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Journal of Neuroinflammation Article Shows ZyVersa's Inflammasome Inhibitor, IC 100, Improves Functional Outcomes in an Animal Model of Multiple Sclerosis

Study was conducted at the University of Miami Miller School of Medicine by acclaimed experts in neuro-inflammation, and leaders at the forefront of inflammasome research

IC 100, a novel monoclonal antibody that inhibits the inflammasome adaptor protein ASC, is ZyVersa's lead anti-inflammatory candidate in development for numerous inflammatory conditions

WESTON, Fla., May 5, 2020 /PRNewswire/ -- ZyVersa Therapeutics, Inc., (ZyVersa) a clinical stage specialty biopharmaceutical company developing first-in-class drugs for treatment of inflammatory and renal diseases, is pleased to announce that the *Journal of Neuroinflammation* has published data showing that inflammasome inhibitor, IC 100, attenuates the inflammatory response causing neuronal damage in multiple sclerosis (MS), and that it improves functional outcomes. Data were collected in the EAE (experimental autoimmune encephalomyelitis) mouse model of multiple sclerosis (MS), which exhibits the key pathological features found in humans.

"MS is a progressive disease resulting in physical, cognitive, and psychological disabilities that greatly impair quality of life," stated Dr. Robert W. Keane, Professor, Physiology and Biophysics, Neurological Surgery and Microbiology, and Immunology, University of Miami Miller School of Medicine. "Although great strides have been made over the last 20 years in

commercializing disease-modifying drugs for MS, there is still a need for treatments that more effectively address relapsing and progressive forms of the disease. Based on the EAE results we are optimistic about the potential of IC 100 as an effective treatment option for MS. We look forward to working with ZyVersa to progress its development into the clinic."

The published data demonstrate that IC 100 penetrates the brain and spinal cord. Accordingly, IC 100 reduces infiltration of $CD4^+$ and $CD8^+$ T cells and $CD11b^+MHCII^+$ activated myeloid cells into the spinal cord and decreases the number of total and activated microglia. This was associated with improvements in functional outcomes, as reflected by a robust reduction in MS clinical disease scores throughout the study, and a 50% reduction in the cumulative MS disease index.

"Results of this study provide proof-of-concept for IC 100 as a promising therapeutic option for MS," said Stephen C. Glover, Co-founder, Chief Executive Officer, and President of ZyVersa Therapeutics. "The EAE model is the "go-to" model in MS drug development. Many of the disease-modifying MS drugs used today were developed, tested or validated based on studies in this model."

To review the publication, Click Here.

About Multiple Sclerosis

MS is a potentially disabling disease of the brain and spinal cord, affecting around 400,000 people in the U.S. and 2.1 million people worldwide. It occurs as a result of the immune system attacking the protective sheath (myelin) that covers nerve fibers, resulting in communication problems between the brain and the rest of the body. Eventually, the disease can cause permanent damage or deterioration of the nerves.

Common signs and symptoms of MS include numbness or weakness in one or more limbs, electric-shock sensations with certain neck movements, tremor, lack of coordination, or unsteady gait. Some people with severe MS may lose the ability to walk independently or at all. Vision problems are also common, including partial or complete loss of vision. Other symptoms may include slurred speech, fatigue, dizziness, and tingling or pain in parts of the body. Significant disability occurs in more than 30% of patients within 20-25 years.

About 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, 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, attenuates the adaptive immune response as well.

For more information about inflammasomes, Click Here to review our White Paper.

About ZyVersa Therapeutics, Inc.

ZyVersa is a clinical stage specialty biopharmaceutical company leveraging advanced, proprietary technologies to develop first-in-class drugs. Our focus is on patients with inflammatory or renal diseases who have significant unmet medical needs. Our lead anti-inflammatory candidate is IC 100, a novel monoclonal antibody that inhibits the inflammasome adaptor protein ASC. IC 100 has potential to treat multiple inflammatory diseases. Our lead renal candidate is VAR 200, a cholesterol efflux mediator for treatment of a rare renal disease, focal segmental glomerulosclerosis (FSGS). A phase 2a clinical trial is planned for initiation this year. For more information, please visit ZyVersa.com.

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