ZyVersa Therapeutics Announces Published Data Supporting the Rationale for Inhibiting Inflammasome ASC with IC 100 to Control Chronic Inflammation

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- Data demonstrate that extracellular ASC specks, independent of IL-1β, govern the pathogenesis and extent of amyloid A (AA) amyloidosis, which is characterized by deposition of insoluble amyloid fibrils in tissues and organs disrupting their structure and function.
- Extracellular ASC interacts with serum amyloid A (SAA) released by the liver during inflammation, forming a scaffold that accelerates SAA aggregation into amyloid fibrils, which are deposited in tissues and organs.
- Amyloid A amyloidosis occurs in a heterogeneous spectrum of chronic inflammatory conditions such as rheumatoid arthritis, Crohn's disease, and inflammatory bowel disease.
- ZyVersa is developing Inflammasome ASC Inhibitor IC 100, which inhibits intra- and extracellular ASC and specks associated with multiple types of inflammasomes to attenuate damaging inflammation and its perpetuation and spread to surrounding tissues.

WESTON, Fla., Aug. 07, 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, announces data published in the peer-reviewed journal, *EMBO Molecular Medicine*, demonstrating that extracellular ASC has a crucial role in aggregation and deposition of amyloid A fibrils leading to associated chronic inflammatory conditions.

"This research highlighting the role of extracellular ASC specks, independent of IL-1β, in the pathogenesis of chronic conditions associated with amyloid A amyloidosis reinforces our selection of ASC as a target for our inflammasome inhibitor IC 100," stated Stephen C. Glover, ZyVersa's Co-founder, Chairman, CEO, and President. "This paper provides one more piece of evidence that inhibiting extracellular ASC specks associated with multiple types of inflammasomes has potential to control damaging inflammation associated with a broad range of inflammatory diseases."

The paper titled, The ASC inflammasome adapter governs SAA-derived protein aggregation in inflammatory amyloidosis, summarizes data from *in vitro* and *in vivo* research investigating the role of ASC in inflammation-associated amyloidosis. Following is a summary of key findings:

- ASC colocalized tightly with SAA in human AA amyloidosis.
- ASC specks accelerated SAA fibril formation.
- Splenic amyloid load was decreased in a Pycard knock-out mouse model of AA Amyloidosis which lacks ASC.
- Treatment with anti-ASC^{PYD} antibodies decreased amyloid loads in wild-type mice suffering from AA amyloidosis.

"Our findings might have therapeutic implications that advance the fields of protein misfolding disorders (PMDs) and chronic inflammatory diseases in general as ASC could be a target of disease-modifying therapies that aim to reduce amyloid deposition and pathology in various proteinopathies," concluded the authors.

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. The lead indication for IC 100 is obesity and its associated metabolic complications. 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 inflammatory or kidney diseases with high unmet medical needs. We are well positioned in the rapidly emerging inflammasome space with a highly differentiated monoclonal antibody, Inflammasome ASC Inhibitor IC 100, and in kidney disease with phase 2 Cholesterol Efflux Mediator^{TM} VAR 200. The lead indication for IC 100 is obesity and its associated metabolic complications, and for VAR 200, focal segmental glomerulosclerosis (FSGS). Each therapeutic area offers a "pipeline within a product," with potential for numerous indications. The total accessible market is over $100 billion. 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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