XBiotech to Launch Novel Candidate Therapy for Stroke

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Company Commencing Phase I/II Study to Test Safety and Efficacy of its New Drug Candidate to Reduce Brain Injury After Stroke

AUSTIN, Texas, Oct. 28, 2021 (GLOBE NEWSWIRE) -- XBiotech (NASDAQ: XBIT) announced today its plan to commence a randomized, placebo-controlled clinical study to test its new True Human™ antibody therapy for reducing brain injury after stroke. The study will be conducted across the United States at leading medical centers that provide advanced stroke care. During a stroke, endovascular catheters and clot-busting drugs may be used in emergency care to unblock an artery and return blood supply to the brain. However, when the artery is re-opened and blood supply returns to the oxygen starved region of the brain, further irreparable damage to brain tissue often ensues. There are no drugs approved for the treatment of this phenomena— known as ischemia-reperfusion injury—which is believed to be the result of inflammation. Ischemia reperfusion injury can result in debilitating brain injury or death. XBiotech's new candidate therapy is intended to reduce brain injury that occurs due to ischemia and reperfusion injury.

Dr. Greg Albers, Director of the Stanford Stroke Center, at Stanford Medical Center, commented "We have the technology to successfully open the clogged artery in many patients that suffer a stroke. However, we are unable to stop the damaging effects of inflammation that occurs after the clog has been displaced. A pharmacological treatment to reduce damage to the brain would represent a breakthrough in neurology."

Stroke is the leading cause of death and disability in the world today—and the prevalence of stroke is increasing. Each year about 692,000 people in the US have a stroke as a result of a blockage of an artery that supplies blood to the brain. On a world-wide basis, about 13 million people suffer a stroke each year and about 5.5 million people die.

Medical technology and drugs have been developed to open stroke-causing clogged arteries in the brain. However, even after the opening of a clogged artery, the volume of brain tissue damaged by the stroke continues to increase. The increasing injury to the brain that occurs after the opening of the clogged artery is believed to be a result of inflammation. When areas of the brain are deprived of oxygen (hypoxia), blood vessels and brain cells are piqued to recruit the body's injury fighting white blood cells. However, the onslaught of white blood cells with reperfusion can cause destruction of hypoxic, but otherwise viable, brain tissue. There is no therapy available to reduce brain injury that occurs due to hypoxia-related inflammation. XBiotech's candidate therapy precisely targets the inflammation process that is believed to result in stroke-related brain injury.

To test its drug candidate, the current clinical study will involve an innovative measure that employs cutting-edge imaging technology and a novel objective assessment of treatment response. Conventional clinical measures, such as modified Rankin Scale, will also be used to assess patient outcomes. The study design was developed by XBiotech in collaboration with a steering committee Chaired by leading Neurologists Dr. Greg Albers, Director, Stanford Stroke Center, Stanford Medical Center, Dr. Brett Cucchiara, Professor of Neurology and Director of Neurovascular Ultrasound Laboratory, University of Pennsylvania Hospital and Dr. Clay Johnston, former Dean of Dell Medical School, University of Texas.

XBiotech's CEO John Simard commented "With stroke being the world's leading cause of death and morbidity, there is no more important use for harnessing the body's natural immunity than in reducing the brain-damaging effects of inflammation in stroke. This novel drug candidate is the product of a remarkable group of researchers and technicians at XBiotech who work tirelessly to discover potentially revolutionizing medicines. The clinical realization would not be possible without the selfless effort of a group of extraordinary physicians, including Dr. Greg Albers, that have helped design this unique clinical study. We will work tirelessly to see that this program realizes all its potential to bring new hope to patients suffering from stroke".

About True Human™ Therapeutic Antibodies
XBiotech's True Human™ antibodies are derived without modification from individuals who possess natural immunity to certain diseases. 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.

About XBiotech
XBiotech is a fully integrated global biosciences company dedicated to pioneering the discovery, development and commercialization of therapeutic antibodies based on its True Human™ proprietary technology. XBiotech is currently advancing a robust pipeline of antibody therapies to redefine the standards of care in oncology, inflammatory and infectious diseases. Headquartered in Austin, Texas, XBiotech has also developed innovative biotech manufacturing technology designed to produce its True Human Antibodies rapidly and cost-effectively. For more information, visit www.xbiotech.com.

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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