

# **XBiotech Reports Positive Phase II Interim Analysis Results From Type 2 Diabetes Study**

## **Interim Results of IL-1a True Human™ Monoclonal Antibody Demonstrate More Rapid Achievement of Glycemic Control Compared to Most Recent FDA Approved Therapy**

AUSTIN, Texas, Oct. 29, 2012 /PRNewswire/ -- XBiotech, a privately held biotechnology company, announced positive interim analysis results today from a Phase II study using a *True Human* monoclonal antibody (MABp1) in patients with type 2 diabetes. Results from this study continue to reinforce the role of IL-1a as a master regulator of chronic inflammation in multiple disease states, and the therapeutic benefits of neutralizing antibodies produced from the XBiotech platform. The Company recently announced [FDA Fast Track Designation](#) for development of cancer associated cachexia therapy, as well as positive results from a Phase II study in [psoriasis](#), using MABp1.

(Logo: <http://photos.prnewswire.com/prnh/20121017/MM95359LOGO>)

According to the Centers for Disease Control (CDC), 18.8 million people have been diagnosed with diabetes. Type 2 diabetes accounts for about 95 percent of diagnosed diabetes patients. Per the CDC, up to 74 percent of those with Type 2 diabetes are pre-insulin dependent. These patients still have a functioning pancreas and are among the approximately 13 million patients who could potentially benefit from treatment with MABp1.

The Phase II clinical study is designed to assess safety and pharmacokinetics of MABp1 in the diabetic patient population. Patients enrolled in the study met the American Diabetes Association (ADA) diagnostic criteria for type 2 diabetes, and were diagnosed >3 months prior to screening. The primary efficacy endpoint of glycemic control, as measured by glycated hemoglobin (HbA1c) levels, evaluates the ability of MABp1 to improve control of blood sugar levels by blocking inflammation in the pancreas.

Interim results from the Phase II MABp1 trial demonstrate patients entering the study with average HbA1c levels of 7.4% achieved a 0.2% decrease in HbA1c level by week 8, a significantly more rapid response than the most recent FDA approved treatment for type 2 diabetes, linagliptin (Tradjenta®). When used as a monotherapy in patients with entry HbA1c levels of = 7.5%, linagliptin did not demonstrate the same 0.2% decrease in HbA1c until week 24.

"This is the first human study directly targeting IL-1a in patients with type 2 diabetes. These preliminary results support the idea that it may be a novel way to improve this disease," said Marc Donath M.D., Head of Endocrinology, Diabetes and Metabolism at University Hospital of Basel, Professor of Endocrinology University of Basel. "It is now

well established that inflammation plays a role in type 2 diabetes and associated cardiovascular disease."

"We are very encouraged by the interim results of this trial and pleased to see the continued benefits that MABp1 is providing to patients across a variety of indications," said Michael Stecher, M.D., Medical Director, XBiotech. "The clinical data we are generating indicate MABp1 is a powerful agent to block chronic inflammation. Given our positive treatment results in both diabetes and psoriasis, we suspect that a common inflammatory process is indeed involved in the progression of these diseases. The ability of MABp1 to selectively block disease-causing inflammation may provide a new approach to treatment for some of the most significant diseases affecting the global population."

### **About *True Human*<sup>TM</sup> Antibodies**

*True Human*<sup>TM</sup> 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*<sup>TM</sup> antibody platform. For more information on how XBiotech is advancing human monoclonal antibody therapy please visit [www.xbiotech.com](http://www.xbiotech.com).

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