ZyVersa Therapeutics Announces IRB Approval of Phase 2a Clinical Trial Protocol to Evaluate Cholesterol Efflux Mediator™ VAR 200 in Patients with Diabetic Kidney Disease

Mar 18, 2024

- *Phase 2a trial is on track to begin in the first half of 2024.*
- *Cholesterol Efflux Mediator™ VAR 200 is in development to ameliorate renal lipid accumulation that damages the kidneys' filtration system, leading to chronic kidney disease and its progression.*

WESTON, Fla., March 18, 2024 (GLOBE NEWSWIRE) -- ZyVersa Therapeutics, Inc. (Nasdaq: ZVSA, or "ZyVersa"), a clinical stage specialty biopharmaceutical company developing first-in-class drugs for the treatment of renal and inflammatory diseases with high unmet medical needs, announces Institutional Review Board (IRB) approval of the Phase 2a clinical trial protocol to evaluate the efficacy and safety of Cholesterol Efflux Mediator VAR 200 in patients with diabetic kidney disease. The clinical trial is on track to begin in the first half of 2024.

Initiation of this clinical trial is a key milestone for ZyVersa. It is the first in human trial for VAR 200 intended to substantiate that the promising preclinical results demonstrated in three different animal models of kidney disease (diabetic kidney disease, focal segmental glomerulosclerosis, and Alport syndrome) translate to patients with kidney disease. The preclinical data demonstrated across all three kidney disease models that VAR 200:

- Reduced cholesterol and lipid levels in the kidneys' filtration system.
- Protected against kidney injury and fibrosis.
- Significantly reduced protein in the urine (proteinuria).

For more information about VAR 200, Click Here.

"A large body of evidence reinforces the importance of addressing kidney accumulation of cholesterol and lipids to help attenuate progression of chronic kidney disease, which affects over 35 million adults in the United States," commented Stephen C. Glover, ZyVersa's Co-founder, Chairman, CEO, and President. "Currently, over 130,000 patients with kidney disease progress to renal failure each year, and more than 800,000 patients are living with renal failure requiring dialysis or transplant to sustain life. We are excited about the potential of Cholesterol Efflux Mediator™ VAR 200 to protect against kidney injury and reduce kidney disease progression."

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.

Corporate, Media, and IR Contact:
Karen Cashmere
Chief Commercial Officer
kcashmere@zyversa.com
786-251-9641