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)

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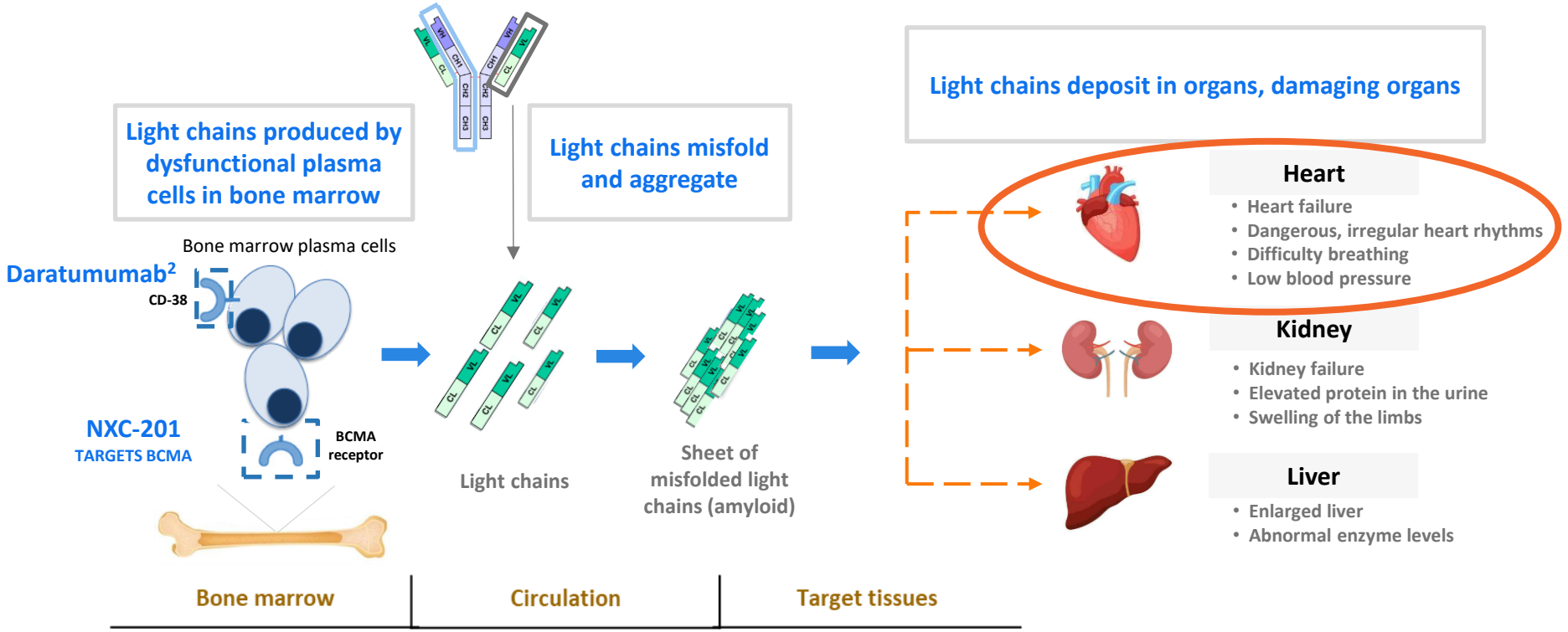
ASTCT CIBMTR

Disclosure

Heather Landau

Advisory role/honoraria: Pfizer, Nexcella, Abbvie, BMS, Alexion, Arcellx, Karyopharm, Janssen
Research funding: Janssen, Nexcella, Abbvie, Alexion, Prothena, Protego

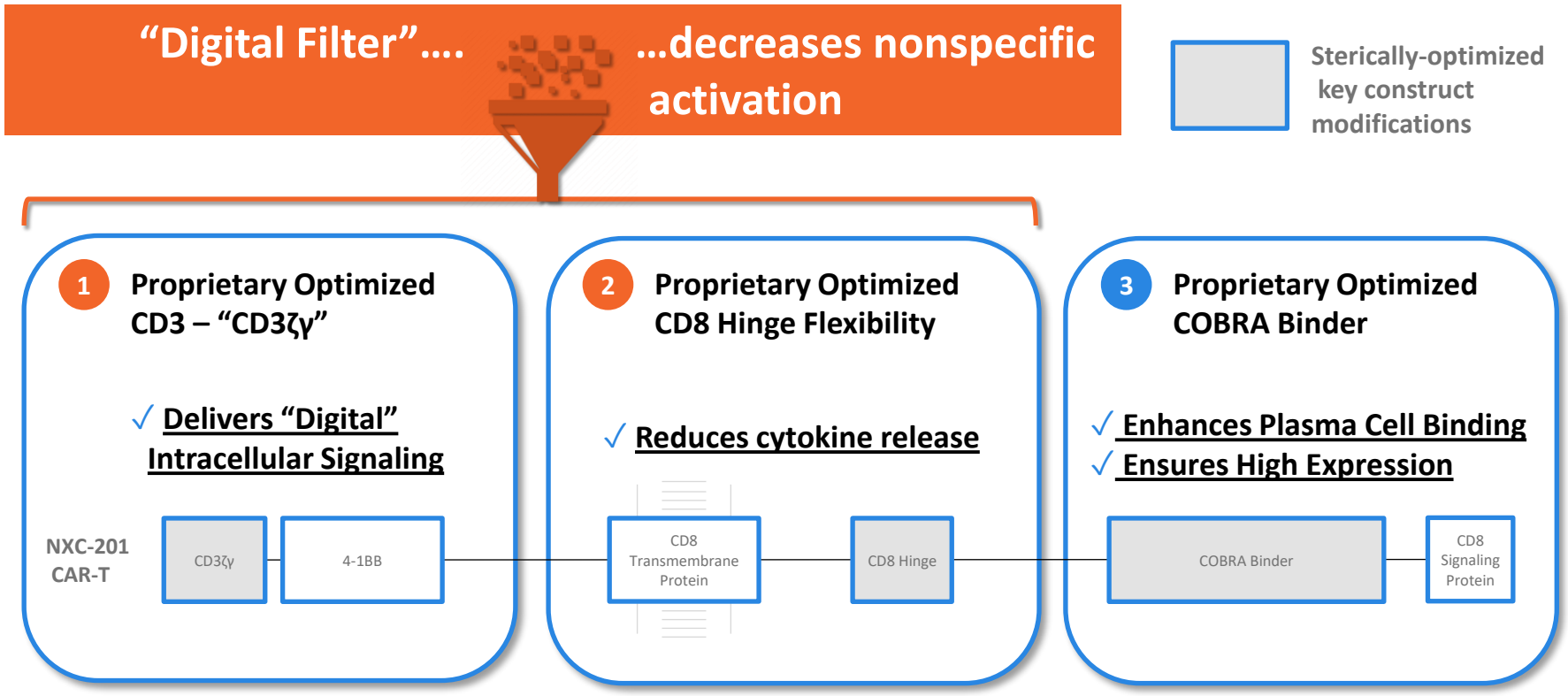
Relapsed/Refractory AL Amyloidosis: ~32,500 U.S. Patients with No FDA Approved Drugs[1]



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

NXC-201: Sterically-Optimized CAR-T construct

N-GENIUS PLATFORM



Manufacturing time: 10 days

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

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

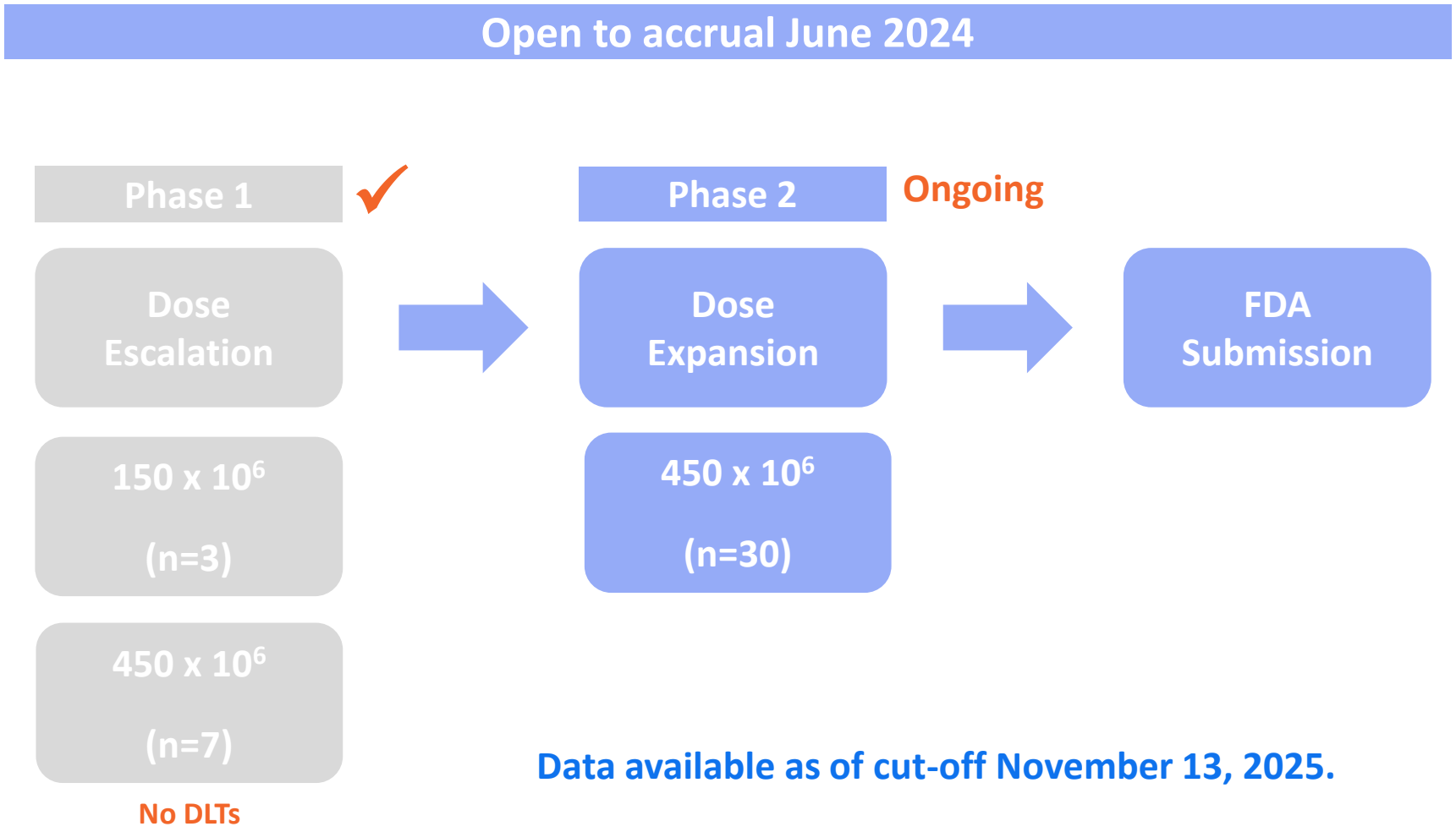
Inclusion	• Exposed to at least 1 line of therapy, including CD38 monoclonal antibody + proteosome inhibitor • Measurable hematologic disease, defined by one of the following: - dFLC* >50 mg/L (or 5 mg/dl) - M-spike > 0.5 mg/dl - dFLC* >20 mg/L (or 2 mg/dl) with abnormal k/l ratio[1]
Exclusion	• Prior 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]

NEXICART-2: Trial Design



NEXICART-2: Patient Characteristics (N=23)

	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	NX2-021	NX2-022	NX2-023	Median (range)
Age	56	67	82	64	62	72	77	66	63	80	65	65	59	49	73	59	71	71	82	64	66	60	74	66 (49-82)
Gender	Female	Female	Male	Female	Female	Male	Male	Male	Male	Male	Female	Female	Female	Female	Female	Male	Male	Female	Female	Female	Female	Male	Male	-
Prior lines of therapy	4*	6**	2	4	4*	3	4*	4*	4*	3*	1	10	4**	1	8*	5	2	9*	2	3*	3*	1	2	4 (1-10)
dFLC (mg/L)	65	24	-	86	42	26	47	121	84	-	-	70	274	26	54	24	194	73	45	22	57	65	310	61 (22-310)
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	Heart	Nerve	Heart / Soft Tissue	-
NYHA stage	I	II	I	I	I	I	I	II	I	II	II	II	I	II	I	I	II	I	I	I	I	I	II	-
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	145	61	1,297	323 (61-2,017)
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	6	3	40††	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	II	I	II	-
At Enrollment	I	II	IIIa	IIIa	II	IIIa	-	II	I	II	II	I	II	I	II	I	IIIa	II	I	I	II	I	II	-
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	0.5	0.9	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	490	6	385	144 (0-10,274)

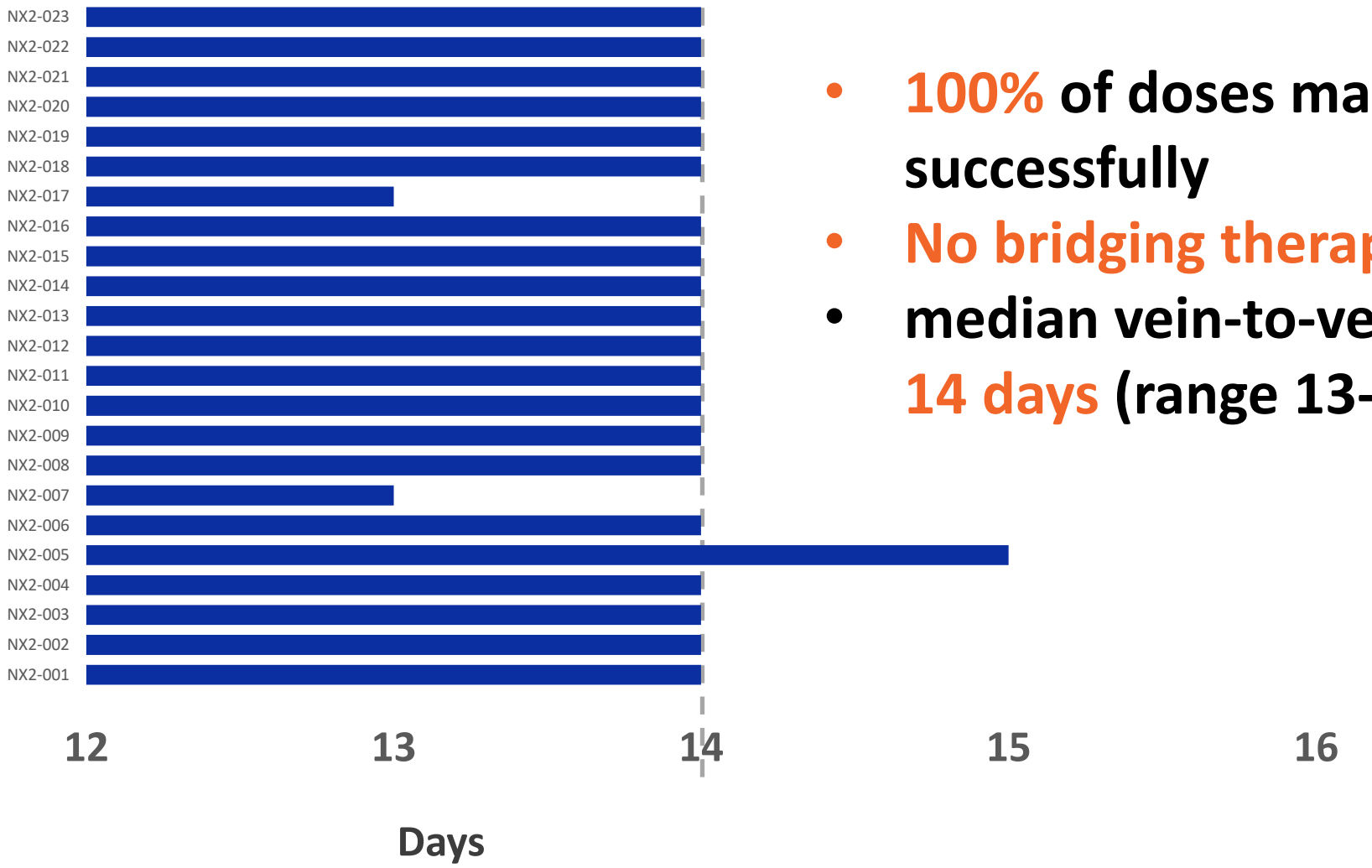
* Prior autologius stem cell transplant

† Denotes Troponin-T

† † Denotes hs-Troponin-T

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

Time from apheresis to NXC-201 infusion



- **100%** of doses manufactured successfully
- **No bridging therapy required**
- median vein-to-vein time = **14 days** (range 13-15)

NEXICART-2: Safety

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	NX2-021	NX2-022	NX2-023	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	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**	Grade 1	Grade 1	Grade 2	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	1	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	2	1 (1-5)
	Neurotoxicity	**None**	**None**	**None**	**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	Grade 3	Grade 3	Grade 4	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	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	Grade 3	Grade 1	Grade 2	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	Grade 2	Grade 1	Grade 1	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	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	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	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	None	Grade 1	Grade 2	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	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**

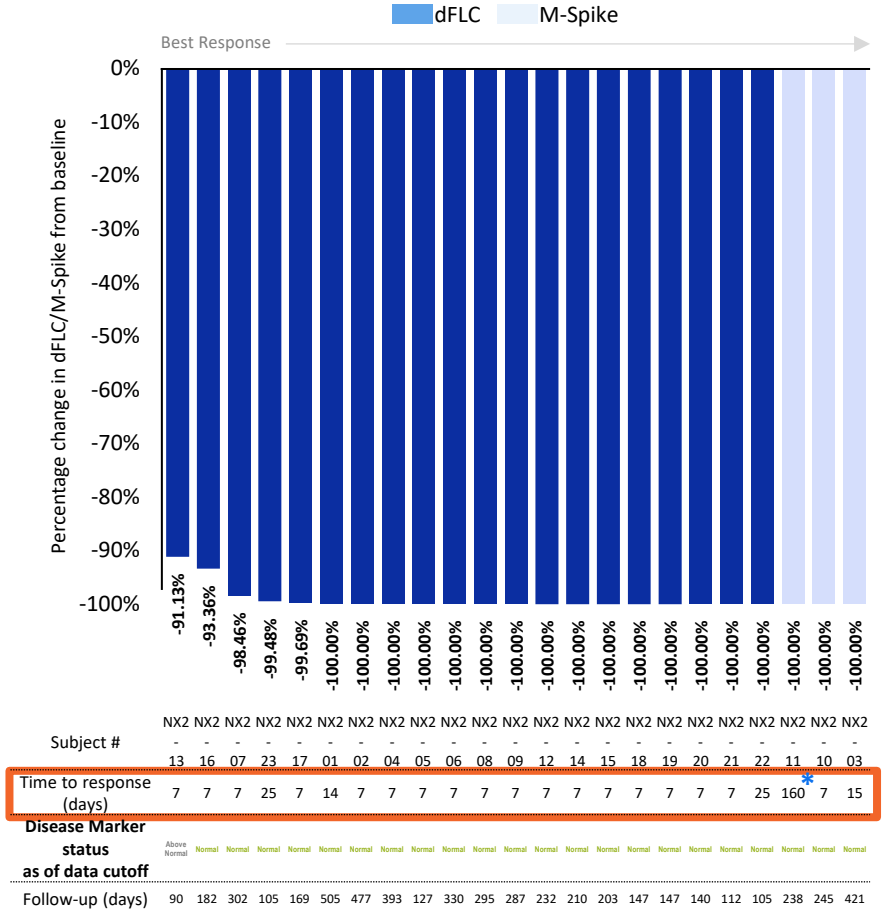
¥ Two patients with pre-existing atrial fibrillation experienced transient arrythmias response to beta-blockers

Note: CRS and ICANS reported according to ASTCT Consensus Grading

Lee DW et al. BBMT 2019.

NEXICART-2 Efficacy

Rapid normalization of pathologic paraprotein



Cut-off November 13, 2025. Median follow up 210 days (7.0 months) (range (days) 90-505)

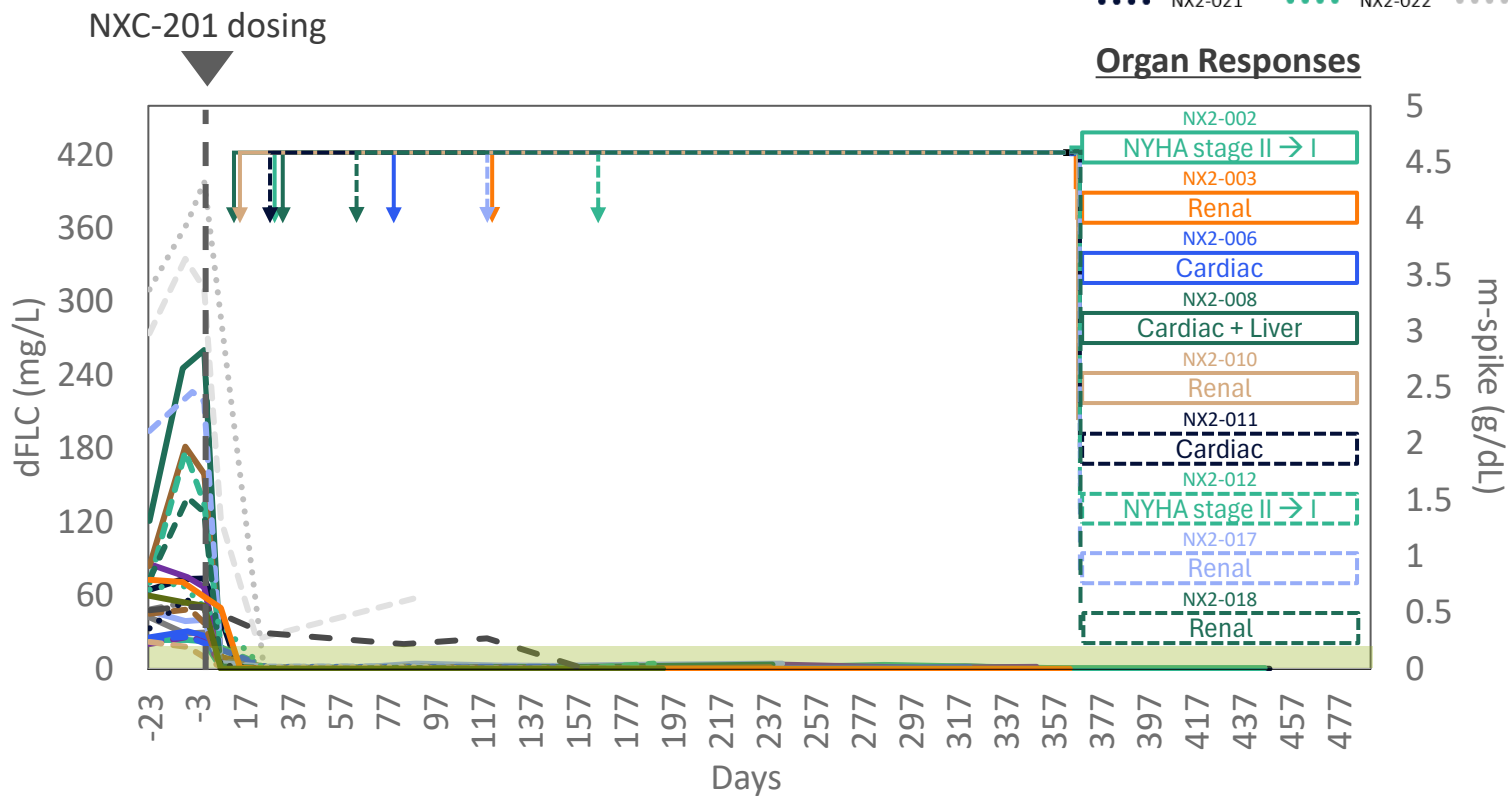
22/23 (96%) patients' disease marker normalized

Immunofixation may persist for longer

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

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

Rapid reduction in paraprotein results in organ responses



- 22/23 (96%) early and deep hematologic responses
- Organ responses in 67% (8/12) evaluable patients (60% ❤, 67% 🫘, 100% 🫀)
- Median time to response ❤ 33 and 🫘 88 days

Clinically meaningful

Palladini G et al. JCO 2012.
Palladini G et al. Blood 2014.

… 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! 🥰🌞💪"

Minimal residual disease (MRD) at day 25, 6 & 12 months by flow cytometry or Clonoseq (10^{-5} or 10^{-6})

91% (21/23) MRD negative at day 25

	D + 25	D + 25 Method / Sensitivity	D + 6M	D + 6M Method/ Sensitivity	D + 12M	D + 12M Method/ Sensitivity
NX2-023	Negative	ClonoSEQ 10^{-5}	NR	NR	NR	NR
NX2-022	Negative	Flow / 10^{-5}	NR	NR	NR	NR
NX2-021	Negative	Flow / 10^{-6}	NR	NR	NR	NR
NX2-020	Negative	Flow / 10^{-5}	NR	NR	NR	NR
NX2-019	Negative	ClonoSEQ / 10^{-5}	NR	NR	NR	NR
NX2-018	Negative	Flow / 10^{-6}	NR	NR	NR	NR
NX2-017	Negative	Flow / 10^{-5}	NR	NR	NR	NR
NX2-016	Negative	Flow / 10^{-5}	NR	NR	NR	NR
NX2-015	Negative	Flow / 10^{-5}	NR	NR	NR	NR
NX2-014	Negative	Flow / 10^{-5}	Negative	Flow / 10^{-5}	NR	NR
NX2-013	Positive	ClonoSEQ / 10^{-4}	Positive	ClonoSEQ / 10^{-4}	NR	NR
NX2-012	Negative	ClonoSEQ / 10^{-6}	Negative	ClonoSEQ / 10^{-6}	NR	NR
NX2-011	Negative	ClonoSEQ / 10^{-6}	Negative	Flow / 10^{-6}	NR	NR
NX2-010	Negative	ClonoSEQ / 10^{-6}	Negative	ClonoSEQ / 10^{-6}	NR	NR
NX2-009	Negative	Flow / 10^{-5}	Negative	Flow / 10^{-5}	NR	NR
NX2-008	Negative	ClonoSEQ / 10^{-5}	Negative	ClonoSEQ / 10^{-6}	NR	NR
NX2-007	Negative	Flow / 10^{-6}	Negative	Flow / 10^{-5}	NR	NR
NX2-006	Negative	Flow / 10^{-6}	Negative	ClonoSEQ / 10^{-6}	Negative ¥	ClonoSEQ / 10^{-6}
NX2-005	Negative	Flow / 10^{-5}	NR	NR	NR	NR
NX2-004	Negative	Flow / 10^{-6}	Negative	Flow / 10^{-5}	Negative	ClonoSEQ / 10^{-6}
NX2-003	Positive	Flow / 10^{-6}	Positive	Flow / 10^{-6}	Positive	ClonoSEQ / 10^{-5}
NX2-002	Negative	ClonoSEQ / 10^{-6}	Negative	Flow / 10^{-6}	Negative	Flow / 10^{-5}
NX2-001	Negative	Flow / 10^{-6}	Negative	Flow / 10^{-6}	Negative	ClonoSEQ / 10^{-6}

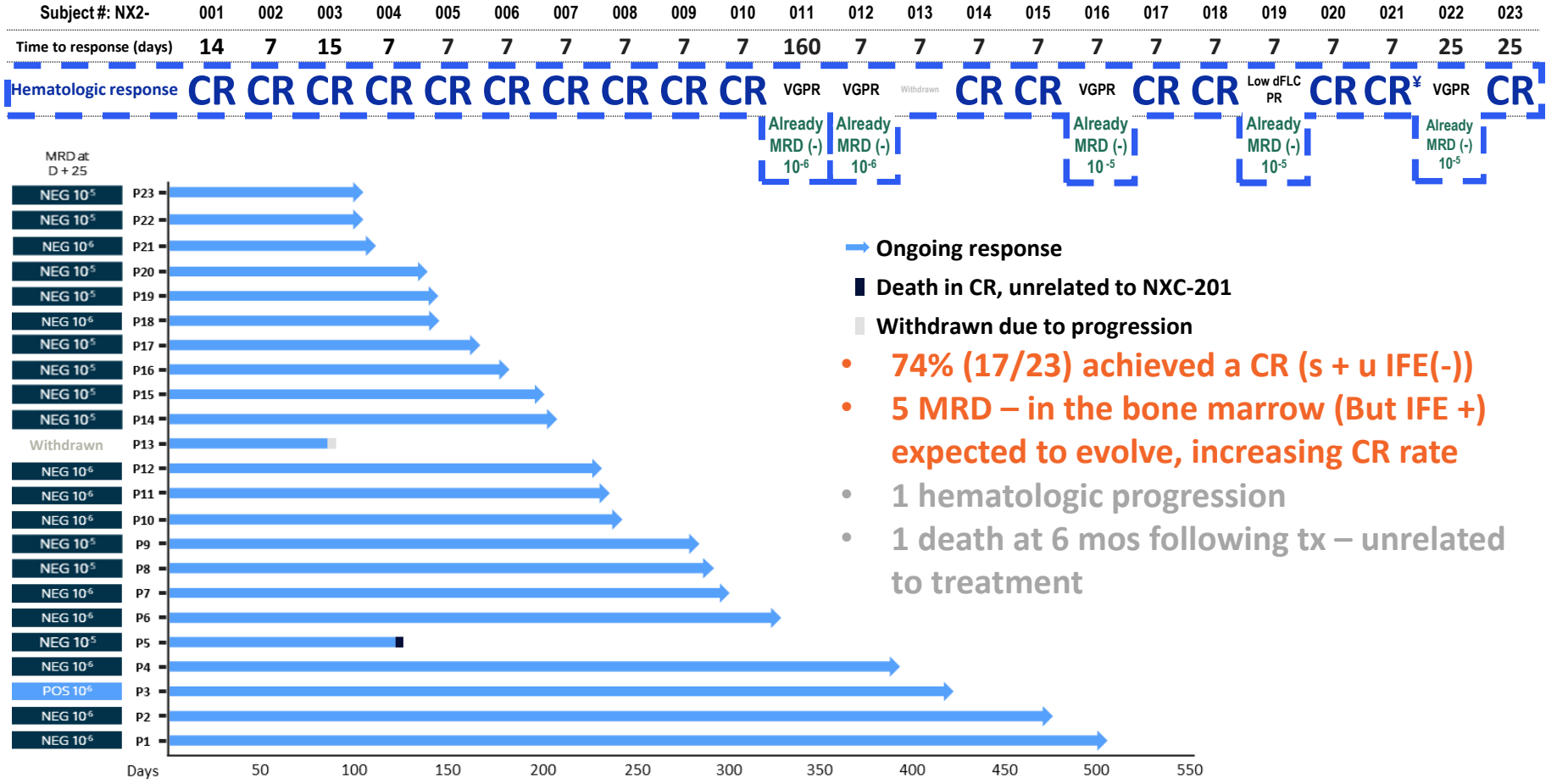
Roshal M et al. Blood Advances 2017.
Sarosiek S et al. Blood Cancer J 2021.

NR: not reported
¥: MRD date 12/15/2025

NEXICART-2: Results

74% complete hematologic response rate (independent review committee)

n=23. Cut-off November 13, 2025. Median follow up 210 days (7.0 months) (range (days) 90-505)



- 74% (17/23) achieved a CR (s + u IFE(-))
- 5 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

Palladini G et al. JCO 2012.
Milani P et al. Blood 2017.
Roshal M et al. Blood Advances 2017.
Sarosiek S et al. Blood Cancer J 2021.

*NR: not reported

¥: CR criteria met on 11/17/2025

Conclusion

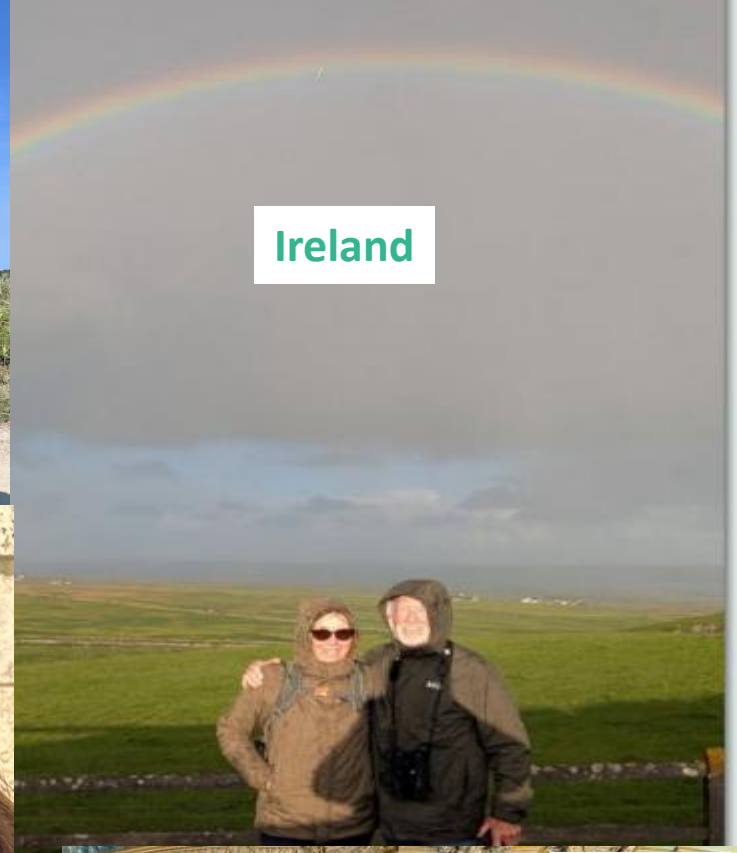
- NXC-201 a novel BCMA-directed CAR-T cell can be administered safely & efficiently to patients with R/R AL amyloidosis – population without a single FDA-approved treatment available – who have a true unmet medical need
  - 100% manufactured and treated; median vein-to-vein time 14 days
  - Low grade CRS and no neurotoxicity of any kind
  - Rapid and deep hematologic responses, median time to response 7 days
  - 21/23 (91%) evaluable patients MRD negative (10^{-6} or 10^{-5})
  - 74% hematologic CR rate (s + u IFE(-)), potential to evolve (up to 96%)
  - Organ responses in 67% (8/12) evaluable patients (60% ❤ 67% 🫘 100% 🫁)

91% remain on study, in hematologic remission, including 5 > 12 months, and 2 > 15 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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