XBiotech Announces Plan to Launch Randomized Phase 2b Study of Bermekimab in Hidradenitis Suppurativa

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AUSTIN, Texas, May 23, 2019 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ: XBIT) announced plans to advance its dermatology program for its true human antibody bermekimab with the launch of a randomized, double-blind, placebo controlled, Phase 2b clinical study in patients with moderate to severe Hidradenitis Suppurativa (HS). This Phase 2b study will evaluate safety and efficacy of bermekimab at different subcutaneous doses compared with placebo. The study will further evaluate efficacy of bermekimab in HS and guide dosing strategies for the anticipated Phase 3 registration study. The Company expects the first patient to be enrolled during the third quarter of 2019.

The Phase 2b study follows two previous successful clinical studies of bermekimab to treat HS. XBiotech recently evaluated bermekimab in a phase 2 study involving two groups of patients with HS: those who had no prior treatment with biologics; and those who had failed the only approved biological therapy to treat HS. The study, which was conducted at eleven research centers across the U.S. showed bermekimab was similarly effective in HS patients regardless of prior treatment with the current approved therapy.

Results of the study demonstrated that weekly treatment with bermekimab was associated with statistically significant improvement in HS, as measured by the FDA-sanctioned Hidradenitis Suppurativa Clinical Response score (HiSCR). In the study, 61% of patients with no prior biological therapy achieved positive HiSCR at 12 weeks, while 63% of patients who had failed previous biological therapy also achieved a positive HiSCR. HS is associated with severe pain and thus pain was a key measure in the study. At the study's endpoint, patients with no prior biological therapy had a 64% reduction in pain compared with baseline, while those who had previously failed anti-TNF therapy had a 54% reduction in pain (for the only approved therapy for HS (Humira), only 43% of patients achieved HiSCR in its Phase III study that did not allow antibiotics; and there was no significant reduction in pain for Humira treated patients in the Phase 3 study).

XBiotech's President & CEO, John Simard, commented, "We are extremely excited about the potential of bermekimab to treat inflammatory skin disease. We are eager to advance this program in HS and to ultimately deliver a new treatment to patients suffering from this devastating disease."

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. 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. The global prevalence of HS is estimated at up to 4% of the population.

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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