



ZyVersa Therapeutics Highlights Data Reinforcing the Potential of Inflammasome Inhibitors to Attenuate Progression of Type 2 Diabetes and Improve Associated Long-term Cardiovascular Outcomes

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- Type 2 diabetes (T2DM), affecting more than 530 million worldwide, is a metabolic disease often coupled with cardiovascular complications including coronary artery disease, heart failure, and stroke.
- Cardiovascular complications are a leading cause of disability and death in people with T2DM. People with T2DM are 2 to 4 times more likely to experience cardiovascular events than people without T2DM, and post-event outcomes are often worse. About half of all diabetes-related fatalities can be attributed to cardiovascular causes.
- The published data provide evidence that inflammasome-induced inflammation plays a central role in the development and progression of T2DM and its cardiovascular complications by promoting insulin resistance, damage to the lining of blood vessels (endothelial dysfunction), and progression of plaque buildup in arteries.
- ZyVersa is developing Inflammasome ASC Inhibitor IC 100. Preclinical data demonstrate that IC 100 attenuates cardiometabolic conditions – it (1) decreased insulin resistance in a diabetic kidney disease model based on reduced fasting glucose; (2) reduced inflammation and plaque in the aorta in an atherosclerosis model; and (3) reduced cardiac inflammation and attenuated cardiac dysfunction in a stroke-related cardiovascular disease model.

WESTON, Fla., Sept. 10, 2025 (GLOBE NEWSWIRE) -- ZyVersa Therapeutics, Inc. (OTCQB: ZVSA; "ZyVersa"), a clinical stage specialty biopharmaceutical company developing first-in-class drugs for treatment of patients with renal and inflammatory diseases who have unmet medical needs, highlights data from a peer-reviewed article, [The Role of NLRP3 Inflammasome in Type 2 Diabetes Mellitus and Its Macrovascular Complications](#), recently published in the *Journal of Clinical Medicine*. The article summarized data from 105 peer-reviewed publications demonstrating that the NLRP3 inflammasome is a central mediator of metabolic inflammation and a key contributor to development and progression of T2DM and its associated macrovascular complications.

"Due to its substantial cardiometabolic comorbidities, diabetes is the eighth leading cause of disability and death worldwide. In 2021, global healthcare expenditures for T2DM were over \$960 billion. These statistics stress the critical need for effective drug therapies to attenuate the development and progression of type 2 diabetes and its associated cardiometabolic comorbidities, commented Stephen C. Glover, ZyVersa's Co-founder, Chairman, CEO, and President. "The review article published in the *Journal of Clinical Medicine* provides a large body of evidence that inflammasomes trigger the inflammation leading to development and progression of type 2 diabetes and associated cardiovascular comorbidities. We are excited about the potential of Inflammasome ASC Inhibitor IC 100 to effectively control the damaging inflammation leading to development and progression of type 2 diabetes and its associated cardiometabolic comorbidities. Unlike the NLRP3 inflammasome inhibitors in development, IC 100 inhibits the adaptor ASC component of multiple types of inflammasomes and their associated ASC specks. Inhibition of multiple inflammasomes is likely important to control inflammation in cardiometabolic conditions since five types of inflammasomes are activated in insulin resistance (AIM2, NLRP1, NLRP3, NLRC4, NLRP6) and three types in various cardiovascular diseases (NLRP1, NLRP3, and NLRC4). Additionally, IC 100 uniquely disrupts the structure and function of ASC specks to attenuate spread and perpetuation of inflammation that leads to multi-organ cardiometabolic conditions. In Q4-2025 we are planning to initiate an IND-enabling IC 100 preclinical study in a diet induced obesity (DIO) model to provide proof-of-concept of its effects on cardiometabolic conditions; results are anticipated in Q1-2026."

Review Article Key Points

Inflammasomes play a central role in the development and progression of T2DM and its cardiovascular complications by linking metabolic stress to chronic inflammation.

- Inflammasomes are activated by metabolic stressors: hyperglycemia, saturated fatty acids, ceramides, and other endogenous danger signals.
- Activated inflammasomes initiate the inflammatory cascade through production of proinflammatory cytokines IL-1 β and IL-18.
- Active caspase-1 cleaves gasdermin D leading to programmed cell death (pyroptosis) and release of cellular contents, including proinflammatory cytokines. This leads to a severe inflammatory response that is perpetuated and spread to surrounding tissues promoting insulin resistance, endothelial dysfunction, and atherosclerotic progression.

The authors concluded that targeting inflammasomes may represent a transformative strategy for attenuating the inflammatory burden in T2DM and improving long-term cardiovascular outcomes.

ABOUT ZYVERSA THERAPEUTICS, INC.

ZyVersa (OTCQB: 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 with 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 various kidney diseases, and Inflammasome ASC Inhibitor IC 100, targeting damaging inflammation associated with numerous CNS and peripheral inflammatory diseases. FSGS is the lead indication for VAR 200, and obesity with cardiometabolic comorbidities is the lead indication for IC 100. 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.

Corporate, IR, and Media Contact

Karen Cashmere
Chief Commercial Officer
kcashmere@zyversa.com
786-251-9641