XBiotech Launches Phase II Clinical Trial Evaluating Vilamakitug for the Treatment of Active Axial Spondyloarthritis

Jun 15, 2026

IND Application for V-SPINE Study Completes 30-Day FDA Review Without Clinical Hold, Clearing Path for U.S. Patient Enrollment

AUSTIN, Texas, June 15, 2026 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ: XBIT) today announced that its Investigational New Drug (IND) application for V-SPINE (PT064), a Phase II, double-blind, placebo-controlled, randomized study evaluating the efficacy and safety of vilamakitug in participants with active axial spondyloarthritis, has successfully completed the U.S. Food and Drug Administration's (FDA) 30-day review period without a clinical hold. The study is now authorized to proceed with patient enrollment in the United States, marking the resumption of XBiotech's rheumatology program.

Study Chair and the Axial Spondyloarthritis Scientific Advisory Board

The clinical protocol was developed under the leadership of Study Chair Marina Magrey, M.D., and with expert guidance from a distinguished panel of SPARTAN leaders and rheumatology experts. Dr. Magrey serves as Division Chief of Rheumatology at University Hospitals Cleveland Medical Center, Professor of Medicine at Case Western Reserve University School of Medicine, and Vice-Chair of the Spondyloarthritis Research and Treatment Network (SPARTAN).

The advisory panel includes:

- **Marina Magrey, M.D.** — Division Chief of Rheumatology, University Hospitals Cleveland Medical Center; Professor of Medicine, Case Western Reserve University School of Medicine
- **Atul Deodhar, M.D., M.R.C.P., FACR, FACP** — Professor of Medicine and Medical Director of Rheumatology Clinics, Division of Arthritis & Rheumatic Diseases, Oregon Health & Science University, Portland
- **Lianne S. Gensler, M.D.** — Director of the UCSF Spondyloarthritis Research Program & Clinic; Professor of Medicine, University of California, San Francisco
- **Walter P. Maksymowych, MB ChB, FRCP(C), FACP** — Professor of Medicine, Division of Rheumatology, University of Alberta; Chief Medical Officer, CARE Arthritis Limited
- **Michael A. Paley, M.D., Ph.D.** — Assistant Professor of Medicine, Division of Rheumatology, Washington University in St. Louis
- **John A. Carino, M.D., M.P.H., FACR** — Vice-Chairman, Radiology and Imaging; Professor of Radiology, Weill Cornell Medicine

About the V-SPINE Study

PT064 will evaluate 400 mg of vilamakitug administered as 16 weekly subcutaneous injections versus placebo in 150 adult participants with active axial spondyloarthritis (axSpA). The primary endpoint is the proportion of participants achieving an ASAS40 response at Week 16. The study also includes a 12-week open-label extension in which all participants receive vilamakitug. Despite the availability of approved biologic therapies, a substantial proportion of patients continue to experience inadequate disease control, representing a significant and persistent unmet medical need.

"The unmet need in axial spondyloarthritis remains real and substantial. IL-1α is a compelling upstream target, hypothesized to play a role in the inflammation, bone erosion, and chronic pain that define this disease. The PT064 protocol is rigorously designed to test whether targeting this upstream pathway translates into meaningful clinical benefit, and I am pleased to have contributed to its development. FDA clearance of the protocol is an important milestone, and I look forward to seeing this study advance for the

benefit of patients."
— Marina Magrey, M.D., PT064 Study Chair

"FDA clearance of the PT064 protocol is a significant step forward for our vilamakitug program and for patients living with axial spondyloarthritis. Vilamakitug is a True Human™ antibody indistinguishable from one naturally occurring in a healthy person with immunity to IL-1α, and we believe it represents a meaningful new approach to treating the inflammation that drives this disease. We are grateful to the members of our axSpA Scientific Advisory Board for their expert guidance in shaping this protocol, and we plan to move expeditiously into enrollment."
— Sushma Shivaswamy, Ph.D., Interim Chief Executive Officer and Chief Scientific Officer, XBiotech

About Vilamakitug

Vilamakitug (also known as XB2001 and Natrunix ™) is an IgG4 monoclonal antibody that neutralizes interleukin-1α (IL-1α), a proximal pro-inflammatory cytokine that can contribute to synovial and entheseal inflammation, osteoclast-mediated bone resorption, cartilage degradation, and inflammatory joint pain in spondyloarthritis. By targeting this upstream inflammatory mediator, vilamakitug is hypothesized to reduce both structural damage and disease activity, including in patients who have had an inadequate response to currently approved biologic therapies.

About XBiotech

XBiotech is a fully integrated, global biopharmaceutical company dedicated to pioneering the discovery, development, and commercialization of therapeutic antibodies. XBiotech currently is advancing a pipeline of therapies across inflammatory disorders, oncology, infectious disease, and dermatology by harnessing naturally occurring antibodies from patients with immunity to certain diseases. Utilizing natural human immunity as a source of new medicines offers the potential to redefine the standards of care for a wide range of diseases.

XBiotech has a deep and continuing history in rheumatology. The Company previously developed and clinically advanced bermekimab, a True Human™ anti-IL-1α antibody evaluated across multiple inflammatory diseases. On December 30, 2019, XBiotech sold bermekimab in a transaction valued at up to $1.35 billion, retaining the right to develop True Human™ anti-IL-1α antibodies in all areas of medicine outside of dermatology. PT064 marks the continuation of that rheumatology legacy, as XBiotech advances vilamakitug — its next-generation True Human™ IL-1α antibody — into a pivotal Phase II study in axial spondyloarthritis. For more information, visit **www.xbiotech.com**.

About True Human™ Therapeutic Antibodies

XBiotech's True Human™ antibodies are antibodies derived without modification from humans who possess natural immunity to certain diseases. XBiotech's True Human™ antibodies are directly sourced from the natural human immune response without modification. XBiotech's True Human™ antibodies have the potential to harness the body's natural immunity to fight disease.

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. Forward-looking statements are not guarantees of future performance. 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
publicrelations@xbiotech.com
tel. 737-207-4600