Initial Safety and Efficacy Data from Nexicart-2, the First U.S. Trial of a CAR-T (NXC-201) in Relapsed or Refractory (R/R) Light Chain (AL)

Heather Landau[1], Shahzad Raza[2], Aaron Rosenberg[3], Jeffrey Zonder[4], Raymond Comenzo[5], Vaishali Sanchorawala[6], Michaela Liedtke[7], Amandeep Godara[8], Michael Rosenzweig[9], Charlotte Hughes[1], Eugene Brailovski[1], Mehrdad Abedi[3], Sham Mailankody[1], Jae Park[1], David Marks[10], Sridevi Rajeeve[1], Jennifer Liu[1]

[1]Memorial Sloan Kettering Cancer Center, New York, NY, United States, [2]Cleveland Clinic Taussig Cancer Institute, Cleveland, OH, United States, [3]UC Davis Comprehensive Cancer Center, Sacramento, CA, United States, [4]Barbara Ann Karmanos Cancer Institute, Detroit, MI, United States, [5]Tufts Medical Center, Boston, MA, United States, [6]Boston Medical Center and Boston University Chobanian & Avedisian School of Medicine, Boston, MA, United States, [7]Stanford University School of Medicine, Stanford, CA, United States, [8]Huntsman Cancer Institute, University of Utah, Salt Lake City, UT, United States, [9]City of Hope, Duarte, CA, United States, [10]Immix Biopharma, Inc., Los Angeles, CA, United States

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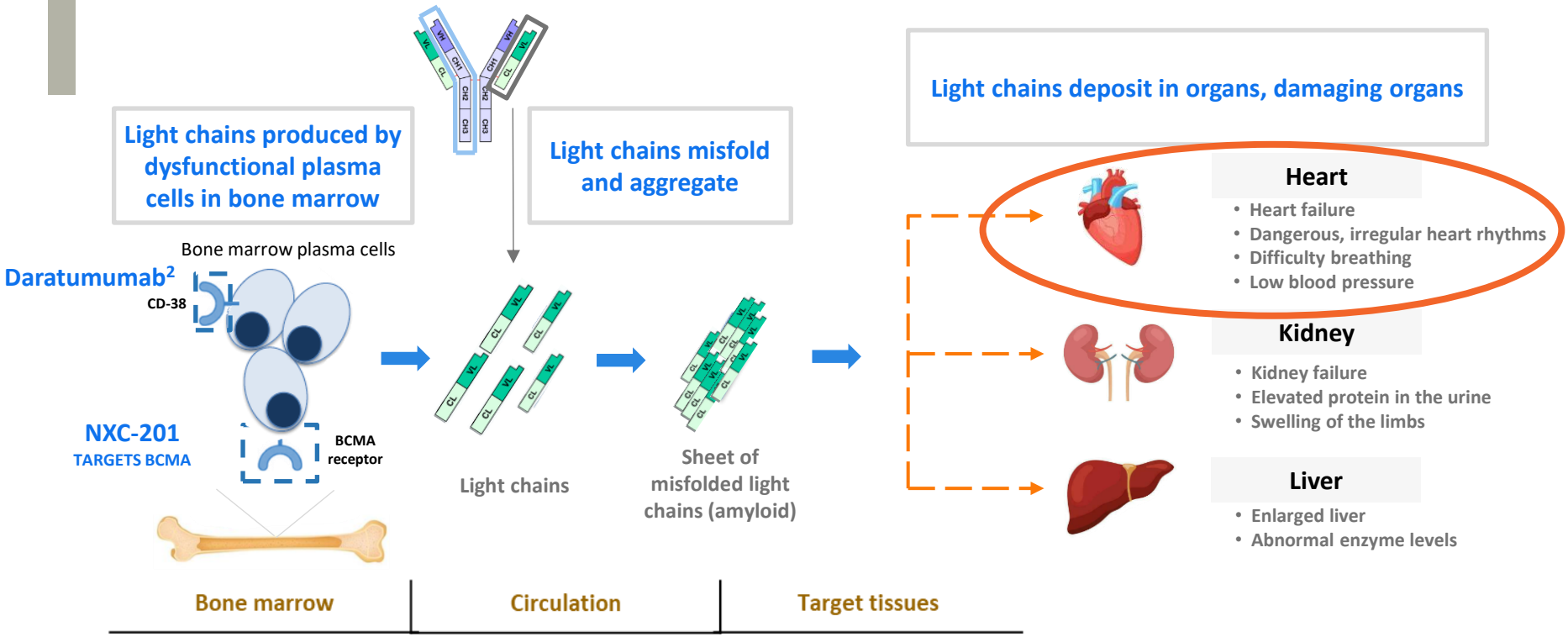
Relapsed/Refractory AL Amyloidosis: ~32,500 U.S. Patients with No FDA Approved Drugs[1]



1. Quock et al. Blood Adv. 2018.
2. Kastritis et al. NEJM 2021.

NXC-201: Sterically-Optimized CAR-T construct

N-GENIUS PLATFORM

"Digital Filter"….  **…decreases nonspecific activation**

Sterically-optimized key construct modifications

1 Proprietary Optimized CD3 – "CD3ζγ"

✓ **Delivers "Digital" Intracellular Signaling**

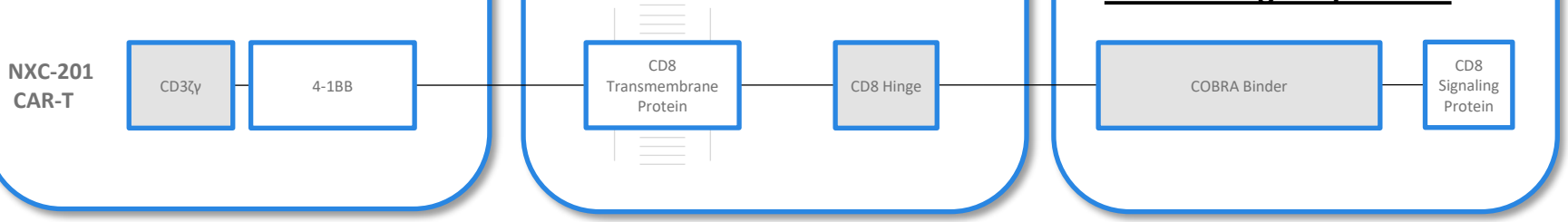
2 Proprietary Optimized CD8 Hinge Flexibility

✓ **Reduces cytokine release**

3 Proprietary Optimized COBRA Binder

✓ **Enhances Plasma Cell Binding**

✓ **Ensures High Expression**



Manufacturing time: 10 days

1. Harush O et al. Haematologica 2022.
2. Lebel E et al. JCO 2024.

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NEXICART-2: First CAR-T Trial Designed For R/R AL Amyloidosis (NCT06097832)

Study design

- Open-label, single-arm, multi-site phase 1/2 study
- n=40 patients

Key criteria

Inclusion	• Exposed to at least 1 line of therapy, including CD38 monoclonal antibody + proteosome inhibitor • Measurable hematologic disease, defined by one of the following: - dFLC* >50 mg/L (or 5 mg/dl) - M-spike > 0.5 mg/dl - dFLC* >20 mg/L (or 2 mg/dl) with abnormal k/l ratio[1]
Exclusion	• Prior anti-BCMA directed therapy • Cardiac: Mayo stage 3b, NYHA class III/IV • Concomitant Symptomatic Multiple Myeloma

* dFLC = difference between the involved and uninvolved free light chain

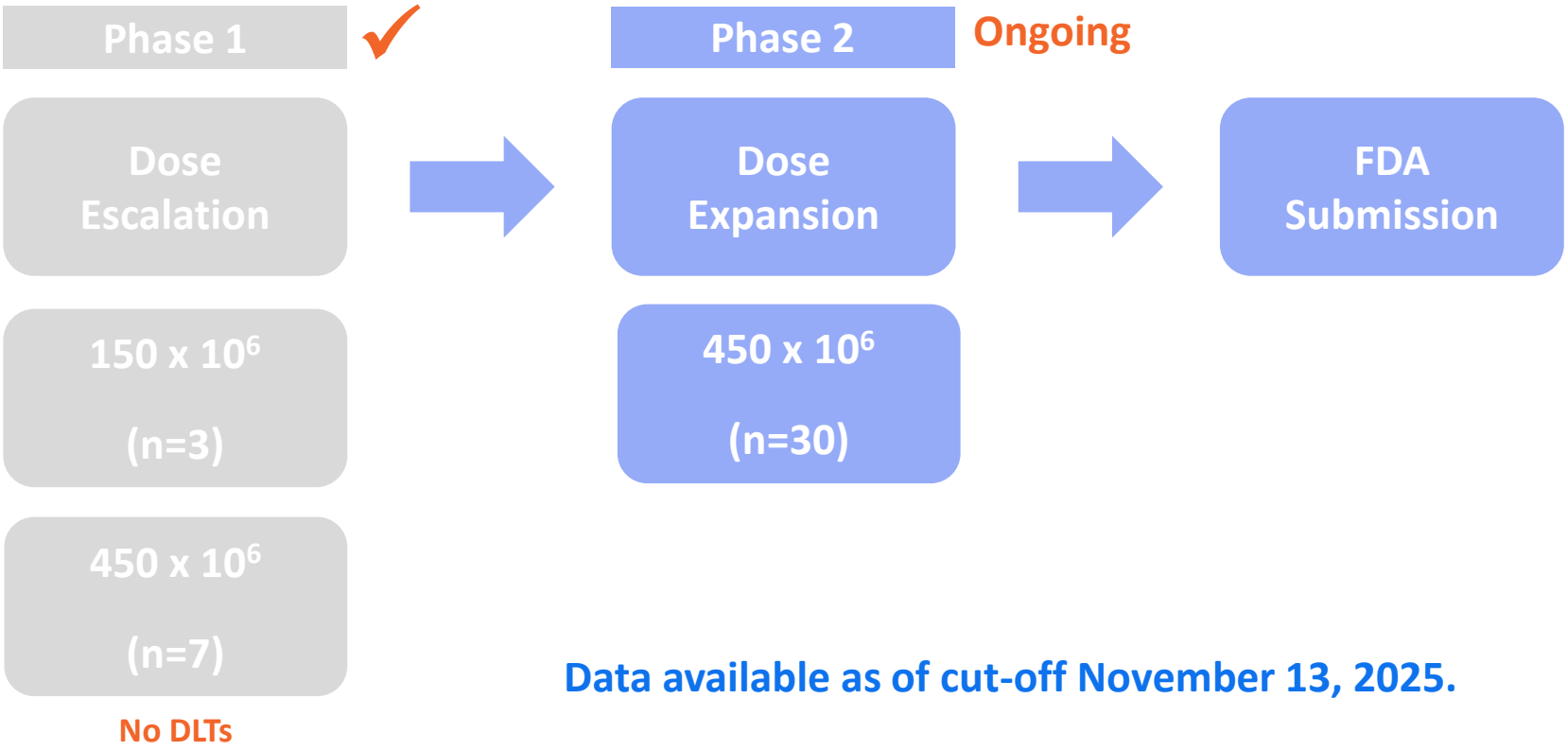
Outcome measures

- Safety
- Efficacy: Complete hematologic response (CR) based on validated criteria[2,3]

1. Milani et al. Blood 2017.
2. Palladini G et al. JCO 2012.
3. Palladini G et al. Amyloid 2021.

NEXICART-2: Trial Design

Open to accrual June 2024



Data available as of cut-off November 13, 2025.

Palladini G et al. JCO 2012.
Palladini G et al. Amyloid 2012.
Milani et al. Blood 2017.

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NEXICART-2: Patient Characteristics (N=20)

	NX2-001	NX2-002	NX2-003	NX2-004	NX2-005	NX2-006	NX2-007	NX2-008	NX2-009	NX2-010	NX2-011	NX2-012	NX2-013	NX2-014	NX2-015	NX2-016	NX2-017	NX2-018	NX2-019	NX2-020	Median (range)
Age	56	67	82	64	62	72	77	66	63	80	65	65	59	49	73	59	71	71	82	64	66 (49-82)
Gender	Female	Female	Male	Female	Female	Male	Male	Male	Male	Male	Female	Female	Female	Female	Female	Male	Male	Female	Female	Female	-
Prior lines of therapy	4*	6**	2	4	4*	3	4*	4*	4*	3*	1	10	4**	1	8*	5	2	9*	2	3*	4 (1-10)
dFLC (mg/L)	65	24	-	86	42	26	47	121	84	-	-	70	274	26	54	24	194	73	45	22	54 (22-274)
M-spike (g/dL) ¥	-	-	0.79	-	-	-	-	-	-	0.65	0.52	-	-	-	-	-	-	-	-	-	-
Organ involvement	Heart/ Soft Tissue	Heart/GI/ Nerve	Kidney	Heart/GI/ Nerve	Kidney	Heart	Nerve/ Skin	Heart/ Liver	Heart/ Tongue	Kidney/ Heart	Heart/ Nerve/GI	Heart/GI	Heart	Heart/GI/ Nerve	Kidney	Nerve	Heart/ Kidney	Kidney	GI	Kidney	-
NYHA stage	I	II	I	I	I	I	I	II	I	II	II	II	I	II	I	I	II	I	I	I	-
NT-ProBNP (ng/L)	146	560	1,297	218	805	989	143	909	289	290	2,017	232	155	355	1,385	113	627	526	231	NA	355 (113-2,017)
hs-Troponin-I (ng/L)	7	6	42	7	11	31	14†	47††	6	52	6	11†	13	10††	8	14††	75††	7	5	0	10 (0-75)
Mayo Stage At Diagnosis	II	II	II	IIIa	I	IIIa	-	II	IIIb	IIIa	II	I	IIIa	II	II	I	IIIa	I	I	I	-
At Enrollment	I	II	IIIa	IIIa	II	IIIa	-	II	I	II	II	I	II	I	II	I	IIIa	II	I	I	-
Creatinine (mg/dL)	0.7	1.1	2.2	0.7	2.7	0.8	1.3	0.8	0.9	0.9	0.5	1.0	0.9	0.6	1.3	1.0	1.0	0.7	0.8	1.2	0.9 (0.5-2.7)
Albuminuria (mg/24 hrs)	143	0	3,032	0	10,274	0	135	360	13	2,153	135	144	136	310	2,061	6	5,660	2,000	140	4,478	144 (0-10,274)

* Prior autologous stem cell transplantation (ASCT)

** Two prior ASCT

¥ M-spike value if used as measurable disease

† Denotes Troponin-T

†† Denotes hs-Troponin-T

Note: NX2-002 M-Spike 0.57 g/dL, NX2-019 M-Spike 0.75 g/dL

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NEXICART-2: Safety

Only low-grade, brief CRS
No neurotoxicity

Subject		NX2-001	NX2-002	NX2-003	NX2-004	NX2-005	NX2-006	NX2-007	NX2-008	NX2-009	NX2-010	NX2-011	NX2-012	NX2-013	NX2-014	NX2-015	NX2-016	NX2-017	NX2-018	NX2-019	NX2-020	Median (Range)
Dose	CART Cell Dose ($x10^6$)	150	150	150	450	450	450	450	450	450	450	450	450	450	450	450	450	450	450	450	450	-
	CRS	**None**	**None**	Grade 2	Grade 1	Grade 1	Grade 1	Grade 1	Grade 1	Grade 1	Grade 1	Grade 2	Grade 1	**None**	Grade 2	Grade 2	**None**	Grade 1	Grade 1	Grade 1	**None**	1 (1-2)
	CRS Onset (days)	**None**	**None**	3	3	1	1	1	1	1	3	2	1	**None**	1	1	**None**	1	1	2	**None**	1 (1-3)
	CRS Duration (days)	**None**	**None**	2	1	1	1	1	4	1	2	1	5	**None**	1	2	**None**	1	1	1	**None**	1 (1-5)
	Neurotoxicity	**None**	**None**	**None**	**None**	**None**	**None**	**None**	**None**	**None**	**None**	**None**	**None**	**None**	**None**	**None**	**None**	**None**	**None**	**None**	**None**	-
Other	Neutropenia	Grade 3	Grade 3	Grade 3	Grade 4	Grade 4	Grade 2	Grade 4	Grade 4	Grade 4	Grade 2	Grade 4	Grade 4	Grade 4	Grade 4	Grade 3	Grade 3	Grade 3	Grade 3	Grade 3	None	3 (2-4)
	Febrile Neutropenia	None	None	None	None	None	None	None	Grade 3	None	None	None	None	None	None	None	None	None	None	None	None	None	-
	Anemia	Grade 1	Grade 2	Grade 3	Grade 1	Grade 3	Grade 1	Grade 2	Grade 2	Grade 1	Grade 1	Grade 2	Grade 2	Grade 1	Grade 3	Grade 3	Grade 1	Grade 2	Grade 2	Grade 3	Grade 3	2 (1-3)
	Thrombocyto-penia	Grade 1	Grade 1	Grade 1	Grade 1	Grade 3	Grade 2	None	Grade 4	Grade 3	Grade 1	Grade 1	Grade 3	Grade 1	Grade 2	Grade 3	Grade 1	Grade 2	Grade 1	Grade 1	None	1 (1-4)
	Acute kidney failure	None	None	None	None	Grade 4*	None	None	None	None	None	None	None	None	None	None	None	None	None	None	None	-
	LFT Abnormalities	None	None	None	None	None	None	None	Grade 1	None	None	None	Grade 3	None	Grade 3	None	None	Grade 1	None	None	None	-
	≥ Grade 3 Infections	None	None	None	None	Grade 5*	None	None	None	None	None	None	None	None	None	None	None	None	None	None	None	-
	Fatigue	None	Grade 2	Grade 2	Grade 2	Grade 1	Grade 1	None	None	None	Grade 2	Grade 2	None	Grade 2	None	Grade 2	Grade 2	None	None	None	None	2 (1-2)
	Cardiac Event	None	None	None	Grade 2¥	None	None	None	None	None	Grade 2¥	None	None	None	None	None	None	None	None	None	None	-

CRS = cytokine release syndrome

***Six months after dosing, deemed not drug related; acute on chronic kidney injury in patient with stage 4 CKD at enrollment**

¥ Two patients with pre-existing atrial fibrillation experienced transient arrythmias response to beta-blockers

Note: CRS and ICANS reported according to ASTCT Consensus Grading

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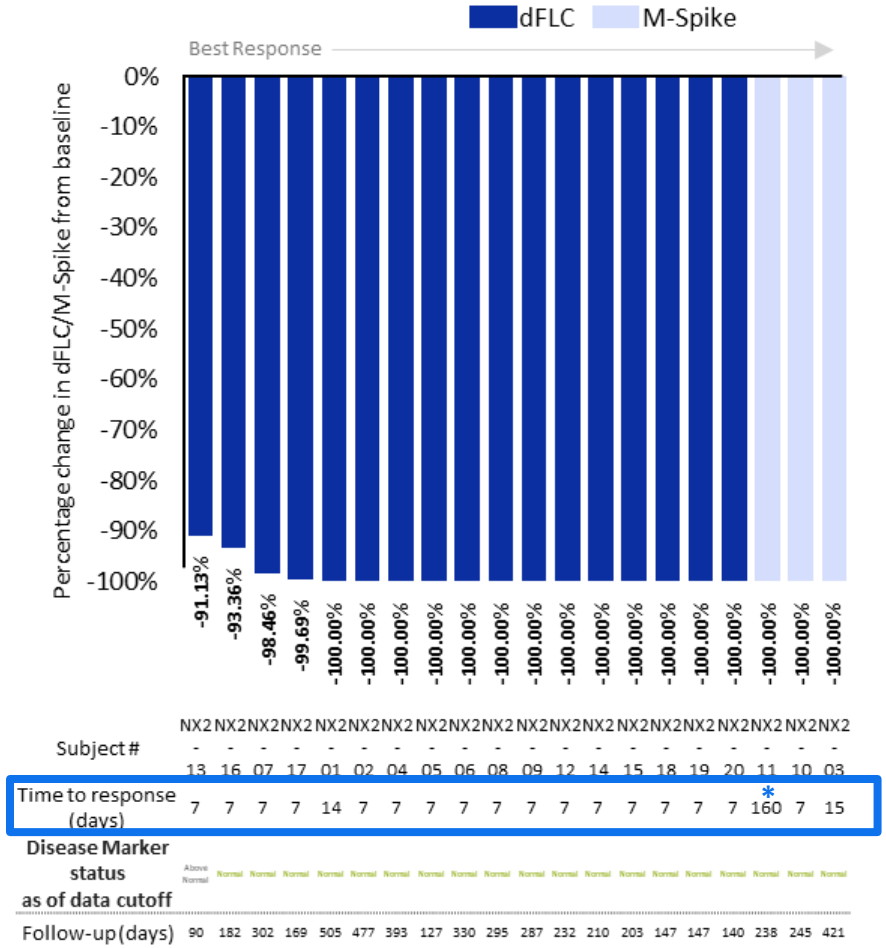
Lee DW et al. BBMT 2019.

NEXICART-2 Efficacy:

Rapid normalization of pathologic paraprotein



Cut-off November 13, 2025. Median follow up 235 days (7.8 months) (range (days) 90-505)

19/20 (95%) patients' disease marker normalized

Immunofixation may persist for longer

Palladini G et al. JCO 2012.
Palladini G et al. Amyloid 2012.
Milani et al. Blood 2017.

* IgG sub-type (NX2-011) having a longer half-life than IgA (NX2-003, NX2-010)

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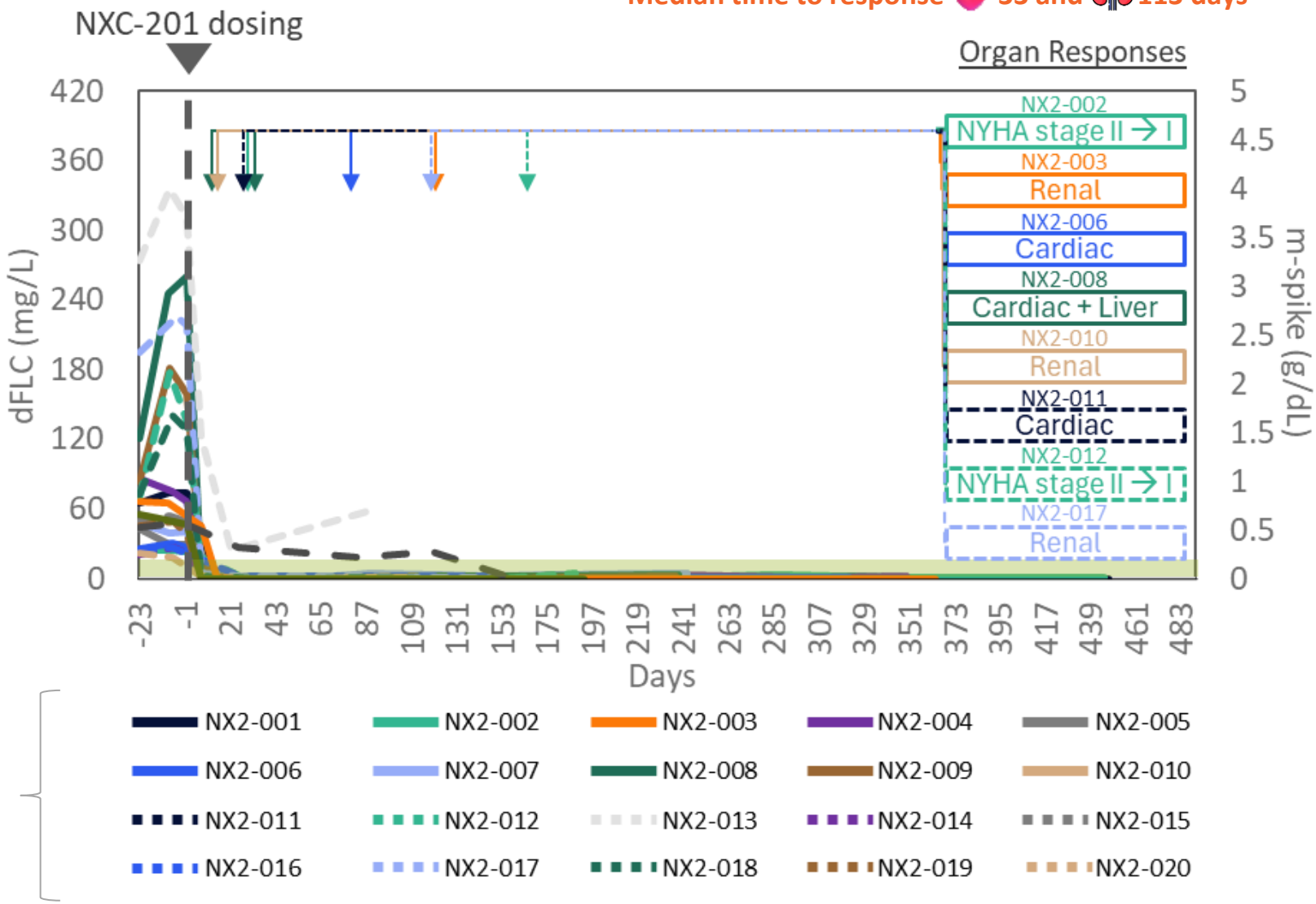
NEXICART-2 Efficacy

- 19/20 (95%) early and deep hematologic responses
- Organ responses in 70% (7/10) evaluable patients (75% ❤, 60% 🫘, 100% 🫁)
- Median time to response ❤ 33 and 🫘 113 days



Palladini G et al. JCO 2012.
Palladini G et al. Amyloid 2012.
Milani et al. Blood 2017.

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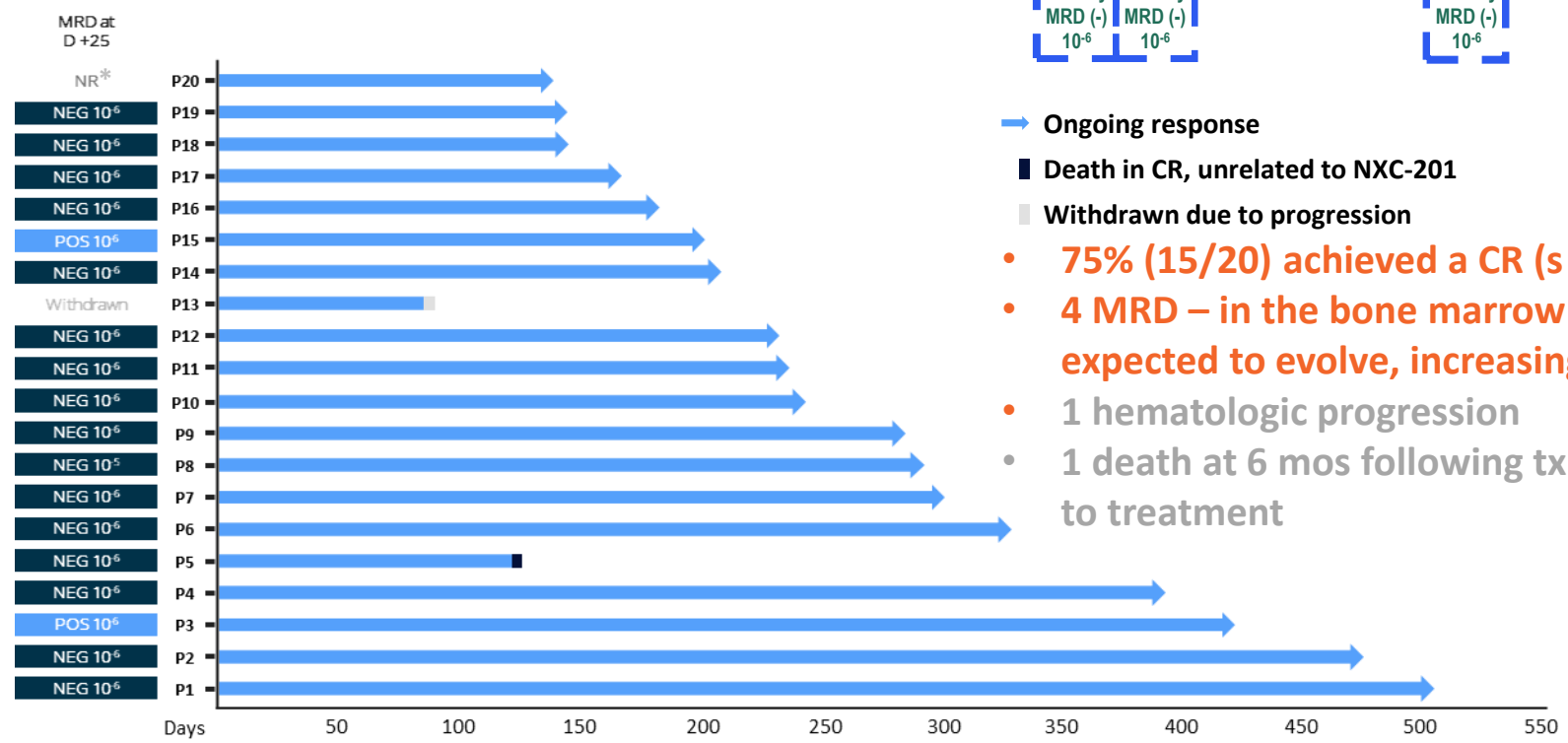
… In Patient's Own Words (day +15)

"Hi Dr Landau! Here we are a week tomorrow since I left the hospital (At day 10 after those magic CAR-T cells came on board)! Just had to tell you I've been very happily & comfortably walking 2-3+ miles each day & doing great on the inclines (even the cross overs on the River walk!) as we explore different nooks & crannies & sidewalk cafes of the beautiful Upper East Side!!! (Eating plenty at those cafes too!) I know you said CAR-T should be easier than stem cell transplant, & that has proven to be more accurate than I could have hoped for!! The hospital path was so much smoother & less eventful than the stem cell days! I never thought I'd be feeling this strong & vibrant, just 15 days after my CAR-T cell infusion!! Nor did I ever guess that I'd be feeling stronger & experiencing less of that horrible leg fatigue, shortness of breath & chest tightness, that was ever increasing & weighing me down for the months preceding this!! AMAZING & truly beyond my wildest dreams!! My family & I can never thank you & your teams enough for all you do continuously to bring these amazing treatment options to us, & for the amazing beautiful way you guide us through! I'd be happy to share my experience with other patients considering CAR- T cells, if that's an option at some point. See you soon! 🥰🌞💪"

NEXICART-2: 75% complete response rate as reviewed by an independent review committee

n=20. Cut-off November 13, 2025. Median follow up 235 days (7.8 months) (range (days) 90-505)

Subject #: NX2-	001	002	003	004	005	006	007	008	009	010	011	012	013	014	015	016	017	018	019	020
Time to response (days)	14	7	15	7	7	7	7	7	7	7	160	7	7	7	7	7	7	7	7	7
Hematologic response	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	VGPR	VGPR	Withdrawn	CR	CR	VGPR	CR	CR	Low dFLC PR	CR
											Already MRD (-) 10^{-6}	Already MRD (-) 10^{-6}				Already MRD (-) 10^{-6}			Already MRD (-) 10^{-6}	



- Ongoing response
- Death in CR, unrelated to NXC-201
- Withdrawn due to progression

- 75% (15/20) achieved a CR (s + u IFE(-))
- 4 MRD – in the bone marrow (But IFE +) expected to evolve, increasing CR rate
- 1 hematologic progression
- 1 death at 6 mos following tx – unrelated to treatment

Minimal residual disease (MRD) negativity was assessed by flow cytometry or clonoSEQ with sensitivity 10^{-6} or 10^{-5}

Palladini G et al. JCO 2012.
Palladini G et al. Amyloid 2012.
Milani P et al. Blood 2017.
Roshal M et al. Blood Advances 2017.

*NR: not reported

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Conclusion

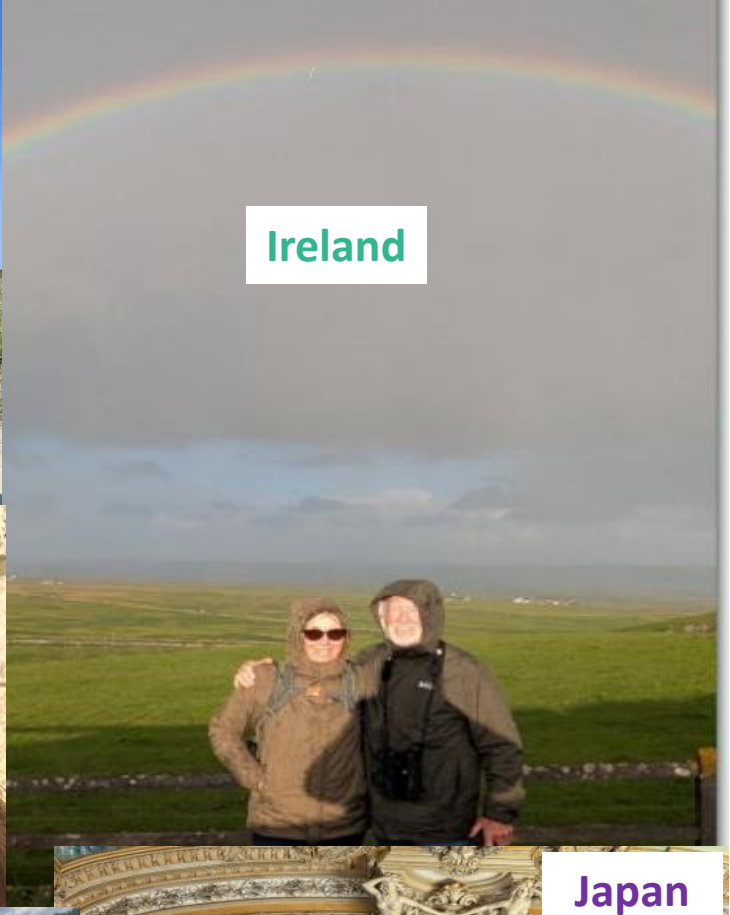
- NXC-201 a novel BCMA-directed CAR-T cell can be administered safely & efficiently to patients with R/R AL amyloidosis – population without a single FDA-approved treatment available – who have a true unmet medical need
  - 100% treated with a vein-to-vein time 14 days
  - Low grade CRS and no neurotoxicity of any kind
- Rapid and deep hematologic responses, median time to response 7 days
  - 16/18 evaluable patients MRD negative (10^{-6} or 10^{-5})
  - 75% hematologic CR rate (s + u IFE(-)), potential to evolve (up to 95%)
  - Organ responses in 70% (7/10) evaluable patients (75% ❤ 60% 🫘 100% 🫁)

90% remain on study, in hematologic remission at median 7.8 months, including 5 > 12 months

Multicenter trial is ongoing and continuing to accrue


Sarasota, FL


Montauk, NY


Ireland


Peru
50
50


Saratoga, NY


Japan


Miami, FL


Alaska

Grateful for….

- The research staff, clinical teams, apheresis units, cell therapy labs and investigators at each participating site
- The patients and their families

Thank you for your attention!

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IMMIX BIOPHARMA

NEXCELLA

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