



XBiotech Announces Enrollment Completion of Phase I Clinical Trial for Hutrukin, a Novel Candidate Therapy for Stroke

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AUSTIN, Texas, Sept. 26, 2023 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ: XBIT) Announces that Hutrukin is being developed by XBiotech as a breakthrough therapy to reduce brain injury after stroke. The last subject in a randomized, open-label, placebo-controlled Phase I dose escalation clinical study has been enrolled. XBiotech discovered, manufactures, and is conducting this clinical study of Hutrukin.

The primary objective of the Phase I study is to evaluate safety and pharmacokinetics of Hutrukin in healthy volunteers. Sequential dose escalation was conducted using three cohorts of subjects, each receiving a single intravenous infusion of either placebo or Hutrukin, with eight subjects in each cohort.

Hutrukin is a candidate drug being developed to reduce brain injury following ischemic stroke. Globally, one in four people over age 25 will experience a stroke—the leading cause of disability and second leading cause of death in the world. An ischemic stroke occurs when a blood clot obstructs a blood vessel that supplies the blood to the brain. Blockage of blood flow to the brain results in brain injury, loss of brain function, or death.

Emergency treatment for stroke includes “clot-busting” drugs or mechanical catheters to re-open arteries, both of which are associated with a phenomenon known as *reperfusion injury*. Reperfusion injury is the damage that occurs to previously healthy brain tissue after a clot is removed from the artery and blood supply is returned to the healthy but hypoxic brain tissue. This secondary damage is believed to be the result of an inflammatory response resulting from the return of blood cells to the region of the brain that had been previously deprived of blood and oxygen (which is the hypoxic brain tissue).

When administered immediately prior to artery-opening procedures, Hutrukin may reduce the inflammatory injuries associated with reperfusion. No drug or treatment is currently available to reduce or prevent reperfusion injury. Hutrukin potentially represents a unique and major advance for stroke victims.

About True Human™ Therapeutic Antibodies

XBiotech's True Human™ antibodies are derived without modification from individuals who possess natural immunity to certain diseases. By harnessing the body's natural immunity to cure disease, True Human™ antibodies have the potential to revolutionize medicine.

About XBiotech

XBiotech is dedicated to pioneering the development of breakthrough therapies derived from natural human immunity. XBiotech discovered genetic engineering tools that enabled identification of rare antibodies present in human donor blood, and has built a pipeline of antibody therapies, including a candidate therapy that could revolutionize arthritis treatment. Headquartered in Austin, Texas, XBiotech has also lead innovation in biomanufacturing technology. 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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