XBiotech Announces First Patient Begins Novel Natrunix Therapy in Phase II Rheumatoid Arthritis (RA) Clinical Trial

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AUSTIN, Texas, Aug. 08, 2023 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ: XBIT) today began treating the first patient in a phase II, double-blind, placebo-controlled, randomized clinical study to evaluate Natrunix as a new treatment for Arthritis. Natrunix blocks a key cause of inflammation involved in pain and joint destruction in rheumatoid arthritis (RA).

The primary endpoint of the Phase II is the American College of Rheumatology (ACR) 20% Response (ACR 20) rate at 12 weeks. Secondary and exploratory endpoints include ACR 50, ACR 70, numerical rating scale (NRS) for pain score, inflamed and painful joint counts, Health Assessment Questionnaire Disability Index (HAQ-DI), Routine Assessment of Patient Index Data 3 (RAPID-3), Clinical Disease Activity Index (CDAI) and safety. These endpoints reflect the expectation that Natrunix may provide needed improvement with respect to pain, tenderness, mobility of joints and quality of life. Approximately 210 subjects will be enrolled into three different arms in the study. All subjects will receive methotrexate (MTX) and be randomized to receive either one of two doses of Natrunix or placebo.

Natrunix is a monoclonal antibody indistinguishable from a naturally occurring antibody from a human donor. Natrunix binds and neutralizes the action of one of the most potent inflammation-causing substances known—interleukin-1. For decades, interleukin-1 was seen as the key target for drugs to treat RA. However, to date, drugs that block interleukin-1 have not lived up to expectations as therapies for RA. XBiotech believes it has solved this puzzle.

Interleukin-1 actually describes two separate and distinct molecules—IL-1a and IL-1b—that are produced at different times and places in the body XBiotech is the first to develop candidate therapies—like Natrunix—that directly and specifically neutralize IL-1a. In recent years, world-class research has shown that in many cases IL-1a may be the crucial target for blocking disease-causing activities of the interleukin-1 inflammatory pathway. Natrunix thus holds promise as a new generation anti-inflammatory therapy for arthritis. As a naturally derived human antibody, it is also by design expected to be among the safest and best tolerated medicines ever developed.

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

Natrunix was discovered by XBiotech researchers at the Company's headquarters in Austin, Texas. 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.

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