FDA Approves XBiotech’s IND in Rheumatology

December 13, 2021

Launching Novel True Human Antibody Therapy Natrunix™ to Treat Rheumatology

AUSTIN, Texas, Dec. 13, 2021 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ: XBIT) today reports that the FDA’s Division of Rheumatology has authorized the Company to commence clinical development of Natrunix, the Company’s novel True Human™ antibody candidate therapy for treating rheumatological disease. The authorization, granted based on the Company’s investigational new drug (IND) application, allows the company to begin clinical development in rheumatology. Natrunix is a new drug, discovered and manufactured at XBiotech’s research and development headquarters in Austin, Texas. The Company believes Natrunix holds promise as a breakthrough therapy for the treatment of inflammatory joint diseases, including osteoarthritis and rheumatoid arthritis (RA).

Natrunix potently and selectively blocks inflammation that affects the joints and is not expected to cause general immunosuppression or have any other serious side effects.

Safe and effective treatments for arthritic disease is needed: one-third of adults 45-64 years old and half over 65 years of age—or about 53 million people in the United States—are currently diagnosed with rheumatological disease. And the number of persons afflicted is expected to increase rapidly—rising by 22% over the next 8 years—affecting 67 million persons in the US by 2030 (The National Arthritis Data Workgroup). The most common form of arthritis, osteoarthritis, currently affects 32.5 million people, including two-thirds of persons living with obesity (CDC 2021). About 300,000 children also suffer from rheumatic disease (Pediatric Orthopaedic Society of North America, 2021). XBiotech believes that Natrunix has the potential to treat all these forms of joint disease.

With IND approval, the Company will first launch Natrunix in a Phase I study to evaluate dosing for subcutaneous injections. Once preliminary dosing has been established, the Company plans to proceed with Phase II studies in RA.

Haritha Pallapotu, Director of Regulatory Affairs, stated, “New therapies are needed for patients with RA—especially those that reduce disease symptoms without diminishing quality of life. Natrunix is being developed to address major rheumatological diseases, and this approved IND provides the path. We believe the True Human antibody therapeutic will be a uniquely effective and safe treatment in rheumatology.”

About True Human™ Therapeutic Antibodies
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 technology. XBiotech 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 is also leading the development of innovative biotech manufacturing technologies designed to more rapidly, cost-effectively and flexibly produce 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.

Contact

Kaitlyn Hopkins
khopkins@xbiotech.com
Tel. 737-207-4600