

Developing Novel Therapies for Acute Inflammatory and Immunologic Diseases






May 2024

Forward-Looking Statements

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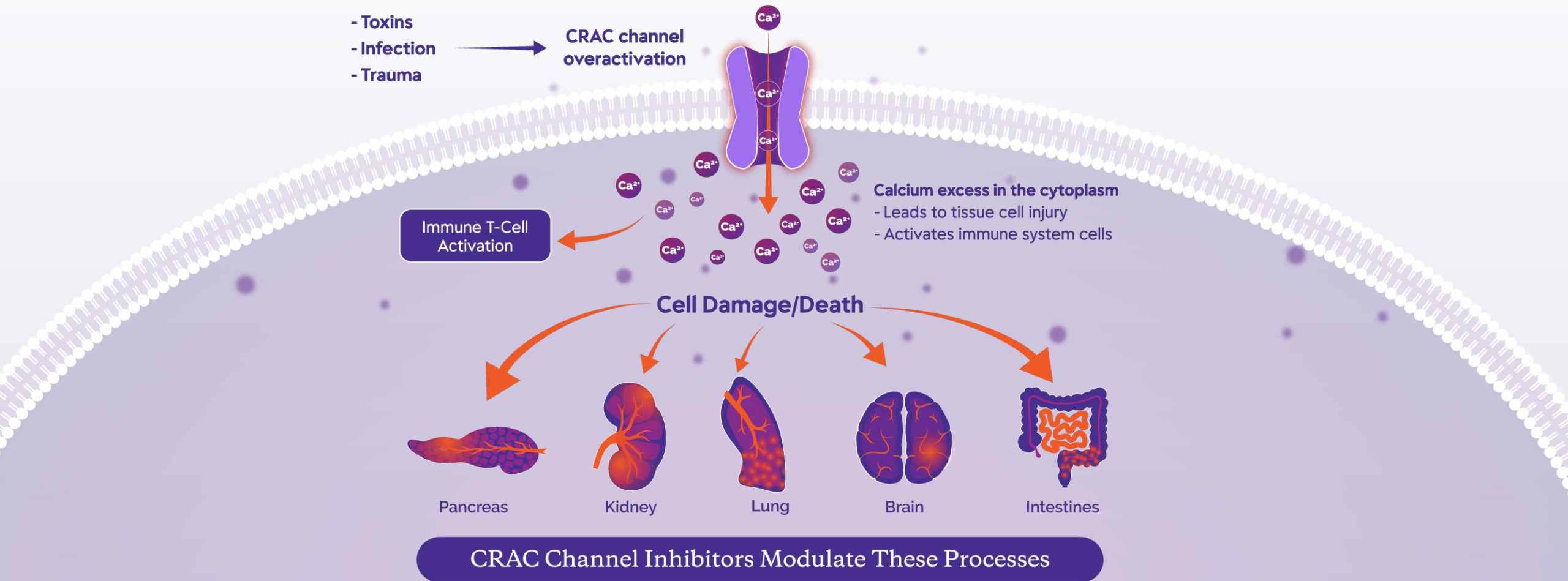
Investment Highlights

	Differentiated Technology	Proprietary technology targeting CRAC channel inhibition to develop novel therapies for life-threatening inflammatory diseases with high unmet need
	Compelling Proof-of-Concept Data	Auxora has demonstrated positive, consistent clinical results and was well tolerated in multiple Phase 2 trials; notably, the 284-patient CARDEA trial in COVID pneumonia patients showed a 56% reduction in 30-day mortality
	Substantial Market Opportunity	~100K target AP population and ~1 million target AKI population represent \$ multi-billion U.S. market opportunities with no approved therapies
	Strong IP	Composition of matter (2036), formulation (2038), and methods of use (2036-2041+) worldwide patent protection
	Cash to Fund Clinical Programs	Completed private placement in 1Q24 which is expected to fund the ongoing CARPO Phase 2b trial in AP patients with data expected in 1H24 and KOURAGE Phase 2 trial in AKI patients with data expected in 2025

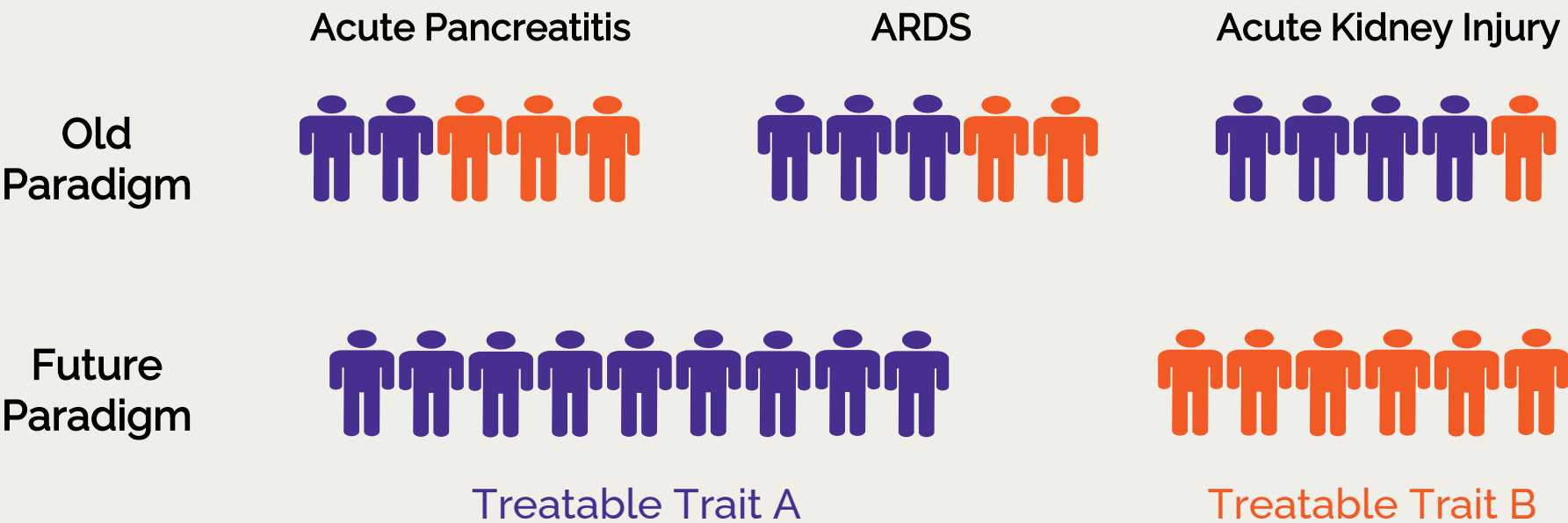
Differentiated Pipeline in Acute and Chronic Inflammatory and Immunologic Diseases

Program ¹	Indication	Phase of Development				Anticipated Milestones
		Preclinical	Phase 1	Phase 2	Phase 3	
Acute Disease (IV)						
Auxora	Acute Pancreatitis	<div></div>	<div></div>	<div></div>	<div></div>	CARPO Phase 2b trial ongoing; Topline data expected in 2Q24
Auxora	Asparaginase-Induced Pancreatic Toxicity in Pediatric Patients	<div></div>	<div></div>	<div></div>	<div></div>	CRSPA Phase 1/2 trial ongoing; Data expected in 2025
Auxora	Acute Kidney Injury	<div></div>	<div></div>	<div></div>	<div></div>	KOURAGE Phase 2 trial first patient expected 2Q24; Data expected in 2025
Chronic Disease (Oral)						
CM6336	Chronic Pancreatitis	<div></div>	<div></div>	<div></div>	<div></div>	IND submission expected in 2025
CM6336	Rheumatoid Arthritis	<div></div>	<div></div>	<div></div>	<div></div>	IND submission expected in 2025

Overactivation of CRAC Channels: Immune System Activation and Tissue Cell Injury



Acute Inflammation: Underlying Cause Across Many Diseases

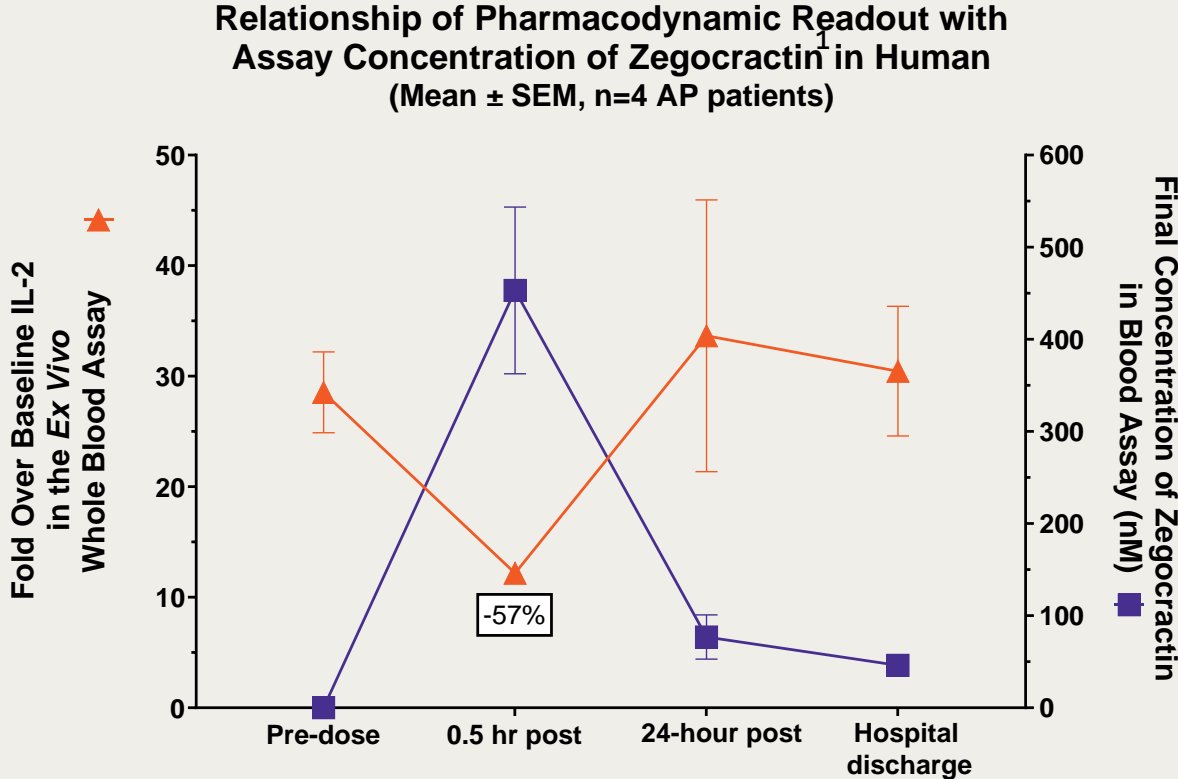


Auxora has demonstrated positive clinical results in all 3 of these large, underserved patient populations

1) Sources: Reddy, Kiran, Carolyn S. Calfee, and Danny F. McAuley. "Acute respiratory distress syndrome subphenotypes beyond the syndrome: a step toward treatable traits?." American Journal of Respiratory and Critical Care Medicine 203.12 (2021): 1449-1451.

IV Formulation Provides Ideal Benefits for Acute Inflammation

Rapid onset of immunomodulatory action reaches peak by the end of 4-hour infusion



Recovery within 24-48 hours of dosing limits the potential for long-term immunosuppression

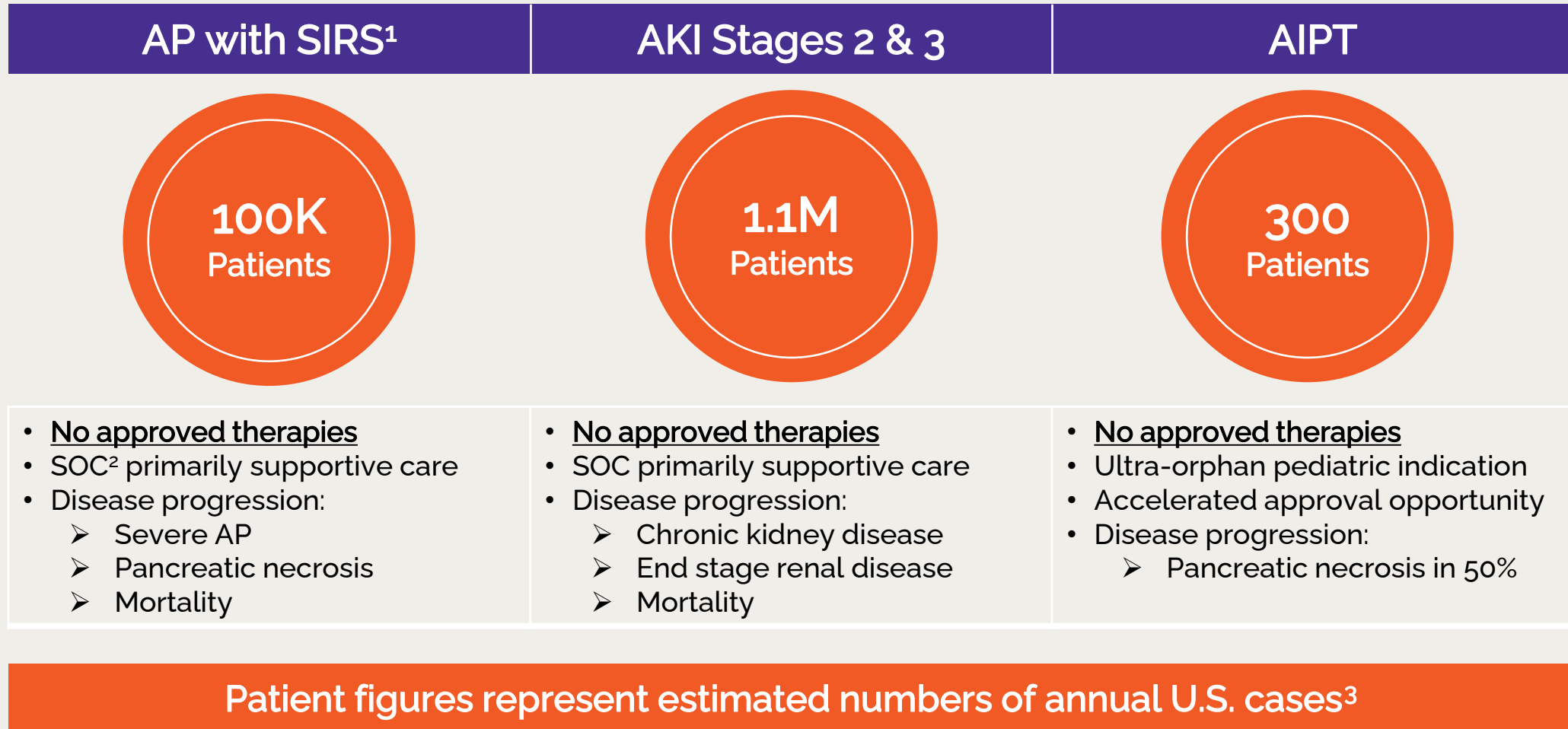
¹) Zegocractin is the active pharmaceutical ingredient in Auxora

Demonstrated Biological Activity and was well tolerated in Multiple Phase 2 Trials

Population	Results
Pancreas	
Asparaginase- Induced Pancreatic Toxicity	<ul style="list-style-type: none"> • Trial ongoing, preliminary results show rapid resolution of pain and food tolerance
Acute Pancreatitis With SIRS	<ul style="list-style-type: none"> • Trial ongoing
Acute Pancreatitis	<ul style="list-style-type: none"> • Target engagement of CRAC channels in peripheral lymphocytes
Acute Pancreatitis Accompanied by SIRS and Hypoxemia	<ul style="list-style-type: none"> • Rapid increase in patients tolerating solid diet (potential trial pivotal endpoint) • >2-day reduction in hospital stay and 50% reduction SIRS
Lung	
COVID-19 with Respiratory Failure On LFO ₂ ¹ or HFNC ²	<ul style="list-style-type: none"> • 56% statistically significant decrease in mortality at Day 30 • 33% reduction in ventilation • >2-day shorter hospital stay • ~40% reduction in reported acute kidney injury
COVID-19 with Respiratory Failure On IMV ³	<ul style="list-style-type: none"> • Open-label trial with varying doses showing pharmacodynamic response

1) LFO₂: Low Flow Oxygen; 2) HFNC: High-Flow Nasal Cannula; 3) IMV: Invasive Mechanical Ventilation

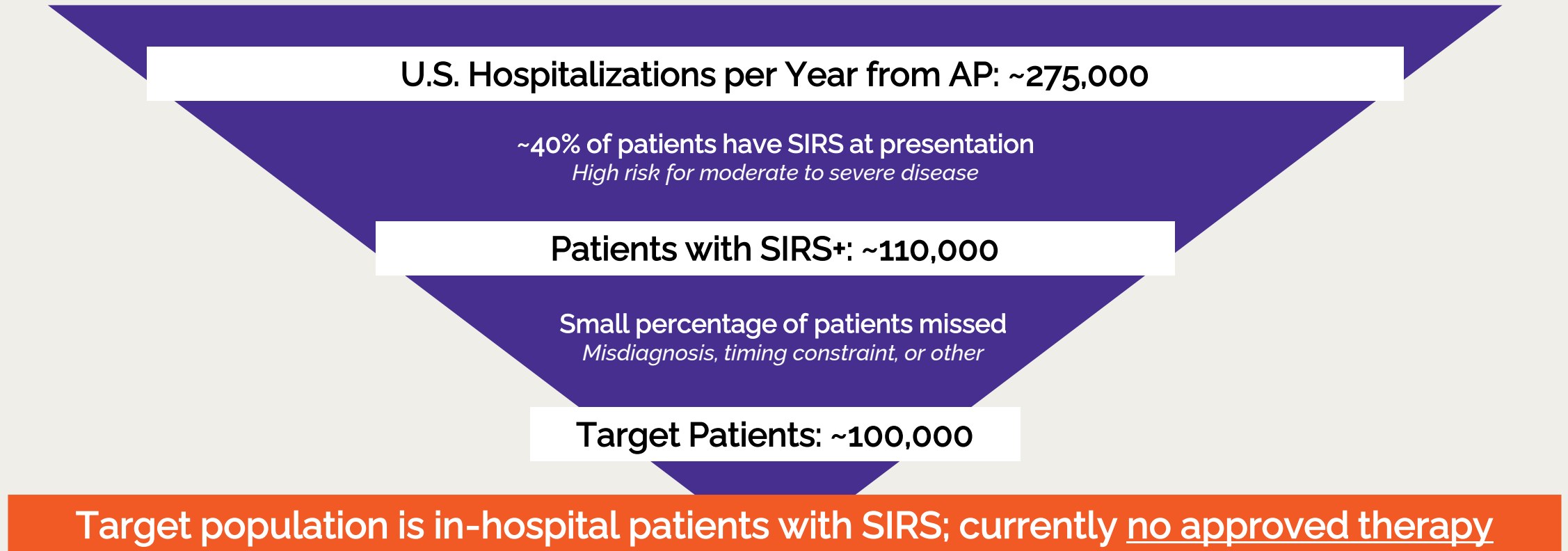
Large U.S. Market Opportunity in Acute Inflammatory Diseases



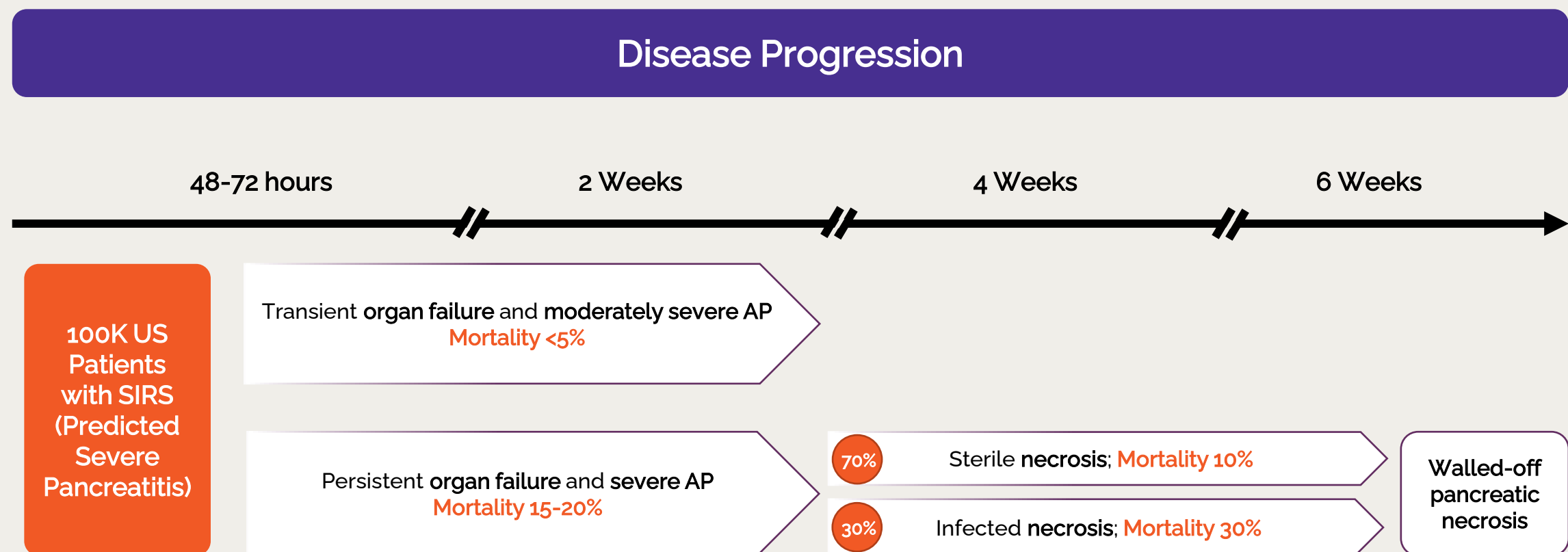
1) **SIRS**: Systemic Inflammatory Response Syndrome; 2) **SOC**: Standard of Care; 3) Sources: Primary Market Research, KOLs, Healthcare Cost and Utilization Project, Pancreatitis Foundation, and <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb231-Acute-Renal-Failure-Hospitalizations.pdf>
Criteria: Based on RIFLE staging criteria for AKI classification; Serum creatinine increase over baseline

Auxora for Acute Pancreatitis (AP)

AP Population: Significant Unmet Need



Patient Journey in Severe AP



1) Source: Adapted from N Engl J Med 2016;375:1972-81. DOI: 10.1056/NEJMra1505202

Potential Clinical Benefits to Patients with Predicted Severe AP

Current standard of care is limited to supportive therapy

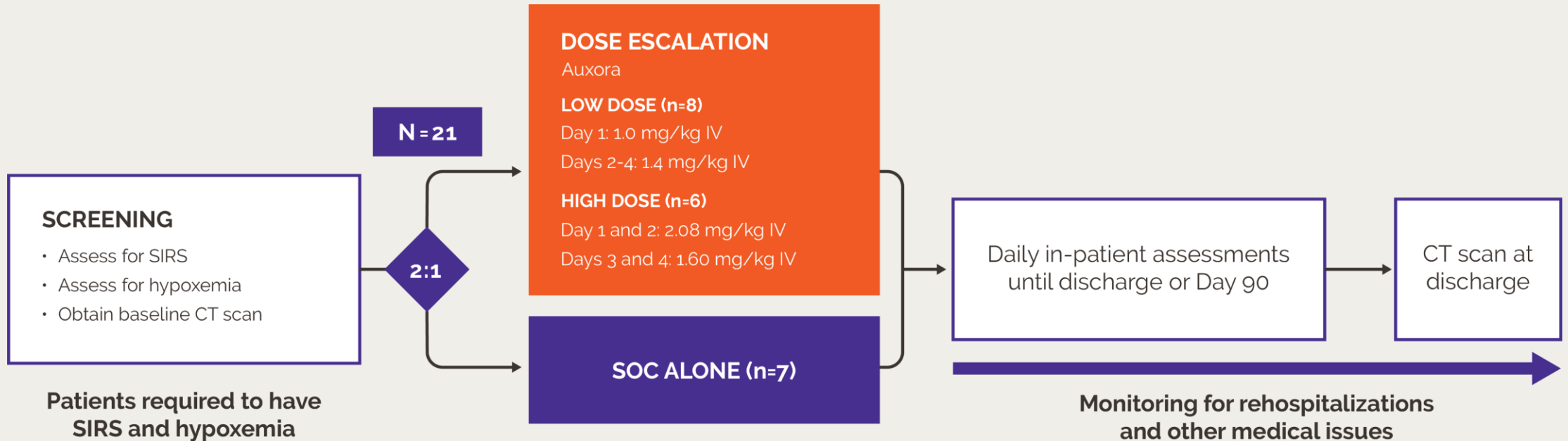
- Fluid resuscitation
- Enteral nutrition for food tolerance
- Antibiotics for infection
- Minimally invasive therapy for local complications

Auxora benefits are expected to drive adoption

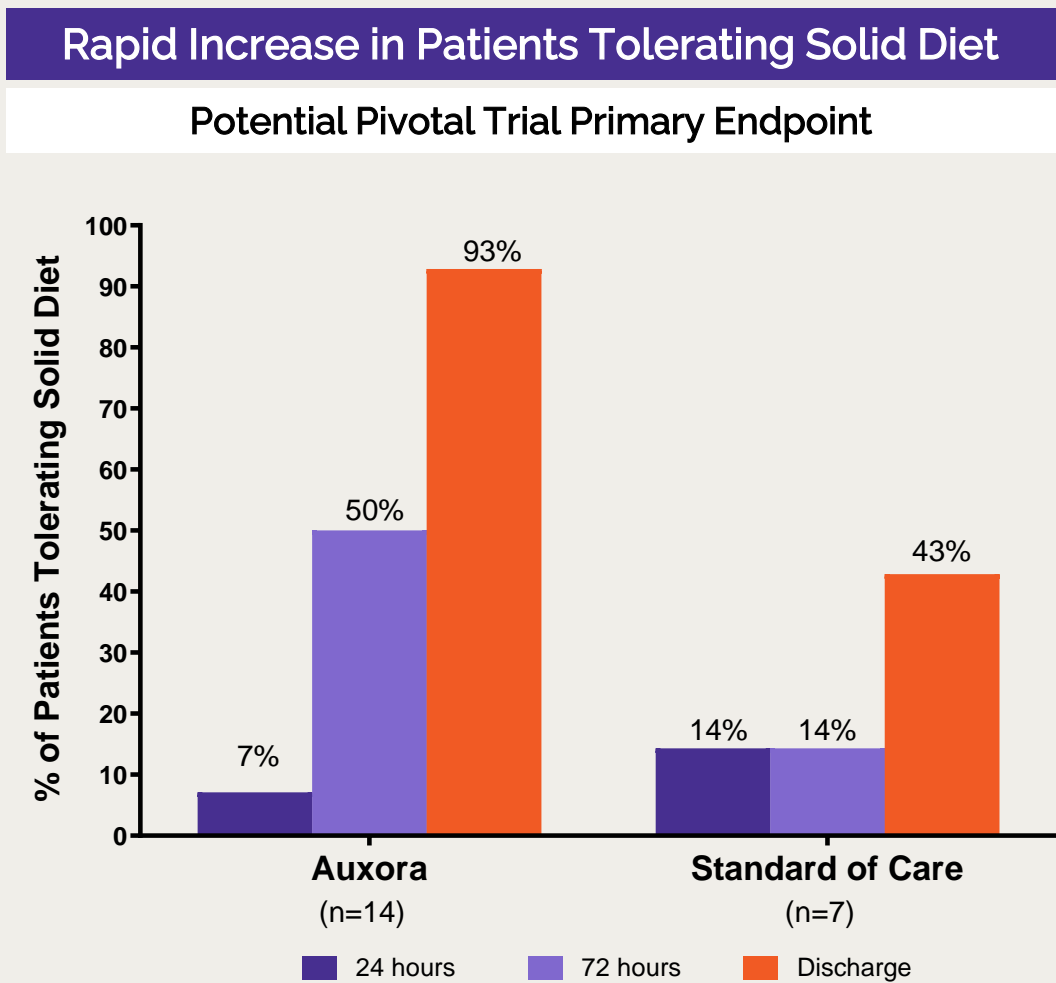
- Reduction in organ failure
- Reduction in pancreatic necrosis
- Earlier food tolerance
- Fewer days in hospital or ICU

AP Phase 2a Clinical Trial

Safety, tolerability, and efficacy trial for various doses of Auxora compared to standard of care



Positive Phase 2a Results on Potential Pivotal Trial Primary Endpoints



>2 Fewer Days Spent in Hospital	
Median Hospital Stay	
SOC patients (n=7)	6.0 days
Auxora-treated patients (n=14)	3.7 days

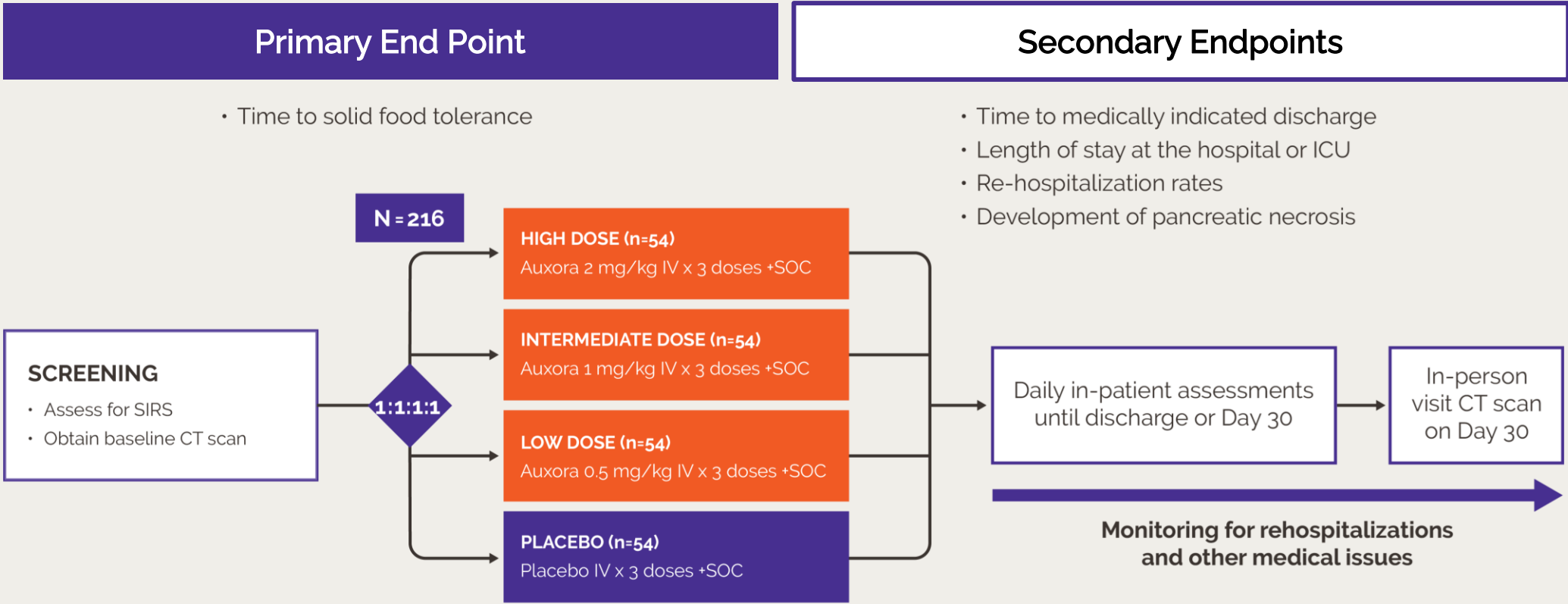
Only Auxora Patients Improved on CTSI ¹ Scores	
Moderate to Severe CTSI ¹ Scores	
SOC patients (n=4)	0/4 (0%)
Auxora-treated patients (n=8)	3/8 (38%)

50% Reduction in Persistent SIRS	
Patients with Persistent SIRS	
SOC patients (n=7)	5/7 (71%)
Auxora-treated patients (n=14)	5/14 (36%)

1) CTSI: CT Severity Index

CARPO Phase 2b Clinical Trial in AP

Ongoing with Data Expected 1H 2024



Responder analysis planned to validate food tolerance endpoint with FDA

CARPO Endpoints

Endpoint	Clinical Importance and Economic Considerations
Study Objective <ul style="list-style-type: none"> ➤ Dose response 	<ul style="list-style-type: none"> • Important evidence of Auxora activity • Clear difference between lowest doses and higher doses would be meaningful
Primary Endpoint <ul style="list-style-type: none"> ➤ Time to solid food tolerance ➤ Solid food tolerance at 48, 72, and 96 hours 	<ul style="list-style-type: none"> • Indication of pancreatic functional recovery • Even a reduction of less than a day could translate to meaningful patient benefit¹ • Expected correlation with patient outcomes—endpoint validation will be conducted
Key Outcome Measures <ul style="list-style-type: none"> ➤ Time to medically indicated discharge ➤ Length of stay in the hospital or ICU ➤ Re-hospitalization for AP by Day 30 	<ul style="list-style-type: none"> • Important indications of activity for regulators and potential co-primary endpoints for registration • Reduction in hospital stay of a day would be meaningful to patients and providers¹ • Direct impact on hospital costs and hospitalist performance metrics • Significant reimbursement limitations for AP readmission to the hospital within 30 days ²
Imaging Measures <ul style="list-style-type: none"> ➤ Change in AP severity by CTSI score from screening to Day 30 ➤ Development of pancreatic necrosis ≥30% and >50% 	<ul style="list-style-type: none"> • Direct evidence of pancreatic recovery • Improvement in mean CTSI scores, reduction in severity category (mild, moderate, severe), or reduction in portion of patients with extensive necrosis would be clinically meaningful and likely correlated with outcomes • 30% necrosis or greater associated with long-term morbidity like diabetes³ • Fewer chronic problems are important to payors and patients
Key Severe Outcomes <ul style="list-style-type: none"> ➤ Incidence, severity, and duration of organ (e.g. respiratory) failure ➤ Mortality by Day 30 	<ul style="list-style-type: none"> • Organ failure, especially respiratory failure and ventilator use, associated with mortality • 20% relative risk reduction in severe outcomes would be meaningful⁴ especially given lack of current therapies • Severe outcomes can add cost to the hospitals especially for patients with long (weeks and months) hospital/ICU stays • Reduced mortality important success metric for providers and hospitals
Exploratory Biomarkers <ul style="list-style-type: none"> ➤ Albumin ➤ Absolute neutrophil count/absolute lymphocyte count ratio ➤ IL-6 levels ➤ NGAL levels 	<ul style="list-style-type: none"> • Biomarkers may provide additional evidence of MOA and potential screening tools or outcome metrics • High IL-6 a hallmark of AP and implicated in other acute inflammatory conditions • Neutrophils indicative of inflammation and potential tissue damage/necrosis • Albumin and NGAL are key measures of extent of disease

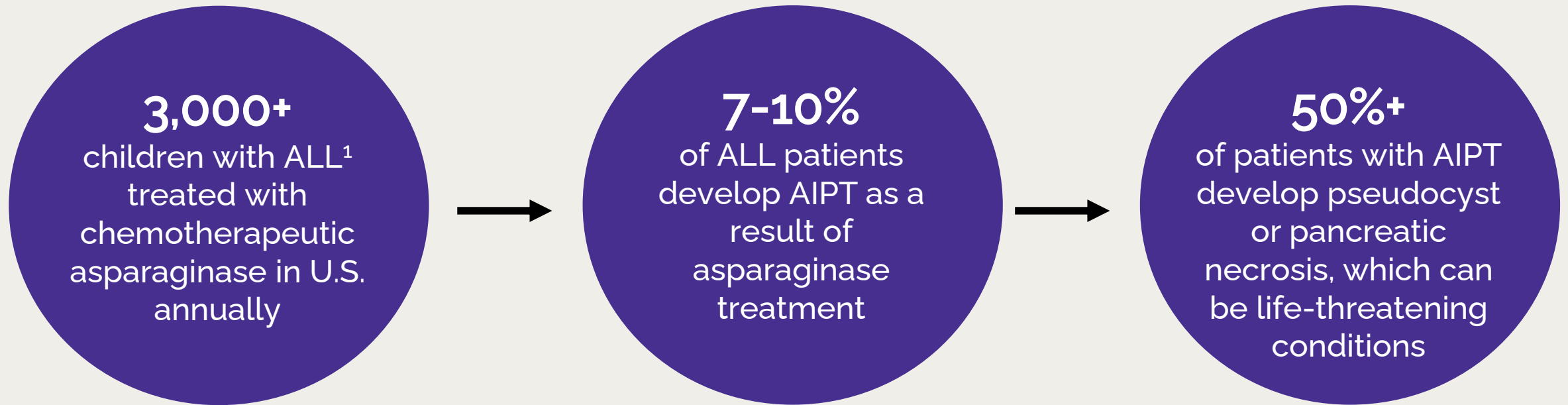
1. Discussions with and feedback from Clinical Advisory Board Members

2. Readmission in acute pancreatitis: Etiology, risk factors, and opportunities for improvement. Bogan BD, McGuire SP, Maatman TK. Surg Open Sci. 2022 Nov 7;10:232-237. Centers for Medicare & Medicaid Services (CMS) Claims Processing Manual, Chapter 3- Inpatient Hospital Billing, 40.2.5. Centers for Medicare & Medicaid Services (CMS), Medicare Quality Improvement Organization (QIO) Manual. Readmission Review, Chapter 4, Section 4240

3. Endocrine and exocrine pancreatic insufficiency after acute pancreatitis: long-term follow-up study. Tu J, Zhang J, Ke L, Yang Y, Yang Q, Lu G, Li B, Tong Z, Li W, Li J. BMC Gastroenterol. 2017 Oct 27;17(1):114. Diabetes following acute pancreatitis. Hart PA, Bradley D, Conwell DL, Dungan K, Krishna SG, Wyne K, Bellin MD, Yadav D, Andersen DK, Serrano J, Papachristou GI. Lancet Gastroenterol Hepatol. 2021 Aug;6(8):668-675.

4. Powering Bias and Clinically Important Treatment Effects in Randomized Trials of Critical Illness. Abrams D, Montesi SB, Moore SKL, Manson DK, Klipper KM, Case MA, Brodie D, Beitler JR. Crit Care Med. 2020 Dec;48(12):1710-1719.

Potential Clinical Benefits to Children with AIPT



Auxora has potential to rapidly resolve AIPT with improvement in food tolerance and pain while preventing development of further complications such as pancreatic necrosis

1) **ALL:** Acute Lymphoblastic Leukemia

2) Sources: Liu C, Yang W, Devidas M, et al. Clinical and Genetic Risk Factors for Acute Pancreatitis in Patients With Acute Lymphoblastic Leukemia. J Clin Oncol. 2016. Abaji R, Gagne V, Xu CJ, et al. Whole-exome sequencing identified genetic risk factors for asparaginase-related complications in childhood ALL patients. Oncotarget. 2017;8: 43752-43767. Rank C, Wolthers B, Grell K, et al. Asparaginase-associated pancreatitis in acute lymphoblastic leukemia: results from the NOPHO ALL 2008 treatment of patients 1-45 years of age. J Clin Oncol. 2019 38:145-154.

Proof-of-Concept Ongoing in AIPT Pediatric Patients Had Rapid Resolution of Pain and Food Intolerance

CRSPA Phase 1/2 Trial in Pediatric AIPT

- Investigator-initiated open-label trial being conducted at St. Jude Children's Research Hospital
- Assess the safety in pediatric patients with ALL who have developed AIPT
- Estimate the efficacy of Auxora to prevent pseudocyst or necrotizing pancreatitis in pediatric patients with AIPT

Trial Status

- Cohort 1 complete (9 patients)
 - 8 patients received four daily infusions of Auxora and had rapid resolution of pain and food intolerance
 - 1 patient received less than a single infusion of Auxora and developed pancreatic necrosis
 - Blinded matched, historical control comparison for Cohort 1 completed
- Cohort 1 dosing selected as recommended dose for patients
- Expanding to additional sites to complete trial (24 patients) with data expected in 2025

Results for First Cohort Compared to Blinded, Matched Historical Controls Presented at ASH 2023

CRSPA First Cohort Data: Presented at ASH 2023

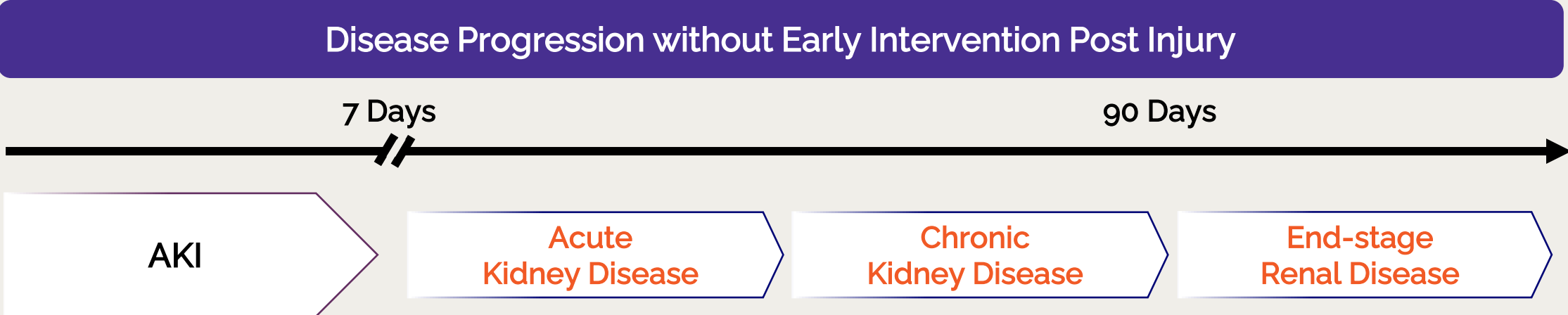
	Total 16 (T16): All AIPT	Matched T16 AIPT cohort	CRSPA evaluable for efficacy
Patients with AIPT	51	16	8
Age: mean (range)	10.3 (2.2-19.4)	9 (2.2-18.4)	8.2 (3.1-17.6)
Female (%)	17 (33.3%)	5 (31.3%)	3 (37.5%)
Low-risk therapy (%)	9 (17.6%)	1 (6.3%)	2 (25%)
Hospital days (range)	12.1 (2-70)	13.4 (2-27)	6.3 (5-8)
ICU needed (%)	11 (21.6%)	3 (18.8%)	1 (12.5%)
ICU days mean (range)	5.1 (1-9)	5 (3-7)	3
TPN needed (%)	27 (52.9%)	11 (68.8%)	0
TPN days mean (range)	37.7 (3-153)	27.2 (4-63)	NA
≥30% pancreatic necrosis (%)	NA	4 (26.7%) *	0
CTSI mean (range)	NA	5.4 (0-10) *	2.4 (0-4)
CTSI ≥ 7 (%)	NA	4 (26.7%) *	0

*One patient in matched T16 cohort was unable to be evaluated for pancreatic necrosis or a CTSI score

CTSI score definitions: 0-3 mild acute pancreatitis, 4-6 moderately severe acute pancreatitis, ≥7 severe acute pancreatitis

Auxora for Acute Kidney Injury (AKI)

Patient Journey in AKI



~3.7M AKI hospitalizations annually (U.S.)



Auxora Target Market: 1.1M¹ Patients

Over half of these patients have respiratory failure with 90-day mortality 50% or greater

1) Source: <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb231-Acute-Renal-Failure-Hospitalizations.pdf>
Criteria: Based on RIFLE staging criteria for AKI classification; Serum creatinine increase over baseline
2) sCr: Serum Creatinine

Potential Clinical Benefits to Patients with AKI

Current standard of care is limited to supportive therapy

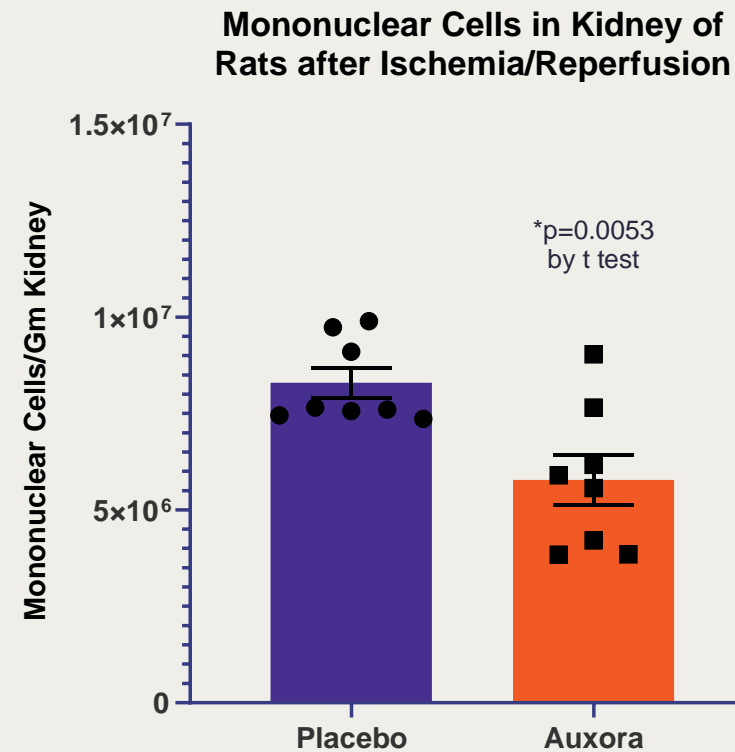
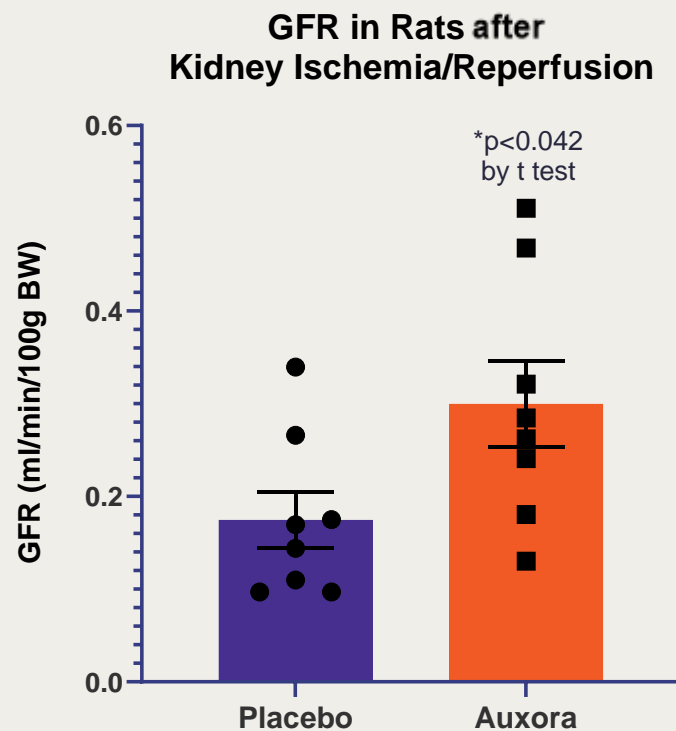
- Fluid resuscitation / Diuretics
- Nutrition
- Correction of underlying cause

Auxora benefits are expected to drive adoption

- Reduced need for dialysis
- Reduced risk of mortality
- Greater recovery of renal function

Improved GFR¹ and Decreased Inflammatory Cell Infiltrates Within 24 Hours in AKI Model

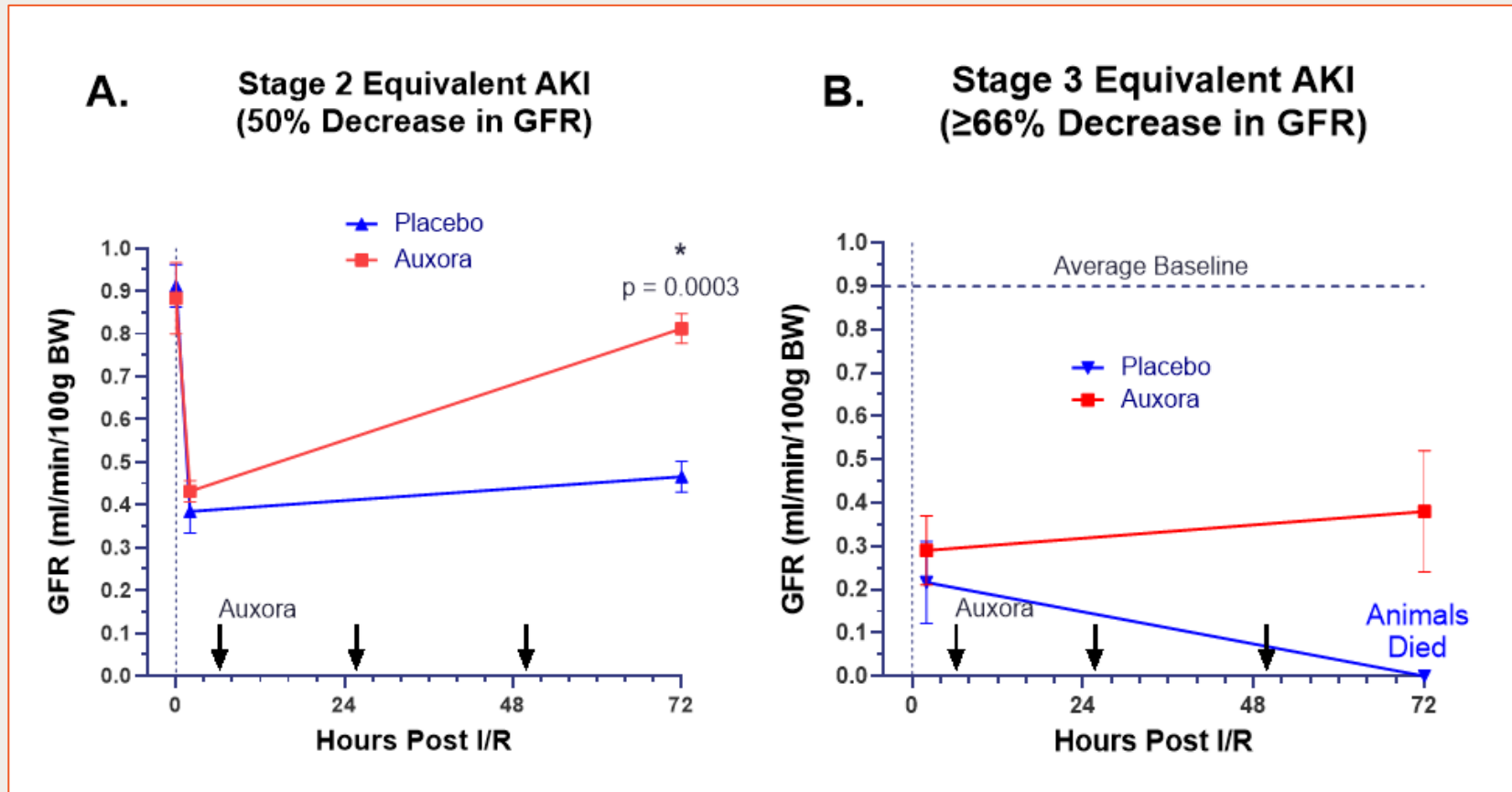
A single dose of Auxora or placebo was administered 30 min after bilateral kidney ischemia/reperfusion



1) GFR: Glomerular filtration rate
2) Data courtesy of David Basile, PhD, Indiana University

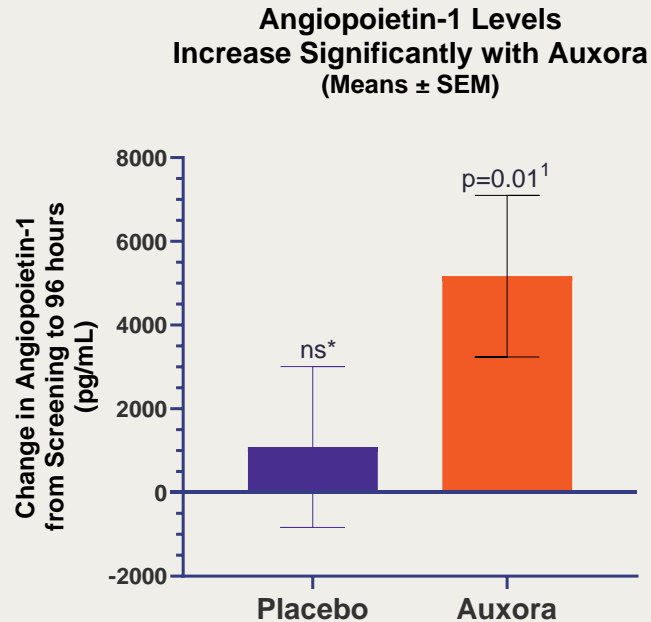
Improved Kidney Recovery and Survival in Severe AKI models

Three doses of Auxora or placebo were administered daily starting 6 hours after ischemia/reperfusion injury

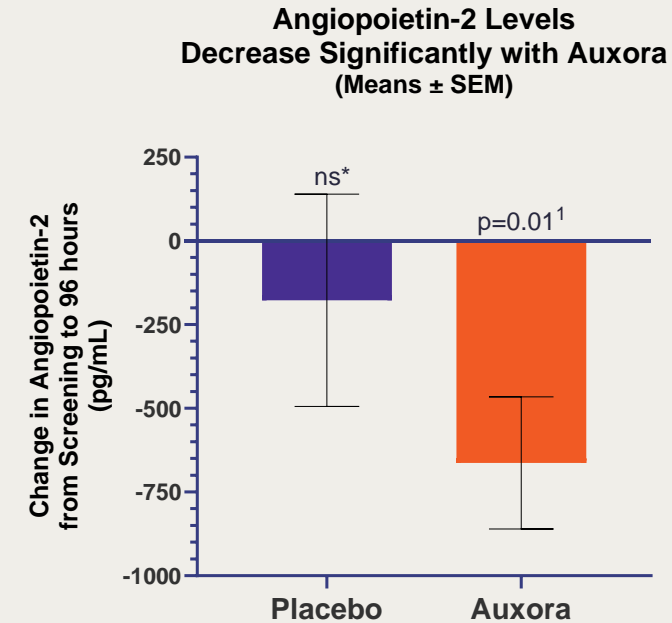


Phase 2 CARDEA Trial: Evidence of Renal Protection

Ang-1/Tie2 signaling maintains vascular integrity



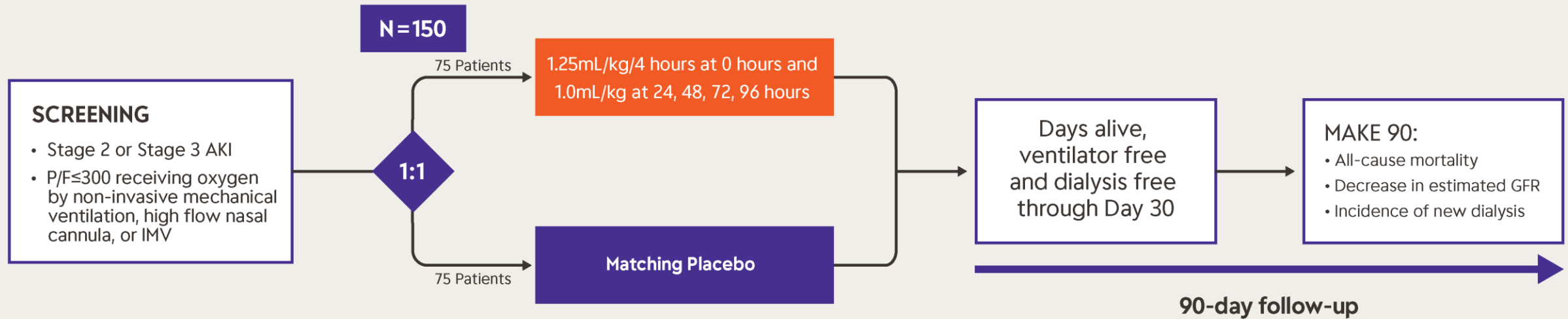
Ang-2/Tie2 results in endothelial inflammation with increased endothelial permeability



Clinical Observations

- Mortality benefit with Auxora vs Placebo observed in patients with compromised kidney function (low GFR) at time of enrollment
- ~40% reduction in reported AKI with Auxora vs Placebo

KOURAGE: Acute Kidney Injury with associated AHRF Phase 2 Trial Design



Auxora for Acute Respiratory Distress Syndrome (ARDS)

Promising Phase 2 Data from Trials in COVID-19 Pneumonia and in Ventilated Patients with Respiratory Failure

CARDEA Phase 2
Severe and Critical COVID-19
Pneumonia Patients
N=284

Trial Complete

- 56% reduction in mortality at Day 30 ($p=0.0165$)
- 33% reduction ventilation ($p=0.18$)
- Three-day shorter hospital stay ($p=0.09$)

Phase 2
COVID-19 Ventilated
Patients N=9

Trial Ongoing; Data Analysis Underway

- Reduction in inflammatory cell-type gene expression by macrophages in lungs
- No reduction in mitochondrial and ribosomal gene expression

**Data Analysis of Biomarker and Mechanism-of-Action in Ventilated Patients
to Inform Development Plan for ARDS expected in 1H24**

Platform Application for CRAC Channel Inhibition

Preclinical Results Supporting Other I&I Indications

Indication	Intended Formulation	Preclinical Observations	Next Steps
Chronic Pancreatitis (CP)	Oral	In vivo efficacy in a mouse model of CP using CM5480 (Szabo et al, 2023)	Confirm with lead oral candidate
Acute Ulcerative Colitis	IV	In vivo efficacy of zegocractin in a mouse model of inflammatory bowel disease (Letizia et al., 2022)	Ongoing discussions with investigators about potential clinical trials
Allergic Asthma	IV or Inhaled	In vivo efficacy of zegocractin in a mouse model of allergic asthma (Kahlfuss et al., 2022)	Pursue strategic partnership
Traumatic Brain Injury (TBI)	IV or Oral	In vivo efficacy of CM5480 in a mouse model of TBI (Mizuma et al., 2018)	Confirm results with lead oral compound or Auxora
Rheumatoid Arthritis (RA)	Oral	In vivo efficacy of zegocractin and CM5480 in rat RA models (CalciMedica unpublished data)	Confirm results with lead oral candidate

Anticipated Milestones

Anticipated Milestones

AP	CARPO Phase 2b Data Expected in 1H24 Phase 3 Initiation Expected in 2025
AIPT	CRSPA Initial First Cohort Data Released at ASH 2023 Trial Expansion Underway; Data Expected in 2025
AKI	KOURAGE First Patient Enrolled Expected in 1H24 Data Expected in 2025
ARDS	Phase 2 Data in Ventilated COVID Patients Publication Expected in 1H24 Will Inform the Development Plan for ARDS
Cash Runway	Current Cash Runway into 2H25