XBiotech Announces First Patient Enrolled in Randomized Multi-Center Clinical Study Evaluating Bermekimab Therapy in Patients with Hidradenitis Suppurativa

Oct 23, 2019

AUSTIN, Texas, Oct. 23, 2019 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ: XBIT) announced today that the first patient was enrolled in its randomized, double-blind, placebo-controlled Phase 2 clinical study evaluating bermekimab in patients with moderate to severe Hidradenitis Suppurativa (HS). The multi-center, international study will enroll approximately 150 patients into three arms: two bermekimab dosing regimens versus a placebo arm over sixteen (16) weeks of therapy. The study is chaired by renowned investigative dermatologist Alice Gottlieb, MD, PhD, Medical Director of dermatology at the Mount Sinai Beth Israel Campus and Clinical Professor at the Icahn School of Medicine at Mount Sinai.

The study's primary endpoint is the percentage of subjects achieving Hidradenitis Suppurativa Clinical Response (HiSCR) at week 12. Multiple secondary efficacy endpoints will be assessed after 12 and 16 weeks of therapy, including: Numerical Rating Scale (NRS) for pain and itch; Modified Sartorius Score; Dermatology Life Quality Index (DLQI); Hospital Anxiety and Depression Scale (HADS); and Patient Global Impression of Change and Severity (PGI-c, PGI-s). Please visit www.clinicaltrials.gov for a more complete description of the study.

Dr. Gottlieb commented, "With bermekimab we now have a potential new tool in the toolbox to treat diseases like hidradenitis suppurativa. Targeting IL-1α represents a new class of medication. I am pleased that we are underway with a large randomized study that we can expect will provide definitive findings for this novel therapy."

John Simard, XBiotech CEO, stated, "HS is a cornerstone for our bermekimab dermatology franchise. We are excited to launch this large randomized study. We expect this study will corroborate the promising safety and efficacy results seen in our previous clinical trials of bermekimab to treat HS, including rapid and dramatic reduction of pain. Our True Human antibody platform harnesses the human body's natural antibody response to disease, and we hope that in the case of HS, bermekimab will offer an effective, safe relief to people with this difficult condition."

Bermekimab has demonstrated its safety and efficacy treating HS in two previous clinical studies. A recent open label study demonstrated that weekly bermekimab is an effective therapy, as measured by improvement in disease according to HiSCR, the key measure of disease in HS. In the study, 61% of patients with no prior biological therapy achieved positive HiSCR at 12 weeks[1], and 63% of patients who had failed previous biological therapy (i.e. adalimumab) achieved a positive HiSCR at 12 weeks. Another unrivaled finding in the study was a significant treatment-related reduction of pain in HS patients. Reducing pain is widely recognized among experts as a key objective for HS treatment, but this symptom has been largely unaddressed by available drugs. Pain was assessed with a patient questionnaire using a numerical rating scale from 0 to 10. A 30% and ≥1-unit reduction in pain score is considered a clinically important relief from pain, and no approved monotherapy for HS has elicited a clinically significant effect on pain[2]. Remarkably**,** a substantial majority of patients treated with weekly bermekimab achieved this endpoint: **67%** and **72%** at week 12 who had prior or no prior anti-TNF therapy, respectively.

An earlier double-blind, placebo controlled, randomized study also evaluated bermekimab in the treatment of HS. The study met its primary endpoint, demonstrating significant improvement of HiSCR in patients treated with bermekimab compared to control after 12 weeks of therapy (response rate of 60% vs 10%, respectively (p=0.035))[3]. These results have been published in the *Journal of Investigative Dermatology*

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[4,5]. Therefore, HS is often devastating for patients with significant impact on quality of life[6]. The Dermatology Life Quality Index (DLQI) for HS is 8.9, being higher than any other skin disorder[7]. Traditional treatments comprise of antibiotics, antiandrogens and surgery. The global prevalence for HS is

estimated at up to 4% of the population[5].

About XBiotech
XBiotech is a fully integrated, global biopharmaceutical company dedicated to pioneering the discovery, development and commercialization of therapeutic antibodies. XBiotech currently is advancing a pipeline of therapies based on harnessing naturally occurring antibodies from patients with immunity to certain diseases. The approach to use natural human immunity as a source of new medicines offers the potential to redefine the standards of care a wide range of diseases. Headquartered in Austin, Texas, XBiotech also is leading the development of innovative manufacturing technology to reduce the cost and complexity of biological drug production. For more information, visit www.xbiotech.com.

About True Human™ Therapeutic Antibodies
XBiotech's True Human™ antibodies are the only available antibodies derived without modification from humans who possess natural immunity to certain diseases. (Unlike all commercially available antibodies, which are called "Humanized" or "Fully Human", XBiotech's True Human™ antibodies are directly sourced from the natural human immune response for specific diseases without modification, and thereby have not been shown to cause immunogenicity.) 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.

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

---

[1] HiSCR response rates at week 12 were 42% and 59% in the so called PIONEER I and PIONEER II Phase III studies with the FDA-approved drug adalimumab, respectively. Only 28% and 46% of patients achieved clinically relevant pain reduction (as defined above) in the PIONEER I and PIONEER II studies, respectively. In the PIONEER II study, patients received adalimumab as a combination therapy with antibiotics. Pain reduction results were not significant (compared to placebo) in PIONEER I.

[2] Only 34 of 122 (28%) of patients treated weekly with adalimumab achieved this endpoint at week 12 in the PIONEER I monotherapy study.

[3] Kanni T et al. MABp1 Targeting Interleukin-1Alpha for Moderate to Severe Hidradenitis Suppurativa not Eligible for Adalimumab: A Randomized Study. J Invest Dermatol. 2017 Nov 9.

[4] Revuz J. *Hidradenitis suppurativa.* *J Eur Acad Dermatol Venereol* 2009; 23: 985-998.

[5] 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.

[6] 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.

[7] 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.

Source: XBiotech Inc.