Phase 2 Clinical Trial of Bermekimab Shows Potential New Standard of Care for Treatment of Hidradenitis Suppurativa, Including Significant Pain Reduction without Antibiotics

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- Significant therapeutic benefit achieved whether or not patients had previously failed treatment with existing FDA-approved biological drug.

- 61-63% of patients achieved a positive HiSCR (the accepted measure of disease severity in HS).

- 67-72% of patients achieved a clinically meaningful reduction in pain.

AUSTIN, Texas, March 05, 2019 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ: XBIT) today released findings for its Phase 2 clinical study for bermekimab presented at the American Academy of Dermatology's annual meeting which concluded today. Held at the Walter E. Washington Convention Center in Washington, D.C., the presentation titled, "Bermekimab Shows Efficacy for Treating Hidradenitis Suppurativa (HS), Including Marked Reduction in Pain" was provided by renown dermatologist, Dr. Alice Gottlieb, M.D., Ph.D., in the major venue Hall A. At the presentation Dr. Gottlieb provided the results for 42 HS patients that received 12 weekly injections of bermekimab therapy. Aside from excellent safety, a major finding of the study was that patients achieved significant therapeutic benefit from bermekimab therapy regardless of whether or not they had previously failed treatment with the only existing FDA-approved biological drug treatment for HS. In what the Company believes to be a breakthrough for the disease, patients having previously failed as well as those who never received anti-TNF therapy had significant reduction in pain. Pain is a hallmark of HS that has so far not been adequately addressed by any therapy.

Dr. Gottlieb showed that by week 12 of treatment, 63% of patients who have previously failed anti-TNF therapy achieved a positive HiSCR (the accepted measure of disease severity in HS); similarly, 61% of patients with no prior anti-TNF therapy achieved positive HiSCR[1]. These results translated into a 46% ($p<0.001$) and 60% ($p=0.005$) reduction in the number of abscesses and inflammatory nodules, respectively, for the two groups. A breakthrough finding was that 67% and 72% of patients achieved a clinically meaningful reduction in pain by week 12[2].The existing FDA-approved biological therapy was only shown to reduce pain when used in combination with oral antibiotics[3]. No antibiotics were used as part of the clinical study with bermekimab.

XBiotech's President & CEO, John Simard, stated, "The results seen with bermekimab in HS suggest a new and important advance for the treatment of this difficult disease. The totality of results we saw presented at the AAD conference have provided compelling evidence that bermekimab could make a significant contribution to the treatment of dermatological disease."

The study enrolled 42 patients, each receiving 400mg subcutaneous weekly doses of bermekimab in a 12-week treatment regimen. There were two treatment groups: 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.

An intravenous infusion formulation of bermekimab was previously used in a randomized, double-blind, placebo controlled Phase 2 study for patients with HS, where bermekimab treated patients had a significantly higher rate of HiSCR compared to placebo. However, this was the first study of bermekimab in HS using a new subcutaneous formulation that is administered from pre-filled syringes. XBiotech invested in new filling equipment and developed the pre-filled syringe manufacturing process to provide a more convenient subcutaneous bermekimab product candidate.

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[4,5]. 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 life[6]. The global prevalence of HS is estimated at up to 4% of the population[5].

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] HiSCR response rates at week 12 were 42% and 59% in the so called PIONEER I and PIONEER II Phase III studies with the FDA-approved drug adalimumab, respectively. Only 28% and 46% of patients achieved clinically relevant pain reduction (as defined above) in the PIONEER I and PIONEER II studies, respectively. In the PIONEER II study, patients received adalimumab as a combination therapy with antibiotics. Pain reduction results were not significant (compared to placebo) in PIONEER I.

[2] The FDA accepted definition of clinically relevant pain reduction is a ≥30% reduction in the NRS pain score in patients that have also achieved a ≥1 unit reduction in pain score. Score is determined at Week 12.

[3] Kimball et al. Two Phase 3 Trials of Adalimumab for Hidradenitis Suppurativa. N Engl J Med. 2016 Aug 4;375(5):422-34.

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

[5] 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.

[6] 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.

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