



## **XBiotech Announces First Patient in Phase 2 Study Evaluating Subcutaneous MABp1 in Patients with Hidradenitis Suppurativa**

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AUSTIN, Texas, July 10, 2018 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBITE) announced today that the first patient has been enrolled in its Phase 2 open label, dose escalation clinical study evaluating the Company's subcutaneous formulation of MABp1 in patients with moderate to severe Hidradenitis Suppurativa (HS). The patient began treatment at Tennessee Clinical Research Center located in Nashville under the care of Dr. Michael Gold.

Dr. Gold commented, "We are very excited to be participating with XBiotech in this ground breaking research endeavor for patients suffering from hidradenitis suppurativa. We are hopeful that this research will unlock some of the important keys to successfully treating our patients."

XBiotech is developing a human-derived antibody (MABp1) which neutralizes IL-1 alpha (IL-1 $\alpha$ ), an inflammatory cytokine that plays a key role in the pathophysiology of a wide range of inflammatory skin disorders<sup>1</sup>. Three phase II studies sponsored by XBiotech have been completed in dermatologic indications (acne, psoriasis, pyoderma gangrenosum)<sup>2,3</sup>. Results from an investigator sponsored phase 2 study evaluating MABp1 for the treatment of Hidradenitis Suppurativa were published in the [Journal of Investigative Dermatology](#) with the study meeting its primary endpoint, demonstrating significant improvement of HS patients treated with MABp1 compared to control after 12 weeks of therapy (response rate of 60% vs 10%, respectively (p=0.035))<sup>4</sup>. This previous HS study, however, involved intravenous infusion of the antibody therapy. This will be the first use of the MABp1 subcutaneous formulation in HS, including the use of pre-filled syringes with a newly developed concentrated formulation of MABp1 for convenient dosing.

For more information on this study, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

### **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<sup>5,6</sup>. Therefore, HS is often devastating for patients with significant impact on quality of life<sup>7</sup>. The Dermatology Quality Life Index (DQLI) for HS is 8.9, being higher than any other skin disorder<sup>8</sup>. Traditional treatments comprise of antibiotics, antiandrogens and surgery. The global prevalence for HS is estimated at up to 4% of the population<sup>2</sup>.

### **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](http://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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<sup>1</sup> Bou-Dargham MJ et al. The Role of Interleukin-1 in Inflammatory and Malignant Human Skin Diseases and the Rationale for Targeting Interleukin-1 Alpha. *Med Res Rev*. 2017 Jan;37(1):180-216.

<sup>2</sup> Coleman KM et al. Open-Label Trial of MABp1, a True Human Monoclonal Antibody Targeting Interleukin 1 $\alpha$ , for the Treatment of Psoriasis. [JAMA Dermatol](#). 2015 May;151(5):555-6.

<sup>3</sup> Carrasco D et al. An Open Label, Phase 2 Study of MABp1 Monotherapy for the Treatment of Acne Vulgaris and Psychiatric Comorbidity. [J Drugs Dermatol](#). 2015 Jun;14(6):560-4.

- <sup>4</sup> 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.
- <sup>5</sup> Revuz J. [Hidradenitis suppurativa](#). *J Eur Acad Dermatol Venereol* 2009; 23: 985-998.
- <sup>6</sup> 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.
- <sup>7</sup> 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.
- <sup>8</sup> 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.



XBiotech Inc.