Serpin Pharma, Inc. Announces Approval to Initiate EASE AKI Phase II Clinical Trial in Germany

MANASSAS, VA, UNITED STATES, February 16, 2026 /EINPresswire.com/ -- Serpin Pharma, Inc., a clinical stage biopharmaceutical company developing first in class LRP1 agonist therapeutics, today announced that its Phase II clinical trial, EASE-AKI, has received unconditional approval to begin enrolling patients in Germany. The study will evaluate SP16, a powerful yet well-tolerated anti-inflammatory peptide, designed to protect the kidneys of patients with chronic kidney disease who are undergoing elective cardiac bypass surgery.

> “SP16, as a novel, possesses the potential to resolve inflammation and serve as a therapeutic agent capable of safeguarding vulnerable patients during high-risk medical procedures.”
>
> *Prof. Mario Schiffer*

The EASE AKI trial is a prospective, randomized, double blind, placebo controlled study enrolling 120 patients undergoing heart bypass surgery. The trial aims to determine whether perioperative administration of SP16 can reduce the incidence and severity of acute kidney injury (AKI) - a sudden loss of kidney function that affects a significant proportion of cardiac surgery patients, especially those with pre-existing chronic kidney disease.

This milestone is being advanced in collaboration with two esteemed nephrology leaders at University Hospital Erlangen, Dr. Mario Schiffer and Dr. Tilman Jobst Schwan, who will serve as principal investigators for the study.

“AKI after cardiac surgery remains a major unmet medical need with no approved pharmacologic therapy,” said Cohava Gelber, PhD, MBA-CEO and Chairperson of the Board of Serpin Pharma. “Receiving unconditional approval to initiate the EASE AKI trial underscores the strength of our clinical package and the promise of SP16 as a novel, inflammation resolving therapeutic capable of protecting vulnerable patients during high risk procedures.”

SP16 is a synthetic peptide designed to activate LRP1, a master regulator that helps the body shut down excessive inflammation and protect tissues from injury. By reducing inflammatory injury and preserving renal tubular integrity, SP16 has the potential to transform perioperative kidney care and reduce downstream complications, hospitalizations, and long term renal decline.

The EASE AKI trial builds on Serpin Pharma’s growing clinical portfolio, including ongoing studies in acute myocardial infarction, chronic inflammatory diseases, and cancer associated pain.
About Serpin Pharma, Inc.

Serpin Pharma is a clinical stage biopharmaceutical company developing first in class therapeutics that activate the LRP1 receptor to resolve inflammation, protect tissues, and prevent organ damage. The company’s lead molecule, SP16, is being evaluated across multiple high value indications including acute kidney injury, acute myocardial infarction, chronic kidney disease, chronic heart failure, and cancer associated pain. Serpin Pharma is headquartered in Manassas, Virginia.

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