ZyVersa Therapeutics Announces Publication Demonstrating That Plasma Levels of NLRP3 Inflammasomes Correlate with Progression of Diabetic Kidney Disease in Patients with Type 2 Diabetes

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- *Diabetic kidney disease (DKD), which affects around 240 million people with Type 2 diabetes worldwide, is the leading cause of end-stage renal disease, which requires dialysis or kidney transplant for survival.*
- *The article published in Alternative Therapies demonstrates that plasma NLRP3 inflammasomes and their resulting proinflammatory cytokines are significantly elevated in early-stage DKD and that levels progressively increase as kidney function worsens, with highly significant elevations (p<0.01) at each stage of disease.*
    - *Data suggest that early DKD intervention with inflammasome inhibitors has potential to attenuate disease progression.*
- *ZyVersa is developing Inflammasome ASC Inhibitor IC 100, which inhibits multiple inflammasome pathways (including the inflammasome NLRP3 pathway) to attenuate initiation and perpetuation of damaging inflammation that is pathogenic in DKD and other inflammatory diseases.*

WESTON, Fla., Dec. 07, 2023 (GLOBE NEWSWIRE) -- ZyVersa Therapeutics, Inc. (Nasdaq: ZVSA, or "ZyVersa"), a clinical stage specialty biopharmaceutical company developing first-in-class drugs for treatment of renal and inflammatory diseases, announces publication of an article in the peer-reviewed journal, *Alternative Therapies,* demonstrating that plasma NLRP3 inflammasomes and their resulting proinflammatory cytokines are significantly elevated in early-stage DKD and that levels progressively increase as kidney function worsens.

In the paper titled, "Correlation Between Plasma NLRP3, IL-1β, and IL-18 and Diabetic Nephropathy in Patients With Type 2 Diabetes," the authors evaluated the plasma of 152 patients with type 2 diabetes and DKD stratified by stage of disease (stages 1-5) and 30 patients with type 2 diabetes without kidney disease who serve as controls. Following are key findings reported in the paper:

- Plasma levels of NLRP3 and proinflammatory cytokines, IL-1β, and IL-18, were significantly higher than controls in patients in each of the 5 stages of DKD, with progressively higher levels as kidney disease progressed (p<0.01).
- NLRP3, IL-1β, and IL-18 levels positively correlated with DKD stage (p= 0.01), based on the Spearman correlation analysis.
- These data are consistent with other studies demonstrating that inflammation has an important role in the development and progression of DKD.

To read the article, Click Here.

"The research published in *Alternative Therapies* reinforces the role of inflammasome-driven inflammation in development and progression of DKD, the leading cause of end-stage kidney disease, which requires dialysis or kidney transplant for survival," commented Stephen C. Glover, ZyVersa's Co-founder, Chairman, CEO and President. "Although substantial progress has been made in slowing progression of DKD with introduction of ACE inhibitors, ARBs, and most recently SGLT2 inhibitors, patients are still progressing to end-stage renal disease. The data published in *Alternative Therapies* suggest that early DKD intervention with inflammasome inhibitors has potential to help attenuate disease progression."

About Inflammasome ASC Inhibitor IC 100

IC 100 is a novel humanized IgG4 monoclonal antibody that inhibits the inflammasome adaptor protein ASC. IC 100 was designed to attenuate both initiation and perpetuation of the inflammatory response. It does so by binding to a specific region of the ASC component of multiple types of inflammasomes, including NLRP1, NLRP2, NLRP3, NLRC4, AIM2, Pyrin. Intracellularly, IC 100 binds to ASC monomers, inhibiting inflammasome formation, thereby blocking activation of IL-1β early in the inflammatory cascade. IC 100 also binds to ASC Specks, both intracellularly and extracellularly, further blocking activation of IL-1β and the perpetuation of the inflammatory response that is pathogenic in inflammatory diseases. Because active cytokines amplify adaptive immunity through various mechanisms, IC 100, by attenuating cytokine activation, also attenuates the adaptive immune response. To review a white paper summarizing the mechanism of action and preclinical data for IC 100, Click Here.

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 other 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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