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Current Status of CAR-T Therapy in Hematology

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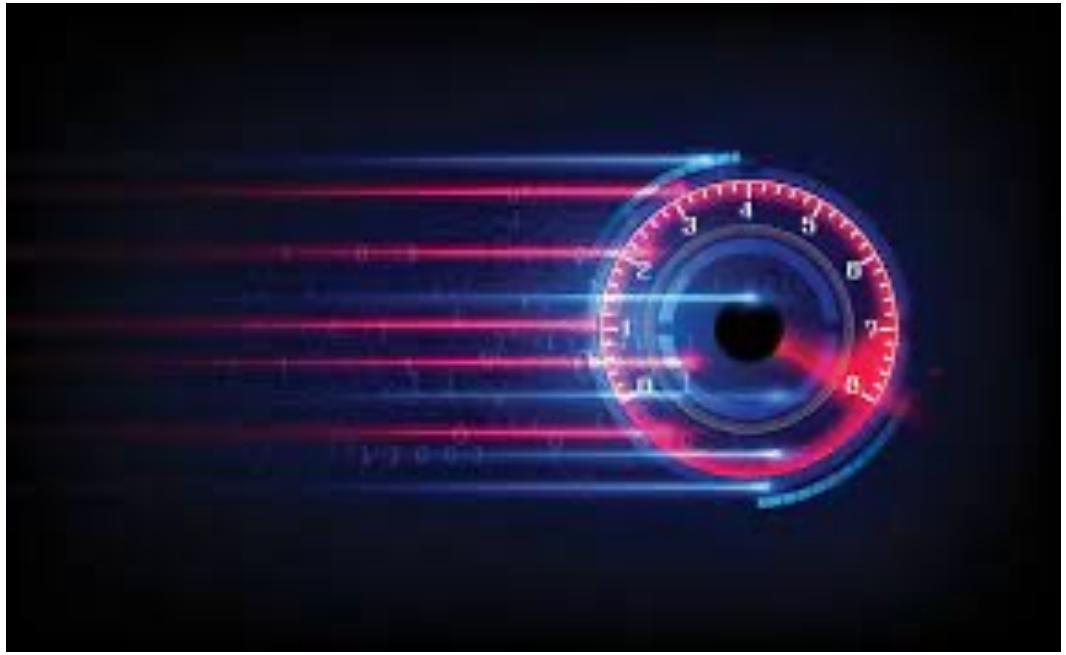
CAR-T in 20 minutes

- Background on CAR-T
- Currently available CAR-T products & indications
- CAR-T toxicity overview



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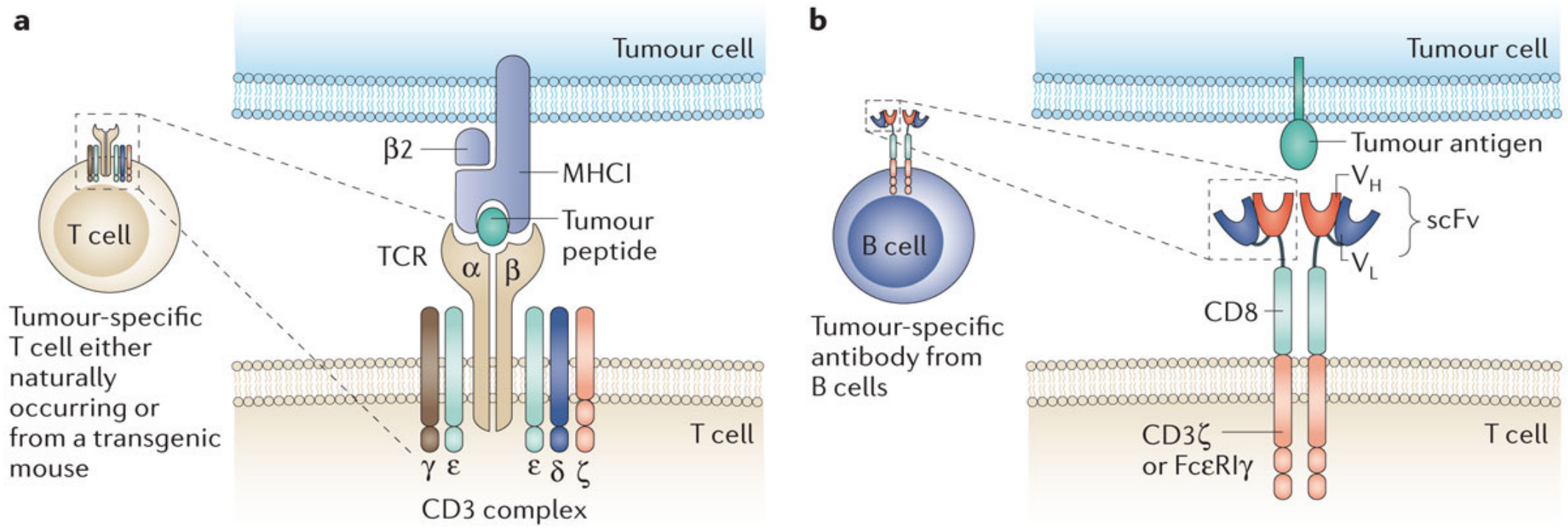
Cellular immunity as cancer therapy



Nature Reviews | Cancer

Nature Reviews Cancer Volume: 13, Pages:525–541 (2013)

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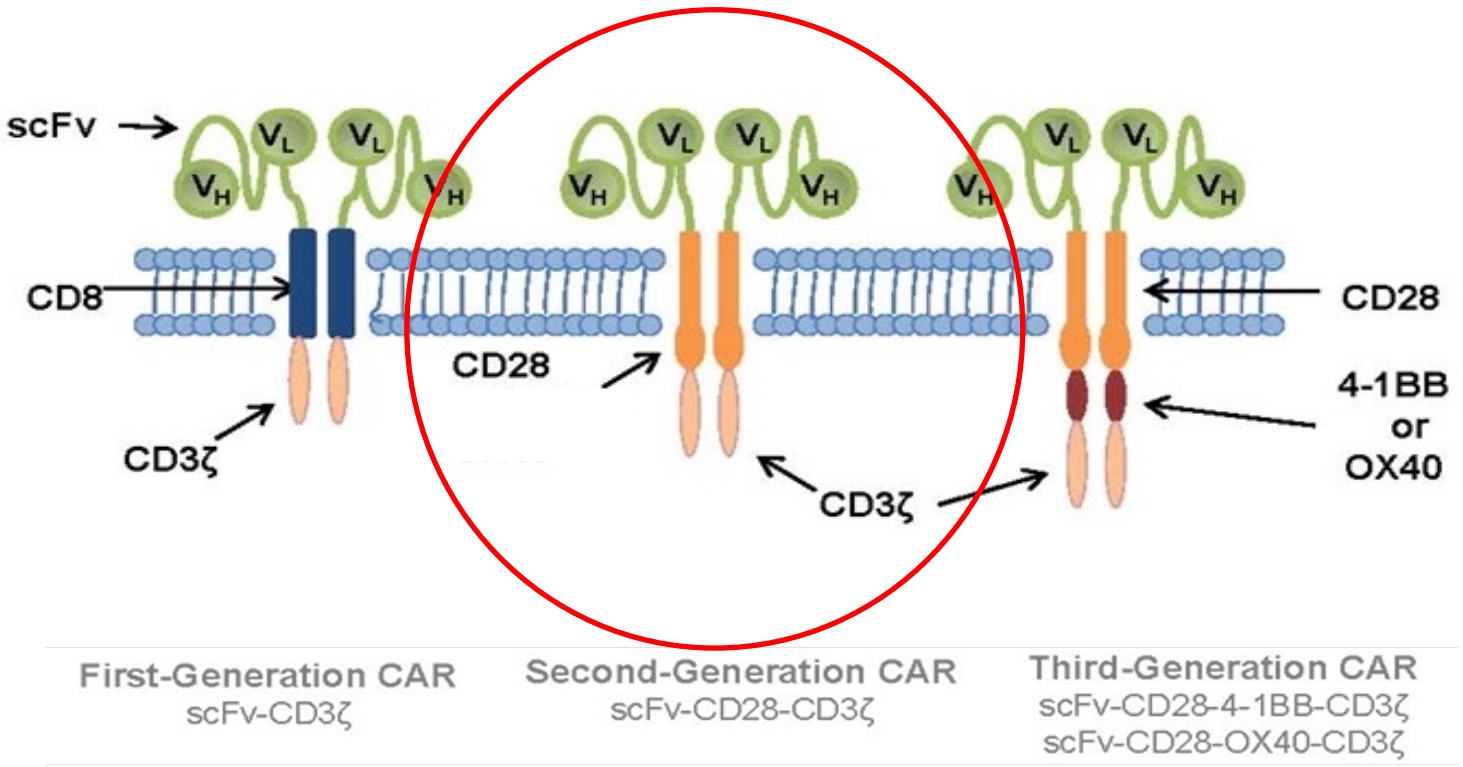
Evolution in CAR design



CAR Components

scFv single-chain variable fragment
- bypasses MHC antigen presentation, allowing direct activation of T cell by cancer cell antigens

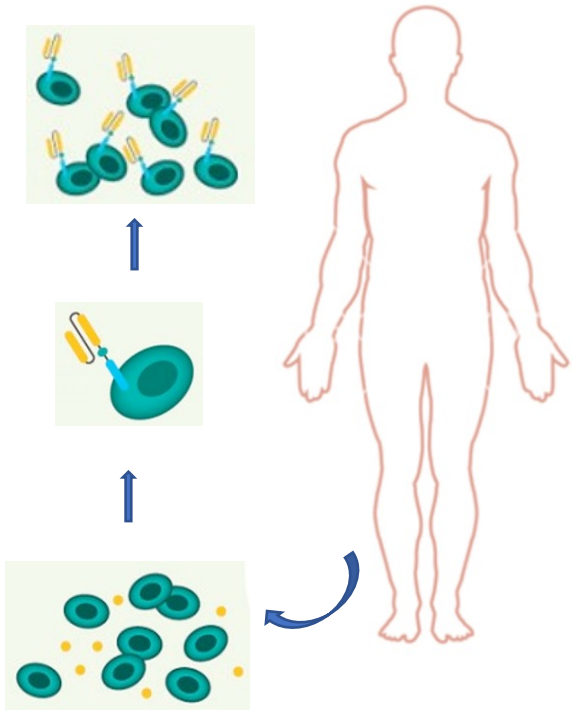
Hinge region
- Essential for optimal antigen binding

Costimulatory domain: e.g., CD28 or 4-1BB
- Enhances proliferation, cytotoxicity, and persistence

Signaling Domain: CD3ζ chain
- Proliferation and activation, and CAR T-cell-mediated killing of tumor cells

The Cell Therapy "Recipe"

Patient



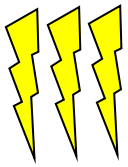
Before Cell Therapy

Disease burden
Cytokine profile
Co-morbidities
Age and geriatric vulnerability

Therapy

Conditioning Regimen

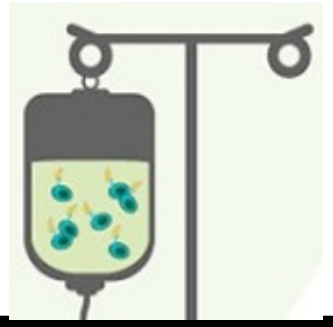
Lymphodepletion



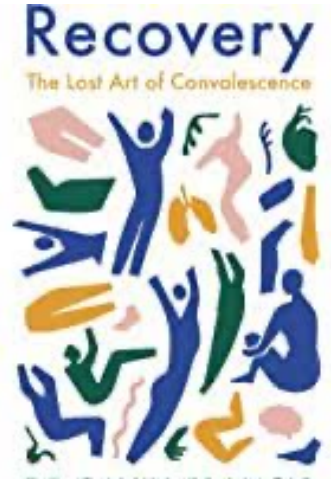
Prophylaxis: Anti-seizure, antibiotics

Immune effector cells

Product/Construct/Co-stim
Target(s)
Dose



Outcomes



After Cell Therapy

Effector cell expansion
Effector cell persistence
Biomarkers
Cytokine release syndrome (CRS)
Neurotoxicity (ICANS)
Immune recovery
Non-relapse mortality (NRM)
Relapse/POD

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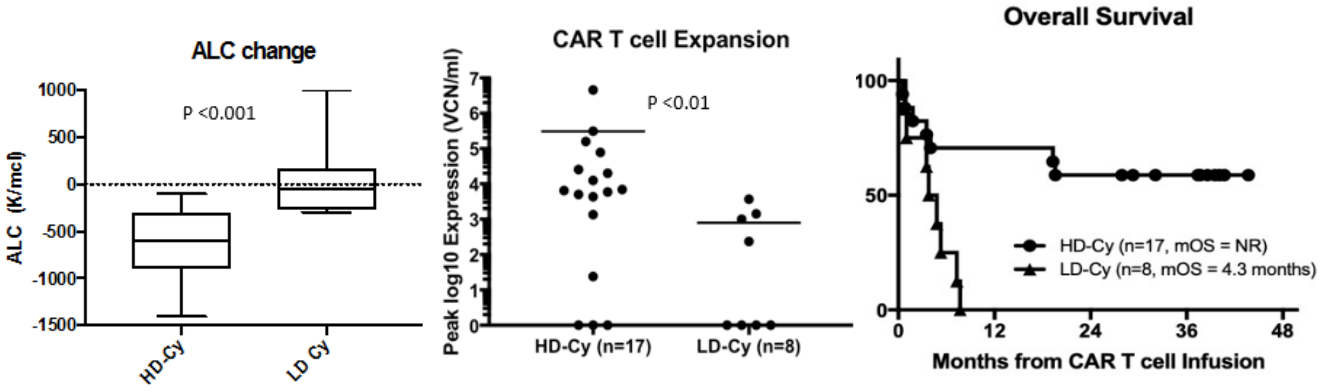
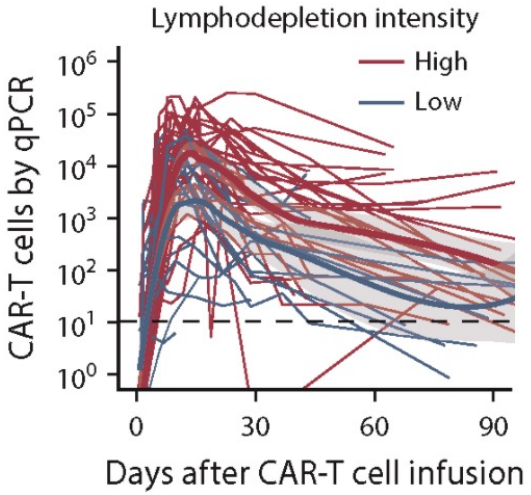
Conditioning (lymphodepletion) matters for CAR-T success

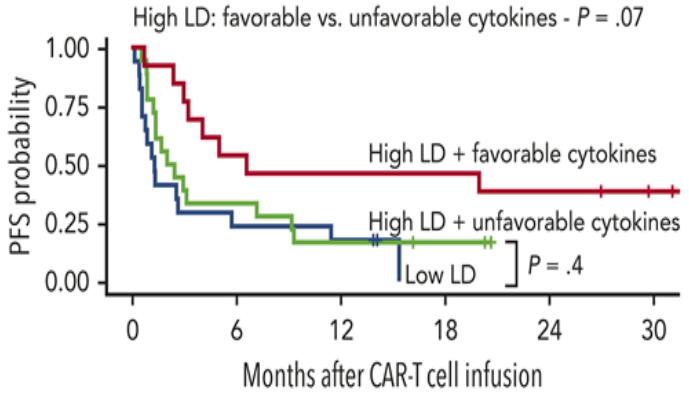
- Lymphodepletion results in:
  - Tumor debulking & tumor microenvironment changes
  - Reduces patient immunogenicity
  - Favorable changes in cytokine milieu
  - ➢ Ultimately allows for more effective T cell expansion and recovery



- Optimal lymphodepleting regimen is unknown.
  - **Flu/Cy** is most used. **Bendamustine** has been a standard during fludarabine shortage

- Intensity of lymphodepletion impacts outcomes.





Curran et al., Blood 2020; Hirayama et al., Blood 2019

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What are advantages of autologous CAR-T cell therapy?

- HLA-independent: no need for donor / HLA matching
- They are target (antigen) specific
- Tend to exert their effects rapidly
- Minimal risk of graft-versus-host disease
- In some diseases (ALL, DLBCL), they offer curative potential

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Currently approved CAR-T products

Product	Indication	Line of therapy
Axicabtagene ciloleucel (axi-cel)	DLBCL FL	2L (transplant eligible), 3L+ 3L+
Tisagenlecleucel (tisa-cel)	ALL DLBCL FL	Refratory or 3L+ 3L+ 3L+
Lisocabtagene maraleucel (liso-cel)	DLBCL	2L+ (regardless of transplant eligibility)
Brexucabtagene autoleucel (brexu-cel)	ALL MCL	2L+ 2L+
Idecabtagene vicleucel (ide-cel)	MM	5L+
Ciltacabtagene autoleucel (cilta-cel)	MM	5L+

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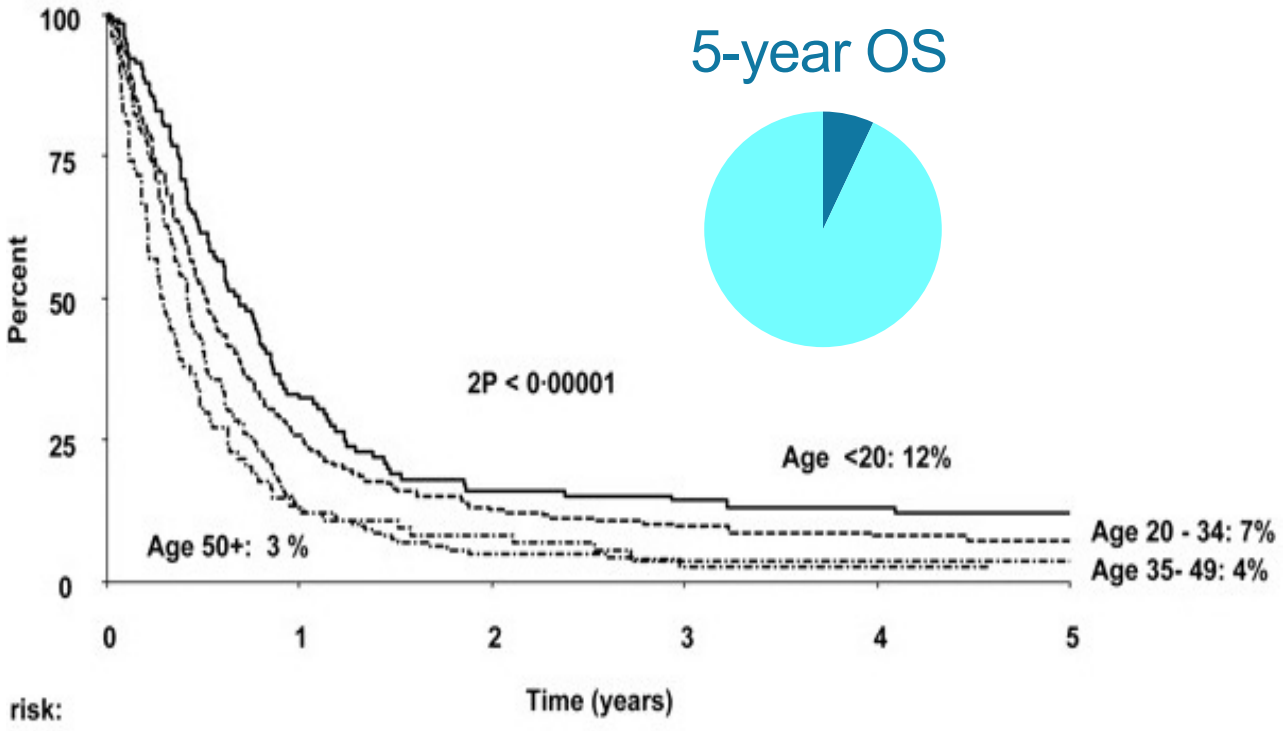
Approved CAR T products and their studies

Historically poor prognosis for relapsed/refractory adult ALL

MRC UKALL2/ ECOG2993 Study (n=609)

Outcome of patients after first relapse:

5-year OS



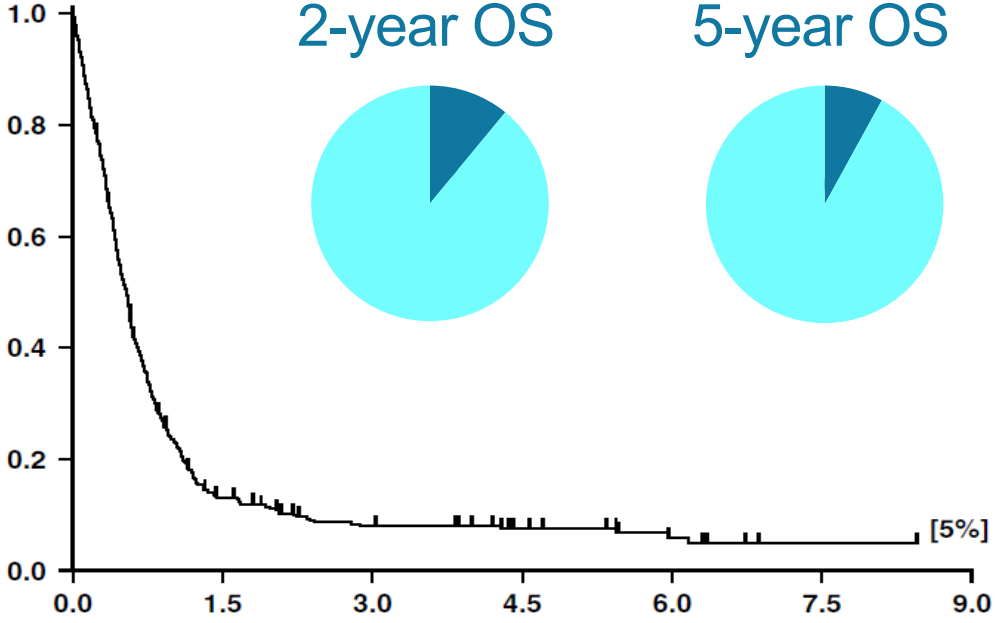
Fielding A, et al. Blood 2007;109(3):944-950.

LALA-94 Study (n=421)

Outcome of patients after first relapse:

2-year OS

5-year OS



Tavernier E, et al. Leukemia 2007;21:1907-1914

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First ever CAR T approval: Tisagenlecleucel for ALL

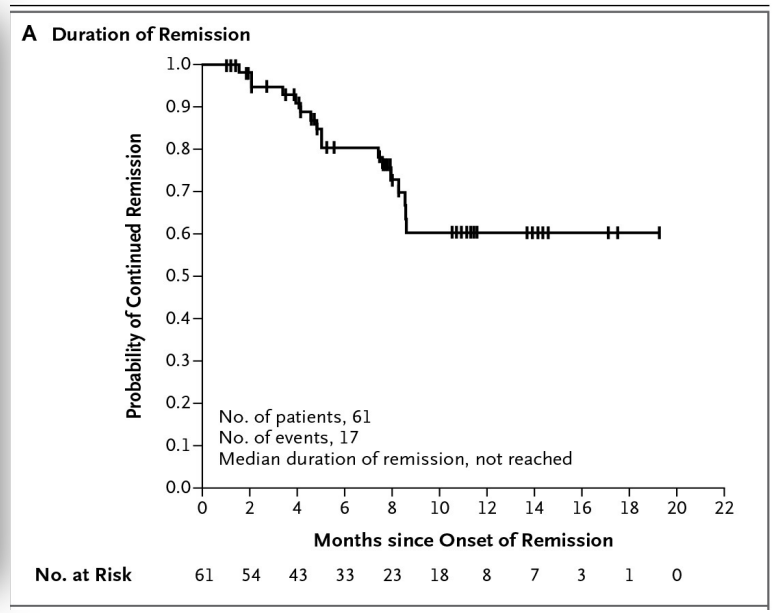
Indication: CD19-directed autologous T cell for the treatment of **patients ≤ 25 y/o with B-cell acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse.**

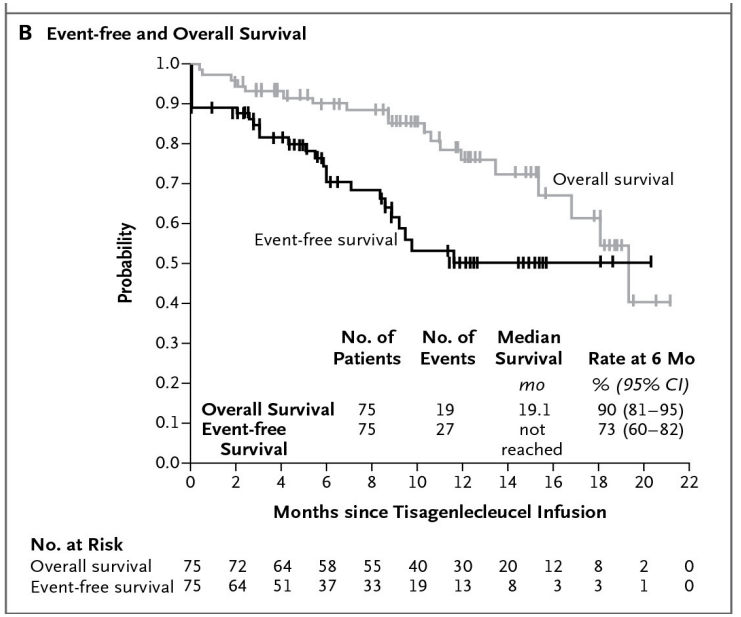
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Tisagenlecleucel in Children and Young Adults with B-Cell Lymphoblastic Leukemia

S.L. Maude, T.W. Laetsch, J. Buechner, S. Rives, M. Boyer, H. Bittencourt, P. Bader, M.R. Verneris, H.E. Stefanski, G.D. Myers, M. Qayed, B. De Moerloose, H. Hiramatsu, K. Schlis, K.L. Davis, P.L. Martin, E.R. Nemecek, G.A. Yanik, C. Peters, A. Baruchel, N. Boissel, F. Mechinaud, A. Balduzzi, J. Krueger, C.H. June, B.L. Levine, P. Wood, T. Taran, M. Leung, K.T. Mueller, Y. Zhang, K. Sen, D. Lebwohl, M.A. Pulsipher, and S.A. Grupp





Maude et al, N Engl J Med 2018

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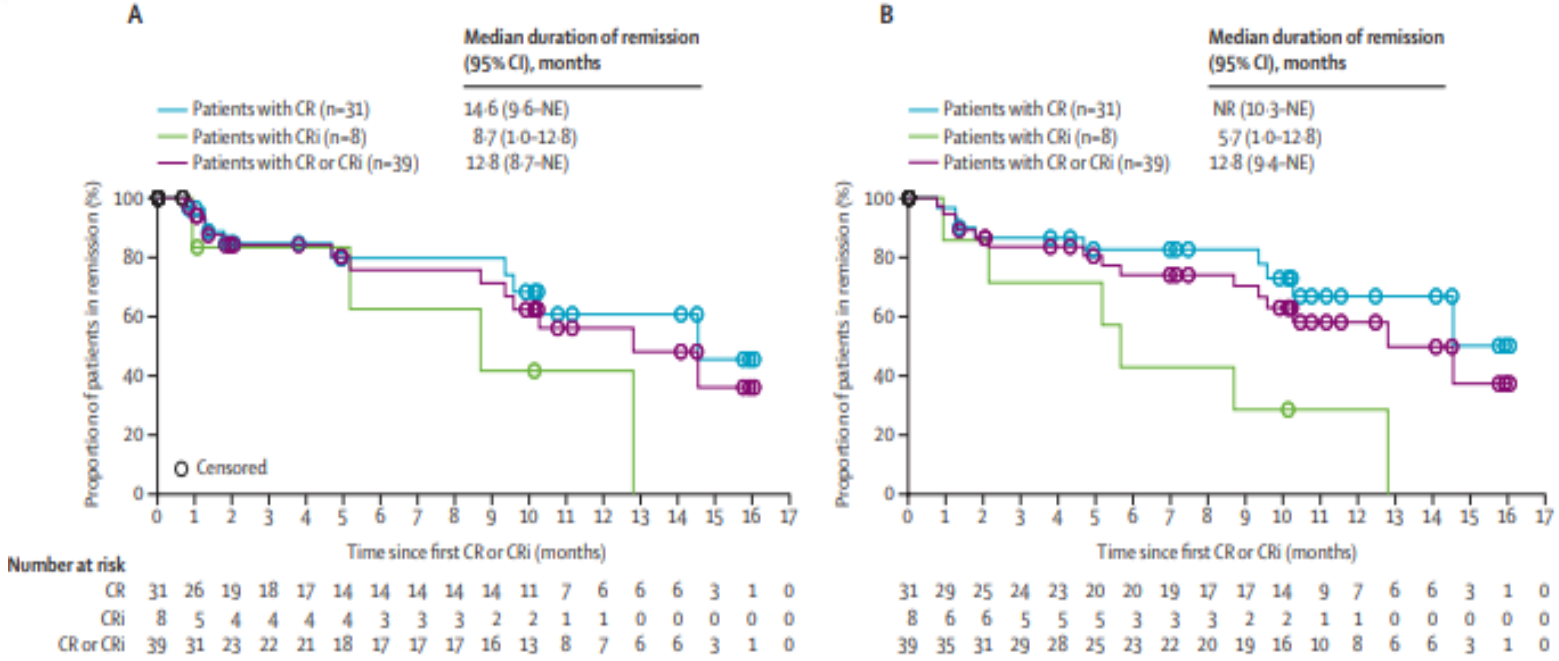
Brexucabtagene for adult ALL

KTE-X19 for relapsed or refractory adult B-cell acute lymphoblastic leukaemia: phase 2 results of the single-arm, open-label, multicentre ZUMA-3 study

Bijal D Shah, Armin Ghobadi, Olalekan O Oluwole, Aaron C Logan, Nicolas Boissel, Ryan D Cassaday, Thibaut Leguay, Michael R Bishop, Max S Topp, Dimitrios Tzachanis, Kristen M O'Dwyer, Martha L Arellano, Yi Lin, Maria R Baer, Gary J Schiller, Jae H Park, Marion Subklewe, Mehrdad Abedi, Monique C Minnema, William G Wierda, Daniel J DeAngelo, Patrick Stiff, Deepa Jeyakumar, Chaoling Feng, Jinghui Dong, Tong Shen, Francesca Milletti, John M Rossi, Remus Vezan, Behzad Kharabi Masouleh, Roch Houot

Indication: CD19-directed autologous T cells for **adult patients with relapsed or refractory B-cell precursor ALL**



Shah et al, Lancet 2021

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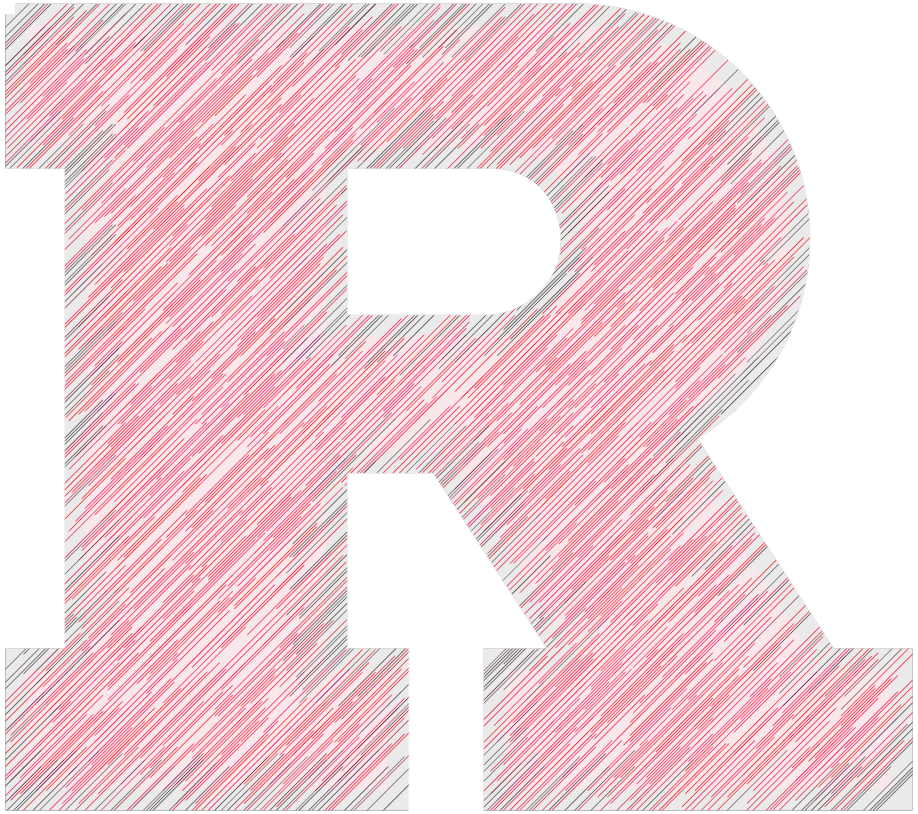
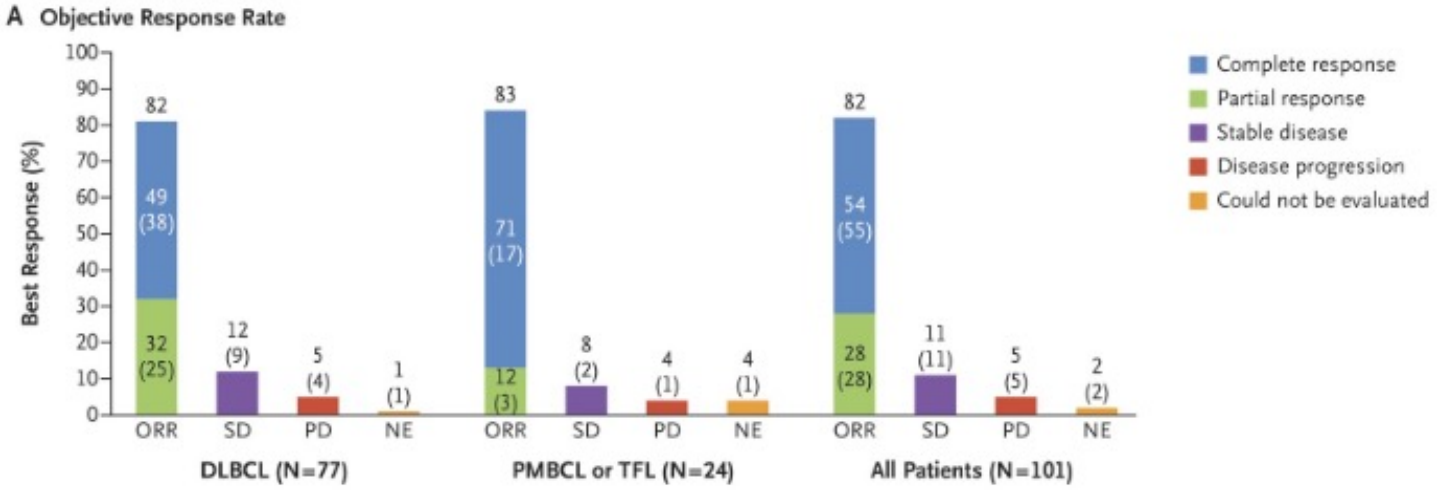
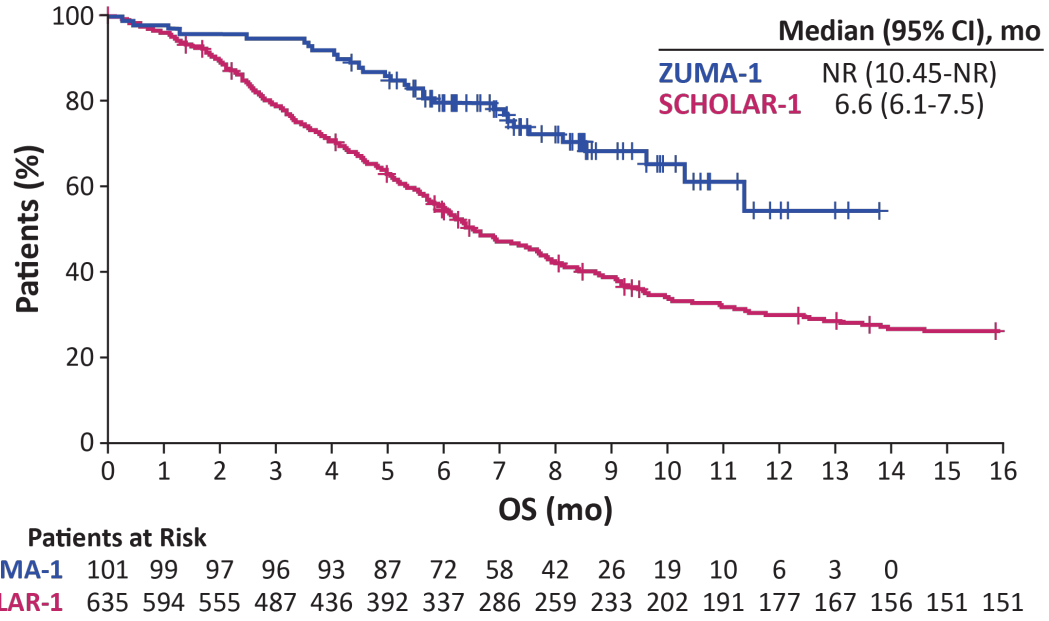
Diffuse large B-cell Lymphoma



Axicabtagene ciloleucel: 1st FDA approval for DLBCL





Neelapu SS, et al. N Engl J Med. 2017

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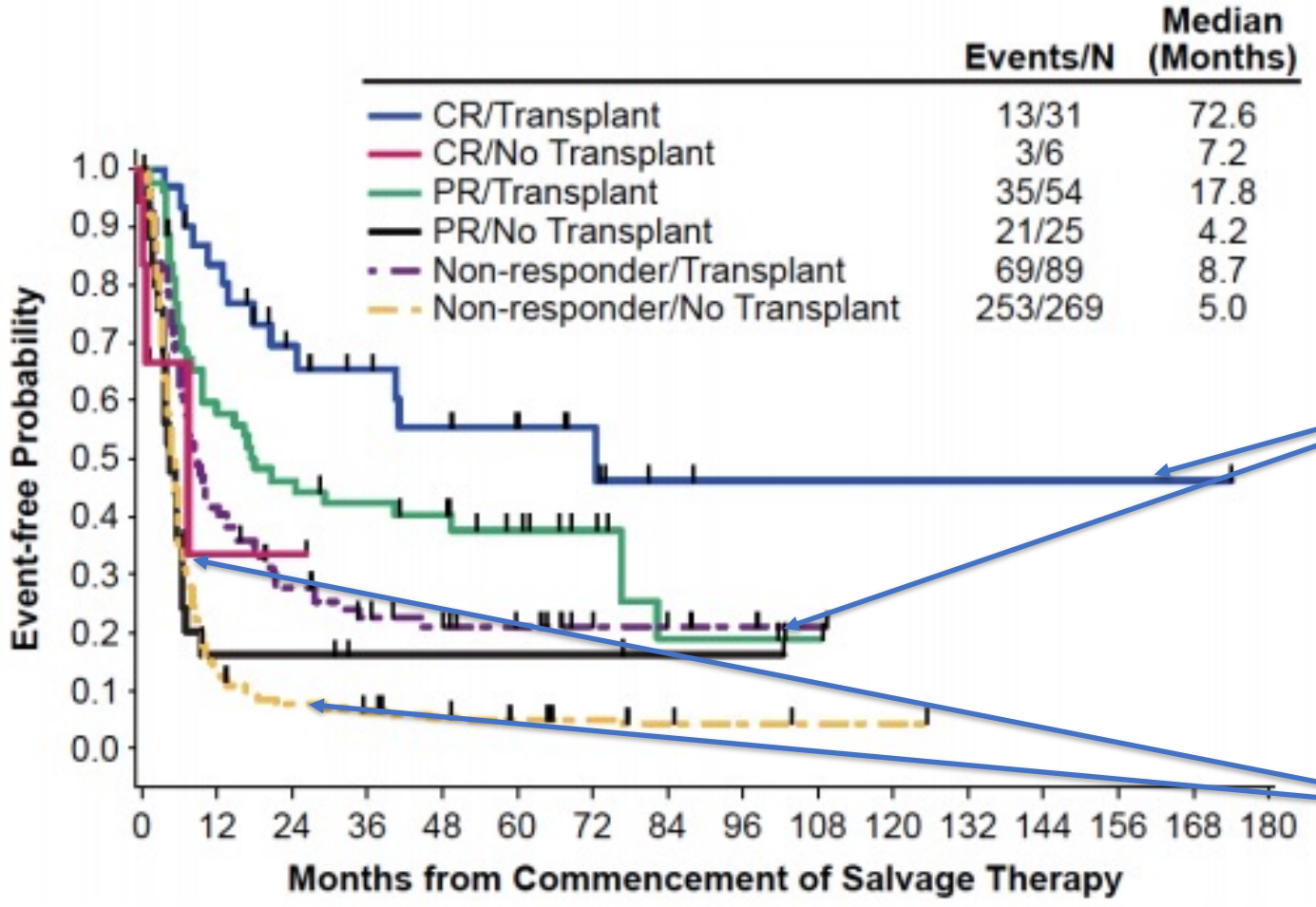
High response rates in rel/ref DLBCL across products

	KTE-C19	CTL019	JCAR017
Drug Name	**Axicabtagene Ciloleucel**	**Tisagenlecleucel**	**Lisocabtagene maraleucel**
Clinical Trial	**ZUMA-1** NCT02348216	**JULIET** NCT02445248	**TRANSCEND** NHL 001 NCT02631044
Dose Level	2×10^6 cells/kg	$0.6\text{-}6.0\times10^8$ cells	$50\text{-}110\times10^6$ cells
Conditioning Chemotherapy	Low dose Flu/Cy x 3 days	Variety; FDA label is Flu/Cy	Low dose Flu/Cy x 3 days
Eligible Patients	DLBCL, HGBL, tFL, PMBL ≥ 2 lines of therapy	DLBCL, HGBL, tFL ≥ 2 lines of therapy	DLBCL, HGBL, PMBL tFL, FL G3B ≥ 2 lines of therapy
Response Rates	ORR = 82% CR = 54%	ORR = 52% CR = 40%	ORR = 73% CR = 54%

Neelapu SS, et al. *N Engl J Med*. 2017, Schuster SJ, et al. *N Engl J Med*.2019; Abramson JS, et al. Lancet 2020.

What about 2L DLBCL? Autotransplant outcomes suboptimal



Underwent auto-HCT
- Standard of care

Did not undergo auto-HCT
- Historically dismal prognosis

Crump et al., Blood 2017

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	ZUMA-7[1]		BELINDA[2]		TRANSFORM[3]	
	Axi-cel (n=180)	SOC (n=179)	Tisagenlecleucel (n=162)	SOC (n=160)	Liso-cel (n=92)	SOC (n=92)
Primary end point	EFS	EFS	EFS after wk 12	EFS after wk 12	EFS	
Median age (range), y	58 (21–80)	60 (26–81)	59.5 (19–79)	58 (19–77)	60 (53.5-67.5)	58.0 (42-65)
Eligibility	R/R at ≤12 mo, ASCT-eligible; no impending organ compromise	R/R at ≤12 mo, ASCT-eligible; no impending organ compromise	R/R at ≤12 mo, ASCT-eligible	R/R at ≤12 mo, ASCT-eligible	Adults with aggressive NHL* R/R ≤12 mo, ASCT eligible, LVEF > 50%	
Bridging therapy	Glucocorticoids only (36% received)	NA	Chemotherapy optional (83% received)	NA	Chemotherapy optional	NA
Disease status at study entry, %						
Refractory to any therapy / relapsed / prior ASCT	74 / 26/ NA	73 / 27 / NA	66 / 34 / NA	67 / 33 / NA	73 / 27 / NA	
Clinical outcomes						
Median follow-up, mo	25	25	10	10	6.2	6.2
Response, %	83	50	46	43	86	48
CR, %	65	32	28	28	66	39
EFS, HR (95% CI); P value	0.40 (0.31–0.51); P<0.001		1.07 (0.82-1.40); P=0.61		0.349 (0.229-0.530); P <.0001	
PFS, %	24-mo, 46	24-mo, 27	NR	NR	12-mo, 52.3	12-mo, 33.9

1. Locke FL, et al. *N Engl J Med*. 11 DEC 2021. 2. Bishop MR, et al. *N Engl J Med*. 14 DEC 2021. 3. Kamdar. ASH 2021. Abstract 91.

Autotransplant vs. CAR T in DLBCL

- **For some cases, CAR T cells may be better than SOC (auto-HCT)**
  - You will start to see more patients getting CAR T cells as 2nd line tx
  - The number of auto-HCTs will likely continue to go down…

- **The real world often does not mirror the clinical trials…**
  - Major problem with access (insurance approval, delays, slot availability, financial toxicity)
  - Most patients need bridging therapy. What happens if they respond?

- **If a patient gets CAR T cells in 2nd line…what happens if there is relapse?**
  - Can/do you try for auto-HCT? (this is an open-ended question)

- **Regardless of results of the randomized studies, there is still a lot of work to do**

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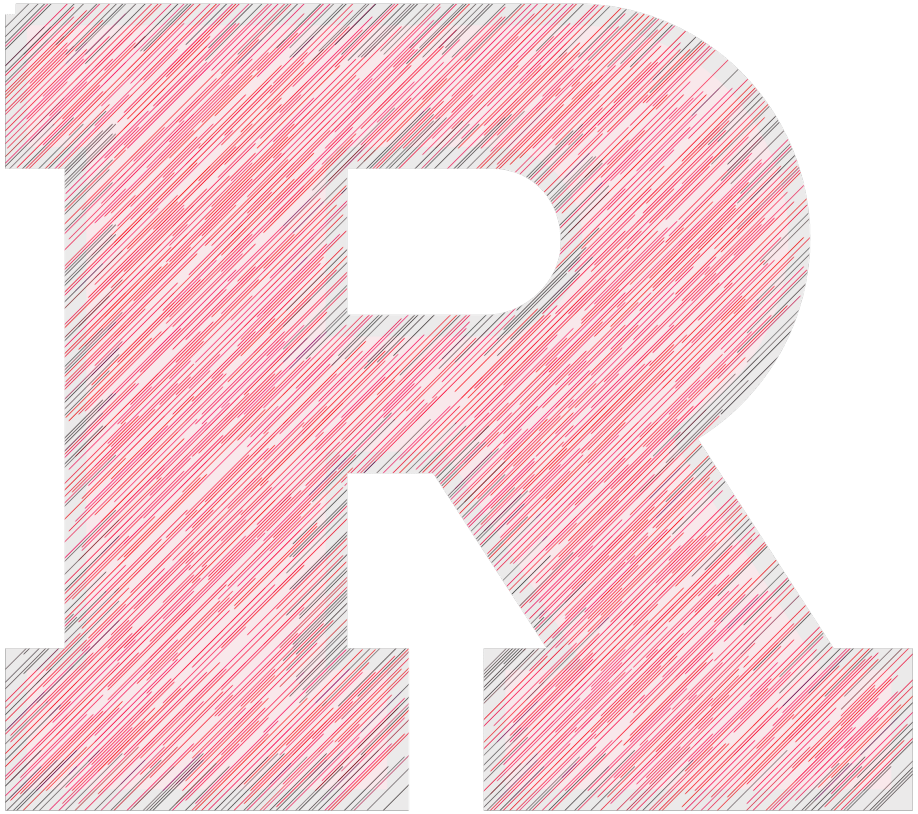
Indolent B-cell Lymphomas



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Brexucabtagene for mantle cell lymphoma

ORIGINAL ARTICLE

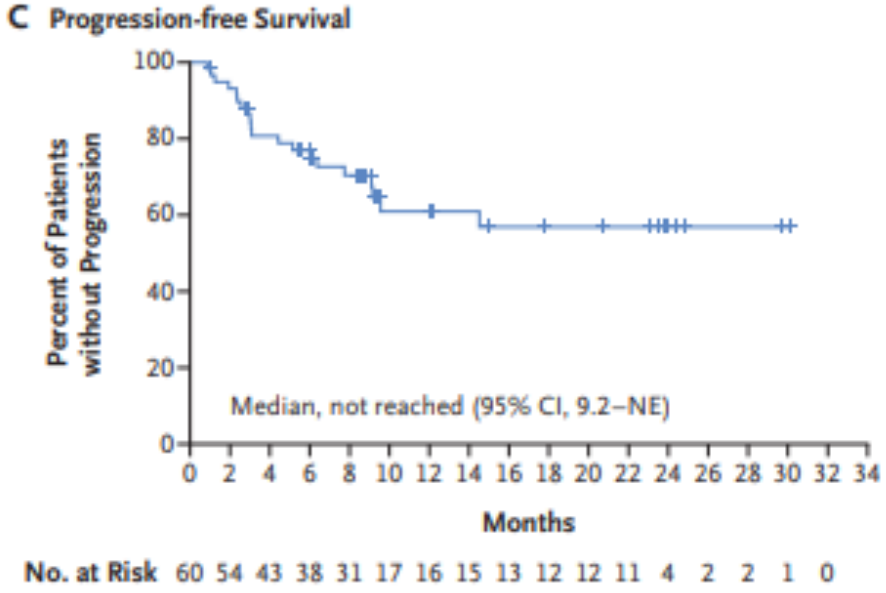
KTE-X19 CAR T-Cell Therapy in Relapsed or Refractory Mantle-Cell Lymphoma

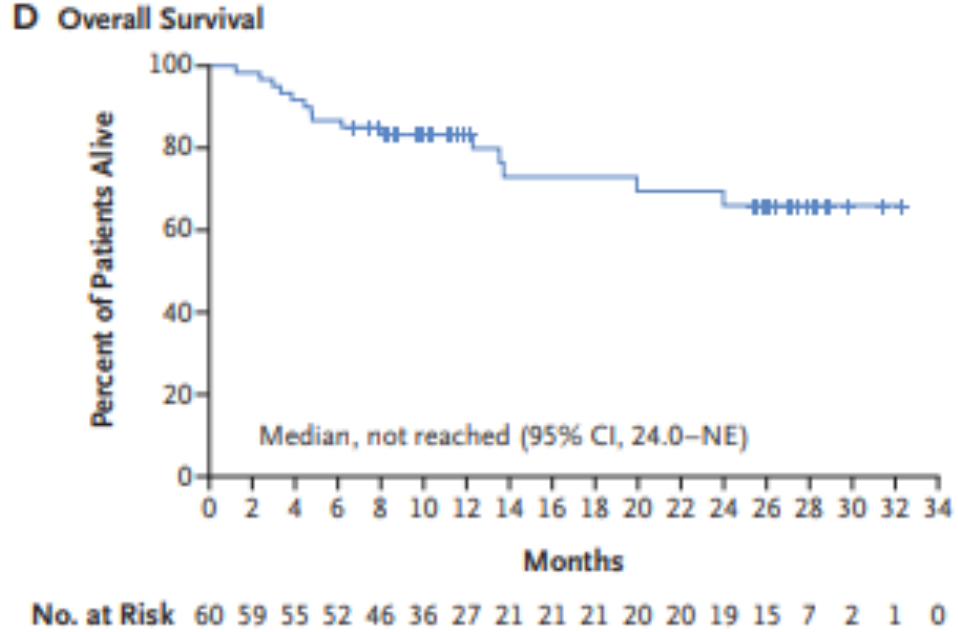
M. Wang, J. Munoz, A. Goy, F.L. Locke, C.A. Jacobson, B.T. Hill, J.M. Timmerman, H. Holmes, S. Jaglowski, I.W. Flinn, P.A. McSweeney, D.B. Miklos, J.M. Pagel, M.-J. Kersten, N. Milpied, H. Fung, M.S. Topp, R. Houot, A. Beitinjaneh, W. Peng, L. Zheng, J.M. Rossi, R.K. Jain, A.V. Rao, and P.M. Reagan

Indication: CD19-directed autologous T cell for **adult patients with relapsed or refractory mantle cell lymphoma**

ORR: 87%

CR: 62%





Wang et al, NEJM 2021

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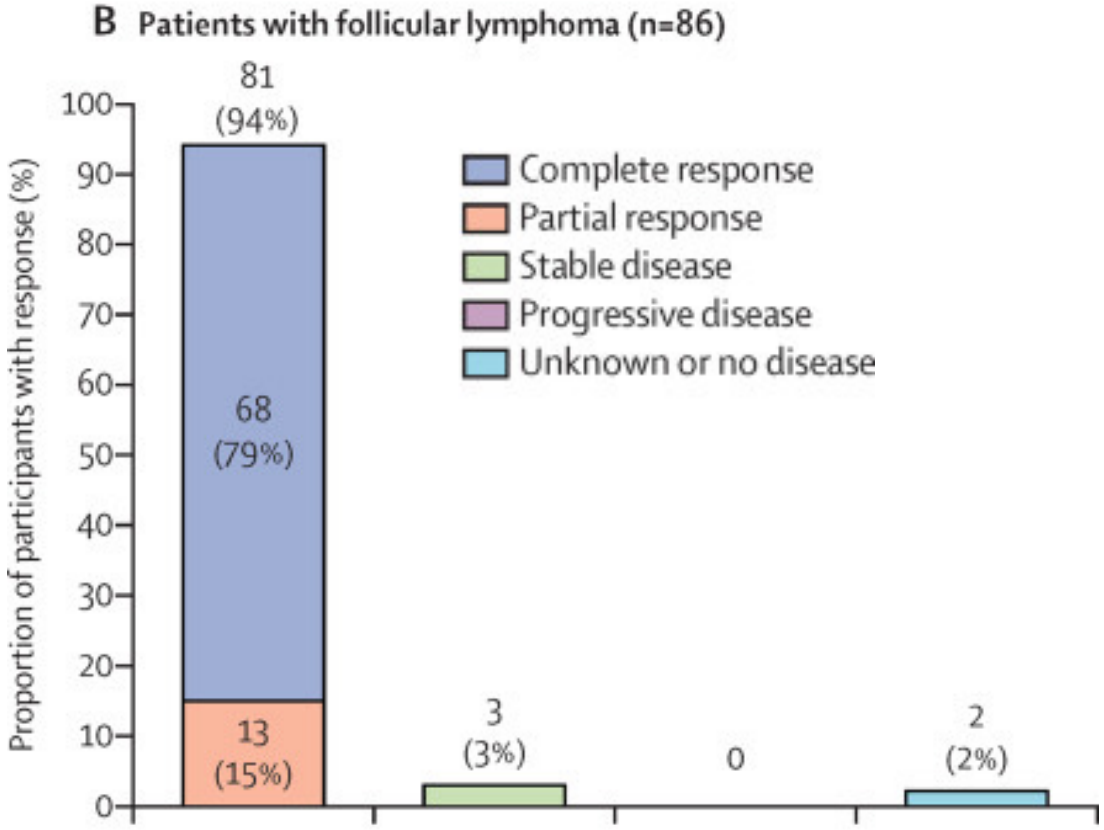
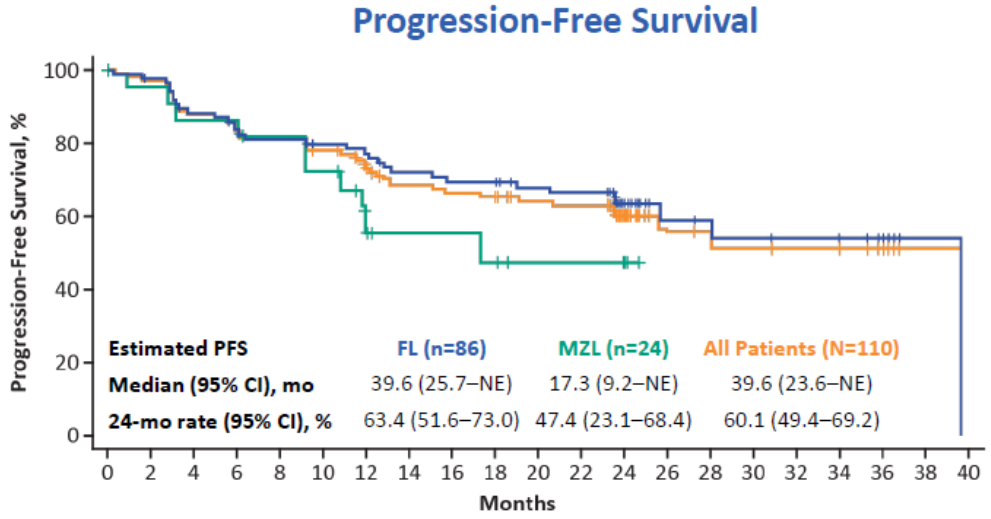
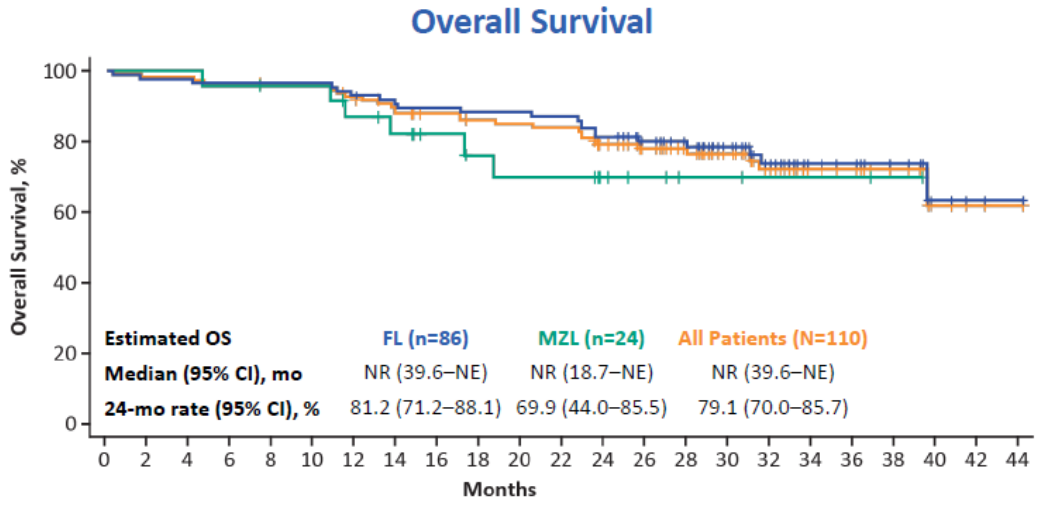
Axicabtagene for multiply relapsed FL



Of FL patients that achieved CR, 68% had ongoing responses, compared to 57% in efficacy-eligible cohort



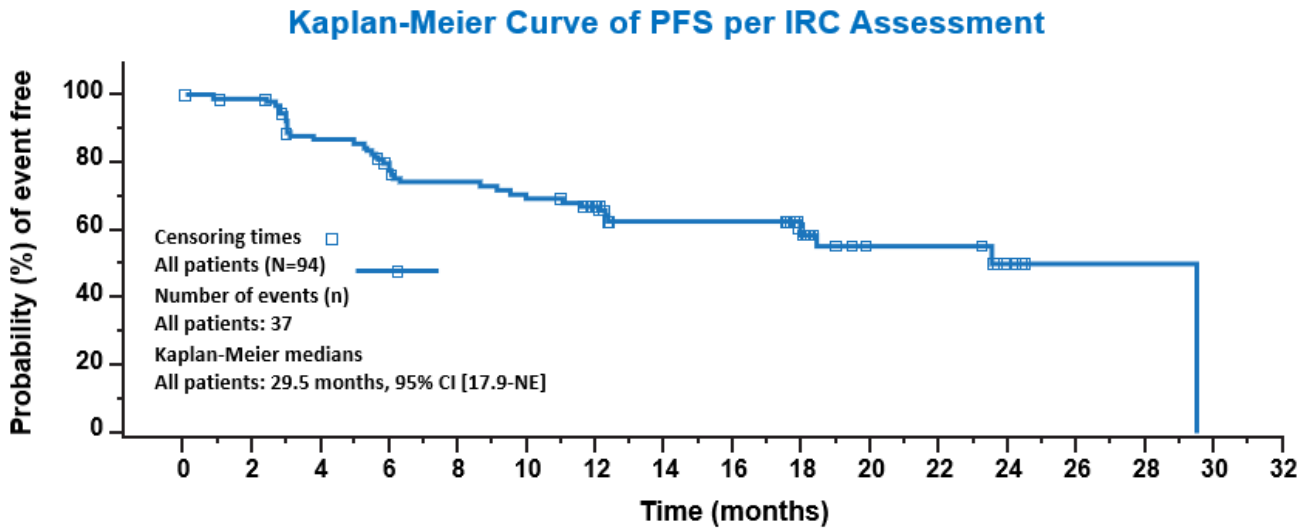


Jacobson, Lancet Oncol 2022. Chavez, TCT, 2022. Neelapu, ASH 2021

Tisagenlecleucel for multiply relapsed FL

Endpoint	% (95% CI)
Overall Response Rate	**88.2 (77.5 – 92.4)**
Complete Response Rate	**69.1 (58.8 – 78.3)**
12-mo progression-free survival	**67.0 (56.0 – 75.8)**

Among CR patients,
- **12mo PFS: 85.5%** (95% CI, 74-92)



With a longer median F/U of 21mo,
Median PFS 29.5 mo (17.9 – NE)

Thieblemont, TCT, 2022

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CAR-T in r/r follicular lymphoma

ZUMA-5 (Axi-cel)	N = 124
Median age, year (IQR)	60 (53 – 67)
ECOG PS 1, n (%)	46 (37%)
Bulky disease, n (%)	64 (52%)
Stage at study entry, III – IV, n (%)	106 (85%)
FLIPI high (≥ 3), n (%)	54 (44%)
Median prior therapies, n (min, max) ≥ 3	3 (2-4) 78 (63%)
POD24, n(%)	68 (55%)
Refractory to last line, n (%)	84 (68%)
Prior autologous HSCT	30 (24%)
Prior therapy, n (%) - Anti-CD20 mAB and alkylator - PI3K inhibitor - Lenalidomide	 123 (99%) 34 (27%) 38 (31%)

ELARA (Tisa-cel)	N = 97
Median age, year (IQR)	57 (49 – 64)
ECOG PS ≥ 1 before infusion, n (%)	42 (43.3)
Bulky disease, n (%)	62 (63.9)
Stage at study entry, III – IV, n (%)	83 (85.6)
FLIPI high (≥ 3) at study entry, n (%)	58 (59.8)
Median prior therapies, n (min, max) ≥ 5	4 (2 -13) 27 (27.8)
POD24, n(%)	61 (62.9)
Refractory to last line, n (%)	76 (78.4)
Prior autologous HSCT	35 (36.1)
Prior therapy - Anti-CD20 mAB and alkylator - PI3K inhibitor - Lenalidomide	 97 (100) 20 (20.6) 16 (16.5)

CAR-T in r/r follicular lymphoma: Tox

ZUMA-5 (Axi-cel)	N = 124
Any adverse events	147 (99)
CRS	121 (82)
Neurological events	87 (59)
Infections	79 (53)
Hypogammaglobulinemia	25 (17)
Neutropenia	4 (3%)
Anemia	56 (38)
Thrombocytopenia	29 (20)

ELARA (Tisa-cel)	N = 97
All adverse events	94 (96.9)
CRS	47 (48.5)
All nervous system disorders ICANS	36 (37.1) 4 (4.1)
Infections	18 (18.6)
Hypogammaglobulinemia	9 (9.3)
Neutropenia	32 (33.0)
Anemia	24 (24.7)
Thrombocytopenia	16 (16.5)

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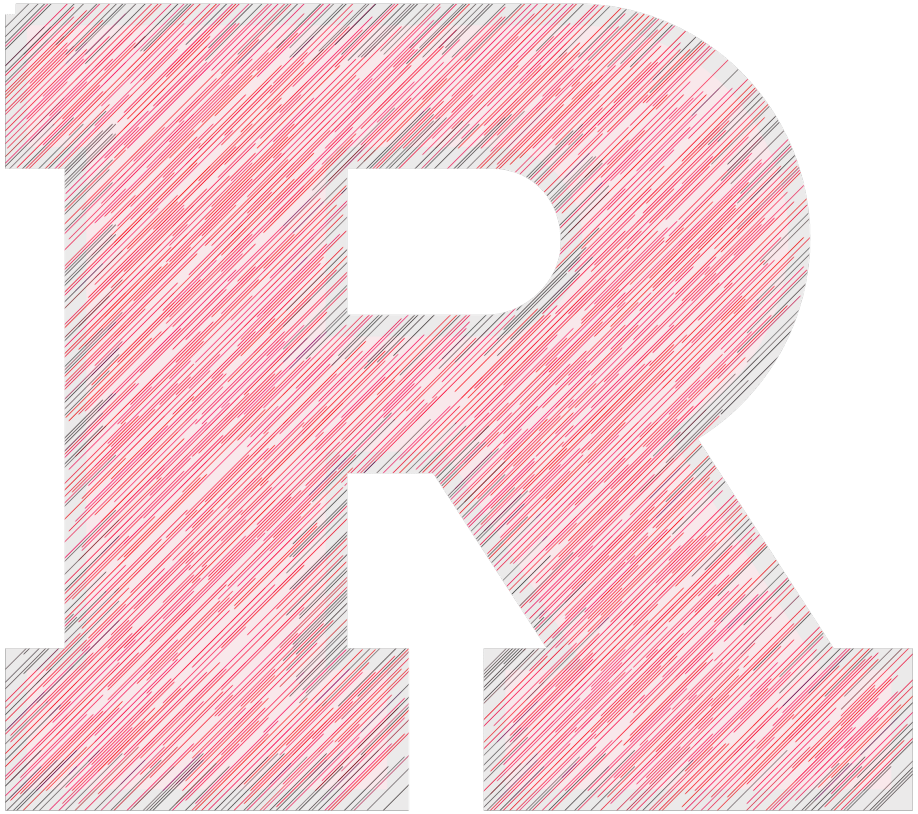
Multiple Myleoma



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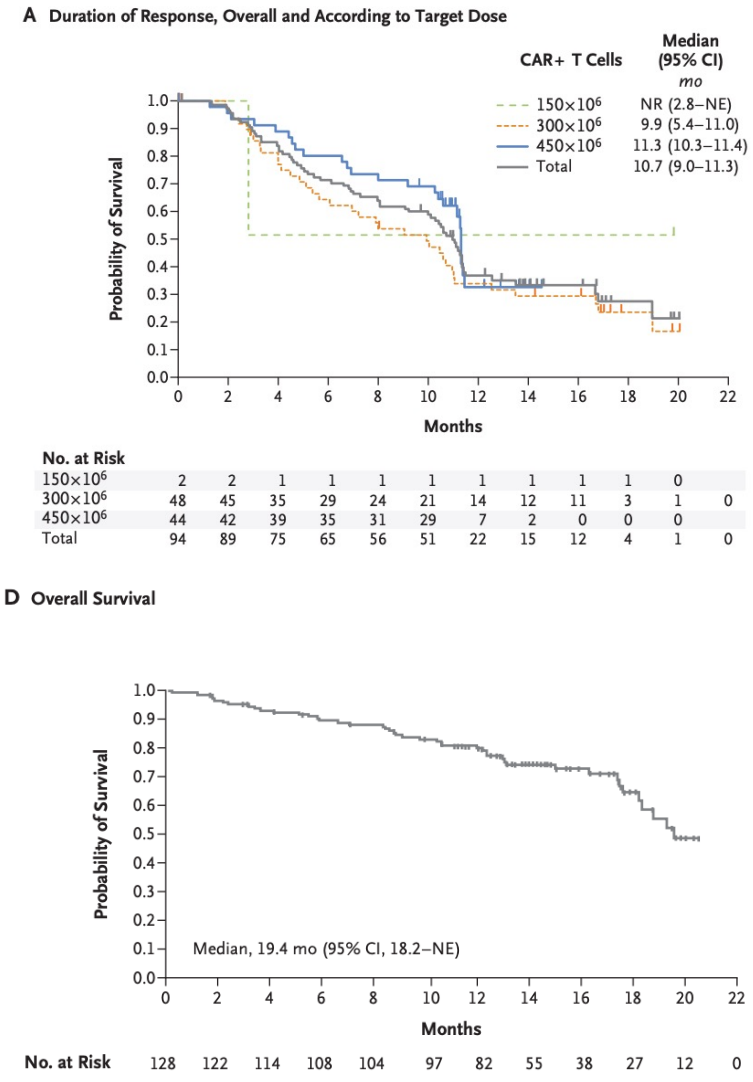
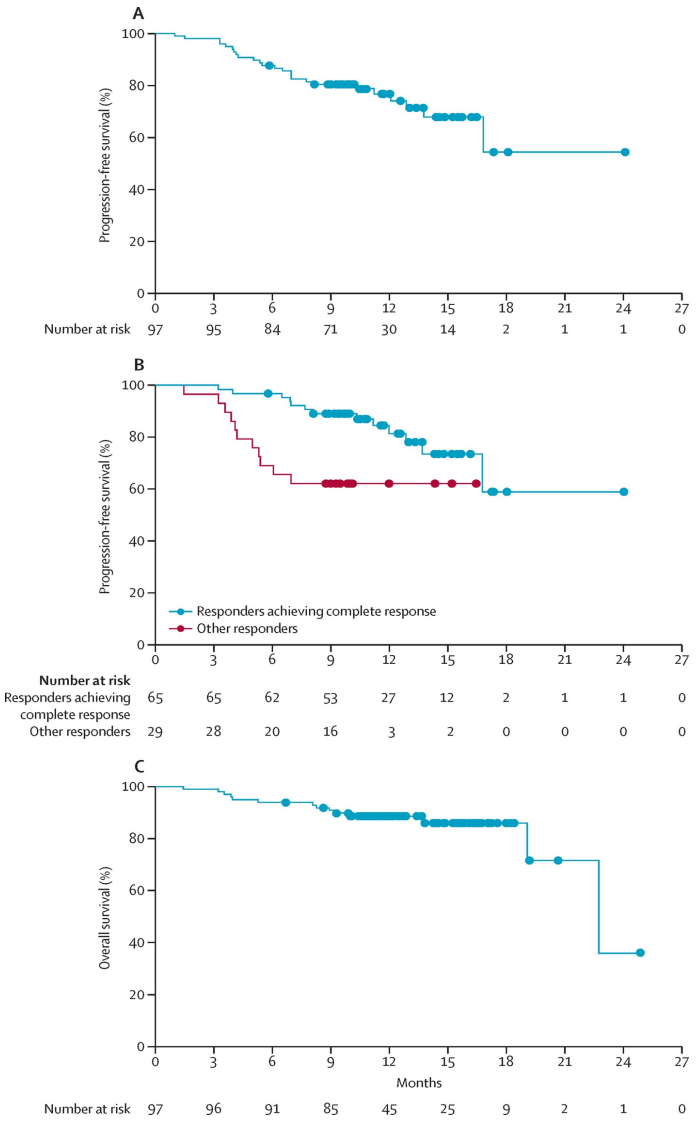
BCMA-directed CAR T cells for rel/ref multiple myeloma



- Adults with MM refractory to at least 4 lines of therapy
- Prior therapy must have included: PI, IMiD, & anti-CD38



Idecabtagene vicleucel

Ciltacabtagene autoleucel

Munshi et al., NEJM 2021; Berdeja et al., Lancet 2021

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CAR T Toxicity

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Adverse events associated with CAR T cells can affect any organ system

Neurologic

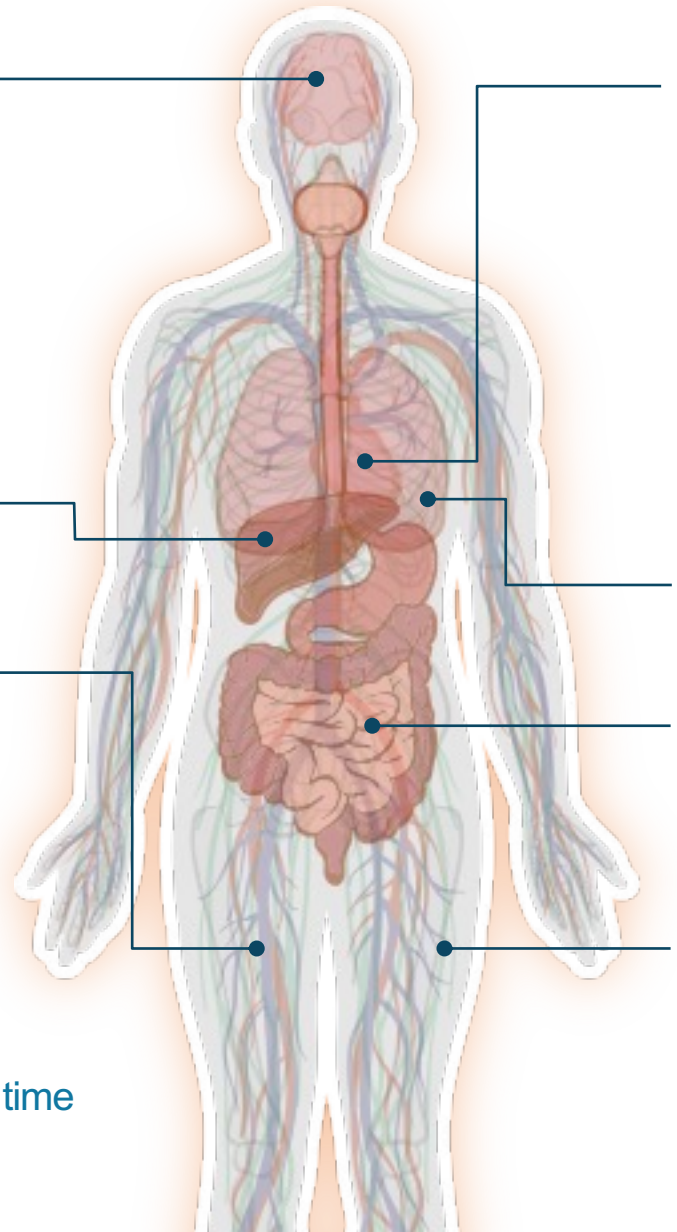
- Headaches
- Delirium
- Aphasia
- Apraxia
- Ataxia
- Hallucinations
- Tremor
- Dysmetria
- Myoclonus
- Facial Nerve palsy
- Seizures

Hepatic

- Transaminitis
- Hyperbilirubinemia

Hematologic

- Anemia
- Thrombocytopenia
- Neutropenia
- Febrile Neutropenia
- Lymphooenia
- B-Cell Aplasia
- Elevated D-Dimer
- Hypofibrinogenemia
- Dissembled Intravascular Coagulation
- Hemophagocytic Lymphohisticyclosis
- Prolonged Prothrombin time
- Prolonged Activated Partial Thromboplastic time



Cardiovascular

- Tachycardia
- Widened pulse pressure
- Hypotension
- Arrhythmias
- Decreased left ventricular ejection fracture
- Elevated Troponins
- QT prolongation

Pulmonary

- Tachypnea
- Hypoxia

Gastrointestinal

- Nausea
- Diarrhea
- Emesis

Musculoskeletal

- Myalgias
- Weakness
- Elevated creatine kinase

Constitutional

- Fevers
- Rigors
- Malaise
- Fatigue
- Anorexia
- Aethralgais

Renal

- Acute kidney injury
- Hyponatremia
- Hypokalemia
- Hypophosphatemia
- Tumor lysis syndrome

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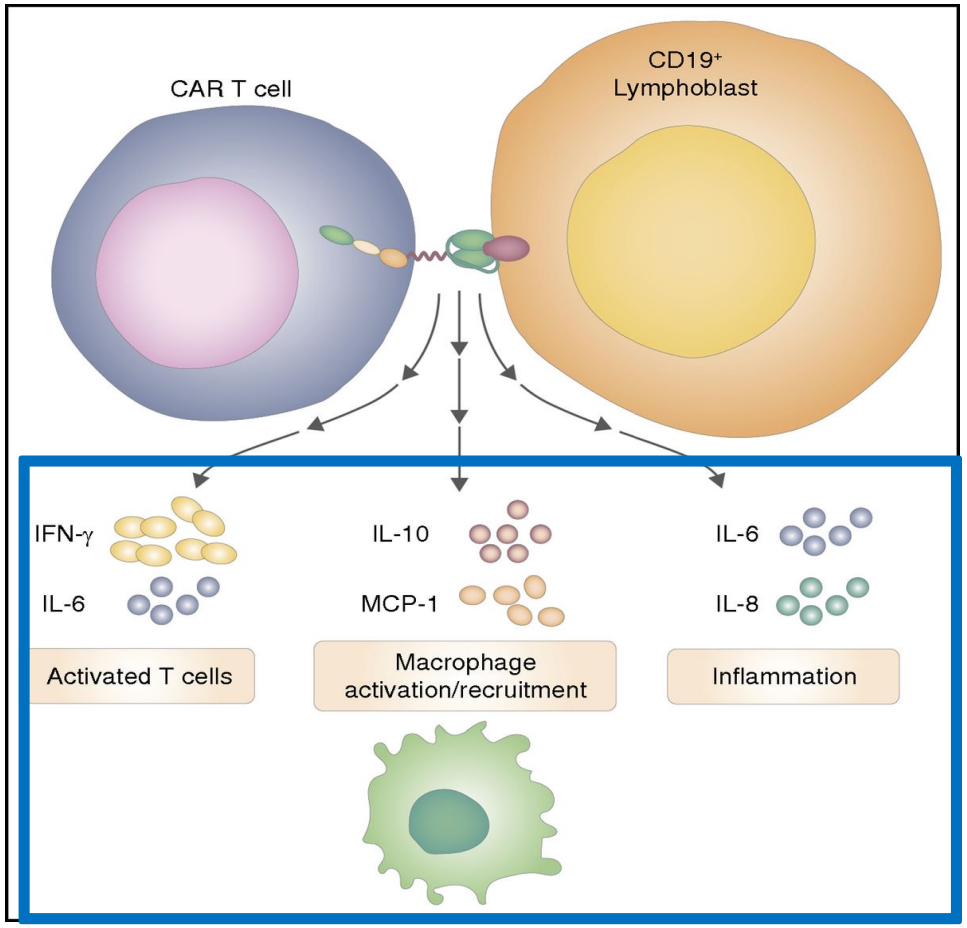
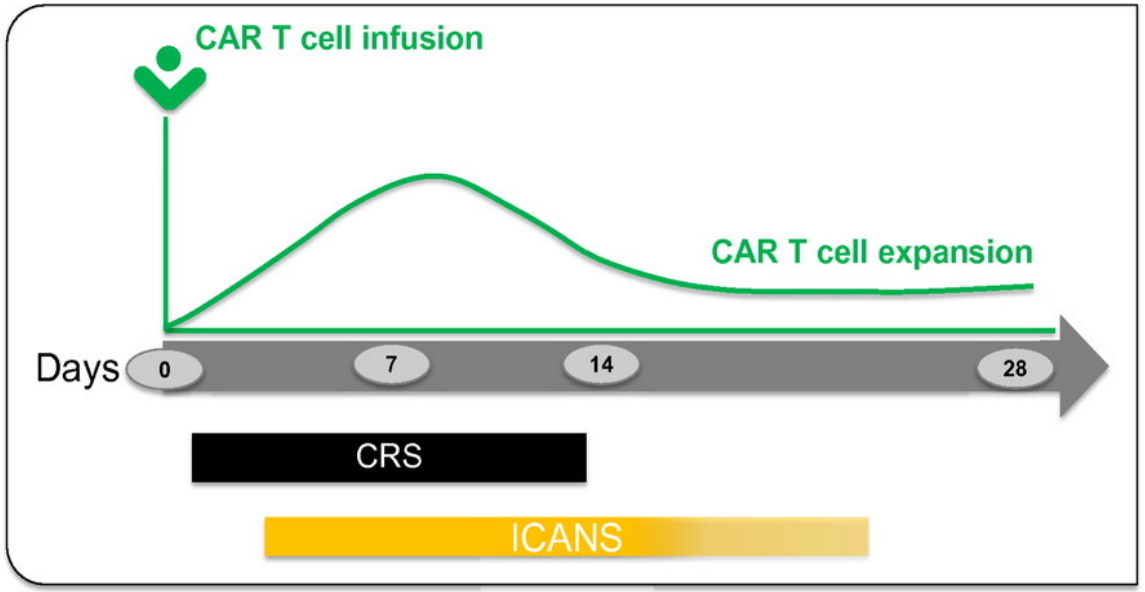
Cytokines drive two key acute toxicities: Cytokine release syndrome and neurotox





Main treatments for CRS and/or ICANS

CRS → IL-6 blockade (tocilizumab - approved)
- Others: siltuximab, steroids, etc.

ICANS → steroids (dexamethasone)
- Others: anakinra, JAK inhibition, etc.

Maude et al., Blood 2017
Santomasso et al., JCO 2019

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We utilize CRS grading to guide treatment decisions

CRS Parameter	Grade 1	Grade 2	Grade 3	Grade 4
Fever	Temperature ≥ 38°C	Temperature ≥ 38°C	Temperature ≥ 38°C	Temperature ≥ 38°C
With				
Hypotension	None	Not requiring vasopressors	Requiring one vasopressor with or without vasopressin	Requiring multiple vasopressors (excluding vasopressin)
And/or*				
Hypoxia	None	Requiring low-flow nasal cannula or blow-by	Requiring high-flow nasal cannula, facemask, nonrebreather mask, or Venturi mask	Requiring positive pressure (e.g., CPAP, BiPAP, intubation and mechanical ventilation)

Abbreviations: ASBMT, American Society of Blood and Marrow Transplantation; BiPAP, bilevel positive airway pressure; CPAP, continuous positive airway pressure; CRS, cytokine release syndrome.

*CRS grade is determined by the more severe event: hypotension or hypoxia not attributable to any other cause.

Santomasso et al., JCO 2019

CRS management (NCCN Guidelines 2022)

CRS Grade	Anti-IL-6 Therapy	Corticosteroids[j,k,l]	Additional Supportive Care
Grade 1 Fever (≥38°C)	For prolonged CRS (>3 days)[h] in p… s… o… t… (not to exceed 800 mg)[i,f]		…s, …F)
Grade 2 Fever with hypotension not requiring vasopressors and/or hypoxia[f] requiring low-flow nasal cannula[g] or blow-by	T… (r… R… in… in… doses total[f]	product[m,n]	• IV fluid bolus as needed • For persistent refractory hypotension after two fluid …ssors, …ogram, …monitoring. …ent • Manage per Grade 3 if no improvement within 24 hours after starting anti-IL-6 therapy • Symptomatic management of organ toxicities
Grade 3 Fever with hypotension requiring a vasopressor with or without vasopressin and/or hypoxia requiring high-flow cannula,[g] face mask, nonrebreather mask, or Venturi mask.	A… if… 24…		…U, obtain echocardiogram, and perform …monitoring …oxygen …nd vasopressors as needed …anagement of organ toxicities
Grade 4 Fever with hypotension requiring multiple vasopressors (excluding vasopressin) and/or hypoxia requiring positive pressure (eg, CPAP, BiPAP, intubation, mechanical ventilation).	A… if… 24…		…modynamic monitoring …lation as needed …l vasopressors as needed …nagement of organ toxicities

Grade 1 → tocilizumab for very early CRS or persistent G1 CRS
- **Supportive care**

Grade 2 → tocilizumab (+/- steroids if persistent/refractory)
- **Supportive care, consider ICU**

Grade 3 → tocilizumab + steroids
- **Supportive care, ICU management**

Grade 4 → tocilizumab + high-dose steroids
- **Supportive care, ICU management**
- **Consider HLH management**

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We also utilize IEC-Associated Neurotoxicity Syndrome (ICANS) scoring to guide treatment decisions

ICE
Orientation: orientation to year, month, city, hospital: 4 points Naming: ability to name 3 objects (eg, point to clock, pen, button): 3 points Following commands: ability to follow simple commands (eg, "Show me 2 fingers" or "Close your eyes and stick out your tongue"): 1 point Writing: ability to write a standard sentence (eg, "Our national bird is the bald eagle"): 1 point Attention: ability to count backwards from 100 by 10: 1 point

Neurotoxicity Domain	Grade 1	Grade 2	Grade 3	Grade 4
ICE score	7–9	3–6	0–2	0 (patient is unarousable and unable to perform ICE)
Depressed level of consciousness	Awakens spontaneously	Awakens to voice	Awakens only to tactile stimulus	Patient is unarousable or requires vigorous or repetitive tactile stimuli to arouse; stupor or coma
Seizure	NA	NA	Any clinical seizure focal or generalized that resolves rapidly; or nonconvulsive seizures on EEG that resolve with intervention	Life-threatening prolonged seizure (> 5 min); or repetitive clinical or electrical seizures without return to baseline in between
Motor findings	NA	NA	NA	Deep focal motor weakness such as hemiparesis or paraparesis
Raised ICP/cerebral edema	NA	NA	Focal/local edema with or without hemorrhage on neuroimaging	Diffuse cerebral edema on neuroimaging; decerebrate or decorticate posturing; or cranial nerve VI palsy; or papilledema; or Cushing triad

Abbreviations: ASBMT, American Society of Blood and Marrow Transplantation; EEG, electroencephalogram; ICANS, immune effector cell–associated neurologic syndrome; ICE, Immune Effector Cell Encephalopathy screening tool; ICP, intracranial pressure; NA, not applicable.

ICANS management (NCCN Guidelines 2022)

Treatment by Grade	No Concurrent CRS[x]	Additional Therapy if Concurrent CRS
Grade 1[v]	• Suppor	b 8 mg/kg IV over 1 hour (not to 0 mg/dose)[aa, †]
Grade 2	• Suppor • 1 dose hours,	6–12 Anti-IL-6 therapy as per Grade 1[aa] Consider transferring patient to ICU if neurotoxicity associated with grade ≥2 CRS
Grade 3[w]	• ICU care is recommended • Dexam every • Consid persist	
Grade 4[w]	• ICU care, consider mechanical ventilation for airway protection • High-d • Consi persis • Treat convulsive status epilepticus per institutional guidelines.	

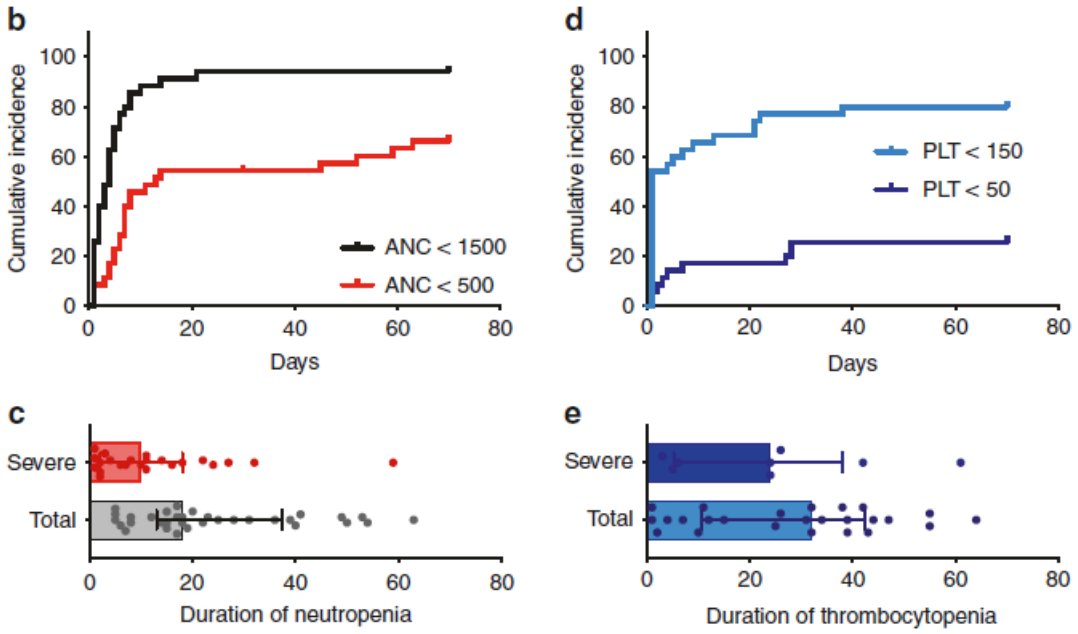
Grade 1 → Supportive care (?consider steroids?)

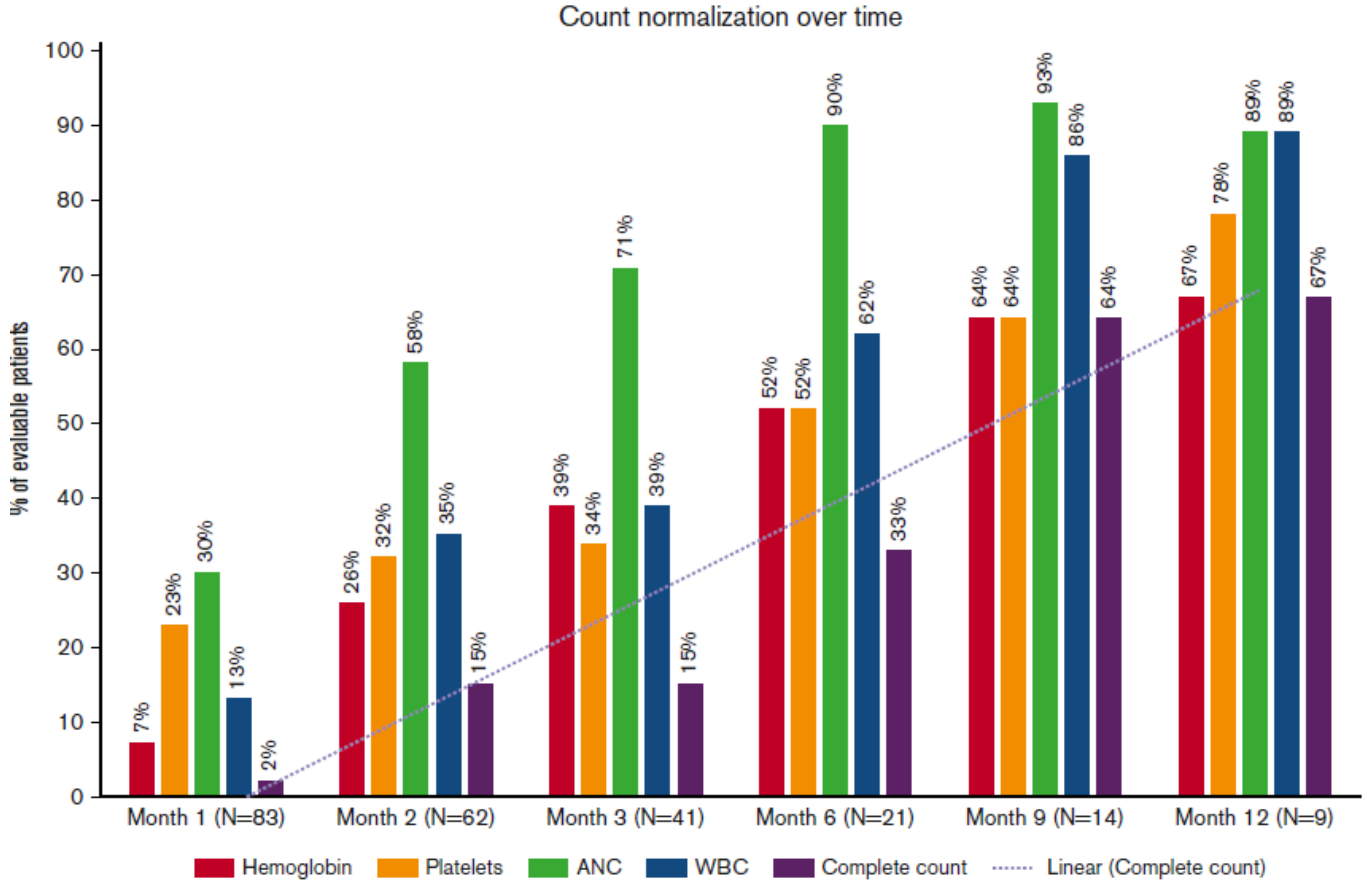
Grade 2 → Steroids, supportive care

Grade 3 → Higher dose steroids
- ICU level care, CNS imaging, assess for seizures

Grade 4 → Very high-dose steroids
- ICU level care, CNS imaging, assess for seizures

Severe (and prolonged) cytopenias are common after CAR T cell therapy





Fried et al BMT 2019; Jain et al., Blood Advances 2020

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How do we choose between CAR T products in specific diseases?

- Availability and access (unfortunately)
  - Collection slots
  - Insurance approvals
  - Overall access to care [we need better access]
- Patient factors (co-morbidities, age, etc.)
- Clinical trial availability

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Bottom Line: Whom to refer, and when

- ALL
  - First relapse unless *very* unfit
- DLBCL
  - First relapse if primary refractory/early relapse
  - Otherwise second relapse
- MCL
  - Second relapse, fit
- FL
  - Second relapse – and now, perhaps post-bispecific?
- MM
  - Fourth relapse after SOC exhausted – again, perhapse post-bispecific?

Bottom Line: Whom to refer, and when

- ALL
  - First relapse unless *very* unfit
- DLBCL
  - First relap
  - Otherwise
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  - Second relapse – and now, perhaps post-bispecific?
- MM
  - Fourth relapse after SOC exhausted – again, perhapse post-bispecific?

Partner with your local CAR-T providers -
We'd rather get involved too early than too late!

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Current Status of CAR-T Therapy in Hematology

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