

# XBiotech-Developed COVID-19 Test Supports Convalescent Blood Treatments Now Approved Under FDA Emergency Use Authorization

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## FDA has Authorized Use of Antibody-Rich COVID-19 Therapy Derived from Convalescent Patients

### Under Collaboration BioBridge Global Will Be Using XBiotech's COVID-19 Antibody Test to Identify the Convalescent Blood Products

AUSTIN, Texas, Aug. 24, 2020 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ: XBIT) announced today that the U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for COVID-19 Convalescent Plasma (CCP) as a COVID-19 treatment, opening the door for XBiotech's antibody screening technology used to identify CCP. XBiotech collaborated with BioBridge Global to develop a test to accurately detect human antibodies present in patient blood that specifically attack the COVID-19 virus. BioBridge Global, which provides blood products to hospitals through its subsidiary, the South Texas Blood & Tissue Center, is using XBiotech's test to identify human bloods from patients that have recovered from COVID-19—so called convalescent plasma. BioBridge utilizes the convalescent plasma to produce naturally immune blood products as treatment for patients hospitalized with the virus.

While XBiotech's testing technology will be used as the first step in the production of anti-COVID-19 convalescent blood products, XBiotech has also used the convalescent blood samples supplied by BioBridge to identify the precise genetic information present in individuals producing these natural antibodies against COVID-19. The Company recently announced it had in fact successfully discovered candidate True Human therapeutic antibodies based on this effort.

The decision by the FDA to approve use of convalescent plasma (or blood with natural anti-COVD-19 antibodies from patients that recovered from the infection) comes from the Agency's extensive review of scientific data developed over the past several months. These preliminary findings show that convalescent plasma is safe and effective in treating COVID-19, such that a 35% better survival rate has been observed in patients 30 days after receiving plasma treatment. Furthermore, there have been approximately 70,000 patients treated to date with no concerning safety signals.

This data strongly supports XBiotech's approach and technology for identifying therapeutic antibodies—which it does for a variety of diseases—from convalescent blood. By identifying and manufacturing the actual antibodies from convalescent patients, the Company is able to produce candidate drug products with highly concentrated purified antibody. This approach allows the Company to harness the body's immune response to the virus and make targeted therapies that could potentially be safe and effective.

### 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 $\alpha$  blocking True Human<sup>TM</sup> 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<sup>TM</sup> antibodies targeting IL- $\alpha$  for all areas of medicine outside of dermatology. While the Company previously was focused on a single True Human<sup>TM</sup> antibody targeting IL-1 $\alpha$ , it now plans to develop multiple product candidates, which will target IL-1 $\alpha$  in specific areas of medicine.

In addition to recent sale of its anti-IL-1α 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-1α 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 30,000ft<sup>2</sup> 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 33,000ft<sup>2</sup> 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 <u>www.xbiotech.com</u>.

#### About True Human<sup>™</sup> Therapeutic Antibodies

XBiotech's True Human<sup>™</sup> 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<sup>™</sup> 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.

# About BioBridge Global

BioBridge Global is a San Antonio-based 501(c)(3) nonprofit corporation that offers diverse services through its subsidiaries – the South Texas Blood & Tissue Center, QualTex Laboratories, GenCure and The Blood & Tissue Center Foundation. BBG provides products and services in blood resource

management, cellular therapy, donated umbilical cord blood and human tissue as well as testing of blood, plasma and tissue products for clients in the United States and worldwide. BBG is committed to saving and enhancing lives through the healing power of human cells and tissue. It enables advances in the field of regenerative medicine by providing access to human cells and tissue, testing services and biomanufacturing and clinical trials support. Learn more at <u>BioBridgeGlobal.org</u>.

# **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 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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Source: XBiotech Inc.