



## **XBiotech Announces First Patient in Phase 2 Study Evaluating MABp1 in Patients with Atopic Dermatitis**

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### **First Patient Begins Therapy with MABp1 for Treatment of Atopic Dermatitis**

AUSTIN, Texas, May 22, 2018 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT) announced today that the first patient has been enrolled in its Phase 2 open label, dose escalation clinical study evaluating MABp1 in patients with moderate to severe Atopic Dermatitis (AD). The patient began treatment at Florida Academic Dermatology Center under the care of the Study's Chair, Dr. Francisco Kerdel.

Dr. Kerdel commented, "Atopic dermatitis is a chronic inflammatory disease characterized by dry and scaly skin and severe, unrelenting itching. An inflammatory substance released by keratinocytes known as IL-1 $\alpha$ , is believed to be a key trigger of inflammation in the disease. By neutralizing the activity of IL-1 $\alpha$ , the new agent we are testing may arrest the disease process and offer relief from the debilitating symptoms. Today we treated a patient and I can report that within one hour of treatment, there was an unequivocal reduction in erythema [redness of the skin] and the patient reported an almost immediate reduction in associated pruritus [itching]. This is an extremely intriguing start for this promising therapy."

John Simard, the Company's President and CEO, added, "Interleukin-1  $\alpha$  is emerging as a key therapeutic target in inflammatory skin diseases. We are extremely excited about the potential of our antibody to represent a breakthrough treatment for atopic dermatitis."

XBiotech is developing a human-derived antibody 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 disorder<sup>1</sup>. Three phase II studies sponsored by XBiotech have been completed in dermatologic indications (acne, psoriasis, pyoderma gangrenosum) as well as one investigator sponsored study in Hidradenitis Suppurativa. In these studies, MABp1 was well tolerated and showed good therapeutic responses<sup>2,3,4</sup>.

#### **About the Study**

The phase 2, open label, dose escalation, multicenter study will consist of two dose cohorts of MABp1 in patients with moderate to severe AD. Dose ranging in the present study will include evaluation of the Company's new highly-concentrated subcutaneous formulation. Ten patients will receive a total of 4 weekly 200mg subcutaneous injections of MABp1. Following a safety assessment for patients in the first dose cohort, ten patients will receive 4 weekly 400mg subcutaneous injections of MABp1. Patients will be followed for 6 weeks to allow for assessment of safety and preliminary efficacy. Various efficacy measures will be assessed including changes in Eczema Area and Severity Index Score (EASI), Dermatology Life Quality Index (DLQI), Patient Oriented Eczema Measure (POEM), and SCORing Atopic Dermatitis (SCORAD), a measure of disease severity in AD.

#### **About Atopic Dermatitis**

Atopic dermatitis (AD) is an inflammatory skin disease affecting as much as 20% of the population in western industrial societies. Chronic eczema in AD and associated pruritus can be a significant cause of morbidity and impact life quality. Disease pathogenesis is complex but ultimately converges on a pathological inflammatory process that disrupts the protective barrier function of the skin. Keratinocytes are a major reservoir of IL-1 $\alpha$  and may be a key source of inflammatory stimulus in AD. IL-1 $\alpha$  is present on leukocytes, where its role in leukocyte trafficking and infiltration may represent a key step in the chronic inflammation of AD. IL-1 $\alpha$  is a key inducer of matrix metalloproteinases activity which could be directly involved in the epithelial barrier breakdown in AD<sup>5</sup>. Loss of regulation of IL-1 results in systemic inflammation with extensive skin involvement<sup>6</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>2</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>3</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>4</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>5</sup> Han et al. Interleukin-1alpha-induced proteolytic activation of metalloproteinase-9 by human skin. *Surgery.* 2005 Nov;138(5):932-9.

<sup>6</sup> Askentijevich et al. An autoinflammatory disease with deficiency of the interleukin-1-receptor antagonist. *N Engl J Med.* 2009 Jun 4;360(23):2426-37.



Source: XBiotech Inc.