ZyVersa Therapeutics Publishes New White Paper Detailing the Role of Inflammasomes and ASC Specks in Neurological Diseases, and Data Supporting Inflammasome ASC Inhibitor IC 100 as a Potential Therapeutic Option

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- *Neurological diseases, which affect up to 16 million people over 18 years old in the US, are the leading cause of physical and cognitive disability.*
- *A growing body of evidence supports that activation of more than one type of inflammasome contributes to development of common neurological diseases, and that extracellular ASC specks are involved in disease progression.*
- *The white paper summarizes the preclinical research of leading inflammasome experts, Drs. Robert W. Keane and Juan Pablo de Rivero Vaccari at University of Miami Miller School of Medicine, demonstrating that Inflammasome ASC Inhibitor IC 100 crosses the blood brain barrier, and that it displays strong pharmacologic and mechanistic proof-of-concept in a variety of neurological conditions.*

WESTON, Fla., Feb. 22, 2024 (GLOBE NEWSWIRE) -- ZyVersa Therapeutics, Inc. (Nasdaq: ZVSA; "ZyVersa"), a clinical stage specialty biopharmaceutical company developing first-in-class drugs for treatment of patients with inflammatory and renal diseases who have significant unmet medical needs, announces availability of a new white paper titled, "Inflammasome ASC Inhibitor IC 100, Promising Therapeutic Potential For Neurological Diseases." The white paper highlights data demonstrating that activation of more than one type of inflammasome and associated release of ASC specks leads to development and progression of common neurological diseases. The white paper then summarizes data from preclinical research led by Drs. Robert W. Keane and Juan Pablo de Rivero Vaccari at the University of Miami Miller School of Medicine demonstrating strong pharmacologic and mechanistic proof-of-concept for Inflammasome ASC Inhibitor IC 100 in animal models and tissue cultures representative of a variety of neurological conditions: multiple sclerosis, age-related inflammation, Alzheimer's disease, traumatic brain injury, and spinal cord injury. Drs. Keane, de Rivero Vaccari, and their colleagues currently have research underway in Parkinson's disease that was funded through a grant with the Michael J. Fox Foundation. To access a copy of the white paper, Click Here.

"We are excited about the potential of targeting multiple inflammasome pathways and ASC specks with Inflammasome ASC Inhibitor I00 to control the damaging inflammation contributing to neurological diseases that negatively impact the quality of life in millions of people," said Stephen C. Glover, Co-founder, Chairman, CEO, and President of ZyVersa. "We are nearing completion of our preclinical program for IC 100 and expect to file an IND in the fourth quarter of 2024, with plans to initiate a phase 1 clinical trial in early 2025."

About Inflammasome ASC Inhibitor IC 100

IC 100 is a novel humanized IgG4 monoclonal antibody that inhibits the inflammasome adaptor protein ASC. IC 100 attenuates 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, and 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.

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 developed to ameliorate renal lipid accumulation that damages the kidneys' filtration system in patients with glomerular 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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