XBiotech's Results from Phase 2 Atopic Dermatitis Study Suggest New Drug to Treat Skin Disease

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Bermekimab Therapy Rapidly and Significantly Reduces Disease

AUSTIN, Texas, Dec. 12, 2018 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ: XBIT) announced today that its open label, proof of concept, multicenter study using bermekimab to treat patients with moderate to severe atopic dermatitis (AD) has completed and the study met all primary and secondary endpoints. Thirty eight patients in two treatment groups received a low (n=10) or high (n=28) dose of bermekimab once weekly for either a 4 or 7-week treatment regimen, respectively. Statistically significant improvement was seen for all efficacy endpoints in the high dose group; and a significant dose response for the high dose compared to low dose group was observed for key endpoints, including the Eczema Area and Severity Index (EASI), Global Individual Sign Score (GISS), Patient Oriented Eczema Measure (POEM), Hospital Anxiety and Depression Scale (HADS), and SCORing Atopic Dermatitis (SCORAD).

While clinically and statistically significant improvement was seen for all clinical endpoints in the high dose group, also notable was the speed, magnitude, and trajectory of responses seen. In the high dose group, for example, after only four weeks of treatment, 61% of patients achieved a 4-point improvement in the Pruritus Numerical Rating Scale (NRS), a key method used to measure itch in clinical trials for atopic dermatitis, and 75% of patients achieved a 4-point improvement by week 7. For the only biological therapy currently approved to treat atopic dermatitis, dupilumab, which was granted breakthrough designation by the FDA, only 16%-23% of patients achieved a 4-point NRS improvement after 4 weeks of therapy; and only 36-41% of patients achieved a 4-point improvement by week 16[1].

Atopic dermatitis, commonly referred to as eczema, is characterized by chronic inflammation of the skin, which results in a breakdown of the skin barrier and leads to dry, thickened, scaly skin, redness, and itching, the latter which can be debilitating and result in significant sleep disturbances and loss of quality of life. A survey of persons suffering from atopic dermatitis found that 91% of patients endured itching every day[2], and another study reported that 36% of patients feel that their primary treatment objective is to reduce itch[3]. Further, international panels of dermatology experts have recommended itch as a crucial determinate of treatment effectiveness in the development of new therapies[4].

Another key measure of efficacy in the XBiotech study was the EASI. In the study, 39% of high dose patients achieved 75% improvement in EASI score (EASI-75) after 4 weeks of therapy and 71% of patients achieved EASI-75 at week 7. Of note, participants were not allowed to use concomitant topical corticosteroids during the study and thus these improvements were most likely due to the study drug alone. The only approved biological therapy, dupilumab, reports only 44-51% of patients achieved EASI-75 by week 16[5].

Dr. Eric Simpson, Professor of Dermatology at Oregon Health & Science University, commented on the bermekimab findings: "These early results with bermekimab are extremely exciting. Patients with moderate-to-severe atopic dermatitis achieved very clinically relevant improvement in not only skin signs, but multiple domains of their life impacted by this chronic disease. It is greatly encouraging to see that blocking the novel target, IL-1 alpha, yields such potent anti-inflammatory effects and treats the key aspects of this disease."

These views were shared by Dr. Alice Gottlieb, M.D., Ph.D., Professor of Dermatology at New York Medical College, who stated, "Bermekimab targets a well-characterized but novel inflammatory pathway for atopic dermatitis. The results seen in the study suggest a proximal link between inflammation and the key symptoms of atopic dermatitis. Bermekimab is a very promising new drug and I look forward to its continued development."

John Simard, XBiotech President & CEO, commented, "Atopic Dermatitis represents an important indication for our bermekimab dermatology program. While the study was small, the dose response and overall results we have seen are outstanding and I am awed by what this therapy could mean to millions of people that suffer from the disease worldwide."

The clinical study enrolled patients at 9 different dermatology research centers across the U.S. Dr. Seth Forman, an investigator in the clinical study in Tallahassee, Florida stated, "Bermekimab provided relief to my patients with skin disease with excellent safety. I look forward to having bermekimab available for my atopic dermatitis patients in the future."

This study evaluated a number of accepted measures of disease severity for atopic dermatitis, including the Eczema Area and Severity Index score (EASI); Dermatology Life Quality Index (DLQI); SCORAD; Pruritus Numerical Rating Scale (NRS); Patient Oriented Eczema Measure (POEM); The Hospital Anxiety and Depression Scale (HADS); and Investigator's Global Assessment (IGA). The two dose groups received weekly subcutaneous injections using XBiotech's recently developed pre-filled syringes that contain a concentrated formula of bermekimab. Improvement was assessed from baseline to the endpoint, which was either 4 or 7 weeks from start of treatment. Significant improvements were indicated by all aforementioned measures for the high dose group.

There's an estimated 18 million people with AD in the United States and the incidence is believed to be increasing in industrialized countries. Nearly 7 million persons in the U.S. are believed to have atopic dermatitis that is considered moderate to severe, which is the disease severity of subjects treated in the present study. Overall, the disease affects about 10% of children and 7% of adults in the U.S. and can often be debilitating, particularly when it is accompanied with severe and unrelenting itch. The economic impact of AD is significant, with an estimate of nearly $40 billion in costs annually.

About True Human™ Therapeutic Antibodies

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] Simpson EL, Bieber T, Guttman-Yassky E, et al; SOLO 1 and SOLO 2 Investigators. Two phase 3 trials of dupilumab versus placebo in atopic dermatitis. *N Engl J Med.* 2016;375(24):**2335**-2348; see pruritus summary at https://www.dupixenthcp.com/atopicdermatitis/about/pruritus-nrs-clinical-trial

[2] Dawn et al. Itch characteristics in atopic dermatitis: results of a web-based questionnaire. *Br J Dermatol*. 2009;160(3):642-644.

[3] Schmitt et al. Determinants of treatment goals and satisfaction of patients with atopic eczema. *J Dtsch Dermatol Ges*. 2008;6(6):458-465.

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[5] https://www.dupixenthcp.com/atopicdermatitis/about/easi-clinical-trial

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