



XBiotech Announces Presentation of Phase 2 Open Label Extension Study Data Evaluating MABp1 for the Treatment of Hidradenitis Suppurativa

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Open Label Extension Results, which Demonstrate Significant Improvements in HS Patients Previously Treated with Placebo, will be Presented at the 7th Conference of the European Hidradenitis Suppurativa Foundation (EHSF)

AUSTIN, Texas, Jan. 19, 2018 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT) announced today that results from an open label extension (OLE) phase of the randomized Phase 2 study evaluating XBiotech's True Human™ antibody, MABp1, as a treatment for Hidradenitis Suppurativa (HS), will be presented at the European Hidradenitis Suppurativa Foundation (EHSF) Conference occurring in Rotterdam Netherlands February 7-9th. The oral presentation titled, "*An open-label extension study of MABp1 targeting interleukin-1alpha for hidradenitis suppurativa (HS)*" will be given by Theodora Kanni, M.D., Ph.D., Attikon University Hospital in Athens Greece, on 8 February 2018 between 1:50 and 2:50pm local time.

The findings being presented come from patients that had received placebo in a previous Phase 2 double-blind, placebo-controlled study. Patients that had originally been allocated to placebo in the Phase 2 study were allowed to receive treatment with the MABp1 antibody therapy in a so called open label extension (OLE) study. Seven of 10 patients that had originally received placebo were treated with MABp1 for 12 weeks. Main endpoints used in the OLE included safety and HiSCR score at the end of the 12 week treatment. At the conclusion of the double-blinded study, only one patient (1 of 10, or 10%) receiving placebo had achieved HiSCR. During the OLE, five patients (5 of 7, or 71.4%) achieved the HiSCR response ($p=0.035$). There was a total of 24 HS exacerbations during the blinded portion of the study compared to just 1 exacerbation during the OLE phase.

Prof. Evangelos Giamarellos-Bourboulis, M.D., Ph.D., who supervises the Outpatients Department for HS of the 4th Department of Internal Medicine at Attikon University Hospital in Athens, Greece where the study was conducted and also served as the Principal Investigator of the study, commented, "Results of the OLE crossover study provide further compelling evidence of the activity for MABp1 in HS. We will work diligently to expand this work and avail this treatment to patients in need."

Results of the Phase 2 study were recently published in the [Journal of Investigative Dermatology](#), reporting that the study met its primary endpoint and demonstrated a significant improvement in HS patients treated with MABp1 compared to control after 12 weeks of therapy (Response rate of 60% vs 10%, respectively ($p=0.035$)). 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-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 included 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 life³. The Dermatology Life Quality Index (DLQI) for HS is 8.9, being higher than any other skin disorder⁴. Traditional treatments comprise of antibiotics, antiandrogens and surgery. Prevalence rates for HS have been estimated at up to 4%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.

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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-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.