

XBiotech Announces Publication of Phase 2 Data from Hidradenitis Suppurativa Phase 2 Study in The Journal of Investigative Dermatology

December 4, 2017

Report Highlights Efficacy of anti-IL-1 alpha Antibody Therapy in the Treatment of the Debilitating Skin Disease, Hidradenitis Suppurativa

AUSTIN, Texas, Dec. 04, 2017 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT) announced today the publication of data from its randomized phase 2 study evaluating XBiotech's True HumanTM antibody, MABp1, as a treatment for Hidradenitis Suppurativa (HS). The results have been published online as an article in press in the prestigious, peer-reviewed *Journal of Investigative Dermatology* in a manuscript titled, "MABp1 Targeting Interleukin-1alpha for Moderate to Severe Hidradenitis Suppurativa not Fligible for Adalimumab: A Randomized Study." The article is planned to be featured in an upcoming print issue of the journal.

"This study features not only the clinical efficacy of MABp1 but also demonstrates its mechanism of action, which is something that is truly unique for a candidate drug treatment for HS," commented Prof. Evangelos Giamarellos-Bourboulis, M.D., Ph.D., who supervises the Outpatients Department for HS of the 4th Department of Medicine at Attikon University Hospital in Greece where the featured study was conducted and also served as the Principal Investigator of the study. He further stated, "MABp1 represents a potential breakthrough in the treatment of HS as it could cover an overtly unmet need for patients either failing or not eligible for adalimumab, the only registered biological treatment of HS to date. Data acquired by this study shed light to the promising efficacy of MABp1 even for naïve patients."

The publication highlights the efficacy of MABp1, in which the study's primary endpoint was met in 60% of MABp1 treated patients compared to 10% of placebo patients (odds ratio 13.50, 95% confidence intervals 1.19-152.51; p=0.035). The clinical efficacy of MABp1 was maintained until week 24 (12 weeks after discontinuation of treatment) at which time point, no patients treated with placebo had a positive HiSCR score (0%) compared to four out of 10 patients (40%) treated with MABp1. Treatment with MABp1 was also accompanied by better patient-reported outcomes. Decrease of the visual analogue scale (VAS) was found in 30% of placebo patients compared with 70% of patients treated with MABp1.

About the Study

The 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-1α), 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.

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

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 technologyXBiotech 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.

Contact

Ashley Otero aotero@xbiotech.com 512-386-2930

⁴ Révuz JE, Canoui-Poitrine 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.



XBiotech Inc.

¹ Revuz J. <u>Hidradenitis suppurativa.</u> J Eur Acad Dermatol Venereol 2009; 23: 985-998.

² Alikhan A, Lynch PJ, Eisen DB. Hidradenitis suppurativa: a comprehensive review. <u>J Am Acad Dermatol.</u> 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. <u>J Invest Dermatol.</u> 2013 Jan;133(1):97-103. doi: 10.1038/jid.2012.255. Epub 2012 Aug 30.