XBiotech Announces Cerebrovascular Medical Advisory Board & Development of New Stroke Therapy

Jan 19, 2021

Appointments Include: Chair, Clay Johnston, M.D., Ph.D. as well as Members Greg Albers, M.D. and Brett Cucchiara, M.D.

AUSTIN, Texas, Jan. 19, 2021 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ: XBIT) announced today the first meeting of its Cerebrovascular Medical Advisory Board (CMAB). The CMAB is comprised of key opinion leaders who specialize in cerebrovascular diseases including ischemic stroke, which is the third leading cause of death and second leading cause of disability in the world. The CMAB is chaired by Clay Johnston, M.D., Ph.D., Dean of Dell Medical School, Vice President for Medical Affairs, University of Texas, Austin. Members of the board include Greg Albers, M.D., Director of Stanford University Stroke Center, and Brett Cucchiara, M.D., Director of the Neurovascular Ultrasound Laboratory at the University of Pennsylvania.

The CMAB is providing expert Medical and Clinical guidance for XBiotech's new candidate neuroprotectant, anti-inflammatory True Human™ antibody therapy to treat stroke. Dr. Clay Johnston commented, "While we have done a great job in increasing reperfusion after stroke, we have failed to address the downstream injury that nearly always occurs. Inflammation is a key part of that injury and blocking IL-1α has real potential in further improving outcomes for patients. Once again, I'm excited about the potential for a neuroprotective agent."

Together with the CMAB, the Company believes it has the potential to provide groundbreaking antibody therapies to patients that will help reduce the impact of strokes and improve recovery of stroke victims. Currently, no neuroprotectant treatment has been approved for the damaging effects of reperfusion injury, representing an extraordinary unmet medical need.

John Simard, President and CEO of XBiotech, commented, "I am indeed honored to have the support of such distinguished medical experts assisting XBiotech in developing a True Human antibody which we believe has unprecedented potential as a neuroprotectant for patients who experience ischemic strokes. We plan to expedite clinical development of this unique new drug."

XBiotech's Cerebrovascular Medical Advisory Board Includes:

- Clay Johnston M.D., Ph.D. currently serves as the inaugural dean of Dell Medical School at the University of Texas in Austin. As a neurologist specializing in stroke care and research, he has published extensively in the prevention and treatment of stroke and transient ischemic attack. He has led several large cohort studies and three international multi-center randomized trials. Dr. Johnston is a graduate of Amherst College and Harvard Medical School. He later received his Ph.D. in epidemiology from the University of California, Berkeley, and was a resident in Neurology at UCSF, where he trained in Vascular Neurology. Dr. Johnston has received national accolades for his research and was elected to the National Academy of Medicine in 2019.

- Greg W. Albers, M.D. is a stroke and vascular neurologist and currently serves as the Director of the Stanford Stroke Center at Stanford Medical Center. Dr. Albers is a Coyote Foundation Professor and a Professor, by courtesy, of Neurosurgery and Neurological Sciences at Stanford University. Dr. Albers' primary research focus is the diagnosis, management, and prevention of ischemic stroke. A prolific and distinguished researcher, he has authored more than 450 articles on topics related to cerebrovascular disease in peer-reviewed journals.

- Brett L. Cucchiara M.D. is a Professor of Neurology and serves as the Director of the Neurovascular Ultrasound Laboratory at the University of Pennsylvania. He specializes in cerebrovascular disease and has extensive experience in stroke clinical trials and biomarker research. Dr. Cucchiara is a member of the American Board of Psychiatry and Neurology.

Brain reperfusion, or opening of the clogged artery, is the cornerstone of emergency treatment for ischemic stroke. However, opening of a clogged artery is associated with a rapid induction of inflammation where the returning blood supply downstream of the clogged artery begins to recirculate in the brain. The brain injury inflicted by the inflammation can be devastating. There is presently no approved drug to reduce injury from reperfusion. XBiotech previously announced a publication, in animal models of stroke, which described a significant reduction in brain injury when an IL-1α neutralizing antibody was used to inhibit inflammation

prior to unblocking of the clogged artery.

On December 30, 2019, XBiotech sold a True Human™ anti-inflammatory antibody in a $1.35 billion transaction. The Company has since worked vigorously to bring a new line of True Human™ anti-inflammatory therapies to the clinic in 2021. XBiotech is now developing a novel True Human™ antibody therapy that neutralizes interleukin-1 alpha (IL-1α) as a neuroprotectant. IL-1α is a trigger in the onset of inflammation. When inflammation is deregulated, or in situations of acute injury, such as that which occurs after reperfusion (the resumption of blood flow after unblocking of an artery), IL-1α enhances the inflammation that leads to worsening of the injury.

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-1α 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-1α for all areas of medicine outside of dermatology. While the Company previously was focused on a single True Human™ antibody targeting IL-1α, it now plans to develop multiple product candidates, which will target IL-1α 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^2 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^2 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, and thereby have not been shown to cause immunogenicity.) 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.

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.

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Next Generation Antibody Therapy

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