ZyVersa Therapeutics Announces Publication Demonstrating that Inflammasome ASC Inhibitor IC 100 Restored Retinal Structure and Function in a Retinopathy of Prematurity Animal Model

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- Publication showed that IC 100 suppressed retinal microglia activation by interfering with ASC speck formation, attenuating retinal inflammation, abnormal retinal vascularization, and retinal thinning, and it led to restored retinal function.
- Retinopathy of Prematurity (ROP), affecting very low birth weight premature infants is a leading cause of childhood blindness worldwide.
- ZyVersa is developing Inflammasome ASC Inhibitor IC 100 to inhibit multiple types of inflammasomes and their associated ASC specks that trigger damaging inflammation and its perpetuation and spread to surrounding tissues.

WESTON, Fla., July 18, 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 that acclaimed inflammasome researchers from the University of Miami Miller School of Medicine and inventors of Inflammasome ASC Inhibitor IC 100 have published a scientific paper in the peer-reviewed journal, *Angiogenesis*. The paper demonstrates the crucial role of inflammasome ASC and ASC specks in the development of oxygen-induced retinopathy and provides data showing that Inflammasome ASC Inhibitor IC 100 attenuates impairment of retinal structure and function.

The paper titled, "IC 100, a humanized therapeutic monoclonal anti-ASC antibody alleviates oxygen-induced retinopathy in mice," summarizes research evaluating mouse models representative of ROP. Following is a summary of key findings:

- ASC specks, which lead to inflammasome activation, were significantly increased in animal model retinas and colocalized with the abnormal vasculature, along with increased microglial activation indicative of retinal inflammation that leads to retinal damage and disease progression.
- IC 100 decreased expression of inflammasome-related molecules (ASC, gasdermin D), inflammatory cytokines (IL-1β, IL-6, and TNF), and VEGF in animal model retinas.
- Importantly, IC 100 reduced ASC speck formation and microglial activation, attenuating inflammation, abnormal vascularization, retinal thinning, and retinal dysfunction.
- The structural and functional improvements demonstrated with IC 100 treatment correlated with corrections of hyperoxia-modulated gene pathways associated with eye development, leukocyte migration, angiogenesis, inflammation, neurogenesis, and VEGF signaling.

"We have demonstrated that IC 100 effectively treated both phases of oxygen-induced retinopathy in a mouse model that resembles ROP in preterm infants, as it decreased retinal vaso-obliteration and intravitreal vascularization," said Dr. Shu Wu, Professor of Pediatrics at the University of Miami. "Our data suggest that IC 100 may have potential therapeutic use in the treatment of preterm infants with ROP."

"This research highlighting that Inflammasome ASC Inhibitor IC 100 attenuated retinal inflammation, abnormal retinal vascularization, and retinal thinning leading to restored retinal function in an animal model of ROP supports the broad range of indications that IC 100 has potential to treat. ROP is the sixth indication with preclinical data demonstrating that IC 100 attenuates pathogenic inflammasome signaling pathways resulting in reduced inflammation and improved histopathological and/or functional outcomes," stated Stephen C. Glover, ZyVersa's Co-founder, Chairman, CEO, and President. "The other promising indications are early Alzheimer's disease, multiple sclerosis, acute respiratory distress syndrome, spinal cord injury, and traumatic brain injury."

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™ 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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