

NXC-201 Clinical Data Update and  
Outlook at ASH 2024 in  
Relapsed/Refractory AL Amyloidosis

4:30pm ET Tue Dec 10



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## Attendees



- **Ilya Rachman, MD PhD, Chief Executive Officer**
- **Gabriel Morris, Chief Financial Officer**
- Moderated by Michael Moyer, Managing Director, LifeSci Advisors

*Agenda: Following formal remarks, there will be a question-and-answer session*

Formal remarks include: 1) review of ex-US NEXICART-1 ASH 2024 results, and 2) discussion of NEXICART-2 U.S. trial ongoing, both in relapsed/refractory AL Amyloidosis

# This Is Pre-Existing Heart Failure in AL Amyloidosis


PRE-EXISTING HEART FAILURE CAUSES PHYSICALLY IRREVERSIBLE DISTORTION OF HEART STRUCTURE, SHAPE AND SIZE

Pre-existing heart failure

Preserved heart function

### Amyloidosis

Acquired & Hereditary Types



AL Amyloid damaged heart removed from patient prior to a successful heart transplant

su model of a normal heart

*The systemic amyloidoses are a group of rare, complex diseases, caused by the misfolding of proteins. These diseases are life-threatening and there are few approved treatments available in the United States.*

**FACTS:**

- 10 in a million diagnosed each year
- NO cure, few approved drugs
- Can affect different organs in different people including heart, kidneys, liver, spleen, nervous system, digestive tract
- Many patients have significant cardiac involvement
- Can lead to life-threatening organ failure
- Patients see average of 4 different doctors before receiving accurate diagnosis
- Many patients die quickly because they are diagnosed too late to benefit from treatment
- There are over 130 hereditary variants of amyloidosis
- 1,600,000 African Americans carry the V122I genetic variant at risk for ATTR Cardiac Amyloidosis

**MOST COMMON SYMPTOMS:**

- Swelling of ankles and legs
- Severe fatigue and weakness
- Shortness of breath, angina
- Peripheral neuropathy—numbness, tingling or pain in hands or feet,
- Carpal tunnel syndrome
- Nausea
- Early satiety significant weight loss
- Palpitations, an irregular heartbeat
- Autonomic neuropathy including gastrointestinal, blood pressure, and sexual dysfunction
- Fainting or feeling faint

# 75% (12/16) Complete Response Rate. No ICANS Neurotoxicity (NEXICART-1)

- **Patient Characteristics:**

- 16 patients dosed (ASH 2024 update: 3 new patients and longer follow-up, median 8.4 months (range 4-31.5))
- 81% (13/16), 69% (11/16), 38% (6/16), had pre-existing Heart, Kidney, Liver involvement, respectively, at enrollment
- Median 4 prior lines (range 3-10) of therapy

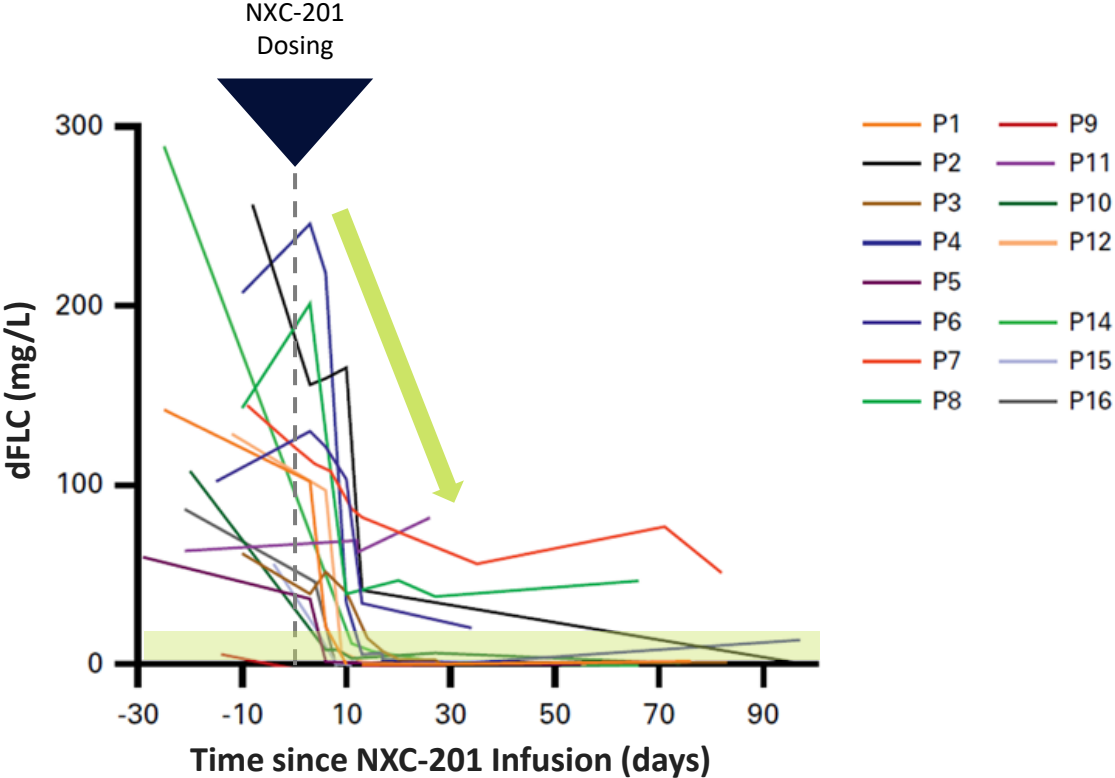
- **Efficacy:**

- 75% (12/16) Complete Response (CR) rate
- Best responder: 31.5 months complete response ongoing as of December 9, 2024 cut-off

- **Safety:**

- No ICANS neurotoxicity observed
- Median CRS duration of 2 days (range 1-5) – 69% (11/16) Grade 1/2, No Grade 4/5

# NXC-201 Produces Rapid and Deep Responses <2 Weeks After Dosing



(Each line represents 1 patient clinical data readout after NXC-201)

Note: Data cut-off as of December 9, 2024. E Lebel et al. Efficacy and Safety of Anti-BCMA Chimeric Antigen Receptor T-Cell (CAR) for the Treatment of Relapsed and Refractory AL Amyloidosis. Presentation. ASH 2024.

# 6 patients had pre-existing heart failure; 10 patients had preserved heart function



PRE-EXISTING HEART FAILURE CAUSES PHYSICALLY IRREVERSIBLE DISTORTION OF HEART STRUCTURE, SHAPE AND SIZE

NEXICART-1



Preserved heart function



Pre-existing heart failure

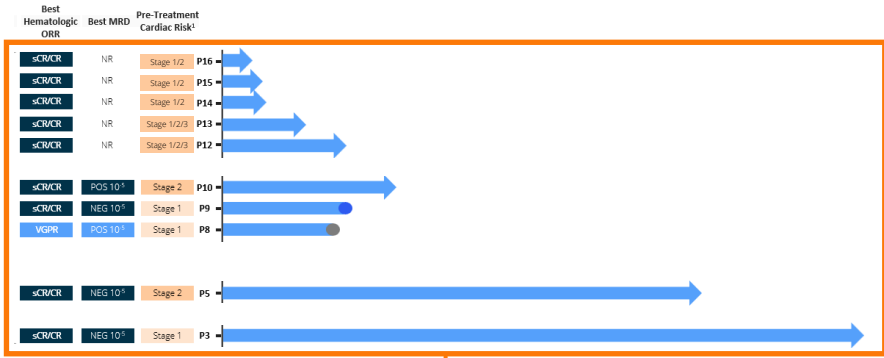
Patient #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	Median (range)	
Age	64	58	82	63	64	72	55	68	78	59	64	--	--	--	--	--	64 (55-82)	
Gender	Male	Female	Male	Male	Male	Female	Female	Male	Male	Male	Female	--	--	--	--	--	11/16 M 5/16 F	
dFLC (mg/L)	143	177	50	550	51	103	196	408	41	108	64	--	--	--	--	--	105 (50-550)	
BMPc (%)	3	15	1	15	1	1	1	10	15	1	1	--	--	--	--	--	1 (0.3-15)	
FISH cytogenetics	t(11:14)	t(14:16) 1Q+	14Q-	t(11:14)	t(11:14)	t(11:14) 1Q+	14Q-	17p-	Normal	17p-	t(4:14) 1Q+	--	--	--	--	--	7/16 (44%) t(11:14)	
Organ involvement	Cardiac, Renal, PNS	Cardiac, Renal, Liver	Renal, GI	Cardiac, Liver, Lung, Soft tissue, PNS	Cardiac, Soft tissue, PNS	Cardiac, Renal, Liver	Cardiac, Soft tissue	Cardiac, Renal, Soft tissue	Renal	Cardiac, Renal, PNS	Cardiac, Renal, GI, Liver, Soft tissue, PNS	--	--	--	--	--	Heart: 13/16 (81%) Kidney: 11/16 (69%) Liver: 6/16 (38%)	
NYHA stage	3	4	1	3	2	4	4	2	1	2	2	--	--	--	--	--	1-2: 10/16 (38%) 3: 3/16 (19%) 4: 3/16 (19%)	
ProBNP (pg/ml)	7,500	2,008	119	2,773	731	28,000	6,600	220	930	669	211	--	--	--	--	--	964 (220-28,000)	
Trop T (ng/L)	60	40	8	78	18.3	110	30	12	9	8	20	--	--	--	--	--	--	
Creatinine (mmol/L)	80	72	110	100	82	108	83	69	220	227	79	--	--	--	--	--	--	
Albuminuria (g/24h)	0.3	0.3	2.4	0.1	0.1	1.0	0	0	0.3	1.4	0	--	--	--	--	--	--	
ALKP (u/L)	45	218	84	140	84	186	166	106	160	59	160	--	--	--	--	--	--	
MAYO stage	3a	3a	1	3a	2	3b	2	1	1	2	2	1 stage 1/2 1 stage 3			1	1	2	--
ECOG PS	0	2	0	0	1	2	4	0	1	1	1	--	--	--	--	--	--	
Concomitant MM	Yes	No	no	No	yes	no	No	no	no	no	no	no	no	no	no	no	2/16	
Compassionate use	No	no	no	yes	no	no	yes	no	no	no	no	--	--	--	--	--	2/16	

# NXC-201 Produces Durable Complete Responses in Patients with Preserved Heart Function



## Duration of response (ASH 2024)

Preserved heart function

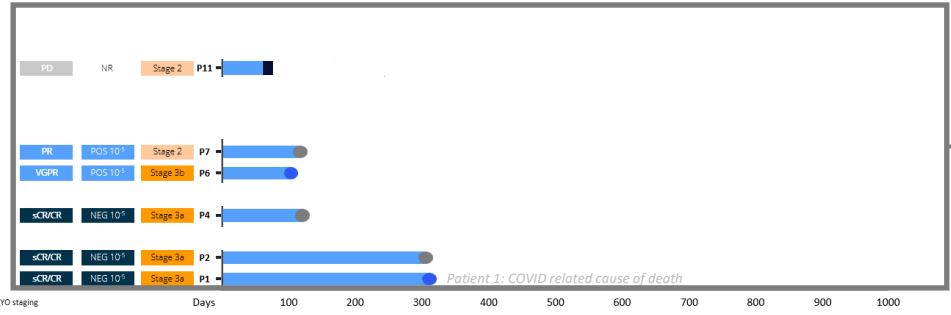


- Ongoing response
- Cardiac death in CR/VGPR
- Cardiac death while in PD
- Discontinued

Target For U.S. AL Amyloidosis Clinical Trial Patient Enrollment:

- 90% complete response rate
- Extended response duration

Pre-existing heart failure



Would have been excluded from U.S. clinical trial

- 50% complete response rate
- Limited response duration due to pre-existing heart failure

sCR: strict complete response, CR: complete response

Note: E Lebel et al. Efficacy and Safety of Anti-BCMA Chimeric Antigen Receptor T-Cell (CART) for the Treatment of Relapsed and Refractory AL Amyloidosis. Presentation. ASH 2024. Exclusion criteria: Mayo Stage 3b, NYHA 3/4, prior BCMA exposure. Patient 12 and patient 13 Mayo staging: one patient is stage 1/2, one patient is stage 3a/3b; Patients 6 and patient 9 death due to cardiac/other.



# 75% Complete Response Rate is the FDA Regulatory Endpoint

NEXICART-1



Preserved heart function



Pre-existing heart failure

Patient #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
CART cells infused ( $\times 10^6$ )	150	450	800	450	800	800	800	800	800	800	800	800	800	800	800	800
Best hematologic response	CR	CR	CR	CR	CR	VGPR	PR	VGPR	CR	CR	PD	CR	CR	CR	CR	CR
Follow-up (months)	10.3	10.2	31.5, ongoing	4.0	24.0, ongoing	3.3	3.8	5.5	6.0	8.7, ongoing	1.3	6.2, ongoing	4.2, ongoing	2.2, ongoing	2.0, ongoing	1.5, ongoing

**Complete response (CR) is FDA Regulatory Endpoint**

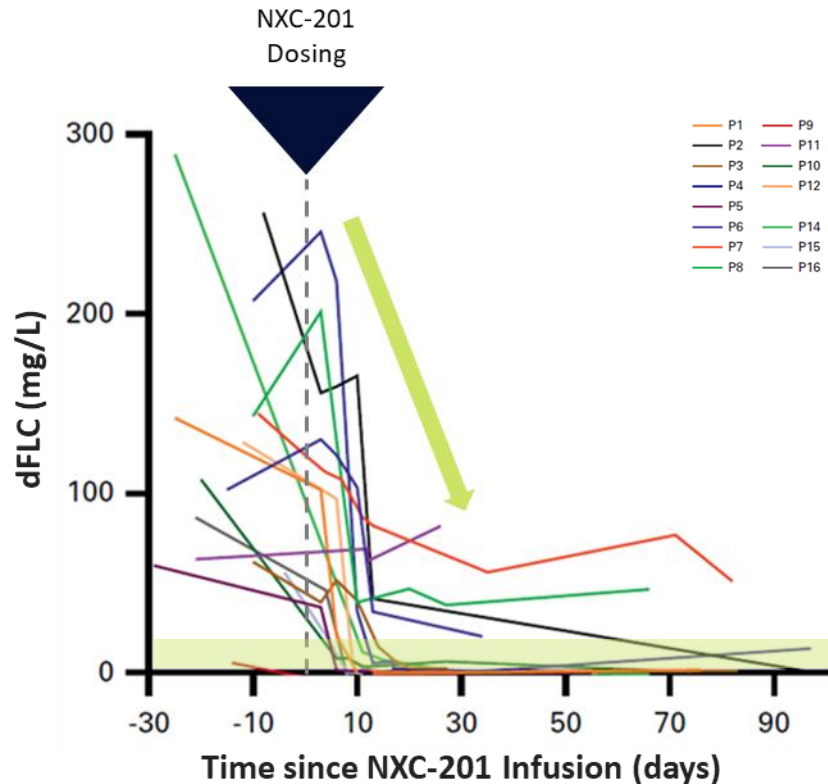
- **75% (12/16) Complete Response (CR) rate** (9 out of 16 were MRD-  $10^{-5}$ )
- Best responder: 31.5 months complete response ongoing as of December 9, 2024 cut-off
- Historical complete response rates for investigators choice is ~3-20%

# Favorable Tolerability: No Neurotoxicity of Any Grade. Short Duration CRS

	Total
ICANS and other neurotoxicity, n/N (%)	<b>0/16 (0)</b>
Treatment-related mortality, n/N (%)	0/16 (0)
CRS, n/N (%)	
No CRS	2/16 (12)
Grade 1	3/16 (19)
Grade 2	8/16 (50)
Grade 3	3/16 (19)
Grade 4/5	0/16 (0)
Time to onset of CRS, days, median (range)	1 (1-3)
Duration of CRS, days, median (range)	2 (1-5)
Tocilizumab use, n/N with CRS (%)	12/14 (86), median of one dose (range, 1-3)
Corticosteroid use, n/N with CRS (%)	3/14 (21)
Vasopressor use, n/N with CRS (%)	2/14 (14)
High-flow oxygen use, n/N with CRS (%)	2/14 (14)

	Total	Grade 3-4
Hematological toxicity, n/N		
Anemia	12/16	5/16
Thrombocytopenia	9/16	0/16
Neutropenia	12/16	10/16
Lymphopenia	16/16	16/16
Organ function toxicity, n/N		
Congestive heart failure exacerbation	3/16	3/16
Acute kidney injury	4/16	0/16
Hepatic injury	6/16	4/16
Infections, n/N		
Febrile neutropenia	5/16	5/16
Early infections (until day +28)	9/16	6/16
Late infections (after day +28)	7/16	5/16

# Rapid Responses to NXC-201 in Relapsed/Refractory AL Amyloidosis Patients were Observed



(Each line represents 1 patient clinical data readout after NXC-201)



The NEW ENGLAND  
JOURNAL of MEDICINE

“An early and deep hematologic response has been found to lead to significantly prolonged survival”

– Vaishali Sanchorawala, M.D.  
Professor, Hematology and Oncology  
Director, Amyloidosis Center at Boston University School of Medicine  
Director, Stem Cell Transplantation at Boston Medical center

doi: 10.1056/NEJMra2304088

## NEXICART-2: Ongoing US Study



# NEXICART-2 US Relapsed/Refractory AL Amyloidosis Trial (NCT06097832)

NEXICART-2 NXC-201 US TRIAL INITIATED IN MID-2024



## Study design

- Open-label, single-arm Phase 1b/2 study
- n=40 patients (majority of which expected to be enrolled in Phase 2 portion)

## Key criteria

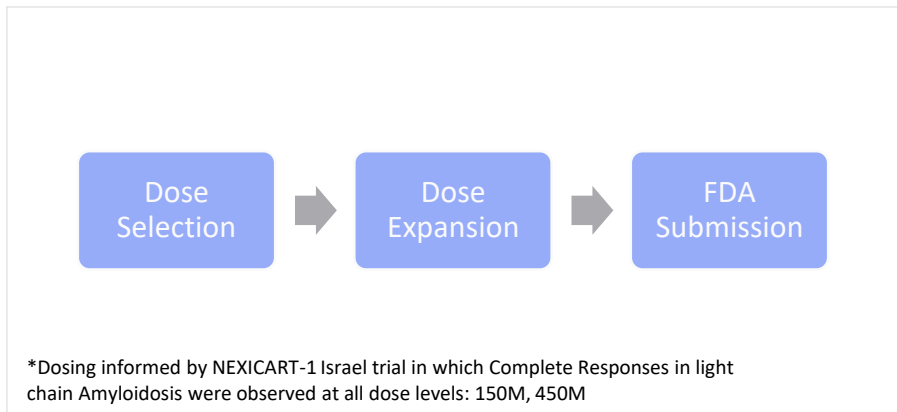
<b>Inclusion</b>	<ul style="list-style-type: none"> <li>• AL Amyloidosis patients exposed to at least 1 line of therapy including a CD38 monoclonal antibody</li> </ul>
<b>Exclusion</b>	<ul style="list-style-type: none"> <li>• Prior anti-BCMA directed therapy</li> <li>• Cardiac: Mayo stage 3b, NYHA stage III/IV</li> <li>• Concomitant Multiple Myeloma</li> </ul>

## Outcome measures

- |  |   |
|--|---|
| <ul style="list-style-type: none"> <li>• Phase 1b:                     <ul style="list-style-type: none"> <li>• Safety</li> <li>• Efficacy: Hematologic response according to consensus recommendations in AL amyloidosis</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>• Phase 2:                     <ul style="list-style-type: none"> <li>• Efficacy: Hematologic response according to consensus recommendations in AL amyloidosis</li> <li>• Safety</li> </ul> </li> </ul> |
|--|---|

## Status

- Lead site Memorial Sloan Kettering and other US sites started mid-2024



Relapsed/Refractory AL Amyloidosis NXC-201 trial	Allows pre-existing severe cardiac patient enrollment?	Allows patients with prior BCMA-targeted therapy exposure?	Allows patients with concomitant Multiple Myeloma?
<b>NEXICART-1:</b> ongoing Israel trial	<b>X Yes</b>	<b>X Yes</b>	<b>X Yes</b>
<b>NEXICART-2:</b> ongoing US trial	<b>✓ No</b>	<b>✓ No</b>	<b>✓ No</b>

Could enrich ongoing NEXICART-2 US trial for patients more likely to benefit from therapy

Note: Hematologic response according to consensus recommendations in AL amyloidosis (Palladini, et al. 2012. "Consensus guidelines for the conduct and reporting of clinical trials in systemic light-chain amyloidosis." Leukemia 26(11): 2317-2325.)

# Single-arm potentially pivotal NEXICART-2 trial designed considering NEXCIART-1 and precedents in AL

		2021 daratumumab (DARZALEX) FDA Approval	NXC-201 NEXICART-2
Patient Characteristics	Line of Therapy	Newly Diagnosed	Relapsed/Refractory
	Standard of Care (SoC) at time of trial	3-drug combination: Cyclophosphamide, bortezomib, dexamethasone	✓ None (no FDA approvals)
	Randomization vs. Standard of Care?	x <b>Randomization vs. SoC</b>	✓ No SoC to randomize against
	Lines of therapy prior to receiving study drug	x <b>None</b>	✓ <b>At least 1 line of therapy including a CD38 monoclonal antibody</b>
Study Design	Statistical Power	Based on the assumption that the percentage of patients with a hematologic complete response would be 15 percentage points higher in the daratumumab group than in the control group; approximately <b>360 patients were required</b> to provide 85% power to detect this difference (two-sided alpha level of 0.05).	Based on NEXICART-1 complete response (CR) rates, with a sample size of <b>40 patients</b> , there is a >99% probability that the lower limit of 95% CI for the NXC-201 CR rate is statistically significantly higher compared to historical controls based on the Clopper-Pearson exact method.
	Primary Endpoint	✓ <b>Hematologic complete response rate for both studies</b>	

Single-arm, open-label FDA approval precedents include: Abecma/BMS (single arm study 100 patients in efficacy results population, FDA approved 2021); Carvykti/J&J (single arm study 97 patients in efficacy results population, FDA approved 2022); Elrexfio/Pfizer (single arm study 97 patients in efficacy results population, FDA approved 2023)

# Q&A

Moderator: Michael Moyer, Managing  
Director

LifeSci Advisors



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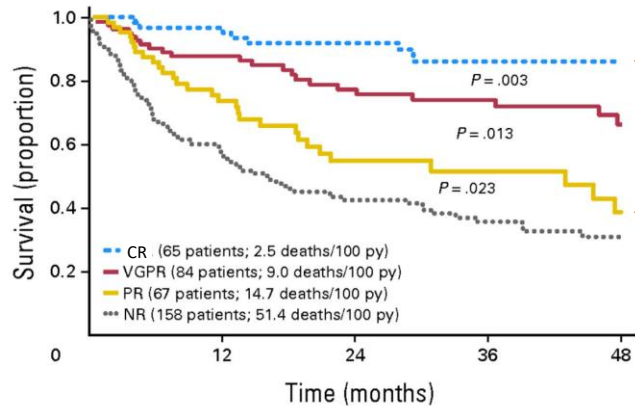




# Complete Hematologic Response is correlated with longer survival

COMPLETE HEMATOLOGIC RESPONSE WAS PRIMARY ENDPOINT IN 2021 DARATUMUMAB APPROVAL STUDY AND ONGOING NEXICART-2 TRIAL

## Complete Hematologic Response (CR) associated with improved survival in AL



### 2x survival at 48 months for CR vs PR

- Complete Hematologic response patients have 85% survival at 48 months
- Partial hematologic response patients have 40% survival at 48 months