



ZyVersa Therapeutics Supports FDA-Authorized Emergency Compassionate Use of Cholesterol Efflux Mediator™ VAR 200 in a Patient with ApoCII Amyloidosis

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- ApoCII amyloidosis, resulting from abnormal organ deposition of toxic fibrillar amyloid proteins, is an ultra-rare condition that mostly affects the kidneys and manifests with protein spillage into the urine (proteinuria) and chronic kidney disease.
- Despite being treated with standard-of-care renal drug therapy (ACEi, SGLT2, statin, and ezetimibe), the patient authorized by FDA to receive VAR 200 is showing continued kidney disease progression. Because her kidney biopsy demonstrated lipid deposition, the treating physician, Dr. Alessia Fornoni, hypothesized that VAR 200 has potential to alleviate lipid accumulation, proteinuria, and disease progression. This is based on VAR 200's consistent results across preclinical studies in three different models of kidney disease, and supporting HPβCD clinical data in patients with lysosomal storage and protein deposition disorders, such as Niemann-Pick disease type C.
- VAR 200, currently in a phase 2a clinical trial for diabetic kidney disease (DKD), was designed to passively and actively reduce renal lipid accumulation to protect against renal injury and fibrosis and improve kidney function.

WESTON, Fla., July 08, 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, is pleased to provide regulatory and product support for FDA-authorized *Emergency Compassionate Use* of Cholesterol Efflux Mediator™ VAR 200 in a patient with ApoCII amyloidosis. *Emergency Compassionate Use*, also called *Emergency Expanded Access*, is a pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational drug for treatment outside of clinical trials when enrollment criteria are not met or there are no comparable or satisfactory alternative therapy options.

The patient with ApoCII amyloidosis will receive treatment at the University of Miami Peggy and Harold Katz Family Drug Discovery Center under the care of the Center Director, Dr. Alessia Fornoni, Professor of Medicine, University of Miami Miller School of Medicine, and VAR 200 inventor. VAR 200 treatment and monitoring will follow the protocol of the ongoing DKD clinical trial, VAR200-0301 ([ClinicalTrials.gov ID: NCT06489340](https://clinicaltrials.gov/ct2/show/study/NCT06489340)).

"We are at a time where Precision Medicine offers new tools to endophenotype patients and to identify the molecular signature that allows us to match the right patient to the right drug. The evidence of lipotoxic glomerular injury in this patient is what prompted me to request emergency compassionate use. I am very excited about the opportunity to test the efficacy of VAR 200 for this new indication, as I believe experimental treatment cases like this one will drive further clinical development for other patients as well," stated Dr. Fornoni.

"We are proud to support Dr. Fornoni's *Emergency Compassionate Use* of VAR 200 in her patient with ApoCII amyloidosis who currently has no other effective treatment options. We are hopeful that VAR 200 will help to improve the course of her disease and quality of life," said Stephen C. Glover, ZyVersa's Co-founder, Chairman, CEO, and President. "We look forward to learning the effects of VAR 200 on proteinuria in this patient with ApoCII amyloidosis, which in combination with the data from our Phase 2a DKD trial, will support the design of our ongoing VAR 200 clinical development program."

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. This press release does not constitute an offer to sell, or the solicitation of an offer to buy, any securities.

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