XBiotech Announces Rapid Enrollment for its Randomized Multi-Center Clinical Study for Bermekimab in Patients with Hidradenitis Suppurativa

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Enrollment Rate Exceeds Expectation, Suggesting High Unmet Need and Anticipation for Bermekimab in HS

AUSTIN, Texas, Nov. 19, 2019 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ: XBIT) today announces rapid enrollment in its randomized, double-blind, placebo-controlled Phase 2 clinical study evaluating bermekimab in patients with moderate to severe Hidradenitis Suppurativa (HS). The study is chaired by renowned investigative dermatologist Alice Gottlieb, MD, PhD (Medical Director of Dermatology at the Mount Sinai Beth Israel Campus and Clinical Professor at the Icahn School of Medicine at Mount Sinai) and will enroll approximately 150 patients. XBiotech announced the first patient enrolled in the study on October 23, 2019. Today, XBiotech is already updating status of the study, reporting that 51 patients have now been randomized, or assigned to an investigational arm of the study.

Dr. Gottlieb commented, “The very strong participation by clinical sites and by patients is indicative of the substantial need for new therapy and of the favorable view of bermekimab.”

Ms. Ashley Otero, XBiotech’s Director of Clinical Operations, stated, “We are extremely excited about the robust enrollment seen to date. After only a few weeks since enrollment of the first patient, we have already randomized over one-third of the intended study population. If this pace continues, we will complete enrollment well ahead of our anticipated timing.”

Bermekimab has been tested in two previous clinical studies. In a recent open label study (n=42), 61% of patients with no prior biological therapy and 63% of patients who had failed previous biological therapy (i.e. adalimumab) achieved a positive HiSCR at 12 weeks. Additionally, the majority of patients in both groups achieved clinically significant reduction in pain from their disease. These results were presented at the American Academy of Dermatology (AAD) in 2019.

In an earlier double-blind, placebo controlled, randomized study which also evaluated bermekimab in the treatment of HS, the study’s primary endpoint was met, demonstrating significant improvement of HiSCR in patients treated with bermekimab compared to control after 12 weeks of therapy (response rate of 60% vs 10%, respectively (p=0.035)). These results have been published in a leading peer reviewed medical journal, the *Journal of Investigative Dermatology*[1].

The primary endpoint for the current study is the percentage of subjects achieving a Hidradenitis Suppurativa Clinical Response (HiSCR) at week 12. Multiple secondary efficacy endpoints will be assessed after 12 and 16 weeks of therapy, including: Numerical Rating Scale (NRS) for pain and itch; Modified Sartorius Score; Dermatology Life Quality Index (DLQI); Hospital Anxiety and Depression Scale (HADS); and Patient Global Impression of Change and Severity (PGI-c, PGI-s). Please visit www.clinicaltrials.gov for a more complete description of the study.

About Hidradenitis Suppurativa

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[1,[2]]. Therefore, HS is often devastating for patients with significant impact on quality of life [3]. The Dermatology Quality Life Index (DQLI) for HS is 8.9, being higher than any other skin disorder[4]. Traditional treatments comprise of antibiotics, antiandrogens and surgery. The global prevalence for HS is estimated at up to 4% of the population [5].

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.

About True Human™ Therapeutic Antibodies

XBiotech’s True Human™ antibodies are the only available antibodies derived without modification from humans who possess natural immunity to certain diseases. (Unlike all commercially available antibodies, which are called “Humanized” or “Fully Human”, XBiotech’s True Human™ antibodies are directly sourced from the natural human immune response for specific diseases without modification, and thereby have not been shown to cause immunogenicity.) 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.

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.