

## Corporate Presentation Q2-2024 Nasdaq: ZVSA



### T H E R A P E U T I C S<sup>™</sup>

Restoring Health, Transforming Lives Through Innovation

ZyVersa Non-confidential

## Cautionary Statement Regarding Forward-Looking Statements 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 estimates are segarding 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.



## **Restoring Health, Transforming Lives Through Innovation**



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## **Corporate Overview**

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## BIO, Stephen C. Glover, CEO

- Over 40 years of biopharma expertise
- GSK, Roche, Amgen, Insmed, Andrx, Coherus and ZyVersa
- Over \$12B in M&A, over \$500M of capital raised, recent \$2B exit with JNJ
- Former Chairman of the BOD at Ambrx, Current Chairman at PDS Biotechnology and ZyVersa
- Member of BOD at the Coulter Foundation at the University of Miami, Miller School of Medicine





## Our Mission: To Develop First-in-Class Drugs at the Forefront of Innovation Driven To Restore Health and Transform Lives

Two Licensed Proprietary Product Platforms Targeting Renal & Inflammatory Diseases Invented by Top Tier Research Scientists at University of Miami Miller School of Medicine

Renal & Inflammatory Disease Pipelines Each Address Multiple Indications ~\$100 Billion Global Total Addressable Markets<sup>1,2</sup>

Renal Orphan Disease-focused Phase 2a Cholesterol Efflux Mediator<sup>™</sup> Drug Candidate to Reduce Damaging Renal Lipid Accumulation

> Novel mAb Inflammasome Inhibitor Targeting ASC to Block Initiation & Perpetuation of Damaging Inflammation

Experienced Management Team Led by Successful, Entrepreneurial Biopharma CEO

Strong Board of Directors and Globally Renowned Scientific Advisors

ZyVera THERAPEUTICS"

1. Chronic Kidney Disease Drugs Market Analysis. Coherent Market Insights, November 2020; 2. Anti-Inflammatory Biologics Market Size, Share & Industry Analysis. Fortune Business Insights, May 2020

## **Experienced Leadership Team**



Stephen C. Glover, Co-Founder, CEO, President & Director

Roche

Andrx

30+ Years

40+

Years

 $\textcircled{\black}{\black}$ 

Coherus



Pablo A. Guzman, MD, FACC, Chief Medical Officer

HolyCross Health

AMGEN insmed





Peter Wolfe, Chief Financial Officer



## **Strong Board of Directors**



Robert Finizio, Executive Director, PleoPharma

Over 20 years in health care

▶ Prior executive roles at TherapeuticsMD, CareFusion, Omnicell, Endoscopy Specialist



Min-chul Park, PHD, CEO and Director, Curebio Therapeutics

Over 10 years in pharmaceuticalsPrevious CEO and Director at Neomics



### Gregory G. Freitag, JD, CPA, Founder and Principal, FreiMc

Over 30 years in Life Science, Medical Device, and Healthcare

Prior executive roles at Axogen, LecTec , Pfizer Health Solutions, Guidant , HTS Biosystems, Quantech



### James Sapirstein, Chairman, CEO & President, First Wave BioPharma

Over 38 years in pharmaceuticals

Prior senior executive roles at Contravir Pharmaceuticals; Alliqua, Tobira Therapeutics, Serono Laboratories, and Gilead Sciences



Andrx

## Renowned Anti-inflammatory Scientific Advisory Board, Recognized As Pioneers/Leaders in Inflammasome Inhibitor Space



#### Daniel G. Baker, MD

Former Vice President, Immunology Research and Development, Janssen Pharmaceutical Companies of Johnson & Johnson



#### Miguel S. Barbosa, PhD

Former Global Head and Vice President of Immunology Research and External Innovation at Janssen Research & Development, Pharmaceutical Companies of Johnson & Johnson



#### William F. Bennett, PhD

Principal, Bioscope Associates
 Formerly: Genentech, Sensus Corporation, Cor Therapeutics



#### Helen Bramlet, PhD: Inventor of Inflammasome Platform

- Professor, Department of Neurological Surgery, UM
- The Miami Project to Cure Paralysis, UM



#### Juan Pablo de Rivero Vaccari, PhD: Inventor of Inflammasome Platform

- Research Assistant Professor, Department of Neurological Surgery, UM
- The Miami Project to Cure Paralysis, UM
- Distinguished Faculty Member, Center for Cognitive Neuroscience and Aging, UM



#### W. Dalton Dietrich, III, PhD: Inventor of Inflammasome Platform

- Kinetic Concepts Distinguished Chair in Neurosurgery & Scientific Director, The Miami Project to Cure Paralysis, UM
- Sr Associate Dean, Discovery Science & Co-director, Institute for Neural Engineering, UM
- Professor, Neurological Surgery, Neurology, Biomedical Engineering & Cell Biology, UM

### Doug H. Farrar

- CEO, Flatirons Biotech, Inc
- Former Cofounder and Chief Technical Officer, Coherus Biosciences
- Former SVP biologic manufacturing at Amgen and Insmed

#### Douglas T Golenbock MD

- The Neil and Margery Blacklow Chair in Infectious Diseases
- Immunology and Professor and Chief, Division of Infectious Diseases and Immunology, UMass Chan Medical School

#### Alan Herman, PhD

- Chairman Emeritus, former Chief Scientific Officer, Coherus Biosciences
- Formerly: Genentech, Amgen, Merck, Coherus Biosciences



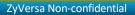
#### Robert W. Keane, PhD: Inventor of Inflammasome Platform

- Professor Physiology & Biophysics, Neurological Surgery & Microbiology, and Immunology, UM
- The Miami Project to Cure Paralysis, UM

### Nicholas A.LaBella, Jr, MS

- President, NL Consulting Services, Inc.
- Former CSO and SVP Research and Development, ZyVersa





# Top Tiered Renal Scientific Advisory Board, Known for Leadership in Glomerular Research and Advocacy



### Sharon G. Adler, MD

- Professor of Medicine, David Geffen School of Medicine, UCLA
- Chief, Division of Nephrology and Hypertension, Harbor-UCLA Medical Center
- Program Director, Nephrology Fellowship Training Program, Harbor-UCLA Medical Center

### Daniel C. Cattran, MD

- Professor of Medicine, University of Toronto
- Chair of the Toronto Glomerulonephritis Registry



### Richard J. Glassock, MD, MACP, FRCP, FASN

Professor Emeritus, David Geffen School of Medicine, UCLA



#### Pablo A. Guzman, MD, FACC

- Chairman, Scientific Advisory Board
- Chief Medical Officer, ZyVersa Therapeutics



### Fernando C. Fervenza

- Professor of Medicine, Mayo Graduate School of Medicine
- Director, Nephrology Collaborative Group



### Marlene Haffner, MD, MPH

- Principal & Founder, Orphan Solutions & Haffner Associates
- Former Director of Orphan Products Development, FDA



### Alessia Fornoni MD, PhD

Professor of Medicine and Chief, Katz Family Division of Nephrology and Hypertension, University of Miami Miller School of Medicine



### Nicholas A.LaBella, Jr, MS

- President, NL Consulting Services, Inc.
- Former CSO and SVP Research and Development, ZyVersa



## Two Proprietary Product Platforms Each With "Pipeline Within a Product" Potential

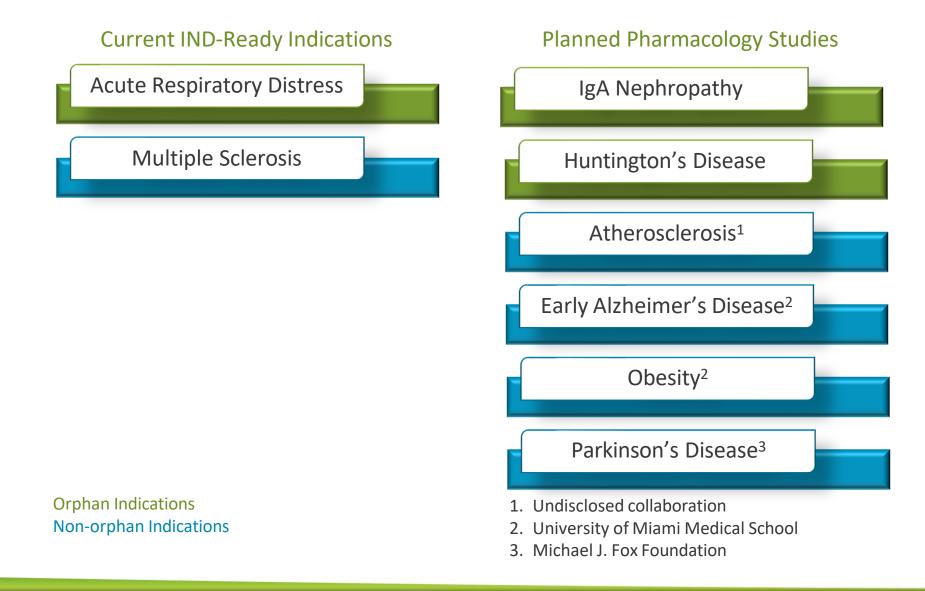
ZyVersa's two licensed proprietary platforms target unmet medical needs with unique MOAs - offer multiple opportunities for expansion beyond initial targeted indications

Product Candidates	Development	Pre-clinical	Phase 1	Phase 2	Phase 3	NDA/BLA Submission	
Renal/Cholesterol Efflux Mediator™							
VAR 200-01: FSGS*				•			Key Milestones: Cholesterol Efflux
VAR 200-02 : Alport Syndrome*							Mediator™
VAR 200-03: Diabetic Kidney Disease		,		>			H1-2024: Initiation of DKD Trial
Inflammasome/ASC Inhibitor							H2-2024: Initial DKD Data
IC 100-01: Acute Respiratory Distress Syndrome*	A		>				
IC 100-02: Multiple Sclerosis			<b>&gt;</b>				
IC 100-03: Parkinson's Disease	J.						Key Milestones: Inflammasome AS
IC 100-04: IgA Nephropathy*							Inhibitor
IC 100-05: Huntington's Disease*							Q3-2024: Pre-IND Meeting
IC 100-06: Atherosclerosis							<u> </u>
IC 100-07: Early Alzheimer's Disease							Q4-2024: IND Filing
IC 100-08: Obesity	j.						

\* Orphan diseases

1. Phase 1 not required by FDA based on VAR 200's established historical safety profile

## Indication Expansion Strategy, Mix of Orphan, CNS, and Non-CNS Conditions



## Building Value: Key Activities, Inflection Points and Regulatory Milestones

### **VAR 200**

Initial study in diabetic kidney disease to gain human experience and POC

### IC 100: Next 12-24 Months

- Initiate acute GLP toxicology studies
- Manufacture clinical supplies
- Expand research program to evaluate up to 3 additional indications
- File IND and begin phase I trials
- Phase I results

Program	Development Stage	Key Activities	IND Status and Target Date	Key Milestones
VAR 200	Phase II	Site selection	IND open	Initial data (H2, 2024)
IC 100	Preclinical	<ul> <li>GMP manufacturing</li> <li>GLP toxicology</li> <li>Indication expansion</li> </ul>	Pre-IND mtg (Q3, 2024) IND filing (Q4, 2024)	Phase I safety read-out (Q1, 2025)



### **Restoring Health, Transforming Lives Through Innovation**



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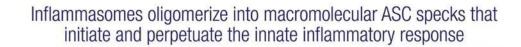
## Inflammasome ASC Inhibitor IC 100

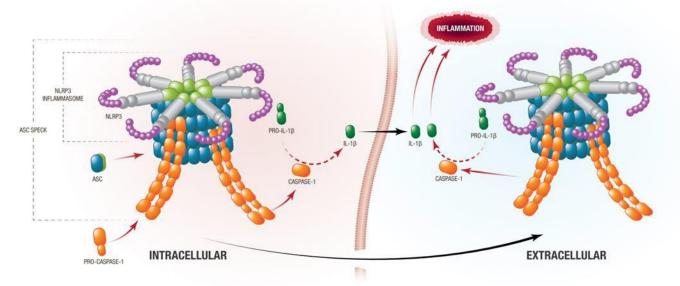
Humanized Monoclonal IgG4 Antibody That Inhibits Initiation and Perpetuation of Inflammation Associated With CNS and Systemic Inflammatory Conditions

## What Are Inflammasomes?

## Inflammasomes

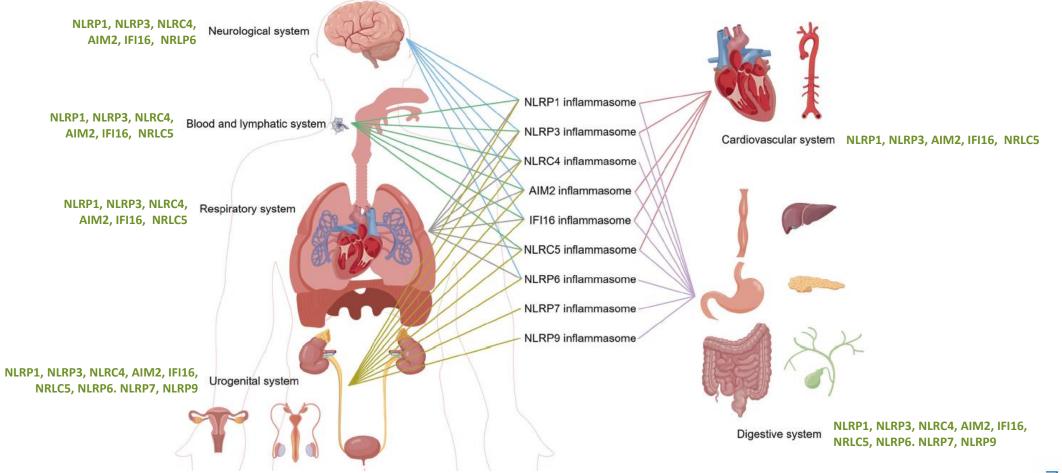
- Initiate inflammation as the first line of defense against bacteria, viruses, and other threats.
- There are multiple types of inflammasomes, each responding to a different threat.
- When dysregulated, they don't shut off once their job is done, perpetuating and spreading inflammation that damages cells, tissues, and organs leading to inflammatory diseases.







Multiple Inflammasome Pathways Play a Causative or Contributing Role in Initiation and Progression of Diseases Affecting All Body Systems





Yao J, Sterling K, Wang Z, Zhang Y, Song W. The role of inflammasomes in human diseases and their potential as therapeutic targets. Signal Transduct Target Ther. 2024 Jan 5;9(1):10.

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## **Restoring Health, Transforming Lives Through Innovation**



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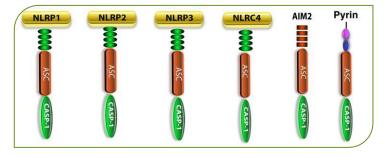
## Why Target ASC?

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## Why Target Inflammasome ASC With IC 100?

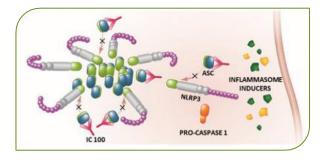
## ASC Inhibition Expected to Better Control Inflammation Across a Broad Range of Conditions

Potentially Inhibits 12 or More Types of Inflammasomes To Control Inflammation Regardless of Its Triggers

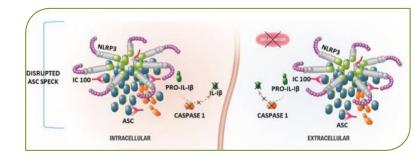


Numerous Diseases Triggered By Multiple Types Inflammasomes			
Disease/Condition	Inflammasomes Implicated		
Multiple Sclerosis	AIM2, NLRP1, NLRP2, NLRP3, NLRC4		
Lupus Nephritis	AIM2, NLRP3		
Diabetic Nephropathy	AIM2, NLRP3		
CNS Injury	AIM2, NLRP1, NLRP2, NLRP3		
Alzheimer's Disease	AIM2, NLRP1, NLRP3		
Rheumatoid Arthritis	AIM2, NLRP1, NLRP3, NLRP6		
Inflammatory Bowel Disease	AIM2, NLRP1, NLRP3, NLRP6, NLRC4		

Inhibits Intracellular ASC to Block Inflammasome Formation & Initiation of the Inflammatory Cascade



Inhibits Intra-and Extracellular ASC Specks, Disrupting Their Structure & Function to Block Perpetuation of Damaging Inflammation



NLRP3 Inhibitors Block Only One Type Inflammasome Don't Address ASC Specks To Block Chronic Perpetuation of Inflammation



## Expected Benefits of IC 100 Over NLRP3 Inhibitors

Penetrates CNS & Peripheral Tissues to Address Inflammatory Signaling Throughout the Body (Vs Separate Compounds for Each)

Uniquely Targets ASC Specks to Alleviate Inflammation Perpetuation and Spread

Targets Multiple Types of Inflammasomes Vs Just NLRP3 To Better Control Inflammation

As mAb, Target Engagement Specificity for Fewer Side Effects (e.g., Liver Damage) & Drug/Drug Interactions

Less Frequent Dosing – Monthly or Quarterly Vs BID or TID for Many Small Molecules for Improved Dosing Compliance/Persistence



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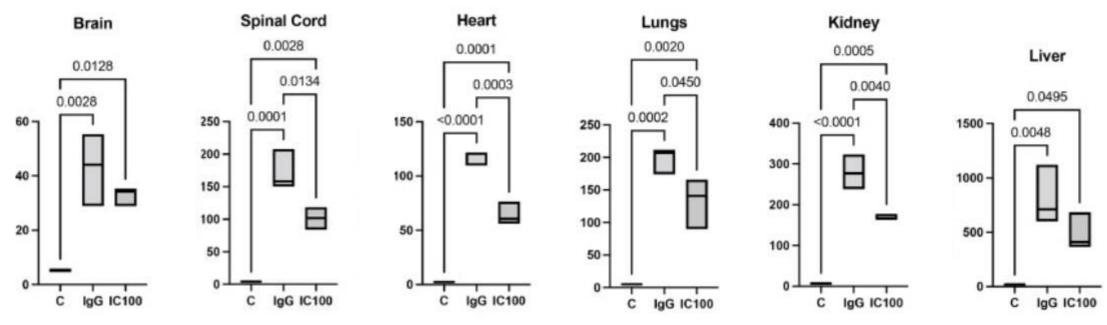
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## About Inflammasome ASC Inhibitor IC 100

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## IC 100 Has Broad Tissue Penetration and Crosses the Blood/Brain Barrier

IC 100 Distribution Was Significantly Higher Than Control in Brain, Spinal Cord, Heart, Lungs, Kidneys, and Liver



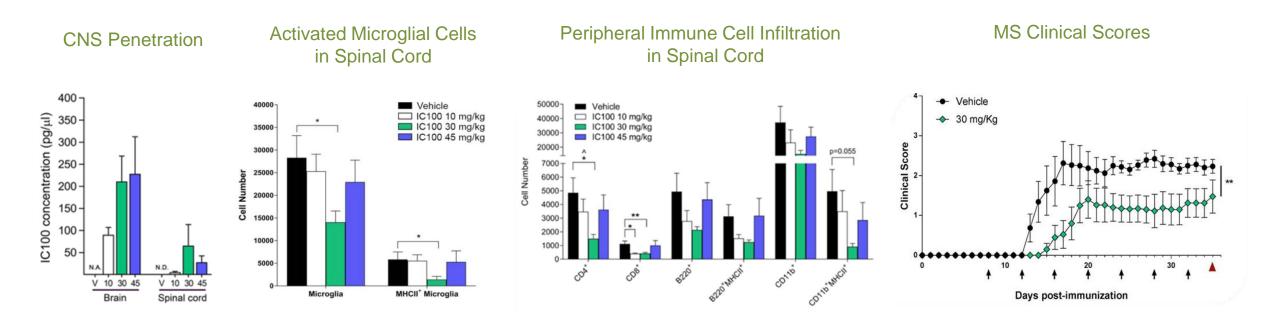
Units: Average radiant efficiency (photons/s/cm<sup>2</sup>/sr/µW/cm<sup>2</sup>); MEAN + SEM

### IC 100 was fluorescently labeled to determine tissue distribution by in vivo imaging in B6 Albino mice

1. Vaccari JPR, Mim C, Hadad R, et al MECHANISM OF ACTION OF IC 100, A HUMANIZED IgG4 MONOCLONAL ANTIBODY TARGETING APOPTOSIS-ASSOCIATED SPECK-LIKE STAINING PROTEIN CONTAINING A CASPASE RECRUITMENT DOMAIN (ASC). Transl Res. 2022 Jul 3:S1931-5244(22)00150-5



# CNS Levels of IC 100 Dosed at 30 mg/kg Reduced Inflammation, and Improved Functionality in EAE Model of Multiple Sclerosis

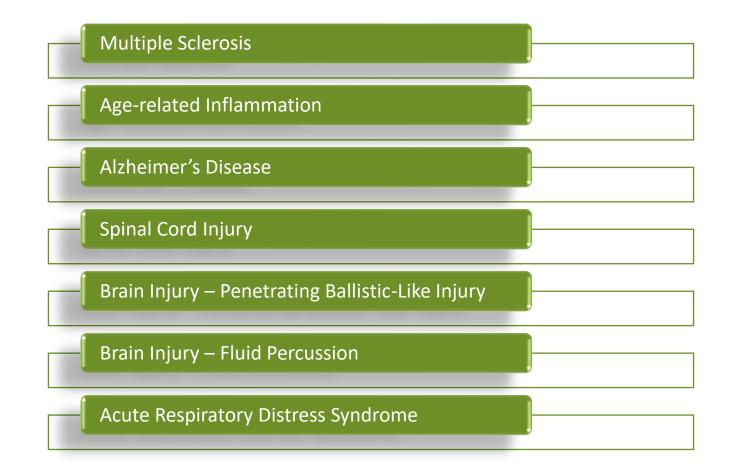




Desu HL, Plastini M, Illiano P, et al. IC100: a novel anti-ASC monoclonal antibody improves functional outcomes in an animal model of multiple sclerosis. J Neuroinflammation. 2020 May 4;17(1):1431.

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IC 100 Has Preclinical Data Substantiating Its MOA in Both CNS and Non-CNS Conditions





## IC 100 Has Preclinical Data Substantiating Its MOA in Both CNS and non-CNS Diseases

Multiple Sclerosis (MS)	Spinal Cord Injury (SCI)	Age-related Inflammation	Alzheimer's Disease (AD)
<ul> <li>MS is characterized by an inflammatory response sustained by innate and adaptive immune mechanisms dependent on lymphocyte and myeloid cell activation</li> <li>IC 100 at 30 mg/kg resulted in a lower number of activated myeloid cells in the spinal cord and spleen, a lower number of microglial cells in the spinal cord, and improved clinical outcomes consistent with these changes</li> </ul>	<ul> <li>Following SCI, expression of NLRP1 inflammasome signaling molecules, including ASC, are increased and NLRP1 inflammasome is activated in spinal cord neurons, triggering an inflammatory response</li> <li>ASC inhibition decreased inflammasome activation, reduced spinal lesions, and improved behavioral outcomes</li> </ul>	<ul> <li>Inflammasome signaling proteins, NLRP1, ASC, caspase-1, caspase-8, and IL-1β are significantly increased in the cortex of aged mice</li> <li>IC 100 inhibits both canonical and non-canonical NLRP1 inflammasome activation that occurs in aged mice</li> <li>IC 100 significantly reduced ASC Specks, IL-1β, and inflammasome protein expression (NLRP1, ASC, caspase-1, and caspase-8)</li> </ul>	<ul> <li>Increased protein expression of NLRP1, NLRP3, ASC, and caspase-1, occurs early in (AD)</li> <li>Expression of ASC correlates with Aβ and p-tau in postmortem AD</li> <li>Inflammasome ASC Inhibitor IC 100 targeting inflammasome ASC, identifies neurons in early stages of AD through imaging</li> </ul>
Penetrating Ballistic-Like Brain Injury Model (PBBI)	Fluid Percussion Brain Injury Model (FPI)	Acute Respiratory Distress Syndrome (ARDS)	
<ul> <li>Following PBBI, expression of inflammasome signaling molecules, including ASC, are increased, and inflammasomes are activated in microglia triggering an inflammatory response and pyroptosis</li> <li>IC 100 decreased inflammasome activation and pyroptosis when compared with vehicle control</li> </ul>	<ul> <li>Following FPI, expression of inflammasome signaling molecules, including ASC, are increased and inflammasomes are activated in cerebral cortex neurons, triggering an inflammatory response</li> <li>ASC neutralization reduced inflammasome activation and decreased brain contusion volume associated with inflammation when compared with IgG control</li> </ul>	<ul> <li>Inflammasome activation and inflammation play a central role in the pathomechanism of lung injury in ARDS</li> <li>IC 100 inhibited inflammasome activation and improved histopathological outcomes in lung tissue</li> </ul>	



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## IC 100 Safety

# 21 Day Non-GLP Repeat Dose Range Finding Studies in Mice and NHP Demonstrated No Drug-related AEs at Doses Up to 300 mg/kg

Parameter	Mice	NHP
Body Weight	No drug-related changes	No drug-related findings
Clinical Observations	No drug-related observations	No drug-related findings
Clinical Pathology	<ul> <li>Clin chem: minimal to mild increases in ALP, CK, TRIG, GLOB, A/G, &amp; PHOS; not considered adverse given the small magnitude of the changes, lack of dose- response relationship, and lack of confirmatory microscopic findings</li> <li>Hematology: mild increases/decreases in LYMPH and MONO resulting in minimally increased/decreased WBC in affected groups; not considered adverse given opposite trends in males/females and non- dose relationship</li> </ul>	<ul> <li>Clinical chemistry: No drug-related findings</li> <li>Hematology: No drug-related findings</li> <li>Clotting: No drug-related findings</li> </ul>
Macroscopic Observations	No drug-related observations	<ul> <li>No drug-related findings day 22; mottled discolored livers day 45 in one of one mid-dose female, one of one each high dose male &amp; Female; liver discoloration an artifactual change</li> </ul>
Microscopic Observations	No drug-related observations	<ul> <li>No drug-related findings day 22 (full tissue list); No drug-related findings in liver on day 45 (only tissue examined)</li> </ul>
Mortality	No drug-related mortality	No drug-related mortality
Toxicokinetic Parameters	<ul> <li>Tmax within 0.5 hour</li> <li>Half-life: 8 to 14 days</li> <li>Systemic exposure increased with increasing dose levels</li> <li>Similar exposure between sexes</li> </ul>	Not yet available
ADA	No anti-IC 100 antibodies	No anti-IC 100 antibodies

*ZyVer* 

## IC 100, a Promising Treatment Option for Inflammatory Diseases

### IC 100: Novel ASC inhibitor for treatment of inflammatory diseases

- Humanized monoclonal IgG4 antibody that binds to a specific region of adaptor ASC, an integral component of multiple types of inflammasomes
- By targeting ASC, potentially inhibits 12 or more types of inflammasomes, and thus IC 100's MOA is independent of triggers and sensors leading to inflammasome activation
- Inhibits inflammasome formation intracellularly, blocking initiation of the inflammatory response
- Inhibits ASC specks, intra-and extracellularly, disrupting speck structure and function preventing perpetuation of the inflammatory response

### IC 100 POC: Strong pharmacologic signals in a broad range of inflammatory conditions

- Primary POC: Multiple sclerosis, Acute Respiratory Distress Syndrome
- MOA POC: Spinal cord injury, traumatic brain injury, aging (Early Cognitive Impairment), and Alzheimer's disease. Ongoing work in Obesity, Parkinson's and Atherosclerosis

### IC 100 Safety:

- Attenuates the immune system, without broad immune suppression
- Lower immunogenicity (9%) than many biologics less potential for acquired drug resistance and drug discontinuation due to side effects
- No drug-related AEs or histopathology changes at weekly doses up to 300 mg/kg for 21 days in non-GLP tox studies (mice & NHP)

### CMC

- Stable, viable cell line established
- Successful manufacturing scale to 200L
- 2,000L cGMP run completed



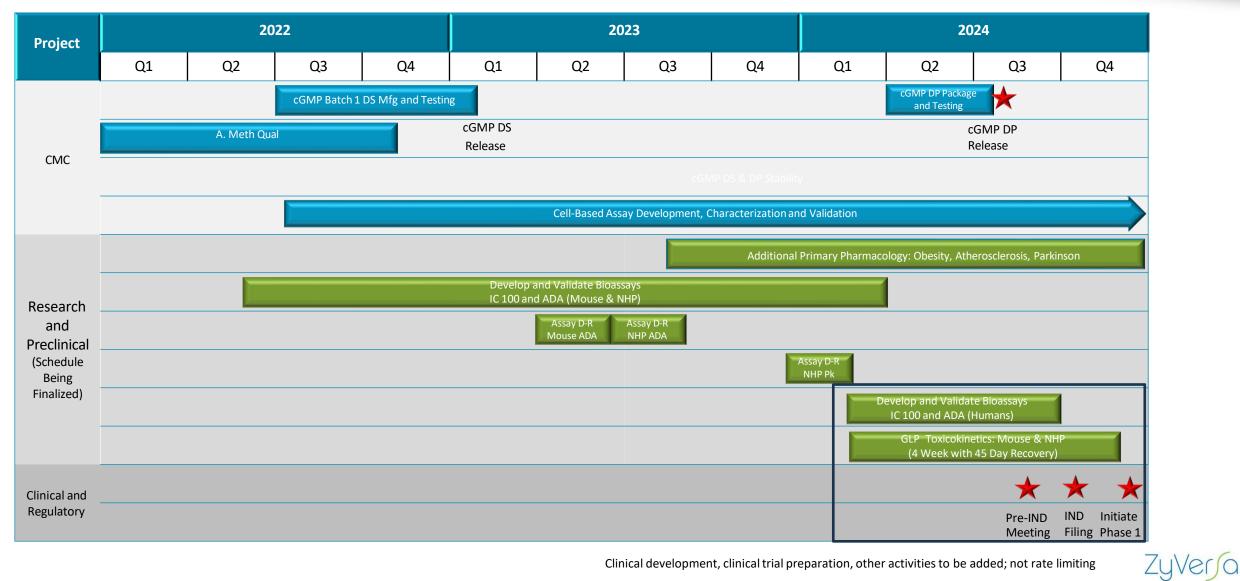
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## **Development Plan Overview**

## Key Milestones: IC 100 Path to IND and Phase 1



Clinical development, clinical trial preparation, other activities to be added; not rate limiting

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### Restoring Health, Transforming Lives Through Innovation



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## Cholesterol Efflux Mediator<sup>™</sup> VAR 200

2-Hydroxypropyl-Beta-Cyclodextrin (2HPβCD) for Renal Disease

## Promising Treatment Option for Renal Diseases Cholesterol Efflux Mediator<sup>TM</sup> VAR 200, Phase 2a-Ready

### FDA clearance for Phase 2a: Study may proceed letter

- Differentiated MOA: Passively and actively mediates removal of excess intracellular lipids that contribute to kidney damage and dysfunction; competitive pipeline targets renal hypertension and inflammation
- Significant Proof of Concept: Pre-clinical data in 3 different animal models of kidney disease (FSGS, Alport syndrome, diabetic kidney disease); robust safety profile
- De-risked Opportunity: FDA concurrence to move directly to phase 2a, bypassing phase 1, based on risk/benefit profile
- Strong IP Protection: 7 years orphan drug exclusivity in US, 10 years in EU; exclusive worldwide license to IP related to 2HPβCD for treatment of kidney diseases
- Opportunity for Indication Expansion: As a cholesterol efflux mediator, offers potential indication expansion across multiple kidney diseases, including FSGS, Alport syndrome, diabetic kidney disease, and other forms of chronic kidney diseases comprising the \$14.5B renal drug market
- Multiple Life Cycle Opportunities Via Drug Delivery Mechanisms

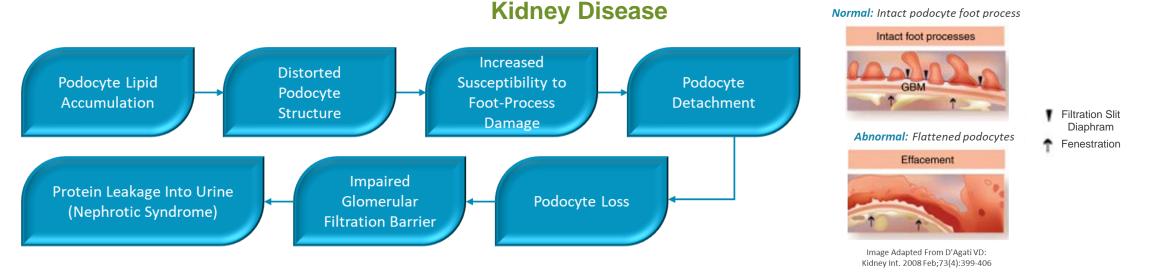


## Why Target Renal Lipids?

FSGS and Other Glomerular Diseases Develop "Foamy Podocytes" Due to Lipid Accumulation



Accumulation of Podocyte Lipids Contributes to Structural Damage, Proteinuria, and Progression of

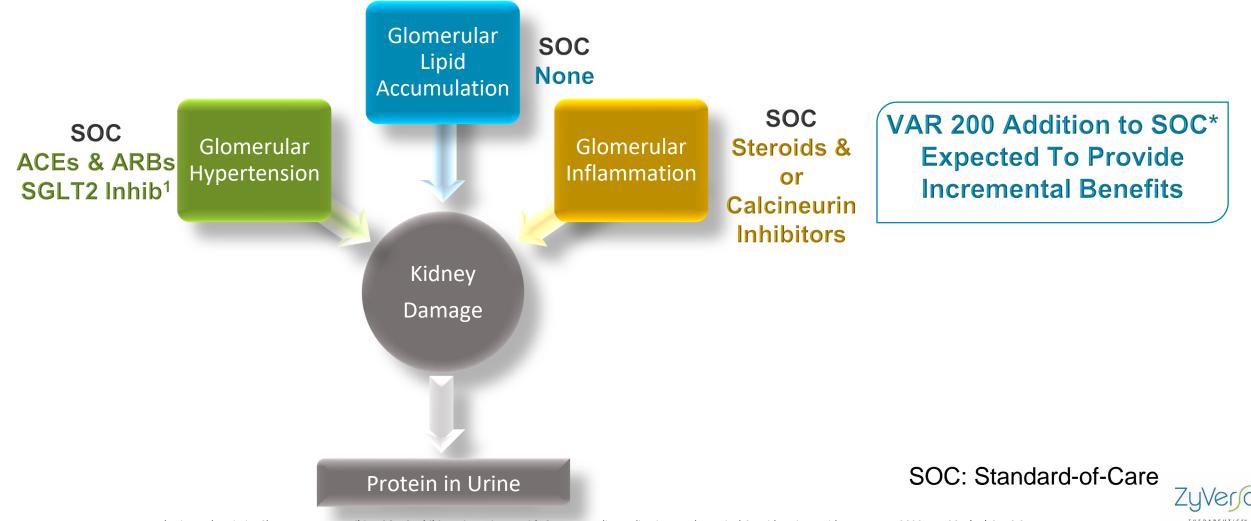




1. Mitrofanova et al, Kidney Int. 2018 Dec;94(6):1151-1159; 2. Ducasa GM, Mitrofanova A, Mallela SK, et al. ATP-binding cassette A1 deficiency causes cardiolipin-driven mitochondrial dysfunction in podocytes. J Clin Invest. 2019;129(8):3387–3400

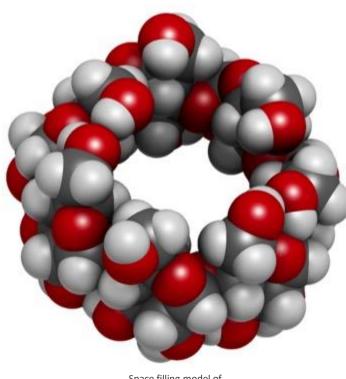
## Kidney Disease Pathologies Are Multifactorial

Current Standard-of-Care (SOC) Addresses Glomerular Hypertension and Inflammation



1. Yau K, Dharia A, Alrowiyti I, Cherney DZI. Prescribing SGLT2 Inhibitors in Patients With CKD: Expanding Indications and Practical Considerations. Kidney Int Rep. 2022 Aug 28;7(11):2546-2547.

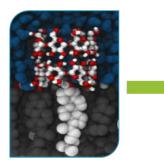
# VAR 200, Cholesterol Efflux Mediator<sup>™</sup> 2-Hydroxypropyl-Beta-Cyclodextrin (2HPβCD) Reduces Podocyte Cholesterol and Lipids



Space filling model of β-Cyclodextrin

### **Comprised of 7 Sugar Molecules Bound Together in a 3-D Ring**

- 2HPβCD has a hydrophobic core that entraps and passively removes intracellular cholesterol from the kidney
- 2HPβCD is believed to mediate active cholesterol removal through upregulation of cholesterol efflux transporters ABCA1 and ABCG1
- Cholesterol removal restores renal structure and function



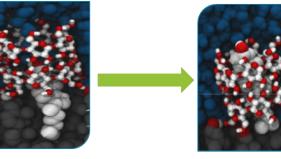


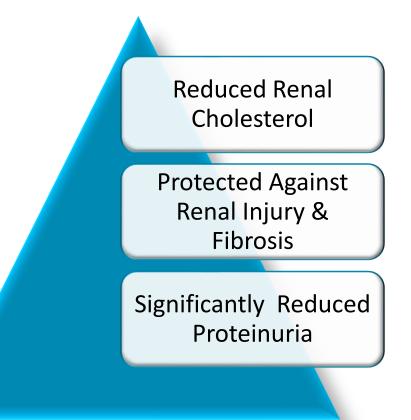
Image of βCD Adapted From Lopez et al: LoS Comput Biol 7(3): e1002020. doi:10.1371/journal.pcbi.1002020



Strong Preclinical Support for VAR 200,

With POC in 3 Different Animal Models of Kidney Disease, Both Genetic and Drug-induced

VAR 200 Demonstrated Similar Response Across FSGS, Alport Syndrome, and Diabetic Kidney Disease Models



### **Restoring Health, Transforming Lives Through Innovation**



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## Cholesterol Efflux Mediator<sup>™</sup> VAR 200 Clinical Plans

## VAR 200 Phase 2 Clinical Trial in Patients With Diabetic Kidney Disease

### **Objectives**

▶ Evaluate the efficacy and safety of Cholesterol Efflux Mediator<sup>TM</sup> VAR 200 in eight patients with type 2 diabetes who have diabetic kidney disease

### **Study Overview**

- Open label trial for real-time data reads
- VAR 200 will be administered IV twice weekly at 6g/dose for 12 weeks
- 4-week post-treatment follow-up

### **Primary Efficacy Endpoint**

Change from baseline to week 12 in urinary albumin to creatinine ratio (UACR)

### **Key Secondary Efficacy Endpoints**

- % Change from baseline to week 12 in urinary protein to creatinine ratio (UPCR) and UACR
- Change from baseline to week 12 in serum creatinine

### **Key Exploratory Endpoint**

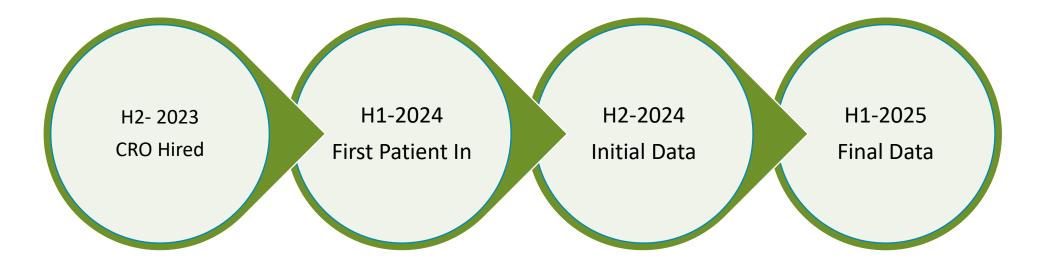
Change from baseline to week 12 in eGFR

### Milestones

- H1-2024: Study initiation
- H2-2024: Initial DKD data



DKD Clinical Trial Is Planned for Initiation Q1-2024





## SMARTDOSE Gen II: Promising Device for VAR 200 SubQ Expansion





### **Patient-centric Wearable Injector**

- User-focused engineering, with enhanced ergonomics
- Easy to use, intuitive design
- Visual, tactile and audible feedback to boost user confidence
- Wireless Bluetooth connectivity for user engagement
- User-loaded self-administration
- Streamlined workflow
- Ability to deliver high volume (10 mL) and high viscosity drug products
- Address a variety of delivery times through adaptable, pre-programmable technology

West Pharmaceutical Services Inc.



## Robust VAR 200 Market Opportunity

Uniquely Targets Renal Lipids

Expected to Slow Progression of Renal Disease

Preclinical Target Validation in FSGS, Alport Syndrome, & DKD

Orphan Disease Focus; Potential in 12 Million<sup>+</sup> DKD Patient Market

Established Safety Profile

Cleared for Phase 2a Clinical Trial in FSGS

Strong IP: Worldwide Exclusive License for Renal Disease; Orphan Drug Exclusivity



## Building Value: Key Activities, Inflection Points and Regulatory Milestones

- Cholesterol Efflux Mediator<sup>™</sup> VAR 200 on target to begin Phase 2a clinical trial in patients with diabetic kidney disease H1-2024.
- Inflammasome ASC Inhibitor IC 100 preclinical program nearing completion, with planned Investigational New Drug (IND) submission Q4-2024, and Phase 1 clinical trial initiation shortly thereafter.
- Inflammasome ASC Inhibitor IC 100 preclinical research funded by The Michael J. Fox Foundation for Parkinson's Research (MJFF) nearing completion, with potential for a second MJFF grant for further research.
- Scientific collaboration to assess Inflammasome ASC Inhibitor IC 100 as a potential treatment for atherosclerosis expected to conclude H1-2024.
- Scientific collaboration to assess Inflammasome ASC Inhibitor IC 100 as a potential treatment for obesity and metabolic syndrome expected to begin Q2-2024.

Program	Development Stage	Key Activities	IND Status	Key Milestones
VAR 200	Phase II	<ul> <li>Site Selection</li> <li>Finalized</li> </ul>	Open IND	<ul> <li>Initial Data H2-2024</li> </ul>
IC 100	Preclinical	<ul> <li>GMP Manufacturing</li> <li>GLP Toxicology</li> <li>Indication Expansion</li> </ul>	<ul> <li>Pre-IND Mtg Q3, 2024</li> <li>IND Filing Q4, 2024</li> </ul>	<ul> <li>Phase 1 Safety Readout Q1-2025</li> </ul>



## Financial Highlights

Financial Information	
Cash, cash equivalents and investments as of 12/31/2023	\$3.1M
Outstanding Shares (common stock/prefunded warrants) as of 3/1/2024	~7.58M
Balance Sheet	No debt

ZVSA (NASDAQ) (3/22/2024)	
Market Capitalization	~\$7.1M
Average Daily Trading Volume	~3.1M shares
Share Price	\$.84



## Corporate Presentation Q2-2024 Nasdaq: ZVSA



### T H E R A P E U T I C S<sup>™</sup>

Restoring Health, Transforming Lives Through Innovation

ZyVersa Non-confidential