XBiotech Announces Presentation of Data from Phase 2 Study Evaluating MABp1 for the Treatment of Hidradenitis Suppurativa

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Data Presented at the 7th Conference of the European Hidradenitis Suppurativa Foundation (EHSF) Provide Results that Corroborate HiSCR findings with iHS4 Scoring as a Measure of Efficacy

AUSTIN, Texas, Jan. 26, 2018 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT) announced today additional data analysis of its Phase 2 study evaluating XBiotech's True Human™ antibody, MABp1, as a treatment for Hidradenitis Suppurativa (HS). The study achieved its primary endpoint, showing significant treatment benefit using the HiSCR endpoint, which is the method used in the development of the only therapy currently approved for the treatment of HS. However, other methods of evaluating disease severity and response to treatment have been proposed. The iHS4 scoring system has recently been proposed as a new measure of HS disease severity [1] but its usefulness as a clinical measure has not been extensively studied. Investigators used data from the Phase 2 study to evaluate the iHS4 scoring method to see how it correlates with the HiSCR findings.

These findings will be presented at the European Hidradenitis Suppurativa Foundation (EHSF) Conference occurring in Rotterdam Netherlands February 7-9th. The poster presentation titled, "*Validation of the iHS4 Score as an Outcome Measure for Hidradenitis Suppurativa (HS): Application in Treatment with MABp1 Targeting Interleukin-1alpha*" will be featured beginning at 10:00 am, on the 8th of February, 2018.

The data presented are thus a retrospective analysis using the iHS4 score for all 20 patients who were randomized to receive either placebo or MABp1 therapy in the Phase 2 double-blind study. At least 30% decrease of the iHS4 score from the baseline at week 12 was associated with 100% sensitivity for positive HiSCR score (the efficacy measure used in the phase 2 study). This change was found in one (10%) and in four (40%) patients allocated to placebo and MABp1, respectively (p= 0.046).

Theodora Kanni, M.D., Ph.D., Attikon University Hospital in Athens, Greece where the study was conducted, commented, "We find these results intriguing as we believe the consistent trend of the iHS4 and HiSCR scores for the Phase 2 data demonstrate its accuracy in measuring outcomes in HS patients. We look forward to future use of this scoring as an additional measure of efficacy in the clinic." Prof. Evangelos J. Giamarellos-Bourboulis, M.D., Ph.D., who was the Principal Investigator and Co-coordinator for the study, also added, "The decrease of the iHS4 score among patients treated with MABp1 is a further proof of its efficacy in HS."

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-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 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 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 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.

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[1] Zouboulis CC, et al. *Br J Dermatol* 2017; 177: 1401.

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