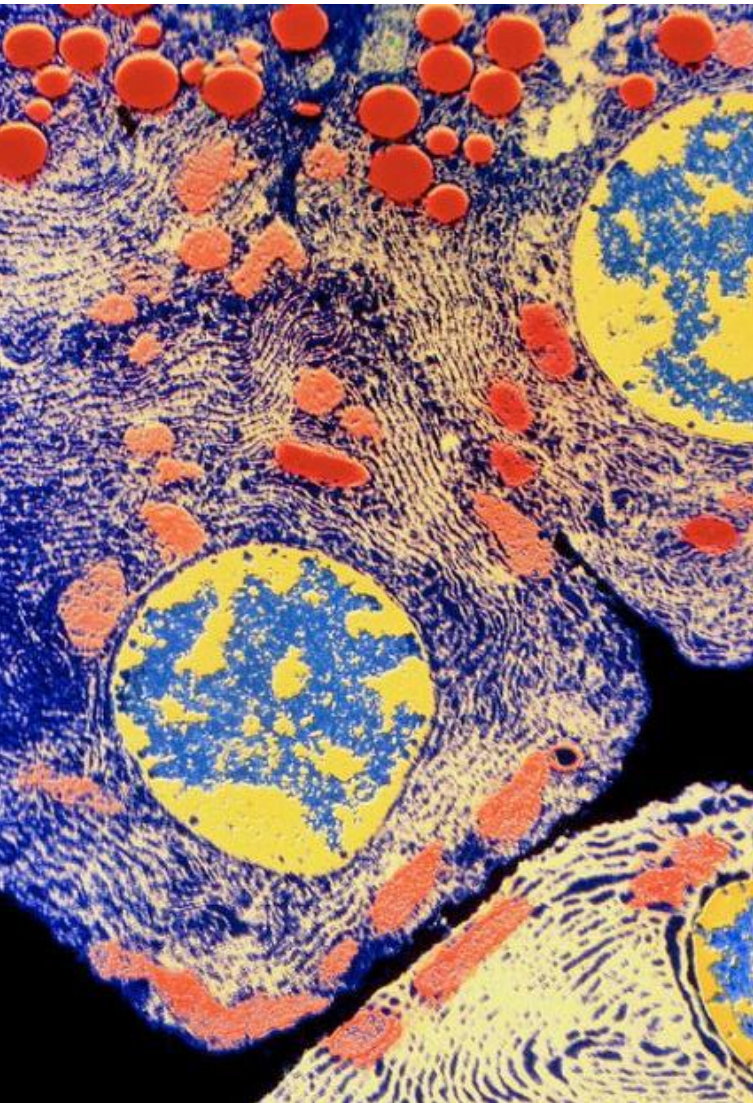




CalciMedica



Developing Novel Therapies for Acute Inflammatory and Immunologic Diseases

CARPO Trial Topline Results

June 27, 2024

Forward-Looking Statements

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CARPO Topline Takeaways

- Primary objective was met with a dose response for multiple endpoints
 - Statistically significant for time to solid food tolerance in high hematocrit patients
 - Statistically significant for severe organ failure in the entire population
- Auxora was well-tolerated
- Auxora is ready for Phase 3 clinical development
 - Pending discussions with FDA following final data
 - Final data, including CT scan (baseline and 30-day) data, expected to be presented at a medical meeting later this year
- Reduction in severe organ failure increases confidence in our KOURAGE AKI trial
 - Magnitude in reduction similar to what was seen in CARDEA and Phase 2a AP trials

Auxora Clinically Active and Well-Tolerated in Multiple Phase 2 Trials

Population	Trial Size	Results
Pancreas		
Acute Pancreatitis With SIRS (CARPO)	N=216	<ul style="list-style-type: none"> • Topline results show: <ul style="list-style-type: none"> ➢ Improvement in clinically significant endpoints ➢ Statistically significant dose response for time to solid food tolerance in patients with hyper-inflammation ➢ Statistically significant dose response in severe organ failure
Acute Pancreatitis Accompanied by SIRS and Hypoxemia	N=21	<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
Asparaginase-Induced Pancreatic Toxicity (CRSPA)	N=9	<ul style="list-style-type: none"> • Trial ongoing, preliminary results show rapid resolution of pain and food tolerance
Lung		
COVID-19 with Respiratory Failure (CARDEA) On LFO ₂ ¹ or HFNC ²	N=284 (Part 2) N=30 (Part 1)	<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 • Mortality benefit in patients with compromised kidney function (low GFR)
COVID-19 with Respiratory Failure On IMV ³	N=9	<ul style="list-style-type: none"> • Open-label trial with varying doses showing pharmacodynamic response

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	████████	████████	████████▶	████████	CARPO Phase 2b trial topline data released; Final data expected in 2H2024
Auxora	Asparaginase-Induced Pancreatic Toxicity in Pediatric Patients	████████	████████	████████▶	████████	CRSPA Phase 1/2 trial ongoing; Data expected in 2025
Auxora	Acute Kidney Injury	████████	████████	████████▶	████████	KOURAGE Phase 2 trial first patient expected 2Q24; Data expected in 2025
Chronic Disease (Oral)						
CM6336	Chronic Pancreatitis	████▶	████████	████████	████████	IND submission expected in 2025
CM6336	Rheumatoid Arthritis	████▶	████████	████████	████████	IND submission expected in 2025

With CARPO results, Auxora is Phase 3 ready pending End-of-Phase 2 Discussion with FDA

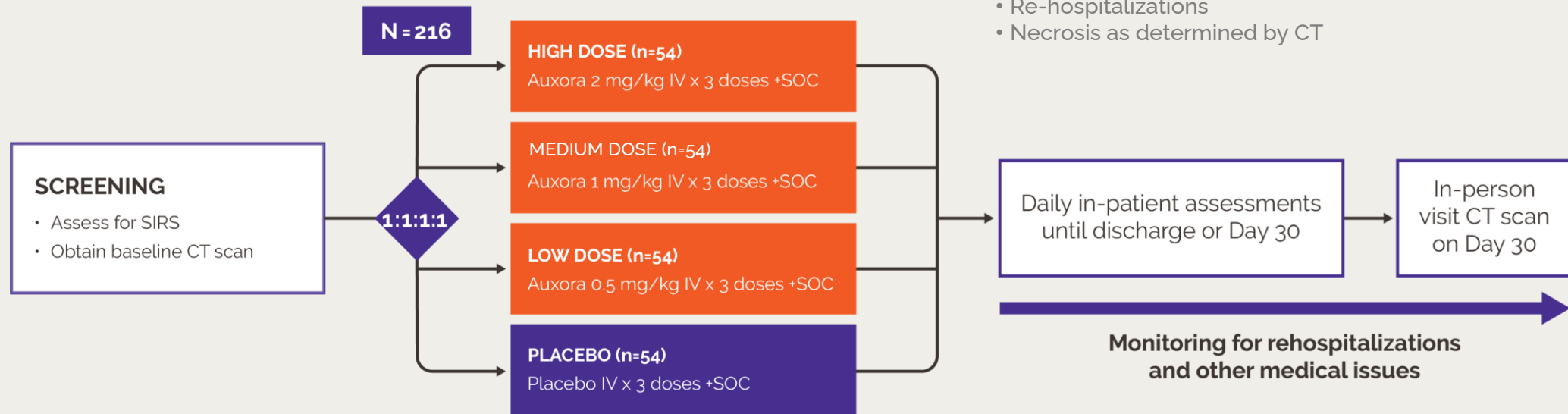
CARPO Phase 2b Clinical Trial in AP

Primary End Point

- Time to solid food tolerance

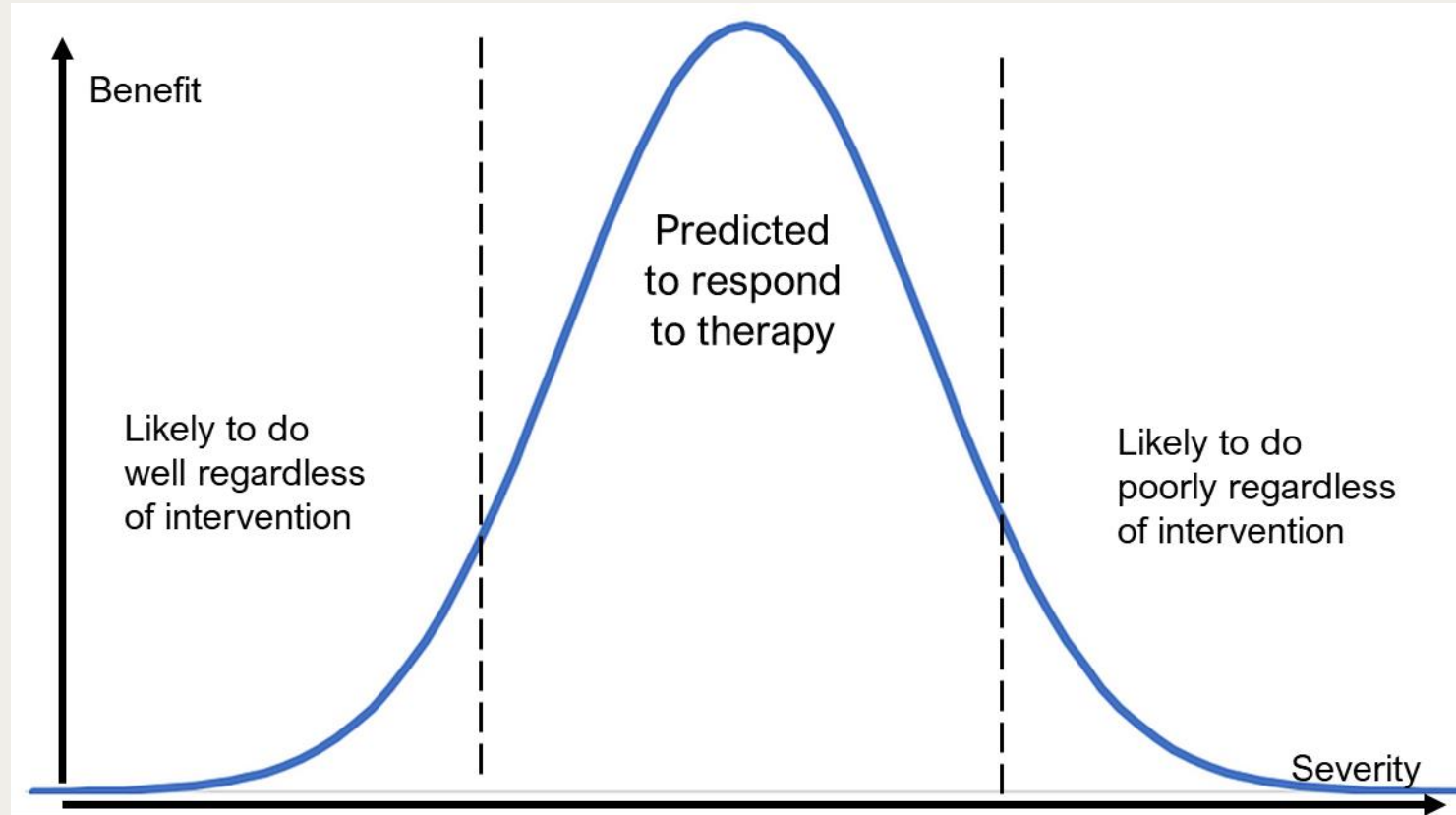
Secondary Endpoints

- Length of hospital stay
- Time to medically indicated discharged
- Severe organ failure
- Re-hospitalizations
- Necrosis as determined by CT



Primary Objective: Dose Response on Primary and Secondary Endpoints

Defining Who to Treat: Patients with Acute Critical Illnesses



Enrich CARPO for Patients with Hyperinflammatory Acute Pancreatitis

- CARPO added inclusion criteria to enroll pre-specified subgroup of patients with an elevated hematocrit
- Inclusion criteria in addition to SIRS
 - Hematocrit $\geq 44\%$ for men or $\geq 40\%$ for women, established biomarker for inflammation
 - HCT biomarker supported by Phase 2a AP trial results

HCT at Baseline	#Patients	Initial NLR	Max D-dimer ng/mL	Max CRP mg/L	Max IL-6 pg/mL	ICU admission
HCT $\leq 44\%$	13	8.41 (5.2, 13.2)	3996(1205, 13235)	195 (86, 343)	108 (41, 442)	2/13 (15%)
HCT $>44\%$	8	19.9 (13.2, 46.7)	4245 (3685, 6205)	380 (248, 395)	391 (245, 849)	6/8 (75%)

- A peripancreatic fluid collection or a pleural effusion on a CECT performed in the 24 hours before Consent or after Consent and before Randomization
- Abdominal examination documenting either abdominal guarding or rebound tenderness

CARPO Baseline Characteristics

	Placebo N=53	2.0 mg/kg N=53	1.0 mg/kg N=56	0.5 mg/kg N=52	Total Auxora N=161	Total N=214
Age (Median) (Min, Max)	42 20, 78	42 19, 91	43.5 22, 84	48.5 23, 85	43 19, 91	43 19, 91
Male (%) Female (%)	33 (62.3) 20 (37.7)	33 (62.3) 20 (37.7)	33 (58.9) 23 (41.1)	32 (61.5) 20 (38.5)	98 (60.9) 63 (39.1)	131 (61.2) 83 (38.8)
HCT (≥44 males, ≥40 females) (% of N)	20 (37.7)	23 (43.4%)	25 (44.6%)	24 (46%)	72 (44.7%)	92 (43.0%)

Note: mITT was 214 patients as 2 enrolled patients did not receive study drug

Time to Solid Food Tolerance

Statistical significance achieved on dose response in patients with hyperinflammatory AP

		Placebo	2.0 mg/kg	1.0 mg/kg	0.5 mg/kg
n= 122		n= 33	n= 29*	n= 31	n= 28
Low Hematocrit	25 th %	36.0	25.0	28.0	19.0
	Median hours	62.0	65.0	68.0	67.0
	75 th %	137.0	100.0	353.0	184.0
n= 92		n= 20	n= 23*	n= 25	n= 24
High Hematocrit	25 th %	41.5	13.0	20.0	37.0
	Median hours	113.5	67.0	64.0	78.0
	75 th %	187.0	117.0	113	187.5

*One hematocrit missing at baseline

Determination of solid food tolerance

- Patient offered a low fat, ≥500-calorie solid meal
- Patient consumes ≥50% of the meal without vomiting or an increase in abdominal pain in the two hours after the meal (as confirmed by clinical trial nurse)

Length of Hospital Stay

		Placebo N=53	2.0 mg/kg N=53	1.0 mg/kg N=56	0.5 mg/kg N=52
LOS mITT	Median days	5.0	4.0	5.0	5.5
LOS mITT	Mean days	7.1	5.9	5.9	7.6
LOS High Hematocrit	Mean days	7.8	6.3	5.7	7.9
22-30 days	n subjects (%)	3 (5.7)	0 (0.0)	1 (1.8)	3 (5.8)

Severe Organ Failure

Statistical significance achieved on dose response

	Placebo N=53	2.0 mg/kg N=53	1.0 mg/kg N=56	0.5 mg/kg N=52
Severe Respiratory (%)	4/53 (7.5)	2/53 (3.8)	2/56 (3.6)	5/52 (9.6)
Severe Renal (%)	1/53 (1.9)	0/53 (0.0)	1/56 (1.8)	2/52 (3.8)
Severe Cardiovascular (%)	1/53 (1.9)	1/53 (1.9)	1/56 (1.8)	3/52 (5.8)
Any severe organ failure (%)	5/53 (9.4)	2/53 (3.8)	2/56 (3.6)	5/52 (9.6)

Definition of severe organ failure

- Severe respiratory failure defined as those patients receiving invasive mechanical ventilation (IMV) or those receiving for ≥ 48 hours use of either high flow nasal cannula (HFNC) or non-invasive mechanical ventilation (NIMV) (Use of NIMV for the treatment of obstructive sleep apnea not considered as meeting the definition of severe respiratory failure)
- Severe renal failure defined as the initiation of renal replacement therapy
- Severe cardiovascular failure defined as the use of vasopressor or inotropic support for ≥ 48 hours

Serious Adverse Event Summary

	Placebo N=53	2.0 mg/kg N=53	1.0 mg/kg N=56	0.5 mg/kg N=52	Total Auxora N=161
Number of TESAEs	20	14	21	23	58
Patients discontinuing study drug due to TESAEs	3	2	2	2	6
Patients with TEAEs leading to death	1	0	1	0	1

TESAE=treatment emergent serious adverse event

TEAE=treatment emergent adverse event

Conclusions and Next Steps

- Auxora is ready for Phase 3 clinical development pending FDA discussion
- Primary objective met with a dose response for multiple endpoints
- Auxora well-tolerated
- Reduction in severe organ failure increases confidence in KOURAGE AKI trial
- Next steps: further analysis of additional data and End-of-Phase 2 meeting with FDA