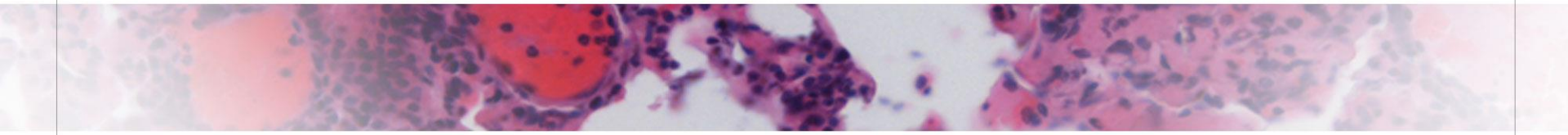
American Society *of* Hematology
Helping hematologists conquer blood diseases worldwide



Abstract: 1023

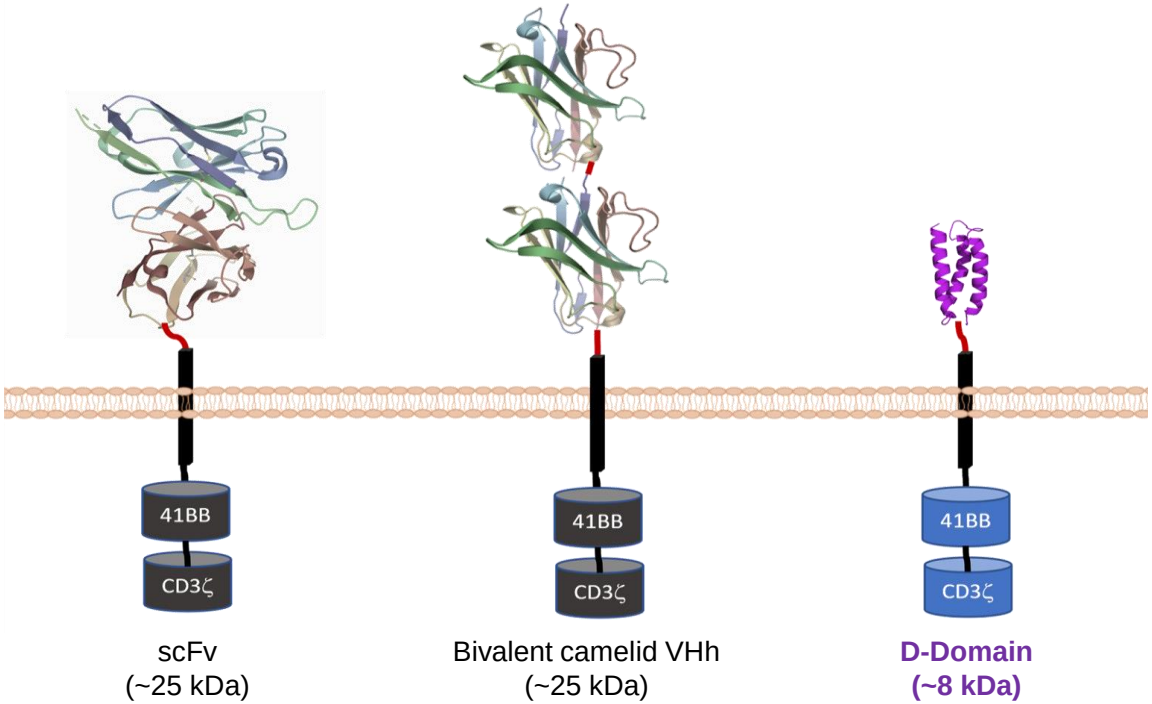
Phase 1 Study Of CART-ddBCMA For The Treatment Of Patients With Relapsed And/Or Refractory Multiple Myeloma: Results From At Least 1-year Follow-up In All Patients

Matthew Frigault, MD, MS[1], *Jacalyn Rosenblatt, MD*[2], *Binod Dhakal, MBBS*[3], *Noopur Raje, MD*[4], *Daniella Cook, BS*[5*], *Mahmoud R. Gaballa, MD*[6], *Estelle Emmanuel-Alejandro*[7*], *Danielle Nissen*[8*], *Kamalika Banerjee*[9*], *Anand Rotte, PhD*[9*], *Christopher R. Heery, MD*[9], *David Avigan, MD*[10], *Andrzej Jakubowiak, MD, PhD*[11] *and Michael R. Bishop, MD*[12]

Presented at ASH 2023

Anitocabtagene autoleucel (anito-cel/CART-ddBCMA)

Autologous BCMA-directed CAR T-cell therapy using a novel, D-Domain binder[1]



scFv
(~25 kDa)

Bivalent camelid VHh
(~25 kDa)

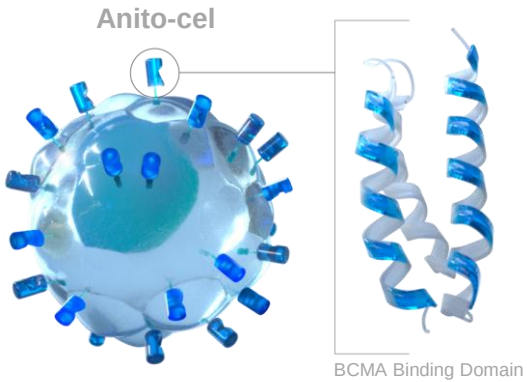
D-Domain
(~8 kDa)

D-Domain Attributes:
Non-Antibody Derived Synthetic Protein[1,2]

Size	**Small D-Domain construct facilitates high transduction efficiency, CAR positivity, and CAR density on the T-cell surface[2-4]**
Stability	**Rapid D-Domain folding, lack of disulfide bonds, and a hydrophobic core enables stability at and beyond physiologic conditions[5,6]**
Structure	**Due to small size and compact structure, D-Domain CARs have a low risk of tonic signaling[6] and potentially more efficient Multiple Myeloma cell killing**

[1]Rotte, et al. *Immuno-Oncology Insights* 2022; 3(1), 13–24; [2]Frigault, et al. *Blood Adv.* 2023; 7(5):768-777; [3]Cante-Barrett, et al. *BMC Res. Notes* 2016; 9:13; [4]Buonato, et al. *Mol. Cancer Ther.* 2022; 21(7):1171-1183; [5]Zhu, et al. *Proc. Nat. Acad. Sci.* 2003; 100(26): 15486-15491; [6]Qin, et al. *Mol. Ther.* 2019; 27(7): 1262-1274.

Anito-cel Phase 1 Results: Background and Methods



Phase 1 first-in-human trial is in patients with relapsed and/or refractory myeloma

- Prior IMiD, PI, and CD38-targeted therapy
- Received ≥3 prior lines of therapies or triple refractory

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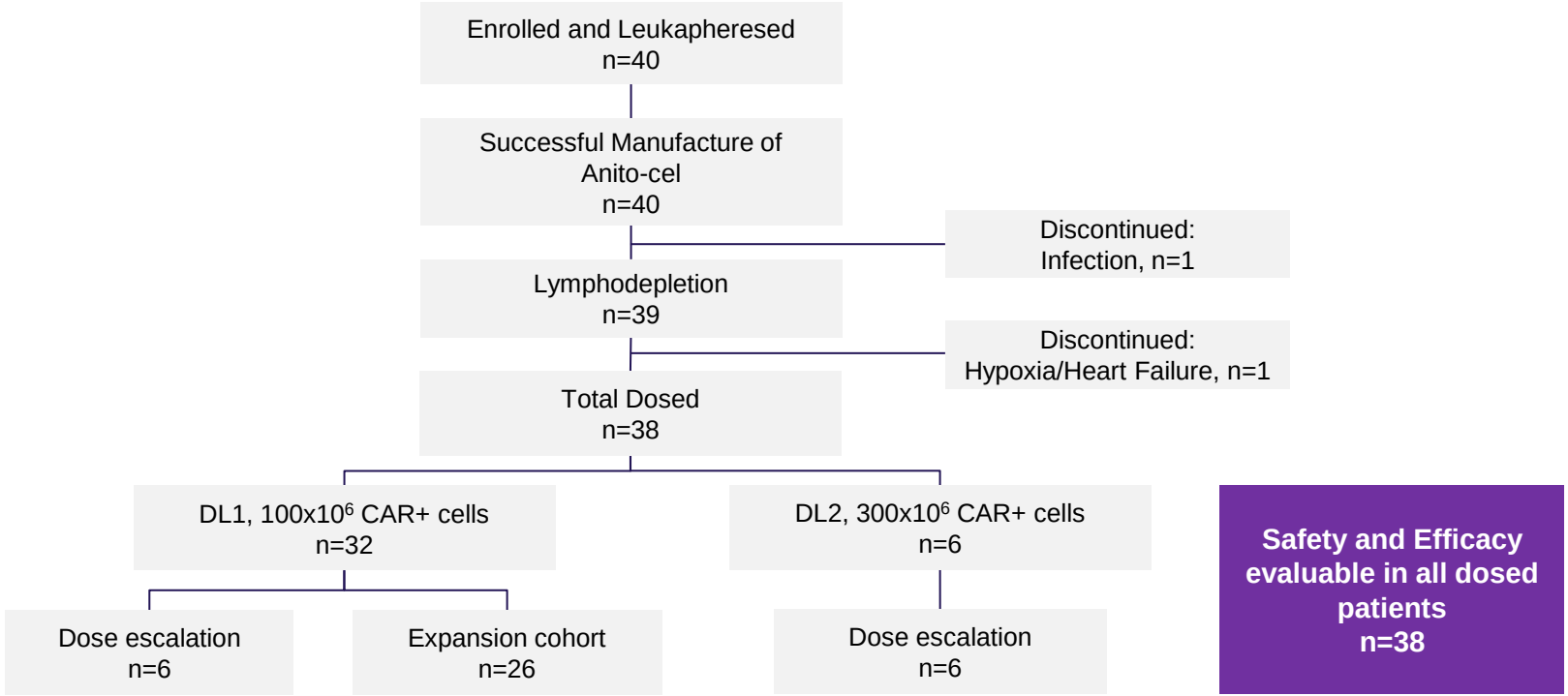
2 Dose Levels evaluated, 6 patients in each dose escalation cohort

- DL1 = 100 $\pm$ 20% x 10^6 CAR+ cells
- DL2 = 300 $\pm$ 20% x 10^6 CAR+ cells

Expansion cohort is enrolled at DL1

Phase 2 pivotal study (NCT05396885) is enrolling patients

Anito-cel Phase 1 Results: Patient Disposition



Median administered dose at DL1, 115 million cells (range, 112-120 million cells)

Anito-cel Phase 1 Results: Patient Demographics

Characteristics	Dose Level 1 100 million CAR-T (n=32)	Dose Level 2 300 million CAR-T (n=6)	Total (n=38)
Age, median (min - max)	66 (44 - 76)	60 (52 - 65)	66 (44 - 76)
Gender	18 Male (56%) 14 Female (44%)	5 Male (83%) 1 Female (17%)	23 Male (61%) 15 Female (39%)
ECOG PS[a]			
0	9/32 (28%)	3/6 (50%)	12/38(32%)
1	23/32 (72%)	3/6 (50%)	26/38 (68%)
High Risk Prognostic Feature[b]	18/32 (56%)	6/6 (100%)	24/38 (63%)
BMPC ≥60%	6/32 (19%)	3/6 (50%)	9/38 (24%)
ISS Stage III (B2M ≥ 5.5) [b]	5/32 (16%)	2/6 (33%)	7/38 (18%)
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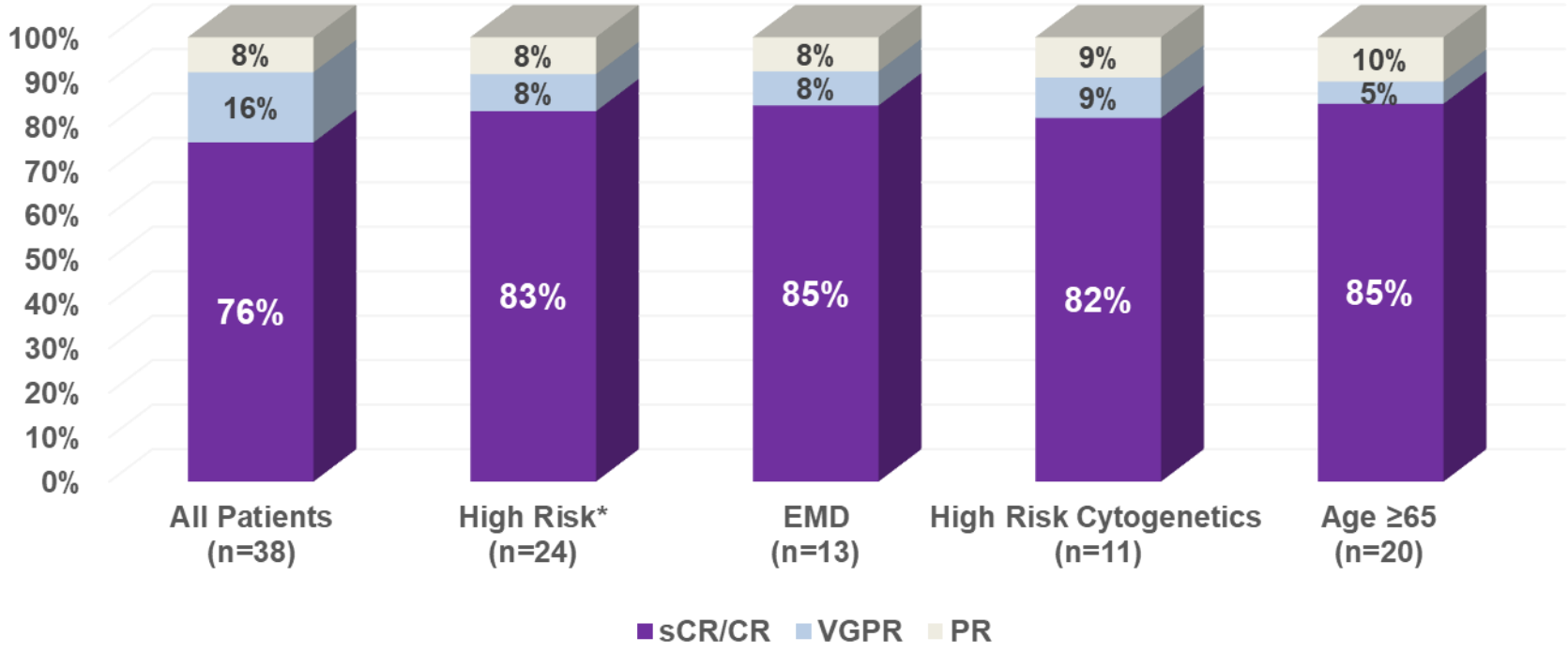
Anito-cel Phase 1 Results: Best Overall Response

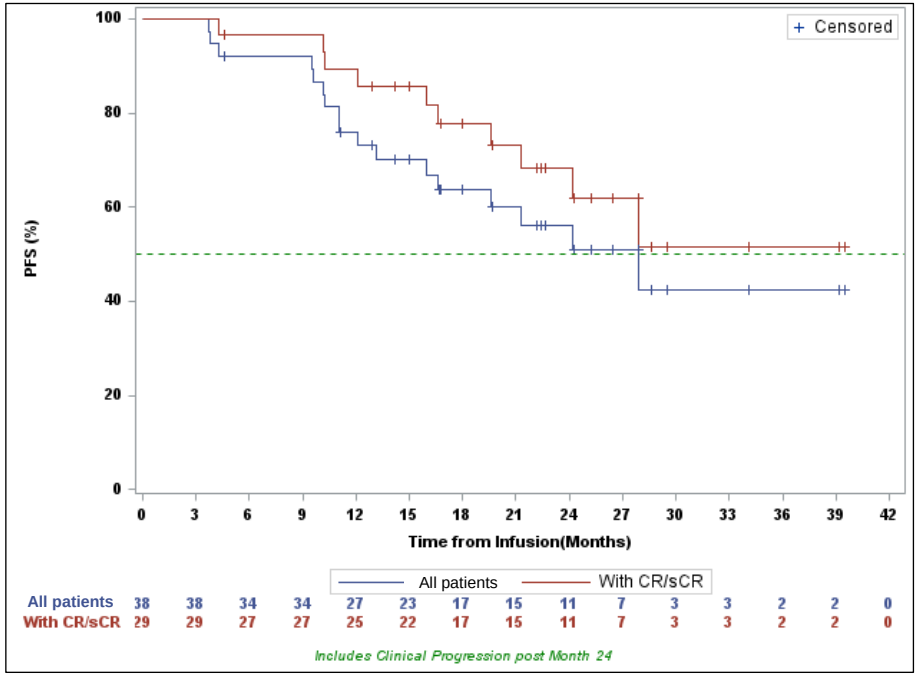
All Patients & High-Risk Sub-Groups



* High Risk defined as a patient with EMD, ISS Stage III (B2M ≥ 5.5), or BMPC ≥ 60%

Anito-cel Phase 1 Results: All Patients, CR/sCR Patients

Median Follow-Up: All Patients 26.5-mo. [14-44]; CR/sCR Patients 26.5-mo. [15-44]



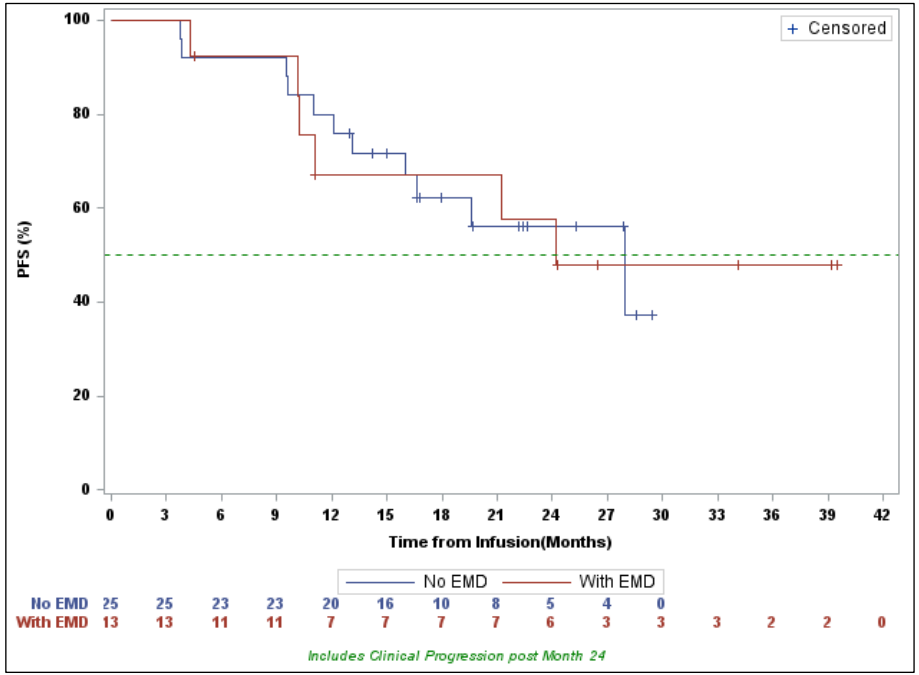
	Time (months)	PFS Estimate (%)	95% Confidence Interval (%)
All Patients (n = 38)	6	92.1	77.5, 97.4
	12	75.9	58.7, 86.6
	18	63.7	45.7, 77.2
	24	56.0	37.3, 71.1

- **Median PFS not reached for all patients (n=38)**
- **Median PFS not reached for CR/sCR patients (n=29, 76%)**
- **89% (n=25/28) of evaluable* patients MRD negative at minimum of 10^{-5} sensitivity**

Note: Data cut-off October 15, 2023; * Evaluable patients had identifiable malignant clone in the baseline bone marrow aspirate

Anito-cel Phase 1 Results: EMD, Non-EMD Patients

Median Follow-Up: EMD Patients ~33-mo. [14-44]; Non-EMD Patients ~25-mo. [15-40]



	Time (months)	PFS Estimate (%)	95% Confidence Interval (%)
With EMD (n = 13)	6	92.3	56.6, 98.9
	12	67.1	34.2, 86.2
	18	67.1	34.2, 86.2
	24	57.5	25.7, 79.9

- **Median PFS not reached for patients with EMD (n=13)**
- **Median PFS not reached for Non-EMD patients (n=25)**

Note: Data cut-off October 15, 2023

Anito-cel Phase 1 Results: Kaplan-Meier Estimates

All Patients & High-Risk Sub-Groups

	Overall	High Risk Features*	Extramedullary disease	High Risk Cytogenetics	≥ 65 years
Patients n (%)	38 (100%)	24 (63.2%)	13 (34.2%)	11 (28.9%)	20 (52.6%)
6-month PFS % (95% CI)	92.1% (77.5%, 97.4%)	91.7% (70.6%, 97.8%)	92.3% (56.6%, 98.9%)	81.8% (44.7%, 95.1%)	95.0% (69.5%, 99.3%)
12-month PFS % (95% CI)	75.9% (58.7%, 86.6%)	74.2% (51.3%, 87.5%)	67.1% (34.2%, 86.2%)	71.6% (35.0%, 89.9%)	85.0% (60.4%, 94.9%)
18-month PFS % (95% CI)	63.7% (45.7%, 77.2%)	64.6% (41.3%, 80.6%)	67.1% (34.2%, 86.2%)	71.6% (35.0%, 89.9%)	74.3% (48.7%, 88.4%)
24-month PFS % (95% CI)	56.0% (37.3%, 71.1%)	58.7% (35.1%, 76.3%)	57.5% (25.7%, 79.9%)	71.6% (35.0%, 89.9%)	61.3% (34.9%, 79.7%)

In all risk subgroups, including High Risk, the est. median PFS has not been reached at 24 months

* High Risk defined as a patient with EMD, ISS Stage III (B2M ≥ 5.5), or BMPC ≥ 60%

Anito-cel Phase 1 Results: Safety

CAR-T-associated AEs Per ASTCT criteria	100 million (n=32)		300 million (n=6)	
Cytokine Release Syndrome (CRS)	**Grade 1/2**	**Grade 3**	**Grade 1/2**	**Grade 3**
	30 (94%)	**0**	**5 (83%)**	**1 (17%)**
Median onset (min-max)*	2 days (1-12 days)		2 days (1-2 days)	
Median duration (min-max)	6 days (1-10 days)		5 days (3-9 days)	
Neurotoxicity (ICANs)	**Grade 1/2**	**Grade 3**	**Grade 1/2**	**Grade 3**
	5 (16%)	**1 (3%)**	**0**	**1 (17%)**
Median onset (min-max)*	4.5 days (3-6 days)		7 days	
Median duration (min-max)	3.5 days (1 - 9 days)		17 days	
Toxicity Management				
Tocilizumab	27 (84%)		5 (83%)	
Dexamethasone	20 (63%)		2 (33%)	

Grade 3/4 AEs (non-CRS/ICANS) ≥5% after cell infusion (n=38)	
Hematologic	
Neutrophil count decreased	31 (81.6%)
Anemia	22 (57.9%)
Thrombocytopenia	16 (42.1%)
Lymphocyte count decreased	15 (39.5%)
White blood cell count decreased	7 (18.4%)
Febrile Neutropenia	5 (13.2%)
Non-hematologic	
Hypertension	3 (7.9%)
AST[a] increased	2 (5.3%)
Cellulitis	2 (5.3%)
Hypokalemia	2 (5.3%)
Hyponatraemia	2 (5.3%)
Hypophosphatemia	2 (5.3%)
Lung Infection	2 (5.3%)
Pain in extremity	2 (5.3%)
Sepsis[b]	2 (5.3%)

- No change in safety profile as previously presented
- No delayed neurotoxicities, no Guillain-Barré syndrome, no cranial nerve palsies, and no Parkinsonian-like syndromes in the entire population through the follow-up period
- One Grade 5 AE post study treatment (unrelated cardiac arrest due to non-study drug overdose)

Note: Median duration numbers updated due to ongoing data review; a) Aspartate Aminotransferase Test; b) Grouped category for sepsis

Anito-cel Phase 1 Results: Conclusions

- **Anito-cel utilizes a novel, synthetic, compact and stable D-Domain binder**
  - D-Domain facilitates high CAR surface expression, low risk of tonic signaling
  - Recommended Phase 2 Dose selected as 115±10 million CAR+ T cells

- **CR/sCR rate 76%; 100% ORR per IMWG**
  - CR/sCR rate >80% in all evaluated sub-groups including high-risk (EMD, high-risk cytogenetics, age ≥65)
  - 89% of MRD evaluable patients (n=25/28) were MRD negative at 10^{-5} or lower

- **Median PFS, DOR, and OS not reached at 2 years of follow-up (median 26.5 months)**
  - CAR-T-ddBCMA continues to demonstrate deep and durable efficacy, including in high-risk patient sub-groups

- **At 2 years of follow-up (median 26.5 months), manageable safety profile**
  - No grade ≥3 CRS and 1 case of Grade 3 ICANS at RP2D. All events resolved without sequelae with routine management
  - No delayed neurotoxicity, no cranial nerve palsy, no Parkinsonian symptoms, no Guillain-Barré syndrome

Pivotal phase 2, iMMagine-1 trial (NCT05396885) is now enrolling;
in co-development with Kite's global cell therapy leadership

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