



FDA Authorizes Phase II Study for Natrunix in Rheumatoid Arthritis Patients

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XBiotech Believes its Drug Candidate Natrunix Could Revolutionize Arthritis Treatment

AUSTIN, Texas, May 22, 2023 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ: XBIT) today reports that the FDA's Division of Rheumatology has authorized the Company to initiate a Phase II clinical study to test Natrunix™ as a treatment for Rheumatoid Arthritis.

The randomized, double-blind, placebo-controlled, trial will examine the effectiveness of Natrunix to treat rheumatoid arthritis compared to placebo in subjects already receiving stable but inadequate treatment with methotrexate (MTX). A total of 210 patients will be randomly distributed in equal numbers into three groups: including two different Natrunix dosages and a placebo group. Change in disease severity will be assessed at multiple time points according to the American College of Rheumatology (ACR) grading scale. Subjects will also be assessed for reduction in pain, number of tender or swollen joints as well as overall disease activity. The study concludes after subjects have received 12 cycles of therapy and follow-up.

Natrunix™ is a preparation using a monoclonal antibody indistinguishable from a naturally occurring antibody present in a healthy human. With billions of different antibodies circulating in the blood of healthy humans, identifying a single antibody molecule is technically challenging. Not a single antibody therapy marketed today or in the past was actually derived from a natural human antibody.

The Phase II study in rheumatoid arthritis is the culmination of XBiotech efforts to pioneer therapies derived from natural human immunity. XBiotech's core proprietary technology enables identification of rare antibodies present in human donor blood that could be used to naturally treat disease, including the candidate therapy Natrunix for the treatment of arthritis. XBiotech also has antibodies to treat infectious disease, such as influenza, Ebola, COVID, Shingles and others.

Natrunix specifically targets and neutralizes a substance—interleukin-1 α (IL-1 α)—that is produced by the human body and is involved in many disease conditions. In chronic illness, such as rheumatoid arthritis, IL-1 α can be a key part of the disease process. IL-1 can mediate the breakdown of joint synovium, bone remodelling, pain, and inflammation in the rheumatoid joint.

There are over 86,000 academic manuscripts and 6,600 review articles describing interleukin-1 (IL-1), making this substance among the most studied subjects in medicine. There are several marketed therapeutics targeting “interleukin-1” (including KINERET™, ARCALYST™ and ILARIS™). Yet the term interleukin-1 actually refers to two different molecules—IL-1 α and IL-1 β —that are produced at different times and places and play very different roles in disease. Remarkably, Natrunix is the only product candidate that exclusively targets and neutralizes the activity of IL-1 α , or the “missing-link,” for the treatment of arthritis.

One in four adults, or over 50 million people in the United States are currently affected by Rheumatoid Arthritis, including 33% of those between the ages of 45-64 and 50% of person over 65 years of age. The number of persons affected by RA is expected to increase, with the CDC predicting that by the year 2040, 78.4 million adults will suffer from RA in the United States. In addition, it is expected that 300,000 children will suffer from juvenile arthritis (Arthritis Foundation, 2023).

About True Human™ Therapeutic Antibodies

XBiotech's True Human™ antibodies are derived without modification from individuals who possess natural immunity to certain diseases. By harnessing the body's natural immunity to cure disease, True Human™ antibodies have the potential to revolutionize medicine.

About XBiotech

XBiotech is dedicated to pioneering the development of breakthrough therapies derived from natural human immunity. XBiotech discovered genetic engineering tools that enabled identification of rare antibodies present in human donor blood, and has built a pipeline of antibody therapies, including a candidate therapy that could revolutionize arthritis treatment. Headquartered in Austin, Texas, XBiotech has also lead innovation in biomanufacturing technology. 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. 512-386-2900