metastatic disease.

Dr. Charles Dinarello, who first described Xilonix's target, Interleukin-1 alpha in 1974, and a world-renowned expert on tumor related inflammation, stated, "We have known of the harmful role of Interleukin-1 alpha on inflammation-driven tumor growth and tumor spread in mice for several years but with the introduction of Xilonix, we now see the benefit of suppressing Interleukin-1 alpha in patients without the side-effects of traditional chemotherapy. Because of the lack of serious side-effects with Xilonix, the drug can be given repeatedly to combat colorectal cancer."

ABOUT XBIOTECH
XBiotech is leading the commercialization of biological therapies—including the discovery and development of True Human™ antibodies. The Company's lead product candidate—in Phase III clinical studies—represents a novel, breakthrough treatment for advanced colorectal cancer. XBiotech has also developed manufacturing technology to reduce infrastructure needs, lessen capital requirements and reduce lead times for biological drugs, ushering in a new era for cost and development efficiency in the biopharmaceutical industry.

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