



ZyVersa Therapeutics Highlights Lipidomic Data in Alport Syndrome and DKD Reinforcing the Need for Drugs to Attenuate Damaging Renal Lipid Accumulation to Mitigate Disease Progression

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- ZyVersa is developing Cholesterol Efflux Mediator™ VAR 200 to mediate removal of damaging excess cholesterol and other lipids from the kidneys' filtration system. VAR 200 directly removes lipids from kidney cells, and it upregulates cholesterol transporters, ABCA1 and ABCG1 for active removal.
- By removing excess renal lipids, VAR 200 is expected to attenuate other pathways that are key contributors to renal disease – inflammation, fibrosis, oxidative and endoplasmic reticulum stress. This is based on a VAR 200 preclinical study in Alport syndrome [[Mitrofanova. Kidney International, Volume 94, Issue 6, 1151-1159](#)], and a publication by Kanbay et al. [[Kanbay. Eur J Clin Invest. 2022 June; 52\(6\)](#)].
- A VAR 200 phase 2a clinical proof-of-concept trial in patients with diabetic kidney disease (DKD) has been initiated and patient screening is underway. Preliminary data are anticipated in Q4-2025. Future studies are planned for patients with rare kidney diseases, focal segmental glomerulosclerosis (FSGS), VAR 200's lead indication, and Alport Syndrome.
- The global drug market for kidney diseases was \$18 Billion in 2024, with \$30 Billion projected by 2034 (Precedence Research).

WESTON, Fla., Sept. 03, 2025 (GLOBE NEWSWIRE) -- ZyVersa Therapeutics, Inc. (OTCQB: 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, highlights key data from a recently published study, [Lipidomics Unveils Critical Lipid Pathway Shifts in Alport Syndrome](#), designed to elucidate how disrupted lipid metabolism contributes to lipotoxicity and progressive kidney damage in AS. To contextualize the lipidomic alterations observed in AS, a comparator group of patients with diabetic kidney disease (DKD) was included since lipotoxicity in this population has been extensively characterized and recognized as a central driver of podocyte injury and chronic kidney damage.

The researchers found that although both AS and DKD share lipotoxicity as a core mechanism, there were some distinct lipid alterations in AS when compared with DKD reflecting differences in metabolic pathways. AS demonstrated more pronounced changes in the lipid classes evaluated, indicating increased cellular stress. Lipid alterations in both AS and DKD were intricately linked to impaired ABCA1 lipid transport out of kidney cells (efflux) and the underlying renal injury processes of lipotoxicity, inflammation, and mitochondrial dysfunction. The study concluded that drugs that mediate renal lipid efflux to attenuate lipotoxicity have potential to mitigate renal disease progression.

"The relationship between lipotoxicity and kidney damage has been well established in chronic kidney diseases including AS, FSGS, and DKD. The authors of this paper expanded on this by identifying the specific lipid alterations that contribute to the lipotoxicity and kidney damage in AS in comparison to lipid alterations in DKD," commented Stephen C. Glover, ZyVersa's Co-founder, Chairman, CEO, and President. "Their data reinforce that impaired efflux of cholesterol and other lipids are key contributors to renal lipotoxicity, and the need for drug therapies, such as Cholesterol Efflux Mediator™ VAR 200, to restore lipid homeostasis and preserve kidney function. Currently, over 130,000 patients with kidney disease 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 are hopeful that attenuating lipotoxicity with Cholesterol Efflux Mediator™ VAR 200 can help to reduce these statistics and improve patients' quality of life. We are looking forward to the preliminary results from our Phase 2a VAR 200 clinical trial in patients with DKD around year's end."

ABOUT ZYVERSA THERAPEUTICS, INC.

ZyVersa (OTCQB: 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 various kidney diseases, and Inflammasome ASC Inhibitor IC 100, targeting damaging inflammation associated with numerous CNS and peripheral inflammatory diseases. FSGS is the lead indication for VAR 200, and obesity with cardiometabolic comorbidities is the lead indication for IC 100. 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, IR, and Media Contact

Karen Cashmere
Chief Commercial Officer
kcashmere@zyversa.com
786-251-9641