



XBiotech Developing Novel True Human Antibody Targeting Interleukin-1alpha (IL-1 α)

April 14, 2020

New antibody to block IL-1 α scheduled to enter clinical trials as next generation anti-inflammatory therapy in 2021

AUSTIN, Texas, April 14, 2020 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ: XBIT) announced today that a novel antibody it has discovered that neutralizes interleukin-1 alpha (IL-1 α) has now been advanced as a product candidate for clinical and commercial development. XBiotech discovered the IgG1 monoclonal antibody from a healthy donor with natural immunity against IL-1 α . Creating medicines from natural human immunity is the hallmark of XBiotech's approach to developing a new generation of breakthrough therapies.

XBiotech recently sold an IL-1 α blocking True Human™ antibody, which it had used successfully in a number of clinical trials, for \$750 million in upfront cash and up to \$600 million in potential milestone payments. As part of the sale, XBiotech agreed not to develop or market anti-IL-1 α antibody treatments for dermatological diseases. However, the Company retained the right to pursue the discovery and development of new True Human™ antibodies targeting IL-1 α for areas of medicine outside of dermatology.

The Company believes that the potential unmet medical need for blocking inflammation through neutralizing IL-1 α is unprecedented. IL-1 α is produced naturally by the body and is present on cells such as platelets or white blood cells and can be released from dead or injured cells. When not properly controlled, or in situations of traumatic or sustained injury, inflammation caused by IL-1 α is believed to contribute to the progression of serious illnesses. IL-1 α is believed to play a role in stroke, heart attack, cancer and rheumatological diseases, among others. Clinical studies conducted by XBiotech and a myriad of scientific research have shown that blocking IL-1 α may have a beneficial effect in numerous medical conditions.

With the discovery, the Company is on schedule to reenter the clinic with a new anti-IL-1 α therapy in 2021. Since there is such vast potential for anti-IL-1 α therapy in multiple areas of medicine, the Company believes there is the opportunity to develop more than one True Human™ antibody, each specialized for specific areas of medicine. This strategy will potentially allow XBiotech to maximize value and exclusivity for its True Human™ anti-IL-1 α antibodies for various unique medical areas. The Company expects this will diversify risk for its anti-IL-1 α therapies, allow for multiple potential collaborations, and facilitate greater resource dedication to each True Human™ anti-inflammatory therapeutic.

John Simard, XBiotech's President & CEO, stated, "We are elated to be able to so quickly advance a new True Human anti-IL-1 α antibody into commercialization. I am very proud of the extraordinary efforts the XBiotech team continues to make to advance our important programs in this extremely difficult environment. There can be no better organization utilizing as good a technological approach or medical target than what we are witnessing here at XBiotech, and the True Human antibody program to target IL-1 α mediated inflammation."

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 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.

On December 30, 2019 XBiotech sold an IL-1 α blocking True Human™ antibody that had been used successfully in a number of clinical trials. The sale of the antibody generated \$750 million in upfront cash and up to \$600 million in potential milestone payments. The Company retained the right to pursue the development of True Human™ antibodies targeting IL- α for all areas of medicine outside of dermatology. While the Company previously was focused on a single True Human™ antibody targeting IL- α , it now plans to develop multiple product candidates, which will target IL-1 α in specific areas of medicine.

In addition to recent sale of its anti-IL-1 α antibody, XBiotech now has other revenue sources. Commencing January 1, 2020 XBiotech began using its proprietary manufacturing technology to produce clinical drug product for a major Pharmaceutical Company under a two year supply agreement. In addition, XBiotech is providing clinical trial contract research operations to conduct two large, double-blind placebo controlled Phase II clinical studies. The financial strength generated from the sale and contract operations is enabling XBiotech to expand both its anti-IL-1 α product development and infectious disease programs.

To accelerate advance of the Company's pipeline, the Company is expanding its existing manufacturing and research center, and planning to build an additional 30,000ft² infectious disease research & development center on its 48-acre property in Austin, TX which is wholly owned by the Company. The expansion and new building will be in addition to the present custom-built 33,000ft² combined manufacturing and R&D facility that currently exists on the campus. XBiotech owns the 48-acre campus—and all structures on the property—debt-free and envisions further expansion of facilities. For more information, visit www.xbiotech.com.

About True Human™ Therapeutic Antibodies

XBiotech's True Human™ antibodies are the only available antibodies derived without modification from humans who possess natural immunity to certain diseases. (Unlike all commercially available antibodies, which are called "Humanized" or "Fully Human," XBiotech's True Human™ antibodies are directly sourced from the natural human immune response for specific diseases without modification.) XBiotech's True Human™ antibodies have the potential to harness the body's natural immunity to fight disease with unprecedented safety, efficacy, and tolerability.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements, including declarations regarding management's beliefs and expectations, including with respect to XBiotech's strategic ambitions, regarding the expected timing of closing of the transaction with Janssen, filings and approvals relating to the transaction, the amount and timing of potential future milestone payments by Janssen, the mechanism of action and potential safety and efficacy of bermekimab, the anticipated timing of clinical studies with bermekimab, the progression and results of such studies, statements regarding the regulatory pathway for bermekimab and the timing of regulatory filings, and statements regarding any capital allocation decisions, including as to potential share repurchases. 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

Ashley Otero

aotero@xbiotech.com

512-386-2930



Source: XBiotech Inc.