ZyVersa Therapeutics Highlights Review Article Substantiating That Inflammasome Activation Is Pathogenic in Multiple Neurological Diseases

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- *Up to 16 million adults in the US are living with a neurological disease, the leading cause of physical and cognitive disability, and 1.2 million new cases are diagnosed annually.*
- *The review article summarizes data demonstrating that inflammation resulting from activation of more than one type of inflammasome contributes to development of neurological diseases and that ASC specks lead to their progression.*
- *ZyVersa is developing IC 100, a monoclonal antibody targeting inflammasome ASC and ASC specks from multiple types of inflammasomes to block initiation and perpetuation of damaging inflammation.*
- *IC 100 preclinical data demonstrate that it penetrates the brain, and that it has promising therapeutic potential for neurological diseases based on preclinical studies representative of multiple sclerosis, Alzheimer's disease, traumatic brain injury, and spinal cord injury.*

WESTON, Fla., Feb. 14, 2024 (GLOBE NEWSWIRE) -- ZyVersa Therapeutics, Inc. (Nasdaq: ZVSA or "ZyVersa"), a clinical stage specialty biopharmaceutical company developing first-in-class drugs for treatment of inflammatory and renal diseases, highlights data from a review article published in *Nature Reviews Neurology.* This article provides increasing evidence that activation of several types of inflammasomes and extracellular ASC specks contribute to the development and progression of multiple neurological diseases including Alzheimer's disease (AD), Parkinson's disease (PD), multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), epilepsy, traumatic brain injury (TBI), and stroke.

In the paper titled, "Inflammasomes in neurological disorders — mechanisms and therapeutic potential," the authors reviewed 297 published papers that included data from cell cultures, preclinical disease models, and human tissue analysis to summarize the current evidence for and understanding of inflammasome activation in various neurological diseases. Key learnings include:

- Many neurological conditions involve an underlying chronic inflammasome-mediated inflammatory process that worsens the trajectory of these conditions.
- Beyond NLRP3, evidence suggests that other inflammasomes, including but not restricted to NLRP1, NLRC4, and AIM2, and their downstream effectors contribute to neuropathology in AD, PD, ALS, MS, stroke, epilepsy, and TBI.
- Inflammasome-induced release of ASC specks into the extracellular space seems to be important in the speed of neurodegeneration in conditions such as AD and PD.

The authors concluded, "Use of inflammasome-targeted therapeutic approaches could improve existing therapeutic strategies for multiple neurological conditions." To review the publication, Click Here.

"We are thrilled to see the large number of studies summarized in the review article published in *Nature Reviews Neurology* that reinforce the role of multiple types of inflammasomes and extracellular ASC specks in the development and progression of numerous neurological diseases," commented Stephen C. Glover, ZyVersa's Co-founder, Chairman, CEO, and President. These studies, in combination with our own preclinical program, substantiate the rationale for targeting inflammasome ASC to inhibit multiple inflammasome pathways and to disrupt the function of ASC specks to control inflammation in numerous neurological diseases." To review a white paper summarizing the mechanism of action and preclinical data for IC 100, Click Here.

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, 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 in 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 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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