ZyVersa Therapeutics Publishes New White Paper Detailing the Critical Role of Inflammasome ASC in Inflammatory Diseases, and Its Potential as a Therapeutic Target

June 13, 2023

- *White paper summarizes the research of leading inflammasome experts, Drs. Helen Bramlett, Juan Pablo de Rivero Vaccari, W. Dalton Dietrich, and Robert W. Keane, University of Miami Miller School of Medicine*
- *ASC, in monomeric form or as ASC specks, is central to initiation, amplification, and perpetuation of damaging inflammation leading to progressive tissue injury and chronic inflammatory diseases*
- *The World Health Organization reports that chronic inflammatory diseases (heart disease, cancer, chronic respiratory disease, and diabetes) significantly threaten human health (led to death in over 33 million people worldwide in 2019)*

WESTON, Fla., June 13, 2023 (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 on the critical role of inflammasome ASC in the development and progression of a wide-range of inflammatory diseases. Data suggest that drugs targeting ASC may provide the best opportunity to control damaging inflammation associated with diseases affecting millions of people worldwide. The white paper titled, "Inflammasome ASC: A Promising Therapeutic Target," can be accessed by Clicking Here.

The white paper highlights groundbreaking research from the labs of Drs. Bramlett, de Rivero Vaccari, Dietrich, and Keane, pioneers in the field of inflammasomes and members of ZyVersa's Scientific Advisory Board. To read their biographies, Click Here.

"After 15 years of research to develop an understanding of how inflammasomes contribute to so many diverse diseases and conditions, we discovered the critical role of the ASC component and developed a monoclonal antibody, known as Inflammasome ASC Inhibitor IC 100," stated Dr. Keane. "ASC is central to formation and activation of multiple inflammasome complexes associated with numerous diseases. ASC forms a large filamentous structure, the ASC speck, which is released from cells, amplifying and perpetuating inflammation. We believe that targeting ASC provides the best opportunity to control damaging inflammation."

Dr. de Rivero Vaccari added, "We have studied IC 100 in animal models of diverse diseases and injuries including multiple sclerosis, age-related inflammation associated with neurodegenerative diseases, Alzheimer's disease, acute respiratory distress syndrome, traumatic brain injury, and spinal cord injury. Each of these conditions demonstrated that IC 100 inhibited inflammasome activation, which resulted in improved histopathology and/or improved functional outcomes. We are continuing our research in other diseases, including Parkinson's disease, for which we were awarded a grant from the Michael J. Fox Foundation."

"ZyVersa, which obtained a worldwide license for Inflammasome ASC Inhibitor IC 100, is honored to collaborate with Drs. Bramlett, de Rivero Vaccari, Dietrich, and Keane to advance development of IC 100 into human trials," said Stephen C. Glover, Co-founder, Chairman, CEO, and President of ZyVersa. "We have progressed manufacturing of IC 100 through GMP production, and our IND-enabling preclinical program has progressed through demonstration of IC 100 safety in dose-ranging toxicology studies in mice and monkeys."

Mr. Glover continued, "We expect to complete the preclinical program for IC 100 by year's end, and file an IND to initiate a Phase 1 trial in early 2024. We are excited about our progress, as we believe Inflammasome ASC Inhibitor IC 100 has potential to transform treatment of debilitating inflammatory diseases."

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.

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

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