



Dr. Alan Kivitz to Chair XBiotech's Natrunix Program in Rheumatoid Arthritis

November 14, 2023

(Phase II Multicenter Study is Proceeding Well with High Anticipation)

AUSTIN, Texas, Nov. 14, 2023 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ: XBIT) today announced that Alan Kivitz M.D. is now Lead Investigator & Study Chairman for its clinical research program for Natrunix in Rheumatoid Arthritis.

XBiotech believes Natrunix will be a breakthrough therapy for rheumatological diseases. The company has now enrolled about 33% of the 210 patients it is recruiting for a Phase II, Double-Blind, Placebo-Controlled, Randomized study, examining Natrunix in combination with methotrexate for the treatment of Rheumatoid Arthritis. There are presently about 25 clinical trial sites across the United States that are participating in the study. Dr. Kivitz, who is actively treating subjects at his clinic in Altoona, Pennsylvanian commented, "Despite all the breakthroughs in our ability to treat Rheumatoid Arthritis there continues to be an unmet need for some patients with this disease. I am excited to be part of a clinical trial program studying a novel approach to RA."

Dr. Kivitz has had a prodigious medical career treating arthritis and rheumatic diseases. He received his medical degree from Albany Medical College, New York, trained in internal medicine at the North Shore University Hospital and Memorial Sloan Kettering Cancer in New York and then completed rheumatology studies at Albany Medical College. Dr. Kivitz has authored over 500 research articles, abstracts, and clinical studies relating to osteoarthritis, osteoporosis and rheumatoid arthritis and has lectured on his findings around the world. Dr. Kivitz has served on advisory boards for major drug developers, including AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Genentech, GlaxoSmithKline, Janssen, Pfizer, Regeneron Pharmaceuticals, Sanofi-Genzyme, Takeda, and UCB. Above all Dr. Kivitz is focused on finding new approaches to treat arthritis and rheumatic disorders.

John Simard, President and CEO of XBiotech commented, "We are honored to have Dr. Kivitz chair this study for which we are eagerly anticipating results."

Nearly forty-years ago investigators began to describe a key role for interleukin-1 in cartilage destruction and disease progression in arthritis and degenerative arthropathies^{1,2} Indeed finding biological therapies to target interleukin-1 was an initial impetus for the nascent biotechnology industry in the late 1980s. But confusion over the nature of the interleukin-1 meant that therapies designed to target its activity failed to hit the mark for all potential disease indications.

The confusion about interleukin-1 is highlighted by the fact that there is in reality no such substance as interleukin-1! Rather, interleukin-1 actually refers to two separate and distinct molecules—IL- α and IL-1 β —each playing unique roles in health and disease. The α and β Interleukin-1 molecules are chemically and physically distinct and under different genetic and post transcriptional regulation. The α and β molecules are thus deployed with disparate temporal and spatial distribution and with unique biological functions. Nonetheless, despite great anticipation for blocking "interleukin-1" activity clinically, no therapeutic besides Natrunix has been developed to specifically and exclusively block IL-1 α activity in rheumatology.

Natrunix exclusively and specifically blocks IL-1 α . Targeting IL-1 α is crucial, since it may be the key interleukin-1 potentiator of pain and inflammation in affected tissues in affected joints. Natrunix is not only unique in how it targets interleukin-1, it also extraordinary because it is a monoclonal antibody (unlike any other marketed therapeutic antibody) derived from a naturally occurring immunoglobulin—identified from a healthy human donor with natural immunity to IL-1 α . XBiotech calls Natrunix a True Human Antibody.

About XBiotech

XBiotech is pioneering the discovery and development of targeted antibodies based on its True Human™ technology. The company's mission is to discover and commercialize its pipeline of truly natural human antibodies for treating serious diseases such as inflammatory conditions like rheumatology, infectious disease, cardiovascular disease and cancer. XBiotech's has several candidate products including those that specifically block the activity of interleukin-1 alpha (IL-1 α). Cloned from individual donors who possess natural immunity against certain targeted diseases, XBiotech's pipeline of True Human antibodies are intended to deliver unmatched safety and efficacy. At the Company's 48-acre campus, located just minutes from downtown Austin, XBiotech has a fully integrated biopharma headquarters, including biological GMP manufacturing facilities, research and QC testing laboratories, quality and clinical operations. 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.

Contact

Wenyi Wei

wwei@xbiotech.com

Tel. 737-207-4600

¹ Bunning et al. The effect of interleukin-1 on connective tissue metabolism and its relevance to arthritis Agents Actions Suppl. 1986:18:131-52.

² Vershure & Van Noorden. The effects of interleukin-1 on articular cartilage destruction as observed in arthritic diseases, and its therapeutic control. Clin Exp Rheumatol. 1990 May-Jun;8(3):303-13.