XBiotech Announces First Subject Enrollment in Phase I Clinical Trial for Hutrukin, a Novel Candidate Therapy for Stroke

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Hutrukin, A Therapy Discovered and Manufactured at XBiotech, Is Aimed to Reduce Brain Injury after Stroke

AUSTIN, Texas, April 17, 2023 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ: XBIT) has enrolled the first subject in a randomized, open-label, placebo-controlled dose escalation clinical study to evaluate safety and pharmacokinetics of Hutrukin.

Hutrukin is being developed as a novel treatment to reduce brain injury following ischemic stroke. There are more than 10 million ischemic strokes each year—the leading cause of death and morbidity in the world today. An ischemic stroke occurs when a blood clot forms in a blood vessel that supplies blood flow to brain. Blockage of blood flow to the brain results in brain injury, loss of brain function or death.

Emergency use of “clot-busting” drugs or mechanical catheters to re-open arteries after a stroke is associated with a phenomenon known as *reperfusion injury*. Reperfusion injury is where the return of blood supply after removing the clot from the artery results in increased brain injury or death. Reperfusion injury is believed to be the result of a massive inflammatory response caused by blood cells as they flow back into the region of the brain that was deprived of blood supply (and oxygen).

Hutrukin therapy is intended to be provided immediately prior to the clot-busting procedure, where the drug may reduce inflammatory injury associated with reperfusion. There is currently no drug known to be effective to reduce reperfusion injury. Hutrukin could, therefore, potentially represent a significant advance in the management of stroke patients.

The current Phase I study will evaluate three dose levels of Hutrukin for safety and will measure the corresponding blood levels of Hutrukin with increasing doses. Findings will guide dosing and safety expectations for the next phase of studies.

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 currently is advancing a robust pipeline of antibody therapies to redefine the standards of care in oncology, inflammatory conditions and infectious diseases. Headquartered in Austin, Texas, XBiotech also is leading the development of innovative biotech manufacturing technologies designed to more rapidly, cost-effectively and flexibly produce new therapies urgently needed by patients worldwide. 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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