XBiotech Pauses Rheumatology program

Dec 23, 2024

Findings from recently completed Rheumatoid Arthritis Study raise questions

AUSTIN, Texas, Dec. 23, 2024 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ: XBIT) announced today data that it is halting its clinical program in rheumatological disease while it seeks to understand the outcome from its recently completed Phase II, Double-Blind, Placebo-Controlled, Randomized study in Rheumatoid Arthritis. The Phase II study failed to meet its primary endpoint amid substantial irregularities that make unequivocal interpretation of the findings difficult. XBiotech was planning launch of additional studies in arthritis as well as other areas of rheumatology, including ankylosing spondylitis, which are now on hold while recent findings are evaluated.

About 230 subjects with moderate to severe rheumatoid arthritis were enrolled into the Phase II arthritis study, which examined the Company's candidate drug, Natrunix, in combination with methotrexate (MTX). The study's primary endpoint was the American College of Rheumatology (ACR) 20 response rate after 12 weeks of treatment. Various other rheumatological assessments were also performed, including NRS-pain scores, arthritic joint counts, quality of life assessments, and safety. The study population was randomized into three groups in a 1:1:1 ratio: 200 mg or 400mg Natrunix weekly in combination with MTX; or placebo weekly with MTX.

Irregularities in the Phase II study involved the highest enrolling clinical sites, including numerous subjects being enrolled multiple times. Although the study did not meet efficacy endpoints, discrepancies found during data analysis suggest caution in interpreting results. Findings of the study are still being analysed in order to better understand the implications of the findings and determine how these results can be used to guide potential further rheumatology studies for Natrunix.

About XBiotech
XBiotech is pioneering the discovery and development of therapeutics based on its True Human™ antibody technology. The Company has several candidate products including Natrunix, which are cloned from individual donors who possess natural immunity against certain diseases. Located just minutes from downtown Austin, the XBiotech campus headquarters includes GMP manufacturing facilities, research and testing laboratories, infectious disease research facilities, quality control and clinical operations. For more information, visit www.xbiotech.com.

Cautionary Note on Forward-Looking Statements and Study Results
This press release contains forward-looking statements, including declarations regarding management's beliefs and expectations that involve substantial risks and uncertainties. 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. 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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