

# Clinical Stage Cell Therapy for AL Amyloidosis and Other Serious Diseases

April 2025



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# Pioneering Cell Therapy in AL Amyloidosis and Other Serious Diseases



## Dedicated team for NXC-201 in AL Amyloidosis and other serious diseases

- Ex-NCI/NIH scientists designed cell therapy for benign tolerability, being developed by Immix
- Scientific advisors from Stanford, Memorial Sloan Kettering, Columbia, Tufts, UCLA
- Experienced management; board members with recent pharmaceutical acquisitions experience

## Sterically-optimized, proprietary CAR-T construct from N-GENIUS platform

- Immix N-GENIUS platform produced NXC-201
- NXC-201 is our lead, sterically-optimized CAR-T with “digital filter” that reduces non-specific activation
- NXC-201 CAR-T construct provides barrier to entry

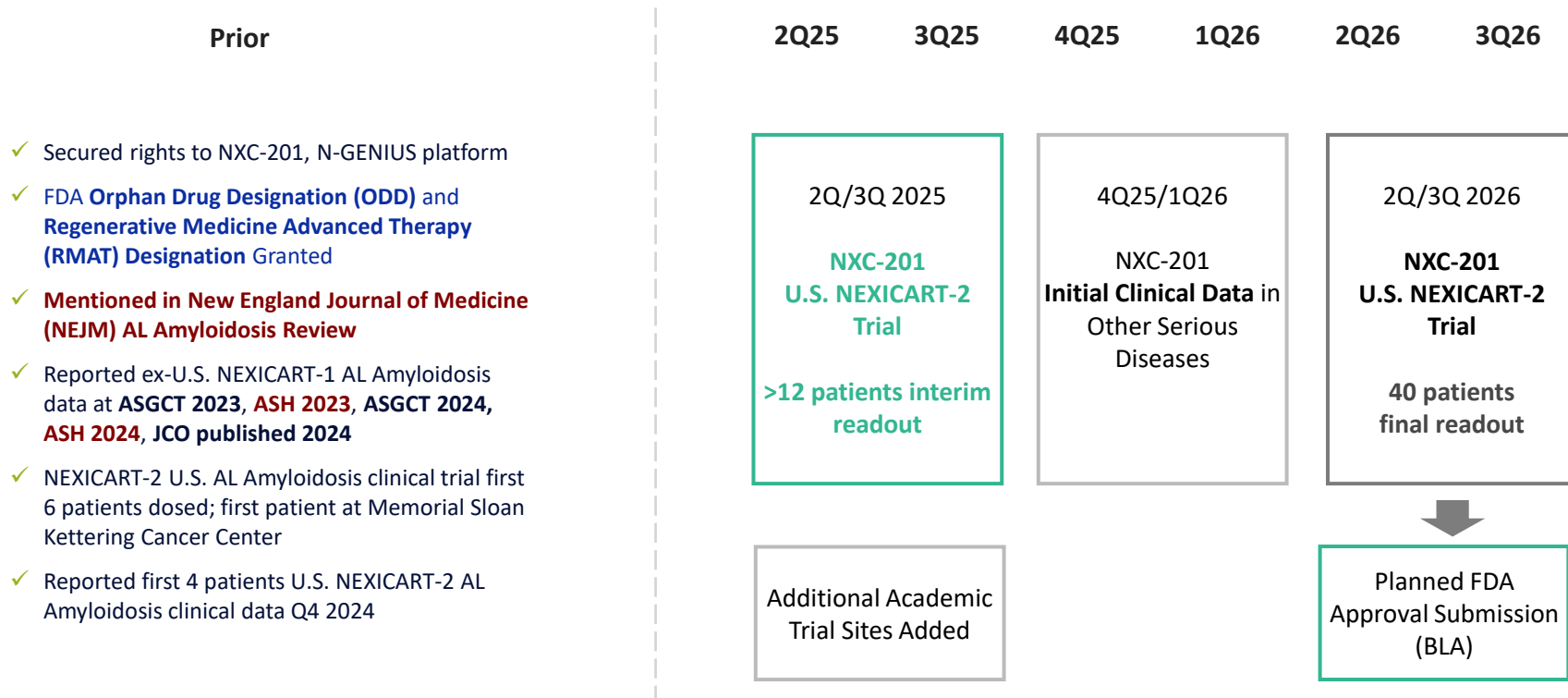
## Sizable AL Amyloidosis market

- Relapsed/refractory AL Amyloidosis: 30,000 U.S. patient prevalence
- Adding ~2,700 U.S. patients per year (~Billion-dollar annual market increase)
- Established billing code for BCMA CAR-T: \$425,000 per dose
- Typical NXC-201 patient has failed front-line therapy (age >65)

## NXC-201: The only CAR-T in development for AL amyloidosis

- No drugs are FDA approved today in relapsed/refractory AL Amyloidosis
- We believe NXC-201 clinical results to-date significantly improve treatment options for relapsed/refractory AL Amyloidosis patients

# Significant Near-Term Milestones



# N-GENIUS Platform: Sterically-Optimized CAR-T construct “Digital Filter” reduces non-specific activation, leading to better tolerability

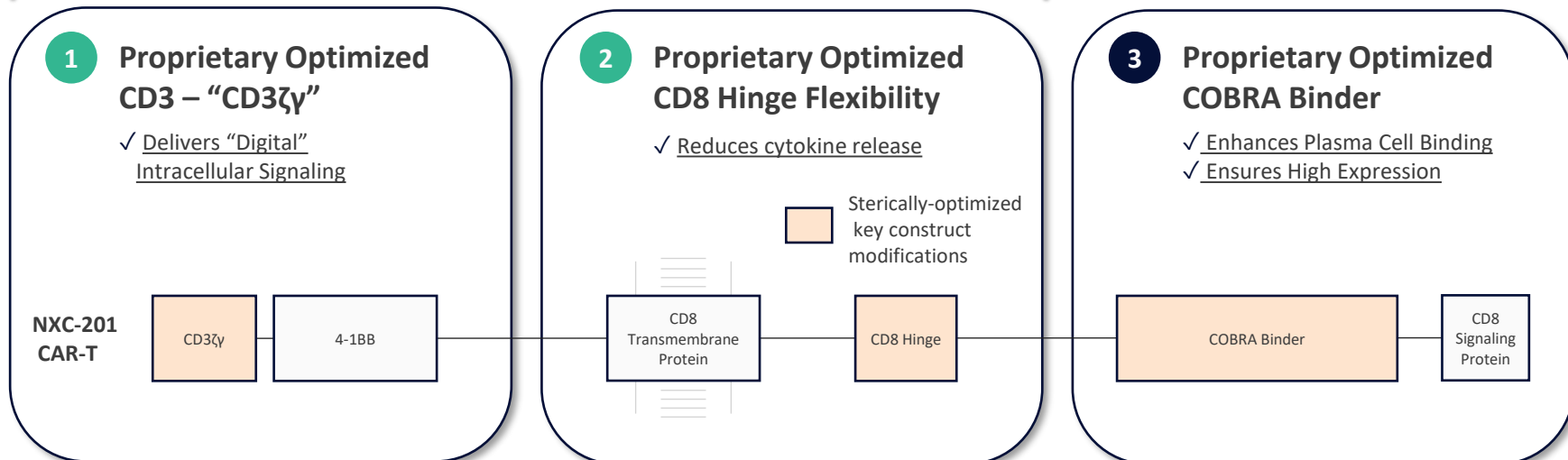
ALL BCMA CAR-TS ARE NOT CREATED EQUAL

## N-GENIUS PLATFORM

NXC-201 sterically-optimized CAR-T’s “Digital Filter” ... ..reduces non-specific activation



- ...Resulting in a NXC-201 75% complete response rate with minimal toxicity in relapsed/refractory AL Amyloidosis
- Background response rates of 0-10% in relapsed/refractory AL Amyloidosis



**TREATMENT OF RELAPSE AND PROGRESSION AFTER INITIAL THERAPY**

No consensus has been established on the criteria for commencing second-line therapy in patients with progressive disease after initial therapy.<sup>73,74</sup> Patients with relapsed disease can be treated by repeating first-line therapy if the response lasted for more than a year, although such patients have a shorter time to relapse without a reduction in overall survival than patients who are treated with a different therapy for relapsed disease.

The potential options available for the treatment of relapsed systemic AL amyloidosis include proteasome inhibitors,<sup>75,76</sup> anti-CD-38 monoclonal antibodies,<sup>77,78</sup> immunomodulatory agents,<sup>79</sup> venetoclax for patients with t(11;14),<sup>80</sup> bendamustine,<sup>81</sup> high-dose melphalan with autologous SCT,<sup>82,83</sup> bispecific antibodies,<sup>84,85</sup> and even chimeric antigen receptor T-cell therapy.<sup>86</sup> Although it is not possible to be prescriptive regarding the sequencing of therapies, the two guiding considerations are the depth and duration of the initial response and the choice of a class of agents not previously used. The limitations imposed by a patient's reduced level of fitness or frailty and end-organ damage must also be considered. Enrollment in clinical trials is encouraged.

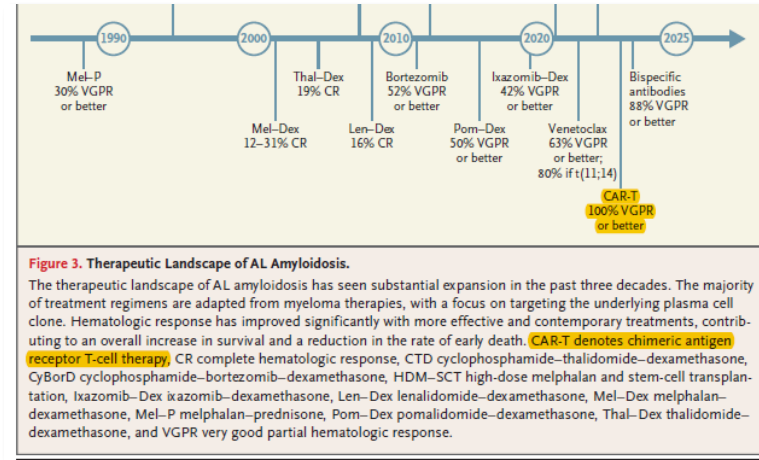
The NEW ENGLAND JOURNAL of MEDICINE

REVIEW ARTICLE

Dan L. Longo, M.D., *Editor*

## Systemic Light Chain Amyloidosis

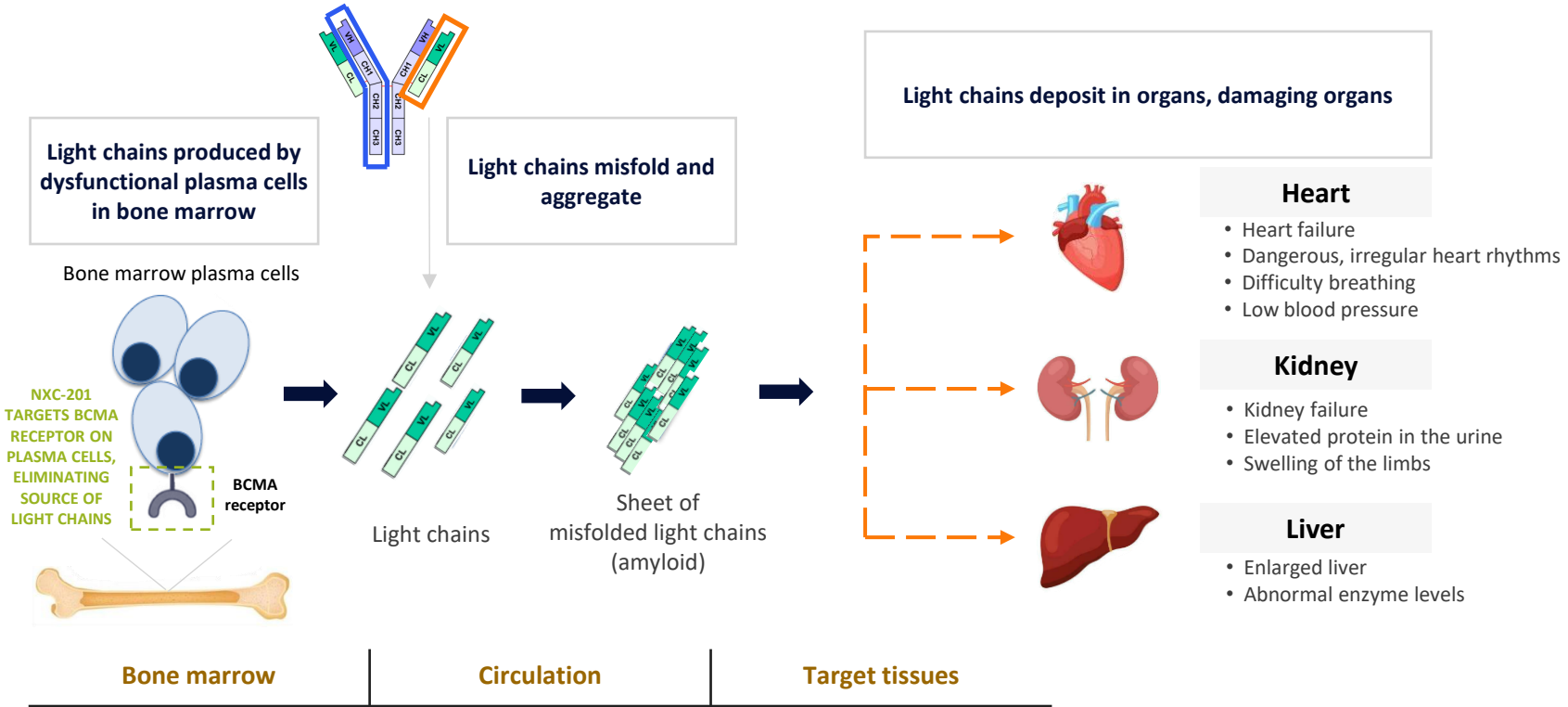
Vaishali Sanchorawala, M.D.



- tory AL amyloidosis: a multinational retrospective case series. *Blood* 2024;143:734-7.
- 86.** Kfir-Erenfeld S, Asherie N, Grisariu S, et al. Feasibility of a novel academic ECMA-CAR-T (HBI0101) for the treatment of relapsed and refractory AL amyloidosis. *Clin Cancer Res* 2022;28:5156-66.
- 87.** Nuvolone M, Nevone A, Merlini G. Targeting amyloid fibrils by passive immunotherapy in systemic amyloidosis.

# AL Amyloidosis: ~33,000 Relapsed/Refractory U.S. Patients with No FDA Approved Drugs

NXC-201 TARGETS AL AMYLOIDOSIS PLASMA CELLS THAT EXPRESS BCMA ON CELL SURFACE



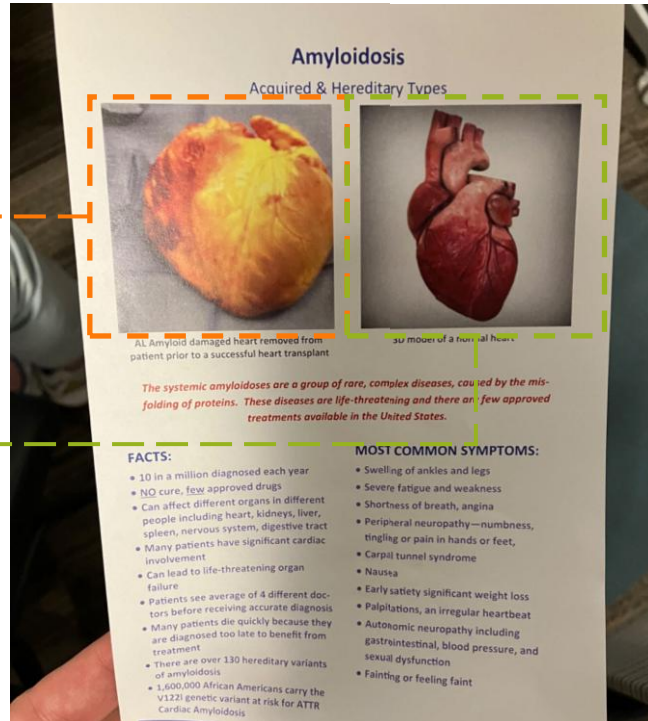
Source: Merlini, G., et al. Nat Rev Dis Primers. Oct 2018, Front. Cardiovasc. Med., Dec 2022, Hemato 2022, 3(1), 47-62; <https://doi.org/10.3390/hemato3010005>. Quock TP, Yan T, Chang E, Guthrie S, Broder MS. Epidemiology of AL amyloidosis: a real-world study using US claims data. Blood Adv. 2018 May 22;2(10):1046-1053. doi: 10.1182/bloodadvances.2018016402. PMID: 29748430; PMCID: PMC5965052. Staron A, et al. Marked progress in AL amyloidosis survival: a 40-year longitudinal natural history study. Blood Cancer J. 2021;11(8):139; Lu R, Richards TA. AL Amyloidosis: Unfolding a Complex Disease. J Adv Pract Oncol. 2019;10(8):813-825.

# This Is Heart Failure Caused by AL Amyloidosis

AL AMYLOIDOSIS CAUSES PHYSICALLY IRREVERSIBLE DISTORTION OF HEART STRUCTURE, SHAPE AND SIZE

Pre-existing heart failure caused by AL Amyloidosis (immediately prior to heart transplant)

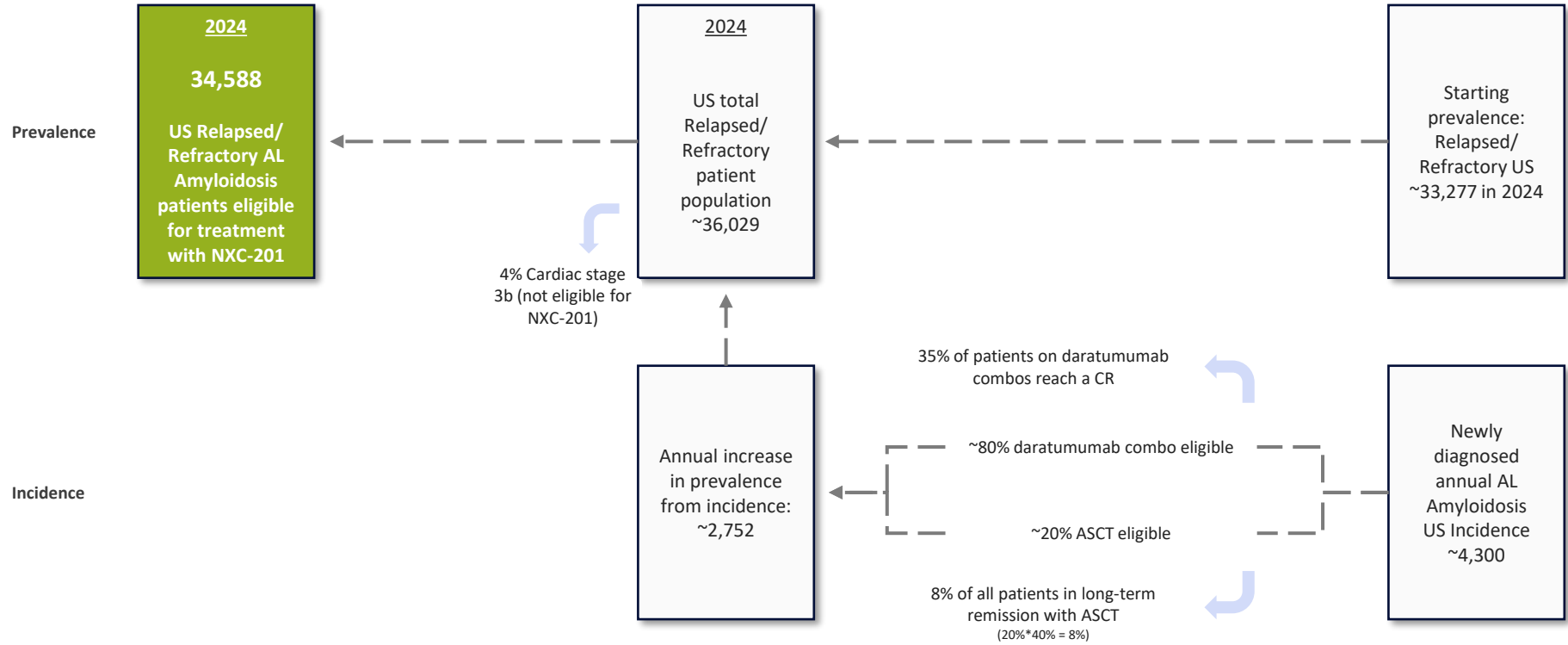
Preserved heart function (normal heart)



- ✓ AL Amyloidosis is a serious, life threatening disease that, when untreated, leads to organ failure including heart, liver, and kidneys (heart shown here)
- ✓ Goal of treatment with NXC-201 is to treat early enough to prevent reaching heart failure stage shown here (just after 1<sup>st</sup> line therapy) (“pre-existing heart failure”)

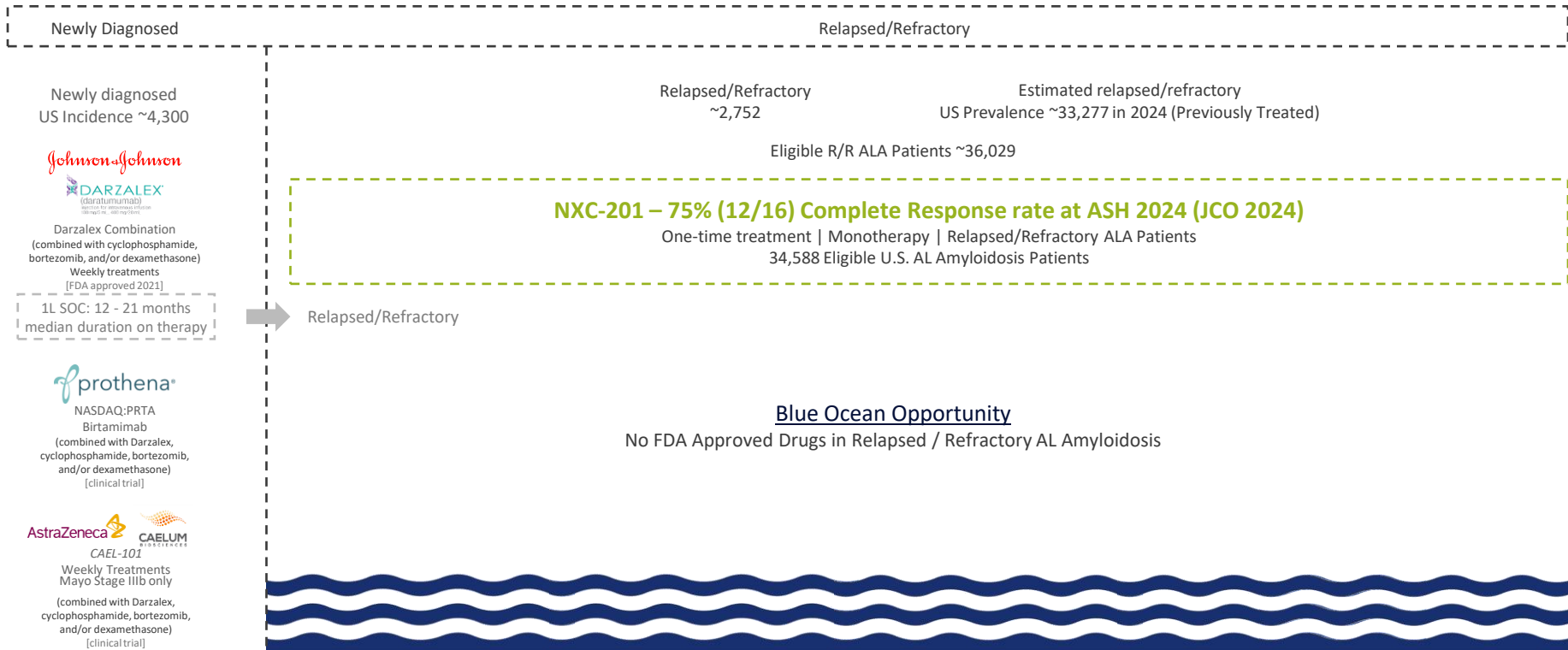


# NXC-201 Addresses Sizable U.S. Relapsed/Refractory AL Amyloidosis Patient Population (1/2)



Source: Incidence and prevalence: Quock T et al, Epidemiology of AL amyloidosis: a real-world study using US claims data. Blood 2018. Incidence growth rate: Laires P et al, Prevalence, Incidence, and Characterization of LIGHT Chain Amyloidosis in the USA: A Real-World Analysis Utilizing Electronic Health Records (EHR). Blood 2023. Daratumumab: Belloffiore C, et al. A real-life study of daratumumab combinations in newly diagnosed patients with light chain (AL) amyloidosis. Hematol Oncol. 2024. Chakraborty R et al, Reduced early mortality with Daratumumab-based frontline therapy in AL amyloidosis: A retrospective cohort study. AJH 2024. ASCT: Bomsztyk J et al, Recent guidelines for high-dose chemotherapy and autologous stem cell transplant for systemic AL amyloidosis: a practitioner's perspective. Expert Review of Hematology 2022. Gustiné J et al, Predictors of hematologic response and survival with stem cell transplantation in AL amyloidosis: A 25-year longitudinal study. AJH 2022. Mayo staging: Zanwar S, et al. Treatment patterns for AL amyloidosis after frontline daratumumab, bortezomib, cyclophosphamide, and dexamethasone treatment failures. Leukemia 2024.

# NXC-201 Addresses Sizable U.S. Relapsed/Refractory AL Amyloidosis Patient Population (2/2)



Note: Public information development plans as of 2023. Dara-CyBorD: Daratumumab, Bortezomib + cyclophosphamide + dexamethasone. BMD: bortezomib, melphalan, and dexamethasone. Source: Dima D, et al. Diagnostic and Treatment Strategies for AL Amyloidosis in an Era of Therapeutic Innovation. JCO Oncol Pract. 2023; Jimenez-Zepeda VH, et al. Understanding real-world treatment patterns and clinical outcomes in AL amyloidosis patients diagnosed in Canada: A population-based cohort study. EJHaem. 2022; Bou Zerdan M, et al. Systemic AL amyloidosis: current approach and future direction. Oncotarget. 2023; Kumar S, et al. Revised prognostic staging system for light chain amyloidosis incorporating cardiac biomarkers and serum free light chain measurements. J Clin Oncol. 2012; Browning S, et al. Hematologic relapse in AL amyloidosis after high-dose melphalan and stem cell transplantation. Blood. 2017; Palladini G, et al. Presentation and outcome with second-line treatment in AL amyloidosis previously sensitive to nontransplant therapies. Blood. 2018; Quock TP, Yan T, Chang E, Guthrie S, Broder MS. Epidemiology of AL amyloidosis: a real-world study using US claims data. Blood Adv. 2018 May 22;10(10):1046-1053. doi: 10.1182/bloodadvances.2018016022. PMID: 29748420; PMCID: PMC5965052; Staron A, et al. Marked progress in AL amyloidosis survival: a 40-year longitudinal natural history study. Blood Cancer J. 2021;11(8):139; Lu R, Richards TA. AL Amyloidosis: Unfolding a Complex Disease. J Adv Pract Oncol. 2019;10(8):813-825. EQ Crusse, E Kastritis, Y Santhorawala, GMMBOTAS Group. Subcutaneous Daratumumab + Bortezomib, Cyclophosphamide, and Dexamethasone (Vcd) in Patients with Newly Diagnosed Light Chain (AL) Amyloidosis: Updated Results from the Phase 3 Andromeda Study. Hematology, Transfusion and Cell Therapy. Volume 43, Supplement 1, 2021. https://doi.org/10.1016/j.htct.2021.10.364. 21-month duration: Kastritis E, et al. 891 Subcutaneous Daratumumab (DARA) + Bortezomib, Cyclophosphamide, and Dexamethasone (VCD) in Patients with Newly Diagnosed Light Chain (AL) Amyloidosis: Overall Survival and Final Major Organ Deterioration Progression-Free Survival Results from the Phase 3 Andromeda Study. Abstract. ASH 2024. Bellofiore C, et al. 12-month duration: A real-life study of daratumumab combinations in newly diagnosed patients with light chain (AL) amyloidosis. Hematol Oncol. 2024.

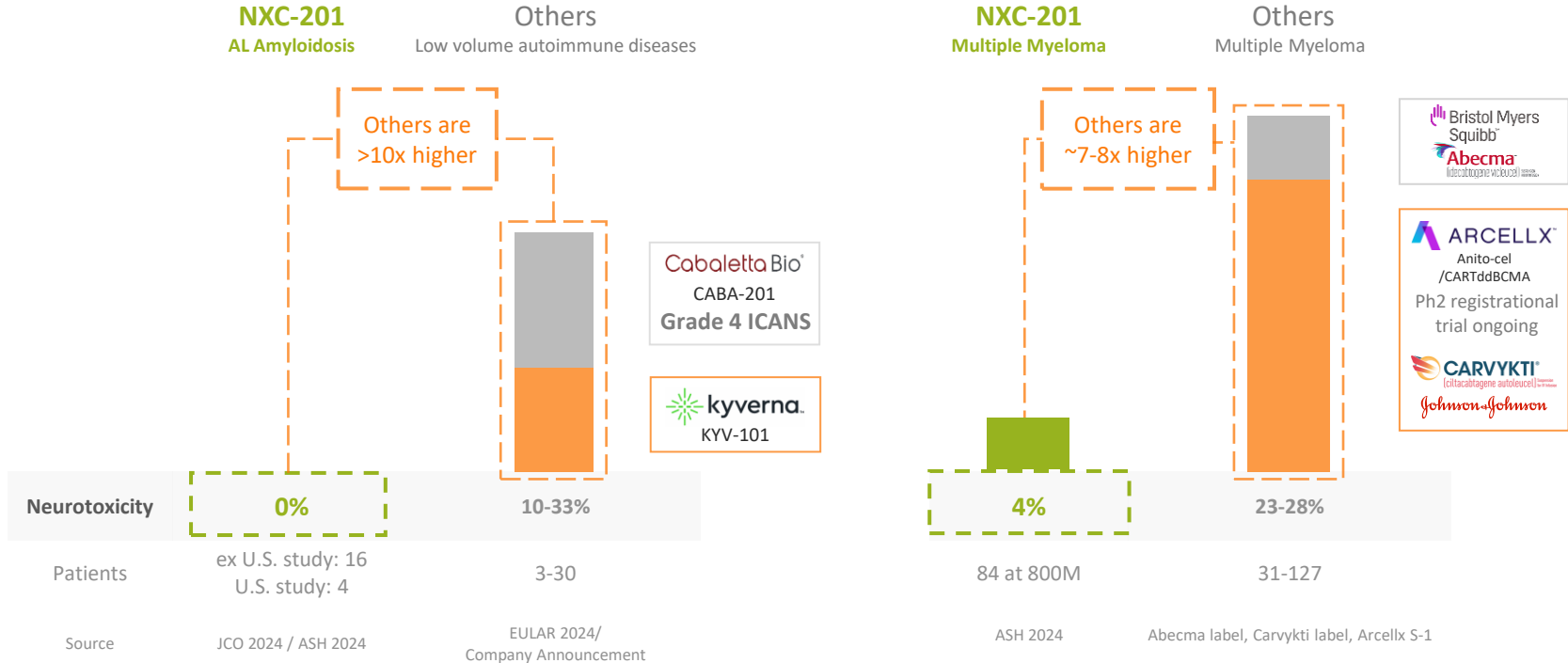
# NXC-201 Advantage: Overcoming Neurotoxicity

ALL BCMA CAR-TS ARE NOT CREATED EQUAL



## LOW VOLUME DISEASE

## HIGH VOLUME DISEASE



Source: Carvykti and Abecma FDA labels, Arcellx S-1. Assayag, et al. Academic BCMA-CART cells (HB101), a promising approach for the treatment of LC Amyloidosis. 27th Annual Meeting of The American Society of Gene and Cell Therapy (ASGCT). Late Breaking Oral Presentation. Baltimore, MD. May, 2024 Assayag, N., et al. European Society for Blood and Marrow Transplantation 49th Annual Meeting. Lebel E, et al. Efficacy and Safety of a Locally Produced Novel Anti-BCMA Chimeric Antigen Receptor T-Cell (CART) (HB101) for the Treatment of Relapsed and Refractory Multiple Myeloma, International Myeloma Society 20th Annual Meeting, 2023... Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across studies. Figures reflect cross-trial comparison and not results from a head-to-head study. Kyverna corporate presentation June 14, 2024. Accessed through <https://www.sec.gov/ix?doc=/Archives/edgar/data/0001994702/000095017024073312/kyx-20240614.htm>. Low volume diseases refers to ANCA vasculitis, autoimmune encephalitis, anti-synthetase syndrome, CIDP, DAGA encephalitis, IgG4-related disease, Lambert-Eaton myasthenic syndrome, lupus nephritis, myasthenia gravis, multiple sclerosis, rheumatoid arthritis, systemic sclerosis, Stiff Person syndrome. Cabaletta 2Q 2024 earnings press release: <https://www.cabalettabio.com/investors/news-events/press-releases/detail/114/cabaletta-bio-reports-second-quarter-2024-financial-results>. High volume disease NXC-201 CRS data from ASH 2024 Abstract which included 84 MM patients. NXC-201 data from NEXCART-1 clinical study.

# NXC-201 Tolerability Drives AL Amyloidosis Leadership

ALL BCMA CAR-TS ARE NOT CREATED EQUAL



NXC-201's short CRS duration makes it **uniquely suitable to treat ALA patients** (in whom the #1 source of mortality is heart failure)

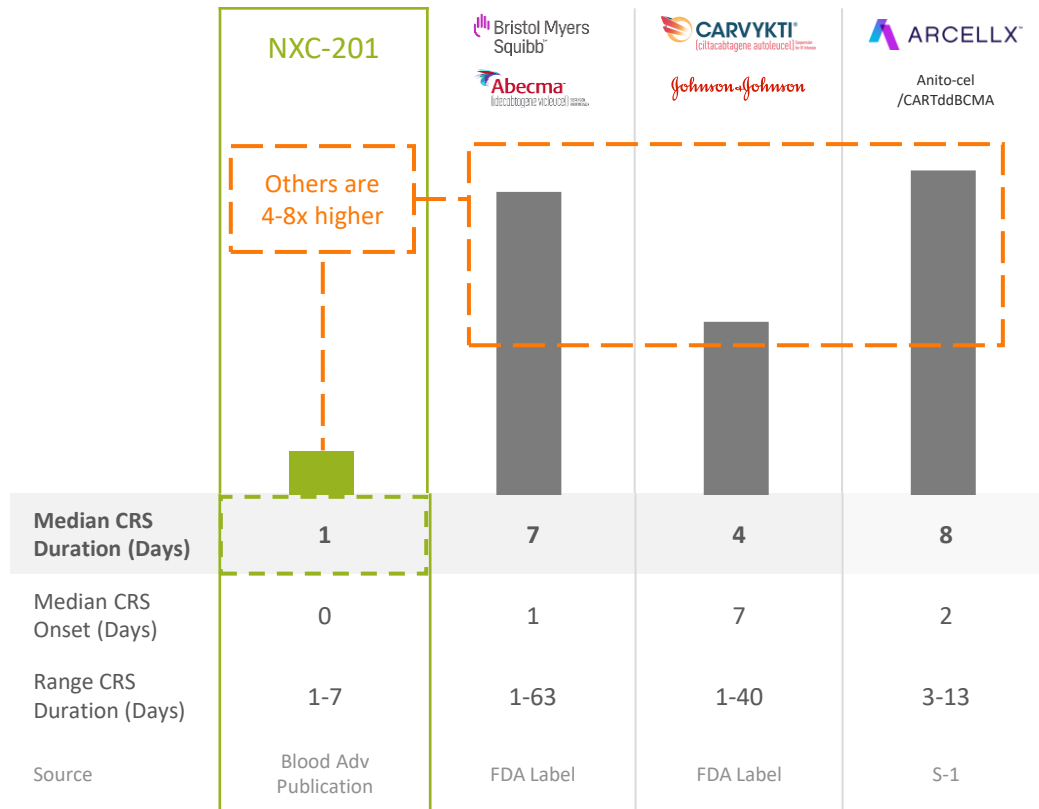
Cardiovascular stress is the key determinant for ability to treat relapsed/refractory ALA patients

- Long CRS duration causes extended cardiovascular stress
- Other CARTs have 4-8x longer CRS duration

“The biggest challenge ... has been applicability of these therapies in amyloidosis **when the patients are particularly frail and have organ dysfunction** ... where the key lies in the safety rather the efficacy in a low-volume disease setting is going to be key ... ”

– *Dr. Susan Bal, MD*  
Assistant Professor, Hematology  
University of Alabama at Birmingham

Source: M. Assayag, et al. Point-of-care CART manufacture and delivery for the treatment of multiple myeloma and AL amyloidosis: the experience of Hadassah Medical Center, European Society for Blood and Marrow Transplantation 49th Annual Meeting, Poster Presentation, April 2023. Nov 2023 KOL discussion <https://livesciences.com/event/immixbio/NXC-201> (formerly HB10101) American Society of Hematology Presentation, Abecma FDA approval label, Carvykti FDA approval label, Arcellx S-1, NXC-201 data from NEXICART-1 clinical study.



Data in Multiple Myeloma

# Pipeline: Only CAR-T in AL Amyloidosis; Expanding To Other Serious Diseases



## Lead Program: NXC-201, a next-generation BCMA-targeting CAR-T for AL Amyloidosis and Other Serious Diseases

Indication	Therapy	Pre-clinical	Phase 1	Phase 2	Upcoming Milestones
Relapsed/Refractory AL Amyloidosis	NXC-201	US FDA and EU EC Orphan Drug Designation (ODD)			<p><b>2Q/3Q 2025:</b> Report interim clinical data readout for NEXICART-2 trial in AL Amyloidosis</p> <p><b>2Q/3Q 2026:</b> Report final topline clinical data readout for NEXICART-2 trial in AL Amyloidosis</p>
Undisclosed select Other Serious Diseases	NXC-201	IND enabled			<p><b>4Q 2025:</b> Report NXC-201 interim clinical data in unaddressed immune-mediated diseases</p>

## Other Emerging Pipeline

Preclinical Candidates	Not yet announced	[Progress bar]			
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# World-Class Team



## Management

	<b>Ilya Rachman, MD, PhD</b> Chief Executive Officer	 Cedars Sinai	 UCLA Health	 UIC COLLEGE OF MEDICINE
	<b>Gabriel Morris, BA</b> Chief Financial Officer	 COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK		
	<b>Graham Ross, MBChB, FFPM</b> Chief Medical Officer	 AstraZeneca	 Roche	 gsk
	<b>David Marks, MBBS, PhD</b> Chief Medical Officer, Cell Therapy	 NHS University Hospitals Bristol and Gloucestershire	 Pfizer	 TECARTUS® Kite/Gilead KYMRIAH® Novartis
	<b>Gerhard Bauer</b> Head of Cell Therapy Manufacturing	 ASCT American Society of Gene + Cell Therapy	 UC DAVIS UNIVERSITY OF CALIFORNIA	

## Board of Directors

	<b>Helen Adams, CPA</b> Former Prometheus Biosciences Board Member	 Prometheus Biosciences	 Deloitte.
	<b>Magda Marquet, PhD</b> ALMA Life Sciences	 ALMA Life Sciences	 ALTHEA
	<b>Jane Buchan, PhD</b> CEO, Martlet Asset Management	 KKR PRISMA	 J.P.Morgan
	<b>Yekaterina Chudnovsky, JD</b> GI Research Foundation	 GI RESEARCH FOUNDATION	 elicio THERAPEUTICS
	<b>Jason Hsu, PhD</b> Founder & Chairman, Rayliant Global Advisors	 RAYLIANT	 research affiliates
	<b>Carey Ng, PhD</b> Mesa Verde Venture Partners	 MESA VERDE VENTURE PARTNERS	 Abbott

## Scientific Advisory Board

	<b>Heather Landau, MD</b> Director, Amyloidosis Program	 Memorial Sloan Kettering Cancer Center
	<b>Suzanne Lentzsch, MD, PHD</b> Director, Multiple Myeloma and Amyloidosis	 COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK
	<b>Michaela Liedtke, MD</b> Co-Director, Stanford Amyloid Center	 Stanford MEDICINE
	<b>Vaishali Sanchorawala, MD</b> Director, Amyloidosis Center	 BU Chobanian & Avedisian School of Medicine
	<b>Marko Radic, PhD</b> Autoimmune CAR-T Pioneer	 THE UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
	<b>Gary Schiller, MD</b> UCLA Professor of Oncology	 UCLA Health

# U.S. NEXICART-2 Trial Designed Based on ex-US NEXICART-1 Trial Experience

NXC-201 clinical data indicate that R/R Amyloidosis patients with preserved heart function are more likely to benefit from treatment

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>

NEXICART-2: 40 patient, single-arm, multi-site, US trial → submit data to FDA

Source: Feasibility of a Novel Academic Anti-BCMA Chimeric Antigen Receptor T-Cell (CAR) (HBI0101) for the Treatment of Relapsed and Refractory AL Amyloidosis, 65th ASH Annual Meeting and Exposition, San Diego, CA, October 2023. R. Chakraborty, et al. Safety and efficacy of teclistamab in systemic immunoglobulin light chain amyloidosis. Blood Cancer Journal. October 2023. N. Forgeard, et al. Teclistamab in relapsed or refractory AL amyloidosis, a multinational retrospective case series. Blood. February 2024. One NXC-201 relapsed/refractory AL amyloidosis patient died of COVID-19

NEXICART-2: US

CAR-T NXC-201 Clinical Trial





# NEXICART-2 U.S. Relapsed/Refractory AL Amyloidosis Trial (NCT06097832)

NEXICART-2 NXC-201 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

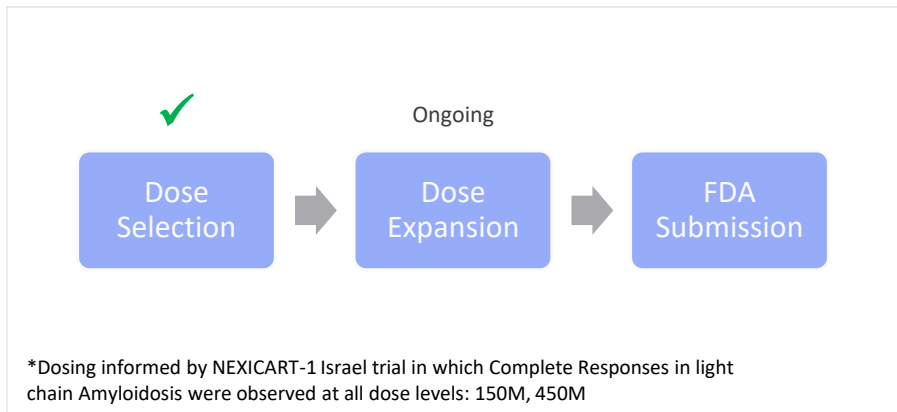
<b>Inclusion</b>	<ul style="list-style-type: none"> <li>• AL Amyloidosis patients exposed to at least 1 line of therapy including a CD38 monoclonal antibody</li> </ul>
<b>Exclusion</b>	<ul style="list-style-type: none"> <li>• Prior anti-BCMA directed therapy</li> <li>• Cardiac: Mayo stage 3b, NYHA stage 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: Complete 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: Complete 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</b> Yes	<b>X</b> Yes	<b>X</b> Yes
<b>NEXICART-2:</b> ongoing US trial	✓ No	✓ No	✓ No

Company believes NEXICART-2 patients are most likely to benefit from NXC-201 therapy

Note: Complete 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.)

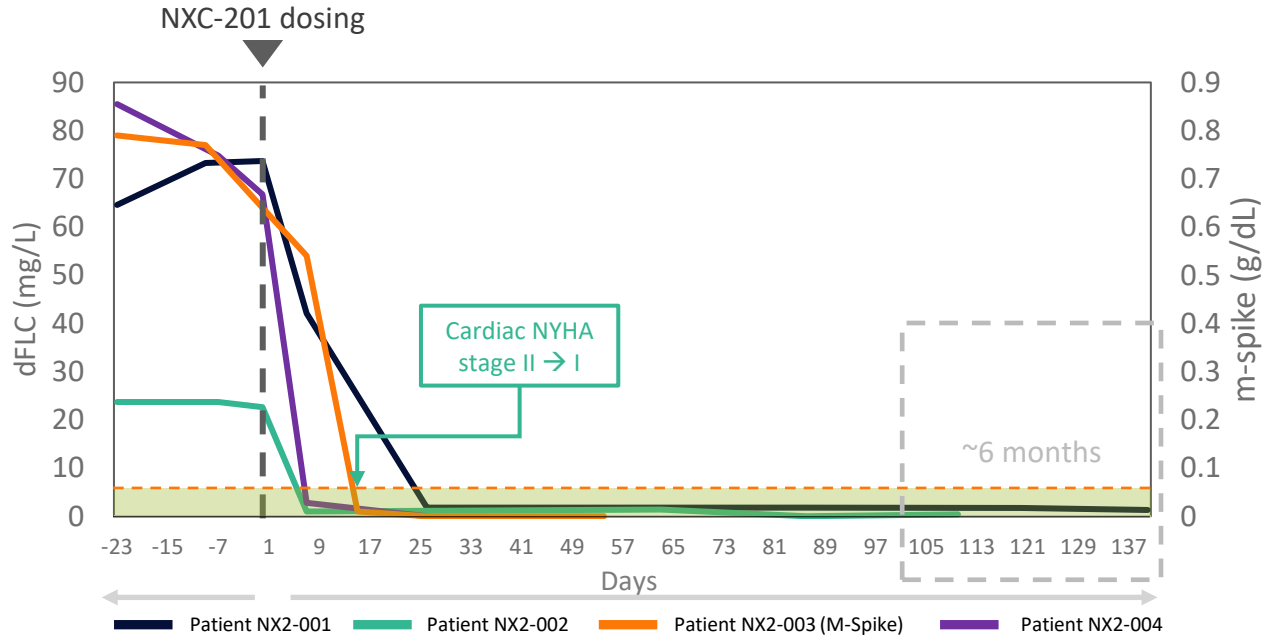
# NEXICART-2: Patient enrollment focused on patients with **preserved heart function**

 Preserved heart function

Patient #	NX2-001	NX2-002	NX2-003	NX2-004	Median (range)
Age	56	67	82	64	66 (56-82)
Gender	Female	Female	Male	Female	-
Prior lines of therapy	4	6	2	4	4 (2-6)
Follow up (days)	141	113	57	29	85 (29-141)
dFLC (mg/L)	65	24	-	86	65 (24-86)
M-Spike (g/dL, if dFLC not inclusion criteria)	-	-	0.79	-	-
FISH cytogenetics	1q21+	1q21+	1q21+	-	-
Organ involvement	Heart	Heart	Kidney	Heart	-
NYHA stage	I	II	I	I	-
NT-ProBNP (pg/mL)	146	560	1,297	218	389 (146-1,297)
hs-Troponin-I (ng/L)	7	6	42	7	7 (6-42)
Creatinine (mg/dL)	0.7	1.1	2.2	1.8	1.5 (0.7-2.2)
Albuminuria (mg/24 hrs)	143	0	3,032	10	77 (0-3,032)
Alk Phos (U/L)	94	40	73	83	78 (40-94)
MAYO stage	Stage II	Stage II	Stage II	Stage IIIA	-

Note: Data cut-off as of November 14, 2024. For patient NX2-001, prior lines of therapy included 1) Cyclophosphamide/bortezomib, dexamethasone, 2) ASCT, 3) Bortezomib/ dexamethasone, 4) Isatuximab. For patient NX2-002, prior lines included 1) Bortezomib/dexamethasone, 2) ASCT, 3) Bortezomib/dexamethasone, 4) Daratumumab, 5) Pomalidomide and dexamethasone, 6) Melphalan. For patient NX2-003, prior lines included 1) Daratumumab, 2) Bortezomib/ Velcade. For patient NX2-004, prior lines included 1) Bortezomib, 2) Dexamethasone, 3) Dara CyBord, 4u) Daratumumab.

# NEXICART-2 Efficacy: Rapid Normalization of Diseased Light Chains within First ~Month; Consistent with Ex-US Dataset



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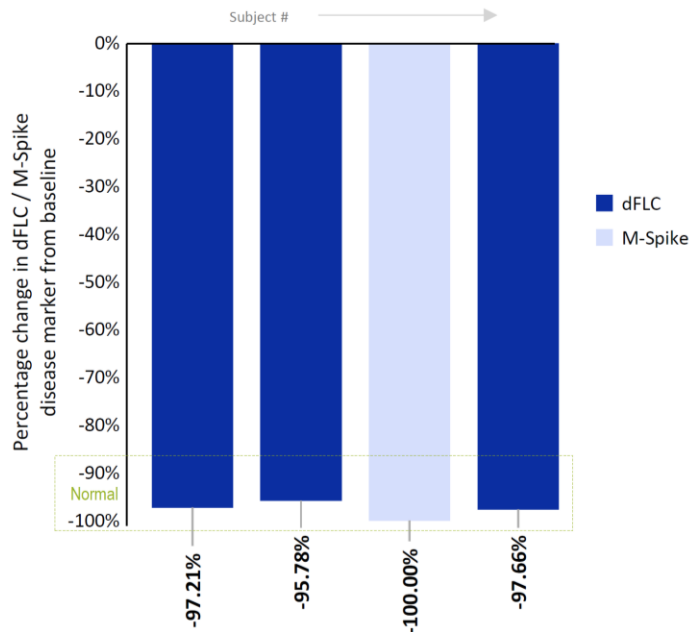
“An early and deep hematologic response has been found to lead to significantly prolonged survival”

– *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 Efficacy: Rapid Normalization of Diseased Light Chains within First ~Month; Consistent with Ex-US Dataset

Subject #	NX2-001	NX2-002	NX2-003	NX2-004
NXC-201 Dose (million CAR+T cells)	150	150	150	450
AL Amyloidosis Disease Markers	Normal	Normal	Normal	Normal
Status as of data cutoff	Normal	Normal	Normal	Normal
Time to normalization (days)	26	7	15	7
Response Status	CR	Pending (already MRD(-) $10^6$ )	CR	Pending (already MRD(-) $10^6$ )



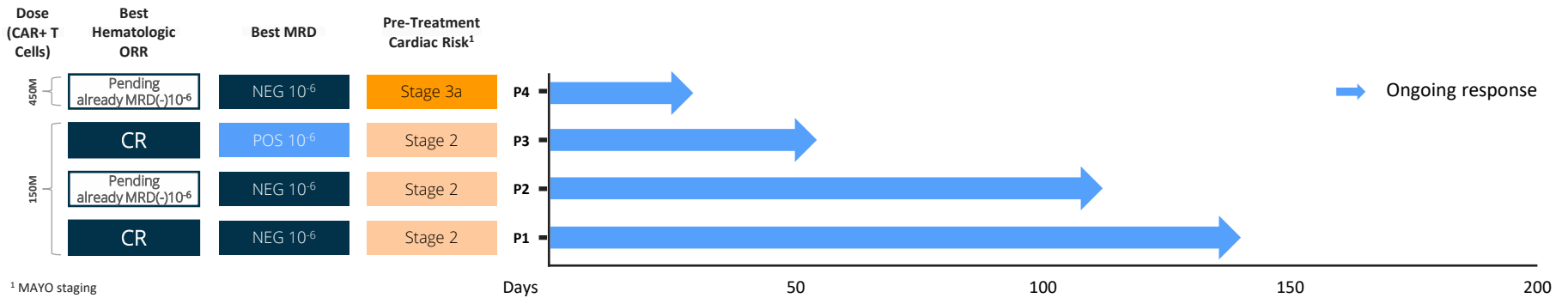
Note: Data cut-off as of November 14, 2024. Vein-to-vein time was 12 days for patients NX2-001, NX2-002, NX2-003, NX2-004. dFLC: difference in free light chain (disease marker). Complete response according to consensus recommendations for AL Amyloidosis treatment response criteria (Palladini, 2012).

# NEXICART-2 Efficacy: Complete Responses in Two Patients and Remaining Two MRD- $10^{-6}$ ; All Patients in Ongoing Response as of Data Cut-off



	1	2	3	4
<b>CART cells infused (<math>\times 10^6</math>)</b>	150	150	150	450
<b>Best hematologic response</b>	CR	Pending already MRD(-) $10^{-6}$	CR	Pending already MRD(-) $10^{-6}$
<b>Follow-up (months)</b>	141	113	57	29
<b>Best MRD</b>	Neg $10^{-6}$	Neg $10^{-6}$	Pos $10^{-6}$	Neg $10^{-6}$

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



Note: Data cut-off as of December 17, 2024. Premkumar VJ, et al. Venetoclax induces deep hematologic remissions in t(11;14) relapsed/refractory AL amyloidosis. Blood Cancer J. 2021 Jan 11;11(1):10. doi: 10.1038/s41408-020-00397-w. PMID: 33431806; PMCID: PMC7801694. Theodorakakou F, et al. Outcomes of patients with light chain (AL) amyloidosis after failure of daratumumab-based therapy. Br J Haematol. 2023 Nov;203(3):411-415. doi: 10.1111/bjh.19042. Epub 2023 Aug 14. PMID: 37580907.

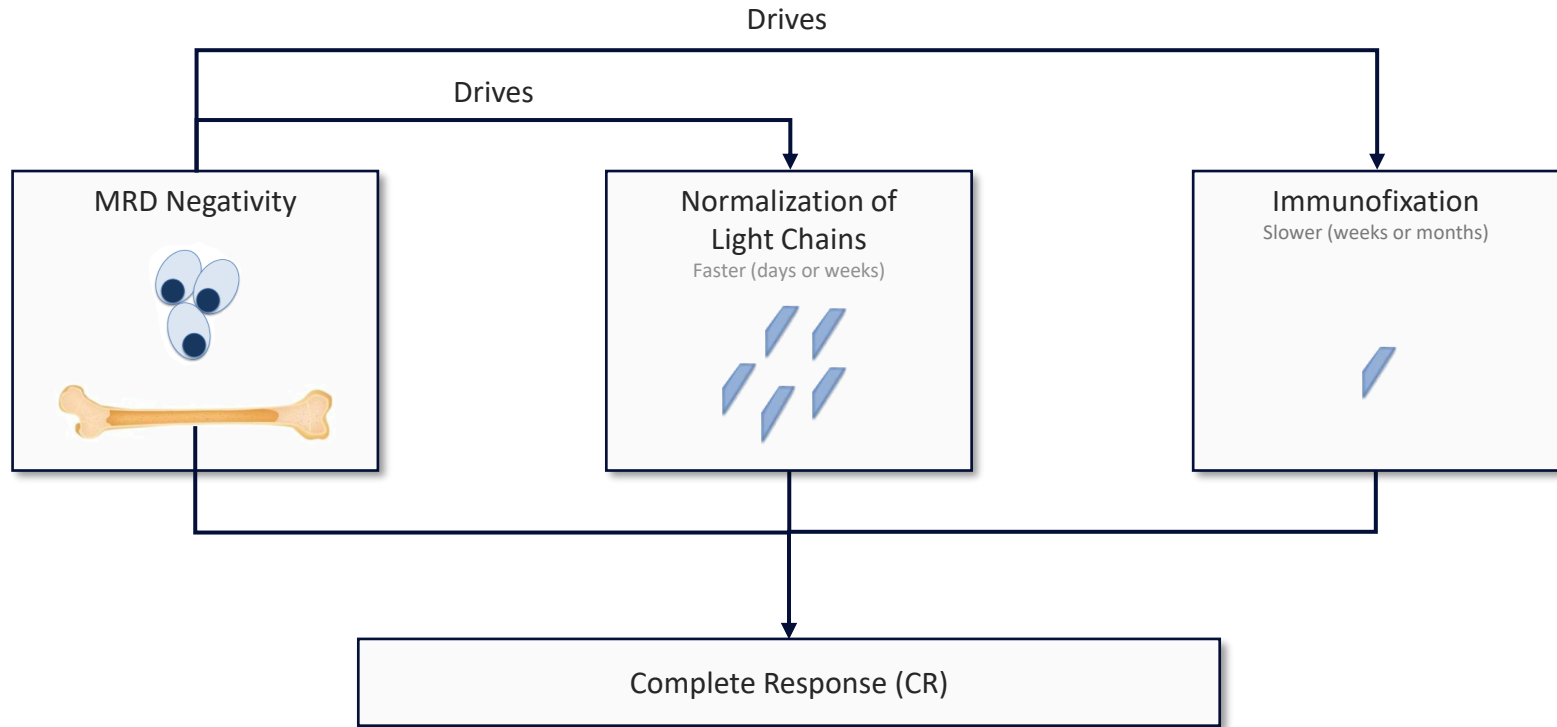
# NEXICART-2 Safety: Consistent or Improved Compared to Ex-US Dataset

- No ICANS neurotoxicity of any kind
- Grade 2 CRS in one patient, Grade 1 CRS in one patient, both with 1 day duration

Patient #	NX2-001	NX2-002	NX2-003	NX2-004
CART Cell Dose ( $\times 10^6$ )	150	150	150	450
Neurotoxicity	None	None	None	None
Cytokine release syndrome (CRS)	None	None	Grade 2	Grade 1
CRS Onset (days)	-	-	3	3
CRS Duration (days)	-	-	1	1
Neutropenia	Grade 3	Grade 3	Grade 3	Grade 4
Febrile Neutropenia	None	None	None	None
Anemia	Grade 1	Grade 2	Grade 3	Grade 1
Thrombocytopenia	Grade 1	Grade 1	None	Grade 1
Acute kidney failure	None	None	None	None
Liver Function Test Abnormalities	Grade 2	None	None	None
Serious Infections	None	None	None	None
Fatigue	None	None	None	None

Note: Data cut-off as of November 14, 2024. CRS and ICANS reported according to ASTCT Consensus Grading (Lee et al. 2019). 001-004 Grade 4 Neutropenia duration of one day. Patient NX2-004 neutropenia to be updated subsequently.

# NEXICART-2: Drivers of Complete Response (CR) in relapsed/refractory AL Amyloidosis



As of Nov 14 data cutoff, all 4 patients are:  
either classified as a **CR**, or are MRD negative ( $10^{-6}$ ) (predicting future CR)

# 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?	✗ Randomization vs. SoC	✓ No SoC to randomize against
	Lines of therapy prior to receiving study drug	✗ None	✓ At least 1 line of therapy including a CD38 monoclonal antibody
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	✓ Hematologic complete response rate for both studies	

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

Note: Source for daratumumab information is ANDROMEDA (NCT03201965). NXC-201 information on this slide is illustrative only and represents current plan.



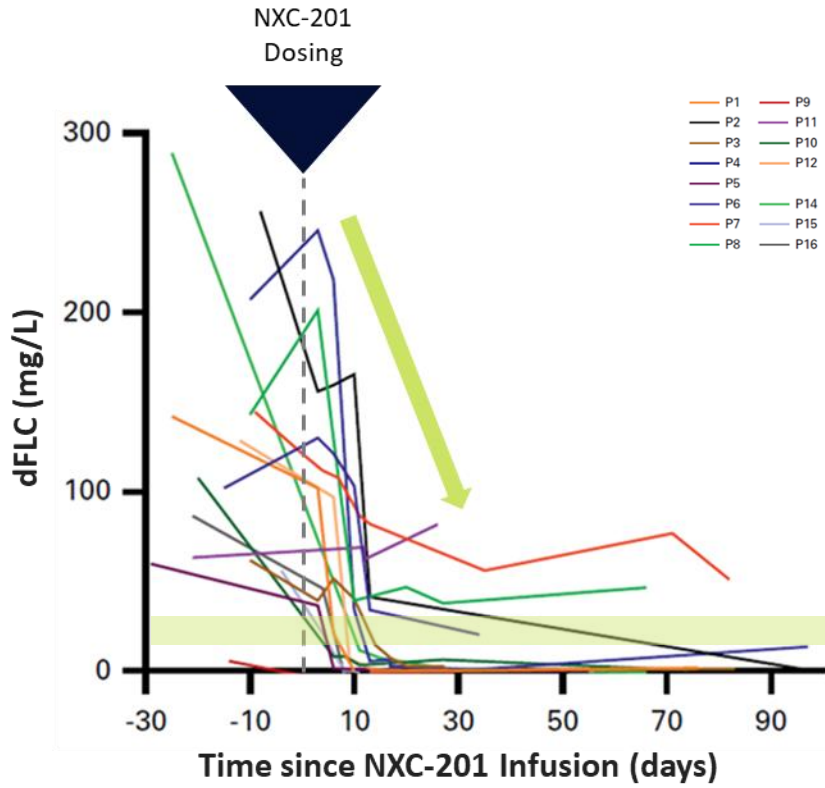
NEXICART-1: Ex-US

CAR-T NXC-201 Clinical Trial



# NEXICART-1: Normalization of Diseased Free Light Chains 30 Days after Dosing

NXC-201 RAPIDLY ELIMINATES DISEASED AL AMYLOIDOSIS PLASMA CELLS AND EXITS WITHIN ~30 DAYS



**Time since NXC-201 Infusion (days)**

(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

Note: Data cut-off as of December 9, 2024. 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.

# NEXICART-1: 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



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	63	67	70	58	64 (55-82)
Gender	Male	Female	Male	Male	Male	Female	Female	Male	Male	Male	Female	Male	Female	Male	Male	Male	11/16 M 5/16 F
Prior lines of therapy	8	6	6	10	3	4	4	7	4	3	8	4	4	3	6	3	4 (3-10)
dFLC (mg/L)	143	177	50	550	51	103	196	408	41	108	64	129	83	275	49	86	106 (41-550)
BMPc (%)	3	15	1	15	0.1	1	1	10	15	1	1	1	0.5	1.5	0.5	0.3	1 (0.1-15)
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+	t(11:14)	t(11:14)	Normal	t(11:14)	Normal	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	Cardiac, Renal	Cardiac, Renal, Soft tissue, GI	Liver	Cardiac, PNS, GI	Cardiac, Renal, GI, Liver	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	3	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	3,158	281	191	107	964	831 (107-28,000)
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	3a	1	1	1	2	--
ECOG PS	0	2	0	0	1	2	4	0	1	1	1	1	1	2	0	1	1 (0-4)
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	no	no	no	no	no	2/16

# NEXICART-1 NXC-201 Produces Durable Complete Responses in Patients with Preserved Heart Function

## Duration of response (ASH 2024)

Preserved heart function

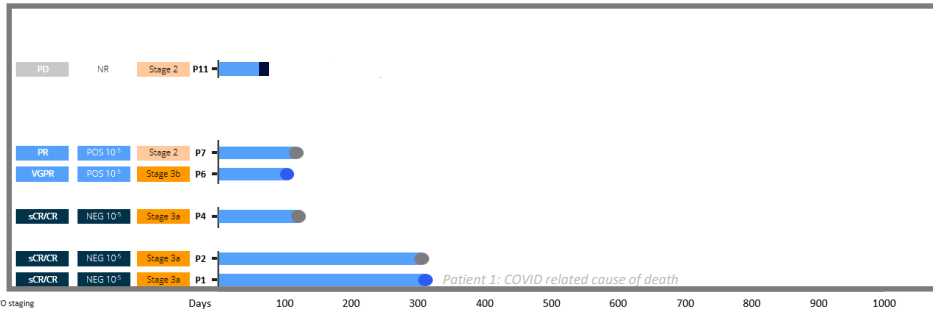


- Ongoing response
- Cardiac death in CR/VGPR
- Cardiac death while in PD
- Discontinued

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 9 death due to depression. Eyal Lebel et al., Efficacy and Safety of Anti-B-Cell Maturation Antigen Chimeric Antigen Receptor T-Cell for the Treatment of Relapsed and Refractory AL Amyloidosis. JCO 0, JCO-24-02252. DOI:10.1200/JCO-24-02252.

# NEXICART-1: 75% Complete Response Rate (is the FDA Regulatory Endpoint)

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 investigator's choice is ~3-20%

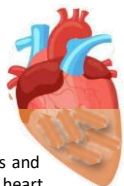
# NXC-201: Potential to Expand to Other Serious Diseases



# CAR-T NXC-201 Targets Plasma Cells (antibody factories of the body)

ANTIBODY FACTORY PLASMA CELLS PRODUCE ANTIBODIES THAT DRIVE IMMUNE-MEDIATED DISEASES

## AL Amyloidosis



Infiltrates and damages heart

AL amyloid antibody deposits

Light chain antibody fragments

## Neurology



- Myasthenia Gravis
- NMO Spectrum Disorder

## Hematology



- Thrombotic thrombocytopenic purpura
- Immune Thrombocytopenia

## Rheumatology



- Systemic Lupus Erythematosus
- Rheumatoid Arthritis

## Vascular



- ANCA vasculitis

Disease-causing antibodies

**ANTIBODY FACTORY PLASMA CELL**  
(NXC-201 therapeutic target)



Note: select indications noted above are for illustrative purposes only.

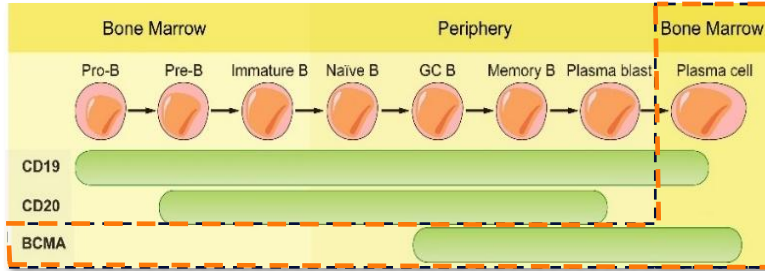
\*Illustrative list of immune-mediated diseases where B cells may play a role in initiating or maintaining disease, and where NXC-201 may provide a potential treatment

Source: MedicTests. Lee, J. et al. Antigen-specific B cell depletion for precision therapy of mucosal pemphigus vulgaris. J. Clin. Invest. 2020. Mackensen, A. et al. Anti-CD19 CAR T cell therapy for refractory systemic lupus erythematosus. Nat. Med. 2022. Qin C, et al. Anti-BCMA CAR T-cell therapy CT103A in relapsed or refractory AQP4-IgG seropositive neuromyelitis optica spectrum disorders: phase 1 trial interim results. Signal Transduct Target Ther. 2023. Granit V, et al. Safety and clinical activity of autologous RNA chimeric antigen receptor T-cell therapy in myasthenia gravis (MG-001): a prospective, multicentre, open-label, non randomized phase 1b/2a study. Lancet Neurol. 2023. McGlothlin J, et al. Bortezomib and daratumumab in refractory autoimmune hemolytic anemia. Am J Hematol. 2023. Yu TS, et al. Abnormalities of bone marrow B cells and plasma cells in primary immune thrombocytopenia. Blood Adv. 2021. Zhang Z, Xu Q, Huang L. B cell depletion therapies in autoimmune diseases: Monoclonal antibodies or chimeric antigen receptor-based therapy? Front Immunol. 2023. Pioli PD. Plasma Cells, the Next Generation: Beyond Antibody Secretion. Front Immunol. 2019

# NXC-201 BCMA CAR-T targeting is uniquely suited to address Other Serious Diseases

NXC-201 BCMA CAR-T TARGETS OTHER DISEASE CAUSING LONG-LIVED PLASMA CELLS

## NXC-201



~80% of all antibodies are produced by plasma cells...

BCMA is expressed on long lived plasma cells

**NXC-201 BCMA CART targets long lived plasma cells (LLPC), targeting the source of disease-causing antibodies**

- CD19 therapies target earlier lineage B-Cells, allowing LLPCs to persist

### Immix Biopharma unaddressed IMD indication selection criteria

High unmet medical need



Limited therapies in development



Biological basis for plasma cell-mediated therapy





# Appendix 1: Technology

April 2025



# N-GENIUS Platform: Sterically-Optimized CAR-T construct “Digital Filter” reduces non-specific activation, leading to better tolerability

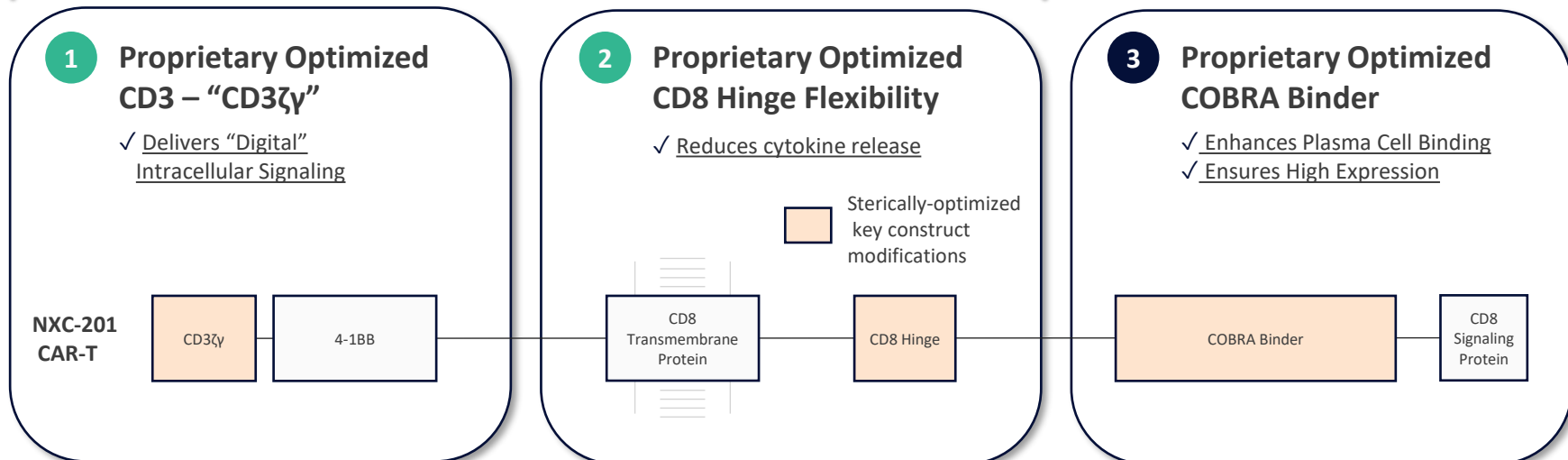
ALL BCMA CAR-TS ARE NOT CREATED EQUAL

## N-GENIUS PLATFORM

NXC-201 sterically-optimized CAR-T’s “Digital Filter” ... ..reduces non-specific activation



- ...Resulting in a NXC-201 75% complete response rate with minimal toxicity in relapsed/refractory AL Amyloidosis
- Background response rates of 0-10% in relapsed/refractory AL Amyloidosis



# Proprietary Sterically-Optimized CD3 $\zeta$ + CD8 Delivers "Digital" Intracellular Signaling, Eliminates Neurotoxicity, Reduces CRS Duration



CD3 $\zeta$

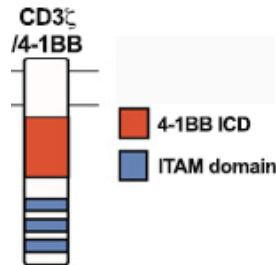
CARs rely on activation of CAR-T cells through CD3 $\zeta$  derived immunoreceptor tyrosine-based activation motifs (ITAMs), typically 3 ITAM motifs per CAR

NXC-201 adds a positively charged amino acid (lysine) next to a tyrosine phosphorylation site, therefore:

- ✓ Impeding phosphorylation of ITAM1 (by affecting protein folding dynamics which block the tyrosine site), thus reducing intracellular reactivity
- ✓ Adding an additional site for ubiquitination, allowing the CAR to be marked for degradation more rapidly than a traditional CAR

The combined effect of these modifications is to drive a "digital" signaling of extracellular activity, that is on when antigen is present and off when not

Modification of ITAMs is a common theme in third-generation CAR design, with publications in Nature Medicine and by Memorial Sloan Kettering on the topic



## nature Signal Transduction and Targeted Therapy

"In activated T cells, the CD3 $\zeta$  chain gets ubiquitinated by CBLB at its multiple lysine residues and induces degradation of surface TCRs"

doi: 10.1038/s41392-021-00823-w

nature  
medicine



Memorial Sloan Kettering  
Cancer Center

"We hypothesized that the redundancy of CD28 and CD3 $\zeta$  signaling in a chimeric antigen receptor (CAR) design incorporating all three CD3 $\zeta$  immunoreceptor tyrosine-based activation motifs (ITAMs)<sup>11,13</sup> may foster counterproductive T cell differentiation and exhaustion. Therefore, we calibrated ITAM activity by mutating tyrosine residues to impede their phosphorylation and downstream signaling"

doi: 10.1038/s41591-018-0290-5

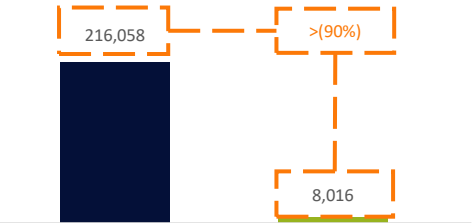
# Proprietary Sterically-Optimized CD3ζ + CD8 Delivers "Digital" Intracellular Signaling, Eliminates Neurotoxicity, Reduces CRS Duration



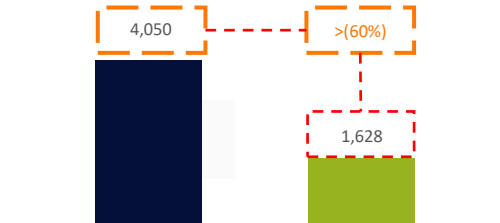
## CD8 Hinge

PreClinical

- NXC-201: Optimized (Decreased) CD8 Hinge Flexibility Resulted In:
- ✓ >90% reduction in cytokine release in preclinical studies
  - ✓ improved human efficacy
  - ✓ zero neurotoxicity



- Literature: Optimized (Decreased) CD8 Hinge Flexibility Resulted In
- ✓ >60% reduction in cytokine release in preclinical studies
  - ✓ improved human efficacy
  - ✓ zero neurotoxicity



Clinical

		IFNγ (pg/mL): K562-BCMA co-culture	
		Interferon-γ (IFN-γ) after 24 h of co-culture of CAR T cells with BCMA+ (K562-BCMA, RPMI-8226, U266-B1, H929) targets.	
		Abecma in MM	NXC-201 in MM
Efficacy	ORR (%)	72	92
	CR (%)	28	64
CRS	CRS, any grade (%)	85	95
	CRS, Grd3+ (%)	9	19
	Duration, CRS (days)	7	1 at 800M
Neurotoxicity	Neurotoxicity, any grades (%)	28	4% (all Grade 1-2)

		IFNγ (pg/mL): K562-CD19 co-culture	
		Kymriah	CD19-BBz(86)
Efficacy	ORR (%)	52	73
	CR (%)	40	55
	CRS, any grade (%)	58	28
CRS	CRS, Grd3+ (%)	22	0
	Duration, CRS (days)	7	n/a
Neurotoxicity	Neurotoxicity, any grades (%)	21	0

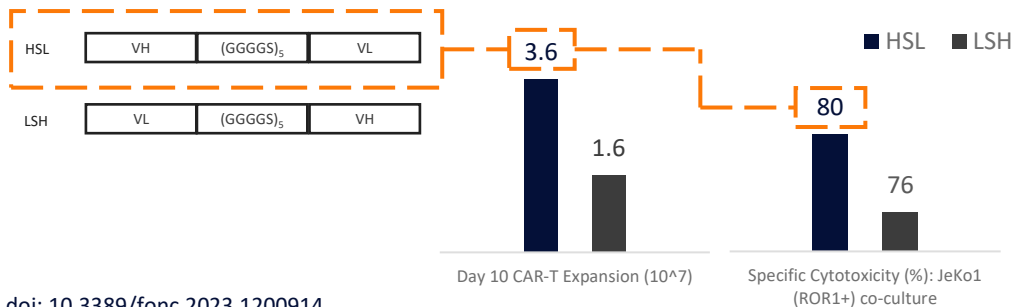
Sterically-optimized (Decreased) CD8 Hinge Flexibility Results in Zero Neurotoxicity, Improved Human Efficacy, and reduction in CRS duration

MM: multiple myeloma  
 Source: E Lebel et al. Efficacy of HBI0101, an Anti-BCMA Chimeric Antigen Receptor T-Cell (CART) for Relapsed/Refractory Multiple Myeloma. Abstract. ASH 2024. S Kfir-Erenfeld et al. Clinical evaluation and determinants of response to HBI0101 (BCMA CART) therapy in relapsed/refractory multiple myeloma. Blood Adv. 2024 Aug 13;8(15):4077-4088. doi: 10.1182/bloodadvances.2024012967. Ying Z, et al. Nat Med. 2019; Schuster SJ, et al. N Engl J Med. 2019; Assayag, M., et al EBMT 2023; Abecma FDA label; Harush O, et al. Haematologica. 2022; Friedman KM, et al. Hum Gene Ther. 2018. Kymriah: Preclinical is an average of CD8+ and CD4+ T-cells, source: Milone MC, et. Al. Mol Ther. 2009 Aug;17(8):1453-64. doi: 10.1038/mt.2009.83. Epub 2009 Apr 21. Erratum in: Mol Ther. 2015 Jul;23(7):1278. PMID: 19384291; PMCID: PMC2805264. \*1 Day CRS occurred in high dose MM cohort as of EBMT 2023. NXC-201 in multiple myeloma data from ASH 2023 95% ORR in patients without prior anti-BCMA therapy exposure

### 3 Sterically-Optimized COBRA Binder Ensures High Expression And Binding Affinity

#### COBRA Binder

COBRA Binder Leads with Heavy Chain



doi: 10.3389/fonc.2023.1200914

#### Biomarker Research

“Glycine (Gly) and serine (Ser) residues provide the flexibility necessary for antigen-binding sites to change conformation and maintain good stability in aqueous solutions... prevent[ing] formation of secondary structures and reduc[ing] likelihood of the linker interfering with the folding and function of the scFv”

September 19, 2022

doi: 10.1186/s40364-022-00417-w

NXC-201  
COBRA Binder: Heavy Chain – Proven Linker – Light Chain Configuration, enabling:

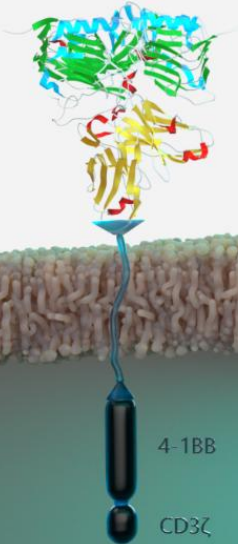
- ✓ Rapid, Sustained CAR-T Expansion
- ✓ Improved Cytotoxicity in the presence of antigen

# Proprietary EXPAND Technology and COBRA Binding Domain Are Differentiated Innovations

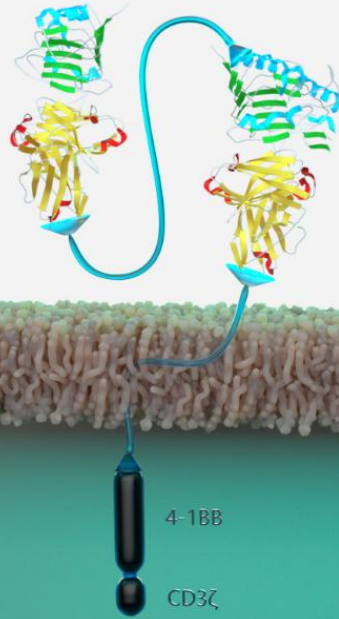
N-GENIUS TECHNOLOGY PLATFORM: STERICALLY-OPTIMIZED BCMA CAR-T NXC-201



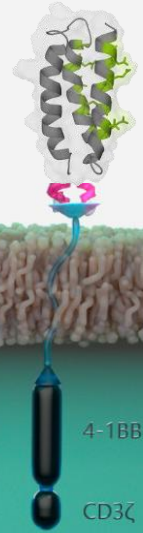
Abecma



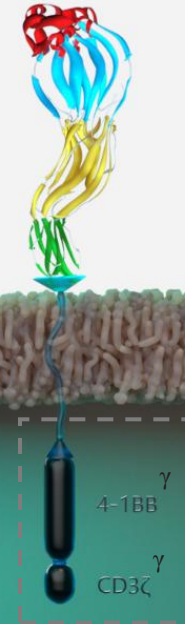
Carvykti



CART-ddBCMA



NXC-201 with  
COBRA Binding Domain



N-GENIUS  
EXPAND Technology

Note: Graphic representation. COBRA = Codon Optimized Binder for Receptor Antigens – Proprietary Binding Domain

# N-GENIUS Sterically-Optimized CARTs Drive Immix's Immune-Mediated Disease Leadership



## N-GENIUS Platform

Through partnership Hadassah Medical Organization, Jerusalem and Bar-Ilan University, Immix is a pioneer in sterically-optimized CAR-T construct development, driving our next-generation industry-leading CAR-Ts in select immune-mediated diseases.

N-GENIUS developed sterically-optimized CAR-Ts allow for a differentiated safety and efficacy profile through modification of key regions of the CAR-T construct, driving a “digital” intracellular signal and overcoming limitations of current clinical stage and commercial CAR-Ts.

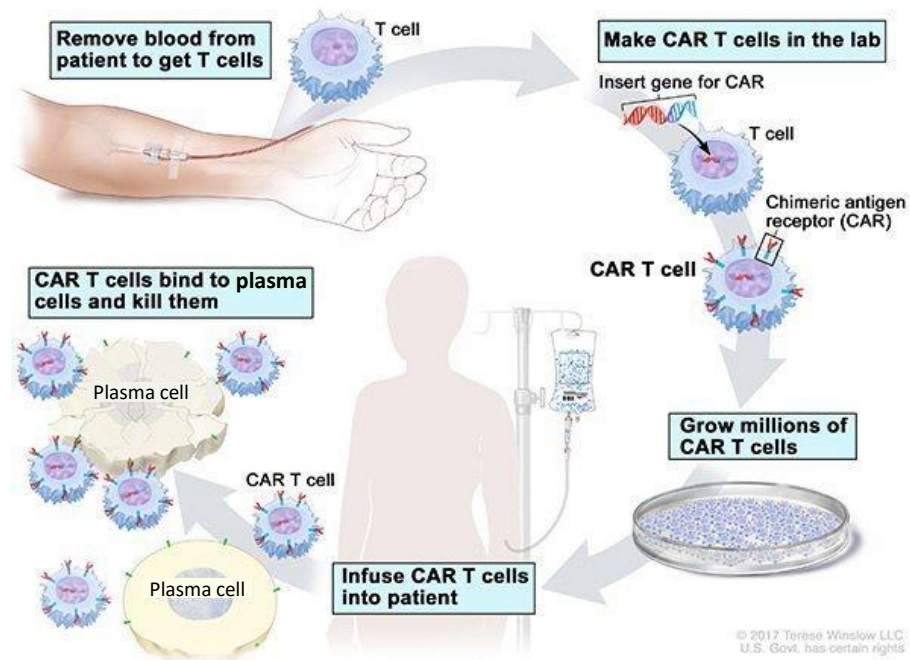
Portfolio of US patents, pending applications, and exclusive patent licenses, which cover our core technology platforms and product



# What is autologous chimeric antigen receptor (CAR)-T cell therapy?

NXC-201 IS A NEXT-GENERATION BCMA TARGETED AUTOLOGOUS CAR-T CELL THERAPY

## CAR T-cell Therapy



## Patient Specific

Personalized treatment using patient's own T cells

## Genetic Modification

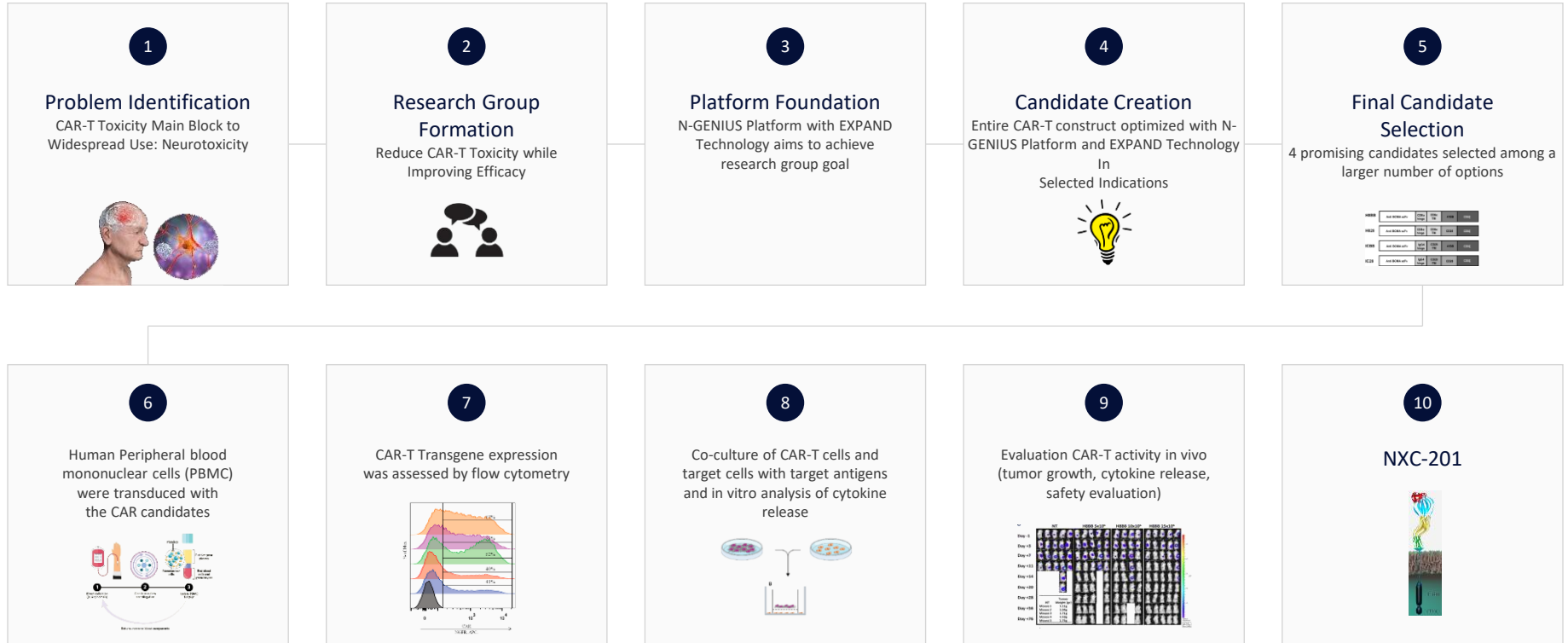
Genetically engineered CARs (chimeric antigen receptors) on T cell surface

## Targeted Therapy

Target cells that express antigens recognized by CARs



# N-GENIUS Platform Process



## Appendix 2: AL Amyloidosis Clinical



# Advantages of CAR-T NXC-201 in Relapsed/Refractory AL Amyloidosis

		NXC-201	Antibody-drug conjugates	Bispecifics
1	One-time treatment	✓	✗	✗
2	High Complete Response Rates	✓	✗	✗
3	Low rates of severe infection	✓	✓	✗
4	No ICANS/Neurotoxicity	✓	✓	✗

NXC-201 uniquely suited for Relapsed/Refractory AL Amyloidosis



Note: High complete response rates defined as >50%, Low rates of severe infection refers to <30%

Source: Feasibility of a Novel Academic Anti-BCMA Chimeric Antigen Receptor T-Cell (CAR-T) (HB0101) for the Treatment of Relapsed and Refractory AL Amyloidosis, 65th ASH Annual Meeting and Exposition, San Diego, CA, October 2023. R. Chakraborty, et al. Safety and efficacy of teclistamab in systemic immunoglobulin light chain amyloidosis. Blood Cancer Journal. October 2023. N. Forgeard, et al. Teclistamab in relapsed or refractory AL amyloidosis, a multinational retrospective case series. Blood. February 2024. Chakraborty R, Bhutani D, Maurer MS, Mohan M, Lentzsch S, D'Souza A. Safety and efficacy of teclistamab in systemic immunoglobulin light chain amyloidosis. Blood Cancer J. 2023 Nov 27;13(1):172. doi: 10.1038/s41408-023-00950-3. PMID: 38012151; PMCID: PMC10682473. One NXC-201 relapsed/refractory AL amyloidosis patient died of COVID-19. Kastritis, et al. Efficacy And Safety Of Belantamab Mafodotin Monotherapy In Patients With Relapsed Or Refractory Light-chain Amyloidosis: A Phase 2 Study By The European Myeloma Network. Abstract. EHA 2024.

# In AL Amyloidosis, NXC-201 Overcomes Limitations of Other Modalities in Performance and Tolerability

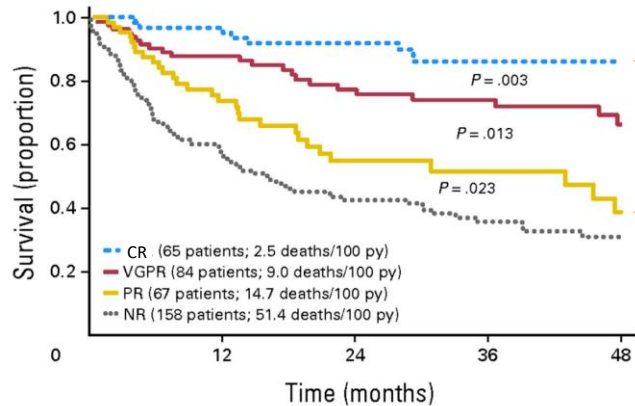
Challenges of bispecifics/ T-cell engagers	NXC-201 overcomes these challenges
<ul style="list-style-type: none"><li>• No clinical trials with clinical data available in relapsed/refractory AL amyloidosis</li><li>• Early data from select centers indicates bispecific responses and tolerability are inferior to CAR-T (NXC-201) in relapsed/refractory AL amyloidosis</li><li>• Retrospective study with 17 R/R multiple myeloma + AL Amyloidosis patients:<ul style="list-style-type: none"><li>✗ 41% CR</li><li>✗ 35% severe infections including death</li><li>✗ Grade 3 ICANS neurotoxicity reported</li></ul></li><li>• Repeat/ongoing dosing with need for healthcare provider to administer</li></ul>	<ul style="list-style-type: none"><li>✓ <b>75% CR in relapsed/refractory AL amyloidosis</b></li><li>✓ <b>0 deaths from infection in relapsed/refractory AL amyloidosis</b></li><li>✓ <b>0% neurotoxicity (0/16) in relapsed/refractory AL amyloidosis patients</b></li><li>• <b>One-time dosing with durable responses</b></li><li>• <b>Ongoing NEXCART-1 relapsed/refractory AL amyloidosis clinical trial with clinical data presented at ASH 2024</b></li></ul>

Advantages of NXC-201 CAR-T in AL Amyloidosis

# 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

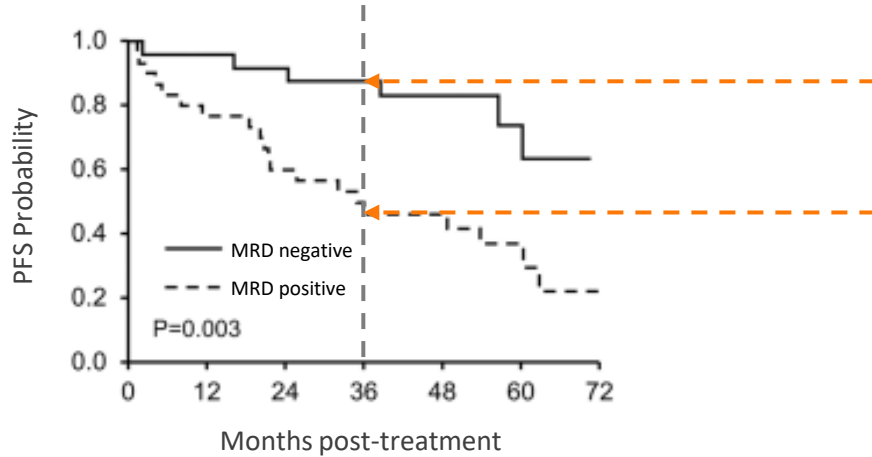


### 2x survival at 48 months for CR vs PR

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

# MRD- is Correlated with Improved PFS in AL Amyloidosis

**MRD negativity is associated with improved Progression Free Survival in AL**



**2x PFS at 36 months for MRD- vs MRD+**  
(patients with CR or VGPR)

- MRD negative patients have 88% 36-month PFS
- MRD positive patients have 46% 36-month PFS

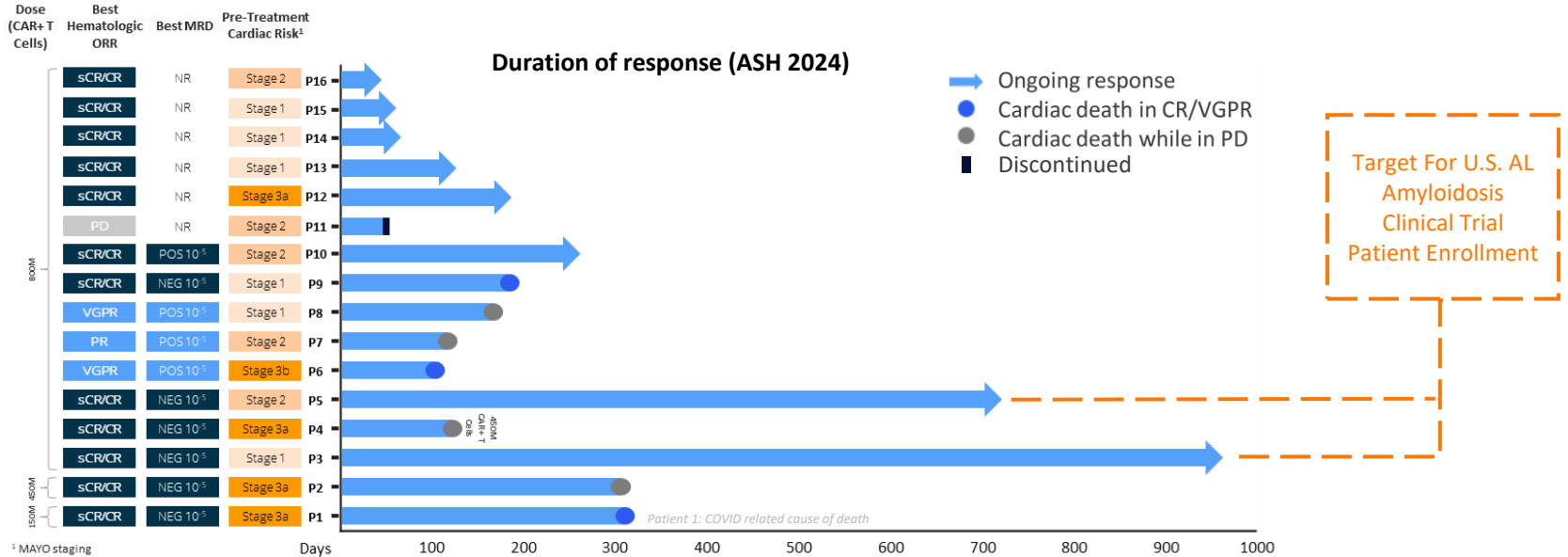
Note: Adapted from Muchtar E, Dispenzieri A, Jevremovic D, Dingli D, Buadi FK, Lacy MQ, Gonsalves W, Warsame R, Kourelis TV, Hayman SR, Kapoor P, Leung N, Russell S, Lust JA, Lin Y, Go RS, Zeldenrust S, Kyle RA, Rajkumar SV, Kumar SK, Gertz MA. Survival impact of achieving minimal residual negativity by multi-parametric flow cytometry in AL amyloidosis. *Amyloid*. 2020 Mar;27(1):13-16. doi: 10.1080/13506129.2019.1666709. Epub 2019 Sep 23. PMID: 31544536; PMCID: PMC7372715.

# NEXICART-1: Durable Responses in NXC-201 AL Amyloidosis Clinical Trial

SWIMMER PLOT ORDER MATCHED TO ASH 2024 PRESENTATION



- Complete hematologic response (CR) of 75% (12/16), a precedent approval endpoint based on the only commercial treatment for AL amyloidosis
- Ongoing NEXICART-2 US trial targeting patients reflective of durable responders



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. Patient 9 death due to depression. Patient 11 prior lines of therapy include 1) BCMA targeted ADC, 2) BCMA targeted bispecific antibody.

# Principal Investigator for NEXICART-2: Heather Landau, MD



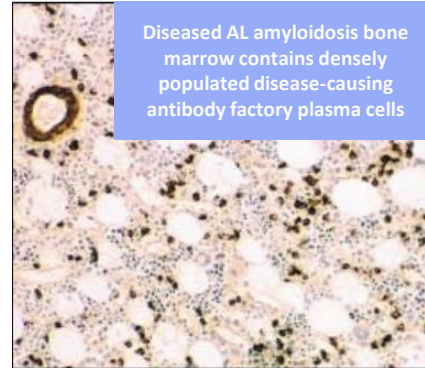
- **Director of the Amyloidosis Program and a Bone Marrow Transplant Specialist & Cellular Therapist at Memorial Sloan-Kettering Cancer Center in New York.**
- Authored more than 100 peer-reviewed publications.
- Dr. Landau received her medical degree from SUNY Upstate Medical University, completed her Internal Medicine residency at University of Colorado and her Hematology & Oncology fellowship at Memorial Sloan Kettering Cancer Center.



AL Amyloidosis pathologic light chains emerge from deep in the bone marrow where they are produced by pathologic antibody factory plasma cells

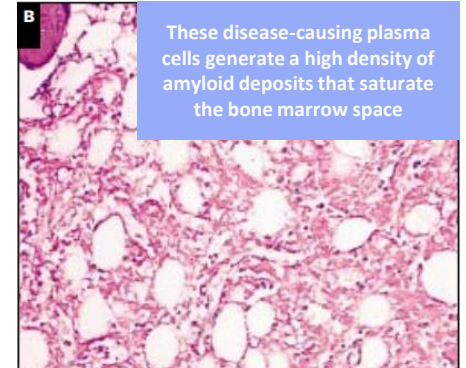
Traditional antibody-based therapies primarily address passively accessible target cells

NXC-201 is the only AL amyloidosis therapy in clinical development that actively penetrates deep into the bone marrow



Diseased AL amyloidosis bone marrow contains densely populated disease-causing antibody factory plasma cells

*Immunoperoxidase with hematoxylin counterstain, x100*



These disease-causing plasma cells generate a high density of amyloid deposits that saturate the bone marrow space

*Periodic acid-Schiff, x100*

**Antibody-based therapeutics have difficulty penetrating deep into organs where disease causing plasma cells reside**

## Inserm

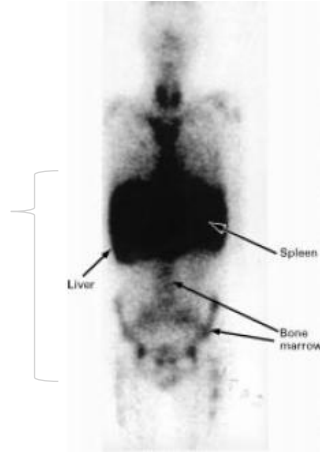
“Plasma cells (PC) were detected in the [organs] of patients ... up to 6 months after rituximab treatment, and the PC population displayed a long-lived program”

doi:10.1172/JCI65689

# Amyloid deposits in AL Amyloidosis are cleared naturally after treatment

## BEFORE TREATMENT

Pre-treatment imaging shows dense amyloid deposits in liver, bone marrow, and other organs in AL patient

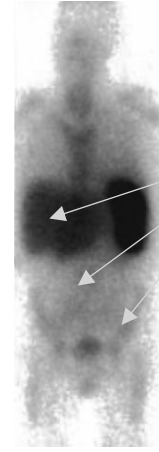


Cytotoxic treatments  
(vincristine,  
adriamycin, and  
dexamethasone)



## 6-MONTHS AFTER TREATMENT

Post-treatment imaging shows clearance of amyloid in organs throughout the body



# NXC-201 Best-in-Disease AL Amyloidosis Clinical Results

## Relapsed/Refractory Light chain (AL) Amyloidosis

	NXC-201 Monotherapy	Darzalex Combination (with cyclophosphamide, bortezomib, and/or dexamethasone)	CAEL-101	<b>Birtamimab Combined with SOC CyBORd</b>
Dosing frequency	1X	Weekly	Weekly	Weekly
Patient #: n=	16	9	10 (renal), 24 (cardiac)	14 (cardiac), 15 (renal)
Hematologic Overall Response Rate	94%	22%	-	-
Hematologic Complete Response Rate	75%	0%	-	-
Hematologic CR + VGPR	88%	22%	-	-
Cardiac response – (NT-proBNP median reduction)	78%		39%	35%
Renal response (%)	33%		20%	60%
Median prior lines of therapy	4	1	2	2
% pretreated with CD38-targeted treatment (Darzalex/other)	100%	100%	?	0%

Birtamimab Source from JCO (Birtamimab development paused + restarted). CAEL-101 source: Edwards CV, et al. Phase 1a/b study of monoclonal antibody CAEL-101 (11-1F4) in patients with AL amyloidosis. Blood. 2021 Dec 23;138(25):2632-2641. doi: 10.1182/blood.2020009039. PMID: 34521113; PMCID: PMC8703360. Darzalex source from Blood. Point-of-care CART manufacture and delivery: Poster. Poster Presentation, ESBMT 2023. Poster ASGCT 2023. Figures reflect cross-trial comparison and not results from a head-to-head study. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across studies. Poster: IMS 2023. Poster: ASH 2023. Darzalex and Investigator's Choice : Theodorakakou, et al, Blood 2022. Astra Zeneca: Blood 2021 12 NXC-201 patients at ASGCT 2024 with no prior exposure to BCMA targeted bispecifics

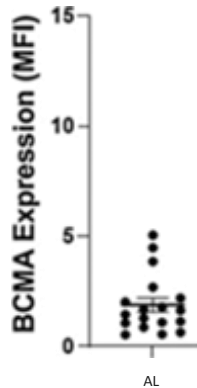
# NXC-201 Designed for High Activity Against Disease-causing AL Amyloidosis Plasma Cells

ALL BCMA CAR-TS ARE NOT CREATED EQUAL

a) Uneven BCMA expression and b) frail patient condition has historically prevented conventional, approved CAR-T use in AL Amyloidosis  
NXC-201 was designed and tested for human AL Amyloidosis treatment, with preclinical testing revealing that:

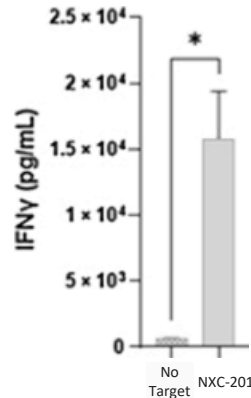
1

BCMA is expressed in 18 AL Amyloidosis patients at a low-medium level...

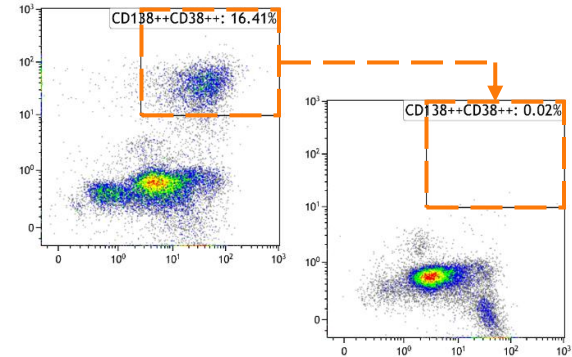


2

...NXC-201 CAR-Ts are activated in presence of the AL Amyloidosis target cells...



...completely eliminating AL Amyloidosis aberrant plasma cells from patient bone marrow.



NXC-201's uniquely favorable tolerability profile (no neurotoxicity + "Single-day CRS") combined with proven preclinical and clinical efficacy make NXC-201 uniquely suited to treat AL Amyloidosis.

Note: NXC-201 (formerly NB10101). Infy TNFα for two patients, AL1, AL2. Far right top right quartile selected diseased AL Amyloidosis plasma cell elimination. Far right graph after 33 days co-incubated with NXC-201.  
Source: Kfir-Erenfeld S, et al. Feasibility of a Novel Academic BCMA-CART (HB10101) for the Treatment of Relapsed and Refractory AL Amyloidosis. Clin Cancer Res. 2022; Rajee N, et al. Anti-BCMA CAR-T-Cell Therapy bb2121 in Relapsed or Refractory Multiple Myeloma. N Engl J Med. 2019;

# NXC-201 May Be a Curative Treatment for AL Amyloidosis

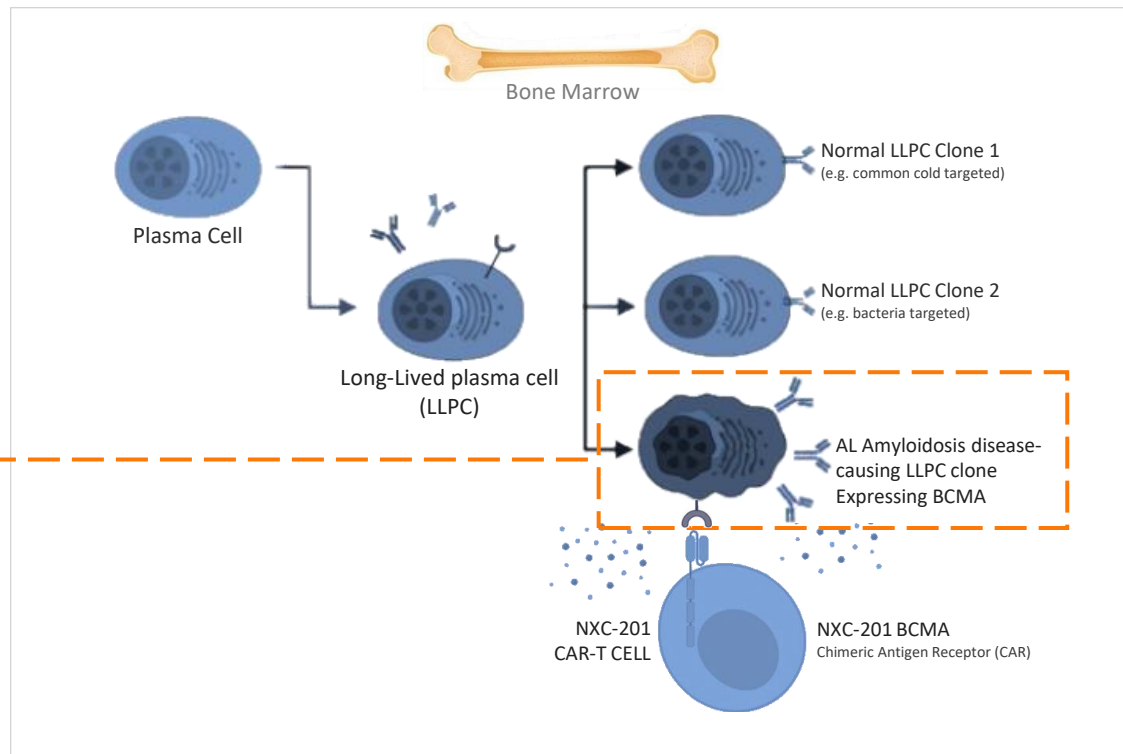
ALL BCMA CAR-TS ARE NOT CREATED EQUAL

AL amyloidosis is caused by dysfunctional plasma cells that can live for years, continuously producing toxic, misfolded amyloid light chain antibody fragments

## AL Amyloidosis disease-causing plasma cells:

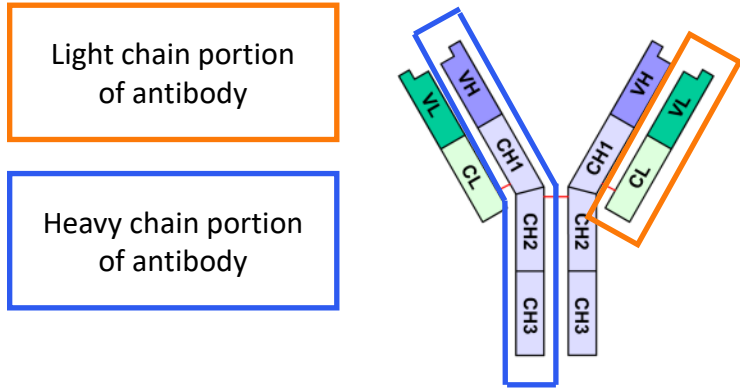
- Are a minority of total plasma cells
- Are 1 of thousands of antibody-specific plasma cells, each of which produces 1 antibody, specific to 1 target (e.g. common flu, cold, a type of bacteria...)
- **Are eliminated by NXC-201 treatment**

Then healthy plasma cells regenerate in the months after NXC-201 treatment, potentially preventing disease relapse

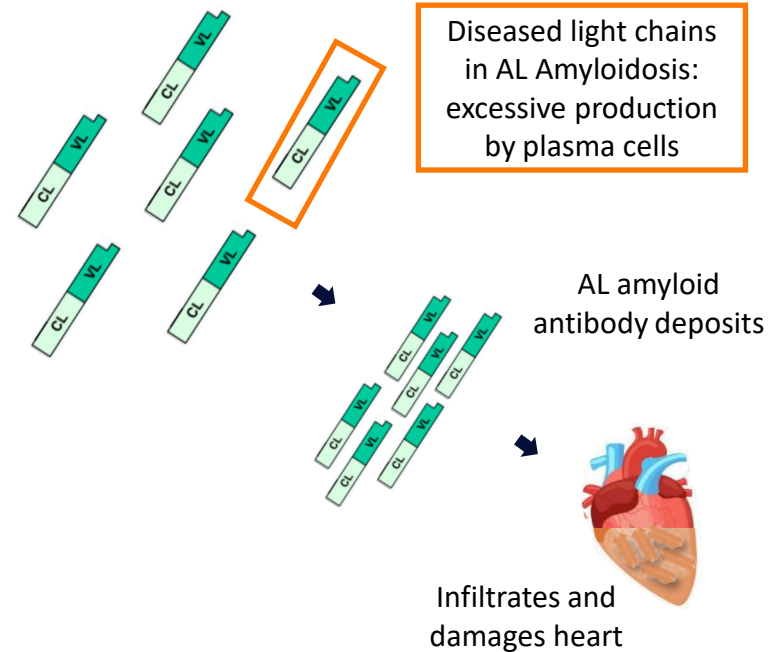


# Pathologic Light Chains in AL Amyloidosis are an Antibody Building Block That Are Overproduced by Plasma Cells

## A LIGHT CHAIN IS A PORTION OF AN ANTIBODY



## IN AL, PLASMA CELLS PRODUCE TOO MANY LIGHT CHAINS



Normal antibody produced by plasma cell

# 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

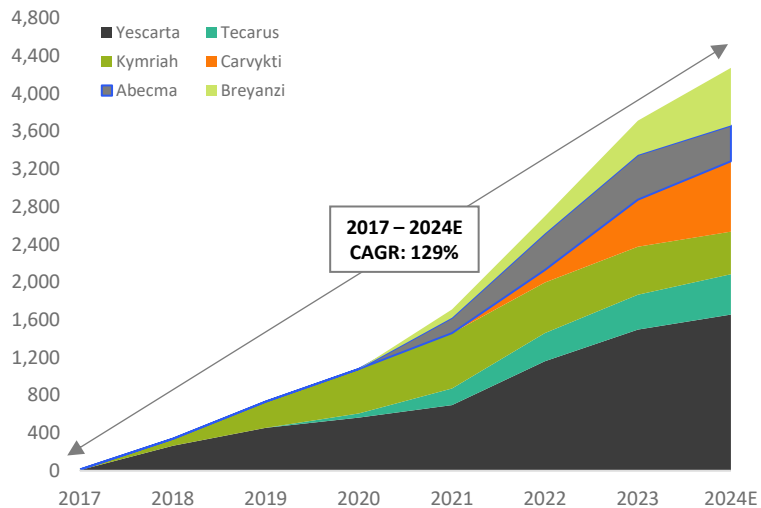
## Appendix 3: Market



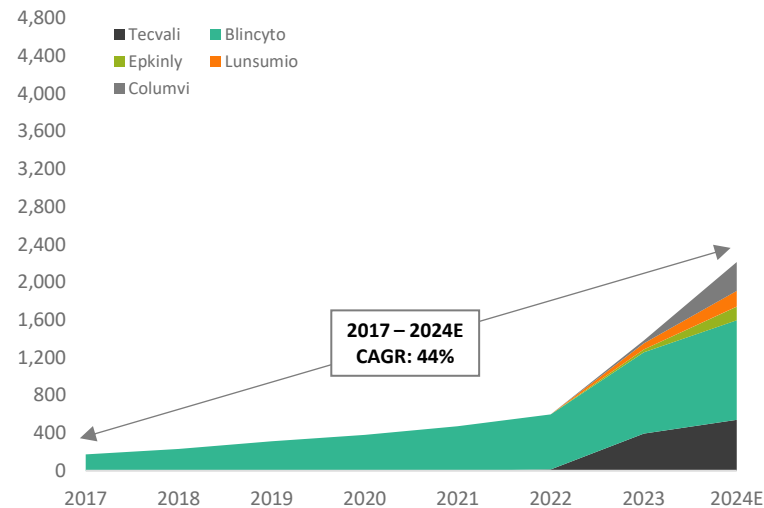


# Robust Global Sales of CAR-T Continue

### Sales of Approved CAR-T (\$M)



### Sales of Approved Bispecifics (\$M)



Note: Full year 2024 sales estimated based on annualized quarterly 2024 actual sales  
Source: Company reports

# Clinical Stage Cell Therapy for AL Amyloidosis and Other Serious Diseases

April 2025

