



XBiotech Meets Primary Endpoint in Phase 2 Study of MABp1 for Treatment of Hidradenitis Suppurativa (HS)

February 16, 2017

Results Demonstrate Efficacy of MABp1 as a Treatment for HS

AUSTIN, Texas, Feb. 16, 2017 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBITE), developer of next-generation True Human™ therapeutic antibodies, today announced topline results from an investigator sponsored randomized Phase 2 study evaluating XBiotech's True Human antibody, MABp1, as a treatment for Hidradenitis Suppurativa (HS), a serious and debilitating chronic inflammatory skin disorder. The study met its primary endpoint, demonstrating significant improvement of HS patients compared to control after 12 weeks of therapy (Response rate of 60% vs 10%, respectively (p=0.035)).

A 20 patient double-blind, placebo-controlled study was designed to evaluate the safety and efficacy of MABp1, the Company's True Human antibody targeting interleukin-1 alpha (IL-1 α), in patients with HS not eligible for anti-TNF therapy. Patients were randomized 1:1 to receive either MABp1 or placebo every 2 weeks for 12 weeks. Patients in the study underwent primary assessment of efficacy using Hidradenitis Suppurativa Clinical Response (HiSCR) scores at 12 weeks, continued by a follow up phase to assess time to relapse after an additional 12 weeks without therapy. Efficacy measures include assessment of HiSCR scores, a validated method for evaluating efficacy in HS patients, as well as quality of life assessment and ultrasonographic evaluation.

"The overall response rate observed in the data is, in my opinion, groundbreaking for the treatment of HS," Dr. Giamarellos-Bourboulis commented, "I am truly encouraged by these results and very much look forward to the future use of MABp1 as a treatment for this devastating condition." Prof. Giamarellos-Bourboulis is supervising the Outpatients Department for HS of the 4th Department of Medicine of ATTIKON University Hospital in Greece where the study was conducted. This center is a well-recognized European reference center for HS with more than 20 peer-reviewed publications in the field, conduct of four randomized trials with biological therapies and active participation in the PIONEER studies providing registration of adalimumab for HS.

About Hidradenitis Suppurativa

Hidradenitis Suppurativa (HS) is a chronic, inflammatory skin disorder affecting areas rich in apocrine glands. Nodules appear in the affected areas and progressively become swollen with spontaneous rupture and release of pus. This process occurs repeatedly leading to formation of deep sinus tracts and painful dermal abscesses ^{1,2}. Therefore, HS is often devastating for patients with significant impact on quality of life ³. The Dermatology Quality Life Index (DQLI) for HS is 8.9, being higher than any other skin disorder ⁴. Traditional treatments comprise of antibiotics, antiandrogens and surgery. The global prevalence for HS is estimated at up to 4% of the population ².

About True Human™ Therapeutic Antibodies

Unlike previous generations of antibody therapies, XBiotech's True Human™ antibodies are derived without modification from individuals who possess natural immunity to certain diseases. With discovery and clinical programs across multiple disease areas, XBiotech's True Human antibodies have the potential to harness the body's natural immunity to fight disease with increased safety, efficacy and tolerability.

About XBiotech

XBiotech is a fully integrated global biosciences company dedicated to pioneering the discovery, development and commercialization of therapeutic antibodies based on its True Human™ proprietary technology. XBiotech currently is advancing a robust pipeline of antibody therapies to redefine the standards of care in oncology, inflammatory conditions and infectious diseases. Headquartered in Austin, Texas, XBiotech also is leading the development of innovative biotech manufacturing technologies designed to more rapidly, cost-effectively and flexibly produce new therapies urgently needed by patients worldwide. For more information, visit www.xbiotech.com.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements, including declarations regarding management's beliefs and expectations that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "would," "could," "expects," "plans," "contemplate," "anticipates," "believes," "estimates," "predicts," "projects," "intend" or "continue" or the negative of such terms or other comparable terminology, although not all forward-looking statements contain these identifying words. Forward-looking statements are subject to inherent risks and uncertainties in predicting future results and conditions that could cause the actual results to differ materially from those projected in these forward-looking statements. These risks and uncertainties are subject to the disclosures set forth in the "Risk Factors" section of certain of our SEC filings. Forward-looking statements are not guarantees of future performance, and our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate, may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

¹ Revuz J. [Hidradenitis suppurativa](#). *J Eur Acad Dermatol Venereol* 2009; 23: 985-998.

² Alikhan A, Lynch PJ, Eisen DB. Hidradenitis suppurativa: a comprehensive review. [J Am Acad Dermatol](#). 2009 Apr;60(4):539-61; quiz 562-3. doi: 10.1016/j.jaad.2008.11.911.

³ Vasquez BG, Alikhan A, Weaver, AL, et al. Incidence of hidradenitis suppurativa and associated factors: a population-based study of Olmsted County, Minnesota. [J Invest Dermatol](#). 2013 Jan;133(1):97-103. doi: 10.1038/jid.2012.255. Epub 2012 Aug 30.

⁴ Révuz JE, Canoui-Poitaine F, Wolkenstein P, et al. Prevalence and factors associated with hidradenitis suppurativa: results from two case-control studies. *J Am Acad Dermatol* 2008; 59: 695-701.

Contact

Ashley Otero

aotero@xbiotech.com

512-386-2930



XBiotech, Inc