ZyVersa Therapeutics Announces First Clinical Site Activation, Initiating Patient Recruitment for Cholesterol Efflux Mediator™ VAR 200's Phase 2a Clinical Trial in Patients with Diabetic Kidney Disease (DKD)

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- Initiation of patient recruitment marks a key milestone in the development of VAR 200, a potential first-in-class treatment for kidney disease addressing renal lipotoxicity.
- There are no available drugs targeting renal lipotoxicity that damages the kidneys' filtration system, causing protein leakage into the urine (proteinuria) and disease progression.
- VAR 200, designed to alleviate renal lipid accumulation, has preclinical data in three types of kidney disease (DKD, Focal Segmental Glomerulosclerosis, Alport Syndrome) demonstrating reduced levels of cholesterol and lipids, protection against renal injury and fibrosis, and improvement in proteinuria.
- This Phase 2a study will provide the first proof-of-concept in patients with kidney disease. Preliminary data is expected in H2-2025, with final results in H2-2026.

WESTON, Fla., June 26, 2025 (GLOBE NEWSWIRE) -- ZyVersa Therapeutics, Inc. (Nasdaq: ZVSA; "ZyVersa"), a clinical stage specialty biopharmaceutical company developing first-in-class drugs for treatment of patients with renal and inflammatory diseases who have unmet medical needs, announces that the Clinical Advancement Center, PLLC in San Antonio, Texas is the first clinical site activated and ready for patient recruitment in our VAR 200 Phase 2a clinical study in patients with DKD. The lead investigator is Pablo Pergola, MD, PhD.

"We are pleased to work with Dr. Pergola and his research colleagues at the Clinical Advancement Center to kick off our first-in-human VAR 200 Phase 2a trial in patients with DKD. We share a similar vision to that of Dr. Pergola and the Clinical Advancement Center – to develop innovative treatments that will change the course of kidney disease and improve patients' quality of life," said Stephen C. Glover, ZyVersa's Co-founder, Chairman, CEO, and President. "It is this vision that led us to develop a drug, VAR 200, that targets a neglected pathogenic pathway in kidney disease – excess accumulation of cholesterol and lipids in the glomerulus, the main filtering unit of the kidney. There is a large body of evidence demonstrating the critical need for therapies to address kidney lipotoxicity, a key pathway in development and progression of DKD and other kidney diseases. Despite newer treatment options for kidney disease, over 130,000 patients progress to renal failure each year in the US, and more than 800,000 patients are living with renal failure requiring dialysis or transplant to sustain life. We believe that adding VAR 200 to standard-of-care drugs, like ACEs, ARBs, and SGLT2 inhibitors that address other pathogenic pathways, will be disease-modifying and better protect against further kidney injury and disease progression. We look forward to seeing the results of this Phase 2a trial, and to progressing VAR 200 to commercialization."

VAR 200's proof-of-concept Phase 2a study will be conducted at one to two US sites and will enroll an adequate number of subjects to complete eight. It is a 16-week open-label study (12 weeks of treatment and a four-week follow-up period) to evaluate the drug's efficacy and safety in patients with type 2 diabetes and diabetic kidney disease with proteinuria. VAR 200 will be administered intravenously twice weekly at a single dose and will be added to the stable drug regimen used by each patient. The primary efficacy endpoint is percent change from baseline to week 12 in urinary albumin to creatinine ratio. Further details can be found at clinicaltrials.gov.

ABOUT CHOLESTEROL EFFLUX MEDIATOR™VAR 200

Cholesterol Efflux Mediator™ VAR 200 (2-hydroxypropyl-beta-cyclodextrin, 2HPβCD) is an injectable drug in phase 2 development to ameliorate renal lipid accumulation that damages the kidneys' filtration system, leading to development and progression of kidney disease. VAR 200 removes excess lipids from the kidney both passively, and actively by upregulation of cholesterol efflux transporters, ABCA1 and ABCG.

Preclinical studies with VAR 200 in animal models of FSGS, Alport syndrome, and diabetic kidney disease demonstrate reduced levels of cholesterol and lipids, protection against renal injury and fibrosis, and improvement in proteinuria. Additional information can be found in the VAR 200 White Paper.

The lead indication for VAR 200 is orphan kidney disease, focal segmental glomerulosclerosis (FSGS). Prior to initiating a Phase 2a trial in patients with FSGS, we are conducting a small Phase 2a trial in patients with diabetic kidney disease, which we expect will provide patient proof-of-concept more quickly than an FSGS study. Alport Syndrome and diabetic kidney disease indications may be pursued based on our indication expansion strategy.

ABOUT ZYVERSA THERAPEUTICS, INC.

ZyVersa (Nasdaq: ZVSA) is a clinical stage specialty biopharmaceutical company leveraging advanced, proprietary technologies to develop first-in-class drugs for patients with renal and inflammatory diseases who have significant unmet medical needs. The Company is currently advancing a therapeutic development pipeline with multiple programs built around its two proprietary technologies – Cholesterol Efflux Mediator™ VAR 200 for treatment of kidney diseases, and Inflammasome ASC Inhibitor IC 100, targeting damaging inflammation associated with numerous CNS and peripheral inflammatory diseases. For more information, please visit www.zyversa.com.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Certain statements contained in this press release regarding matters that are not historical facts, are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995. These include statements regarding management's intentions, plans, beliefs, expectations, or forecasts for the future, and, therefore, you are cautioned not to place undue reliance on them. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. ZyVersa Therapeutics, Inc. ("ZyVersa") uses words such as "anticipates," "believes," "plans," "expects," "projects," "future," "intends," "may," "will," "should," "could," "estimates," "predicts," "potential," "continue," "guidance," and similar expressions to identify these forward-looking statements that are intended to be covered by the safe-harbor provisions. Such forward-looking statements are based on ZyVersa's expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the statements due to a number of factors, including ZyVersa's plans to develop and commercialize its product candidates, the timing of initiation of ZyVersa's planned preclinical and clinical trials; the timing of the availability of data from ZyVersa's preclinical and clinical trials; the timing of any planned investigational new drug application or new drug application; ZyVersa's plans to research, develop, and commercialize its current and future product candidates; the clinical utility, potential benefits and market acceptance of ZyVersa's product candidates; ZyVersa's commercialization, marketing and manufacturing capabilities and strategy; ZyVersa's ability to protect its intellectual property position; and ZyVersa's estimates regarding future revenue, expenses, capital requirements and need for additional financing.

New factors emerge from time-to-time, and it is not possible for ZyVersa to predict all such factors, nor can ZyVersa assess the impact of each such factor on the business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Forward-looking statements included in this press release are based on information available to ZyVersa as of the date of this press release. ZyVersa disclaims any obligation to update such forward-looking statements to reflect events or circumstances after the date of this press release, except as required by applicable law.

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