XBiotech Announces First Patient Enrolled in Placebo-Controlled Clinical Study Evaluating Its anti-IL-1α Therapy Bermekimab in Patients with Atopic Dermatitis (Eczema)

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AUSTIN, Texas, Nov. 12, 2019 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ: XBIT) has enrolled the first patient in a randomized, double-blind, placebo-controlled Phase 2 clinical study to evaluate its IL-1a blocking antibody therapy in patients with moderate to severe Atopic Dermatitis (AD) (also known as Eczema). Chaired by award-winning dermatologist Seth B. Forman, MD, of ForCare Medical Group in Tampa, FL, the study will assess weekly bermekimab therapy to reduce inflammatory skin lesions, itch, and pain in patients suffering from eczema.

The study will compare three groups of patients over 16 weeks of treatment: a weekly dosing group, a biweekly dosing group, and a placebo group. Percentage of patients who achieve a 75% reduction in skin disease after 16 weeks of treatment will be the primary measure of response. The Eczema Area Severity Index (EASI) scoring system will be used to assess severity of inflammatory skin lesions. Another crucial assessment will be patient itch, which is often severe and unrelenting in this disease. A numeric rating scale (NRS) will be used to assess itch and pain at various timepoints ranging from 4-16 weeks. For more information on this study please visit www.clinicaltrials.gov.

Dr. Forman commented, “We are now understanding that IL-1alpha (IL-1 α) plays a primary role in inflammatory skin diseases. Earlier Phase 2 results using the IL-1α blocker, bermekimab, showed unprecedented treatment effects such as reduction of inflammatory lesions, itch, and pain in patients with eczema. I look forward to the outcome of this study.”

Bermekimab was previously tested in a clinical study of patients with moderate to severe AD. Those results were previously presented at the annual conferences of the American Academy of Dermatology (AAD) and the European Academy of Dermatology and Venerology (EADV) by renowned dermatologists Dr. Eric Simpson and Dr. Alice Gottlieb, respectively. The findings showed that after only 8 weeks of bermekimab therapy, 75% of patients had achieved 75% improvement in disease severity as assessed by EASI score (the current standard of care for biological therapy involves a 16 week treatment regimen and is associated with 44-51% of patients achieving 75% improvement). Bermekimab therapy was also associated with a dramatic reduction in itch and pain, with three fourths of patients achieving clinically significant reduction in itch, and 86% achieving clinically significant reduction in pain after only 8 weeks of treatment.

John Simard, the Company’s President and CEO, stated, “I am grateful to Dr. Forman for leading this important study. Results from our earlier study suggest that bermekimab has the potential to change the paradigm for treating moderate to severe AD and to improve quality of life for millions of patients suffering from this disease.”

Inflammation plays a major role in the induction and progression of several skin diseases, including eczema or atopic dermatitis[1]. Bermekimab blocks the action of the potent inflammatory substance IL-1α found in skin. It has been demonstrated that IL-1α is necessary for inducing chronic skin inflammation through aberrant stores of intracellular IL-1α in keratinocytes, which constitute approximately 90% of skin cells. IL-1α secretion has shown not only to be necessary component in driving skin inflammation, but by itself sufficient to do so[2]. Therefore, neutralizing IL-1α activity through an inhibitor such as bermekimab has promise to resolve chronic skin inflammation and looks to be a key target for treating atopic dermatitis, along with other inflammatory skin diseases.

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-1α and may be a key source of inflammatory stimulus in AD. IL-1α is present on leukocytes, where its role in leukocyte trafficking and infiltration may represent a key step in the chronic inflammation of AD. IL-1α is a key inducer of matrix metalloproteinases activity which could be directly involved in the epithelial barrier breakdown in AD[3]. Loss of regulation of IL-1 results in systemic inflammation with extensive skin involvement[4].

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.

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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Source: XBiotech Inc.