XBiotech Reports Positive Phase II Interim Analysis Results in Vascular Disease

First Report of MAB Use in Restenosis and Fourth Clinical Indication to Demonstrate Therapeutic Benefit of IL-1a True Human™ Monoclonal Antibody (MABp1)

AUSTIN, Texas, Nov. 20, 2012 /PRNewswire/ -- XBiotech, a privately held biotechnology company, announced positive interim analysis results today from a Phase II study in patients receiving MABp1 to reduce restenosis after percutaneous revascularization of the Superficial Femoral Artery (SFA). Patients receiving MABp1 demonstrated a 58 percent reduction in Major Adverse Cardiovascular Events (MACE) and 60 percent longer patency in treated vessels compared to control patients. This is the first report of MAB therapy in restensois and fourth clinical indication where the Company's lead candidate, MABp1, has demonstrated strong safety and effectiveness. Positive results in cachexia, psoriasis, and type 2 diabetes have also recently been reported by XBiotech.
(Logo: http://photos.prnewswire.com/prnh/20121017/MM95359LOGO)

The Phase II clinical study is a randomized, open-label multi-center trial involving some of the most prestigious cardiac hospitals in the country. The study is being lead by Hosam El-Sayed, M.D., Ph.D., R.V.T, Assistant Professor of Cardiovascular Surgery, Weill Cornell Medical College, Methodist DeBakey Heart and Vascular Center, The Methodist Hospital, Houston, Texas. Dr. El-Sayed's career includes positions as Assistant Professor of Surgery in the Vascular Surgery Division of Baylor College of Medicine and the Michael E. DeBakey VA Medical Center, Assistant Professor of Surgery at the University of Cincinnati, and Vascular Surgery Chief at the Cincinnati VA Medical Center.

Patients enrolled in the study had claudication or calf pain at rest and hemodynamically significant occlusion of the SFA, with average lesion lengths of 15 cm. The primary efficacy endpoint, measured by vessel patency, evaluates the ability of MABp1 to reduce restenosis by blocking vascular inflammation after revascularization using balloon angioplasty, atherectomy or stent placement. The incidence of MACE was the secondary endpoint based on the high incidence of cardiovascular-related morbidity and mortality in patients requiring revascularization of the femoro-politeal artery.
At the time of the interim analysis, 42 patients had enrolled in the study—including 21 patients in the control arm receiving standard of care (SOC) and 21 patients in the treatment arm receiving SOC and MABp1. Patients were treated with MABp1 and evaluated for 12 months. Adverse events reported in both groups appeared to be related to underlying disease, and no obvious side effects from MABp1 treatment were observed.

"The challenge we face in endovascular surgery today is keeping vessels open after being treated by endovascular interventions," said lead investigator Hosam El-Sayed MD, Ph.D., RVT, Assistant Professor of Cardiovascular Surgery, Weill Cornell Medical College, Methodist DeBakey Heart and Vascular Center, The Methodist Hospital, Houston, Texas. "While the emerging technology drug–eluting stents and balloons have helped to address the high rate of restenosis, they are limited to local delivery of drugs within the vessel. As a systemic drug, MABp1 is capable of addressing both restenosis within the vessel, as well as the underlying cardiovascular and cerebrovascular complications associated with vascular disease. This represents an entirely new treatment approach and a paradigm shift in current thinking. Based on the encouraging interim results, incorporating this simple and safe monoclonal antibody therapy into current treatment practices has the potential to provide significant benefit to patients and a new option for endovascular surgeons."

"Vascular inflammation is the cause of vascular diseases such as atherosclerosis," said Michael Stecher, M.D., Medical Director, XBiotech. "Our MABp1 therapy blocks a key mediator of vascular inflammation. Patients with advanced arterial disease treated with MABp1 after revascularization have shown reduced arterial occlusion and reduced overall complications from the disease. Based on the interim results, we believe MABp1 may ultimately provide a treatment for millions of patients suffering with vascular disease."

About *True Human*™ Antibodies

True Human*™** antibodies represent the next generation of therapeutic antibodies. These antibodies are identified using the Company's proprietary platform technology to ensure faithful reproduction of the original human antibody gene. ***True Human antibodies are "invisible" to the body's immune system and thus have the potential for better safety, efficacy and patient tolerability compared to earlier generation antibody therapeutics.

About XBiotech

XBiotech is pioneering breakthrough therapies that improve the safety and efficacy of antibody therapeutics. The Company's lead product candidate inhibits chronic sterile inflammation by targeting IL-1a, a master regulator of inflammation. The clinical development program addresses tremendous unmet medical need in multiple disease indications including, acne, psoriasis, cachexia, cancer, type 2 diabetes and cardiovascular disease. XBiotech is also revolutionizing scalable, flexible manufacturing systems for the production of biological therapies. Using minimal infrastructure and disposable bioreactor technology – to dramatically reduce capital requirements, operating complexity, and lead times - the Company has established a compelling commercialization path for its ***True Human*™** antibody platform. For more information on how XBiotech is advancing human monoclonal antibody therapy please visit www.xbiotech.com.

Contact:
Investors:
John Simard

XBiotech
info@xbiotech.com
512.386.2930
Media:
Aaron DeLucia
Porter Novelli
aaron.delucia@porternovelli.com
512.241.2249
SOURCE XBiotech