XBiotech Announces Upcoming Phase 2 Clinical Studies in Dermatology

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XBiotech to Launch Two Phase 2 Clinical Studies to Study Subcutaneous Administration of MABp1 for Treatment of Hidradenitis Suppurativa and Atopic Dermatitis

AUSTIN, Texas, April 16, 2018 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT) announced today that it would evaluate a new subcutaneous formulation of the Company's True Human™ monoclonal antibody, MABp1, in two separate Phase 2, open label, dose escalation studies in patients with moderate to severe Atopic Dermatitis (AD) and Hidradenitis Suppurativa (HS). The Company is conducting final preparations for study launch including the first clinical site initiation scheduled later this month.

Francisco Kerdel, M.D., founder of Florida Academic Dermatology Centers and the Study Chair for the Atopic Dermatitis study, commented, "The antibody targeting Interleukin-1 alpha represents potentially a new era in the management of inflammatory skin disorders. MABp1 is a first-of-its-kind being isolated from a human immunoregulatory response that blocks inflammation. New therapies are needed and we are excited about the potential for MABp1 in the clinic."

Alice Gottlieb, M.D., Ph.D., Professor of Dermatology at New York Medical College and Study Chair for the Hidradenitis Suppurativa study, commented, "We need new targets for therapies for Hidradenitis Suppurativa (HS). The development of adalimumab, a TNF blocker, for HS represented a major advance, however, patients still experience inadequate responses. Targeting IL-1 alpha with the monoclonal antibody MABp1 may provide more complete clinical responses and new hope for patients suffering with HS."

MABp1 is a human-derived antibody which targets and neutralizes IL-1 alpha (IL-1α), an inflammatory cytokine that plays a key role in the pathophysiology of a wide range of inflammatory skin disorders[1]. Three phase II studies sponsored by XBiotech have been completed in dermatologic indications (acne, psoriasis, pyoderma gangrenosum) as well as one investigator sponsored study in Hidradenitis Suppurativa. In these studies, MABp1 was well tolerated and showed good therapeutic responses[2,3,4]. Dose ranging of the Company's new subcutaneous formulation for MABp1 is planned to be studied in 4 week and 12 week open label treatment regimens for AD and HS. These findings will establish the basis for further randomized studies with the subcutaneous formulation.

HS Study

The phase 2, open label, dose escalation multicenter study will consist of two dose cohorts of MABp1 in patients with moderate to severe HS. Patients entering the study will not have received any previous approved biological therapies for the treatment of HS. Ten patients will receive a total of 12 weekly 200mg subcutaneous injections of MABp1. Following a safety assessment for patients in the first dose cohort, ten patients will receive 12 weekly 400mg subcutaneous injections of MABp1. Patients will be followed for 12 weeks to allow for assessment of safety and preliminary efficacy. Various efficacy measures will be assessed including: Hidradenitis Suppurativa Clinical Response (HiSCR) from baseline to 12 weeks, changes in patient reported outcomes from baseline to week 12 including Dermatology Life Quality Index (DLQI), Visual Analog Scale (VAS) for disease and VAS for pain, assessment of Physician's Global Assessment (PGA), Disease Severity Score and modified Sartorius score at week 12, and change in inflammatory lesion count.

AD Study

The phase 2, open label, dose escalation multicenter study will consist of two dose cohorts of MABp1 in patients with moderate to severe AD. Ten patients will receive a total of 4 weekly 200mg subcutaneous injections of MABp1. Following a safety assessment for patients in the first dose cohort, ten patients will receive 4 weekly 400mg subcutaneous injections of MABp1. Patients will be followed for 6 weeks to allow for assessment of safety and preliminary efficacy. Various efficacy measures will be assessed including changes in Eczema Area and Severity Index Score (EASI), Dermatology Life Quality Index (DLQI), Patient Oriented Eczema Measure (POEM) and SCORing Atopic Dermatitis (SCORAD), a measure of disease severity in AD.

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[5,6]. Therefore, HS is often devastating for patients with significant impact on quality of life [7]. The Dermatology Quality Life Index (DQLI) for HS is 8.9, being higher than any other skin disorder[8]. Traditional treatments comprise of antibiotics, antiandrogens and surgery. The global prevalence for HS is estimated at up to 4% of the population [2].

About Atopic Dermatitis

Atopic dermatitis (AD) is an inflammatory skin disease affecting as much as 20% of the population in western industrial societies. Chronic eczema in AD and associated pruritus can be a significant cause of morbidity and impact life quality. Disease pathogenesis is complex but ultimately converges on a pathological inflammatory process that disrupts the protective barrier function of the skin. Keratinocytes are a major reservoir of IL-1α and may be a key source of inflammatory stimulus in AD. IL-1α is present on leukocytes, where its role in leukocyte trafficking and infiltration may represent a key step in the chronic inflammation of AD. IL-1α is a key inducer of matrix metalloproteinases activity which could be directly involved in the epithelial barrier breakdown in AD[9]. Loss of regulation of IL-1 results in systemic inflammation with extensive skin involvement[10].

About True Human™ Therapeutic Antibodies

Unlike previous generations of antibody therapies, 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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