



Bermekimab Successfully Treats Hidradenitis Suppurativa, Including Significant Reduction in Pain

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Bermekimab Treats HS Patients Even After Failure with Leading Biological Therapy

AUSTIN, Texas, Jan. 23, 2019 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ: XBIT) announced today the successful outcome of its multicenter, open label, confirmatory study using bermekimab to treat patients with moderate to severe Hidradenitis Suppurativa (HS). Primary and key secondary endpoints were met in this study with significant, differentiating findings. The Company previously published data from its [double-blind placebo controlled study](#) in HS using bi-weekly, intravenous infusions of bermekimab in which safety and primary efficacy endpoints were met. The present study, which tested a new concentrated subcutaneous formulation in a convenient pre-filled syringe, confirmed and expanded upon the previous findings.

The present study enrolled 42 patients, each receiving 400mg subcutaneous weekly doses of bermekimab in a 12-week treatment regimen. There were two treatment groups of subjects: those who had failed prior anti-TNF therapy (n=24); and those with no prior anti-TNF treatment history (n=18). The study was conducted at eleven different dermatology research centers across the U.S.

Bermekimab was well-tolerated with no safety concerns. Statistically significant improvement was seen for efficacy endpoints in both anti-TNF and anti-TNF naïve groups, including the Hidradenitis Suppurativa Clinical Response Score (HiSCR); Dermatology Life Quality Index (DLQI); Physician's Global Assessment (PGA); Change in inflammatory lesion count; Disease Activity Score (DAS); and Visual Analogue Scales (VAS) for Disease Impression and Pain. These efficacy findings differentiate bermekimab from the available treatments for HS.

Assessing the percentage of patients who achieve a HiSCR response is a key measure to determine treatment effectiveness¹. The HiSCR response is achieved during the treatment period if a patient has at least 50% reduction in the number of inflammatory lesions (abscesses + inflammatory nodules), and has no increase in the number of abscesses or draining fistulas. Abscesses, inflammatory nodules, and draining fistulas are the painful and disfiguring lesions associated with HS. For subjects who received bermekimab with no prior anti-TNF therapy, 61% (11/18) of patients achieved HiSCR. For patients who received bermekimab after failure of prior anti-TNF therapy (ie, adalimumab), 58% (14/24) of patients still achieved HiSCR by week 12.

The Chair of the present study, Dr. Alice Gottlieb, M.D., Ph.D., Clinical Professor of Dermatology, Department of Dermatology, Icahn School of Medicine at Mount Sinai, NY, NY, stated, "We need more effective treatments for HS. Bermekimab provides hope for potent therapies which address novel targets. I am very excited about this drug for hidradenitis suppurativa and atopic dermatitis." (For more information on XBiotech's results in atopic dermatitis, please see link: [XBiotech Atopic Dermatitis Results](#))

Dr. Gregor Jemec, MD, DMSci, Professor and Chairman, Dept. of Dermatology, Zealand University Hospital, University of Copenhagen commented, "I'm very pleased to see these promising results of a new treatment option."

Another major finding in the study was a significant treatment-related reduction of pain in the HS patients. Pain is widely recognized among experts as a key objective for HS treatment, but this symptom has been largely unaddressed by available approved therapies. 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. Remarkably, 67% and 72% of patients who had prior or no prior anti-TNF therapy achieved this endpoint at week 12, respectively. No approved monotherapy for HS has shown a significant effect on pain².

John Simard, Chairman and CEO of XBiotech, stated, "We are very grateful to the investigators and patients who participated in this important study. There is a substantial unmet medical need for patients suffering from HS, including lack of adequate treatment for pain, making these findings of utmost importance for patients and caregivers. We further believe that our results in HS differentiate bermekimab from current treatments and look forward to delivering bermekimab as a new treatment option."

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^{3,4}. Pain is a paramount condition in patients suffering from HS, as this chronic inflammation and accompanying pain account for the fact that HS is ranked first among skin disorders in terms of adversely affecting quality of life⁵. The global prevalence for HS is estimated at up to 4% of the population⁴.

Results from an investigator-sponsored phase 2 study evaluating MABp1 (bermekimab) 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 bermekimab compared to placebo control after 12 weeks of therapy [response rate of 60% vs 10%, respectively (p=0.035)]⁶.

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 technology. XBiotech 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 HiSCR has been accepted as a primary measure of treatment efficacy by the FDA and was used in the clinical development of adalimumab, the only approved biological therapy for HS. In adalimumab's Pioneer I phase 3 trial, its only monotherapy phase 3 study, which included 153 patients in the treatment arm, 42% of subjects receiving the drug achieved a positive HiSCR at 12 weeks.

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

⁴ 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.

⁵ Canoui-Poitrine F, Revuz JE, Wolkenstein P, Viallette C, Gabison G, Pouget F, et al. [Clinical characteristics of a series of 302 French patients with hidradenitis suppurativa, with an analysis of factors associated with disease severity](#). *J Am Acad Dermatol* 2009; 61: 51-57.

⁶ 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.



XBiotech Inc.