2025 Oncology Fellows Program:
New Horizons in Quality Cancer Care™

Exploring New Frontiers in Cancer Treatment: The Expanded Role of Cellular Therapies

Christopher R. D'Angelo, MD
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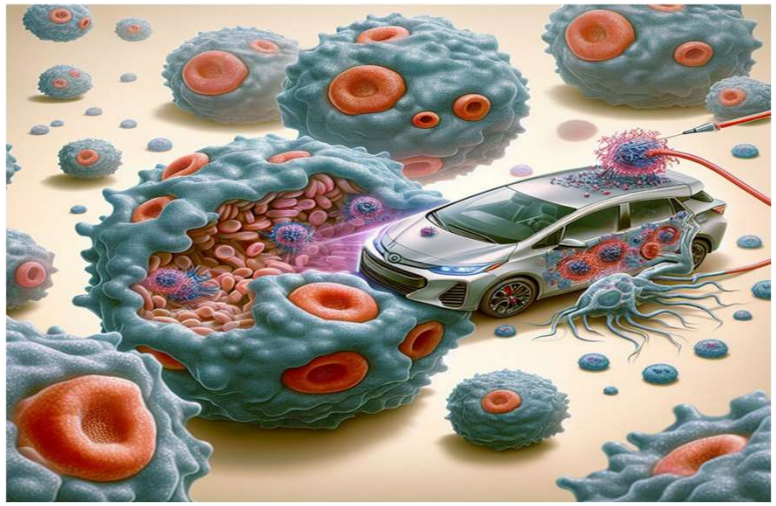
New Frontiers in CAR T-Cell Therapy for Hematologic Malignancies

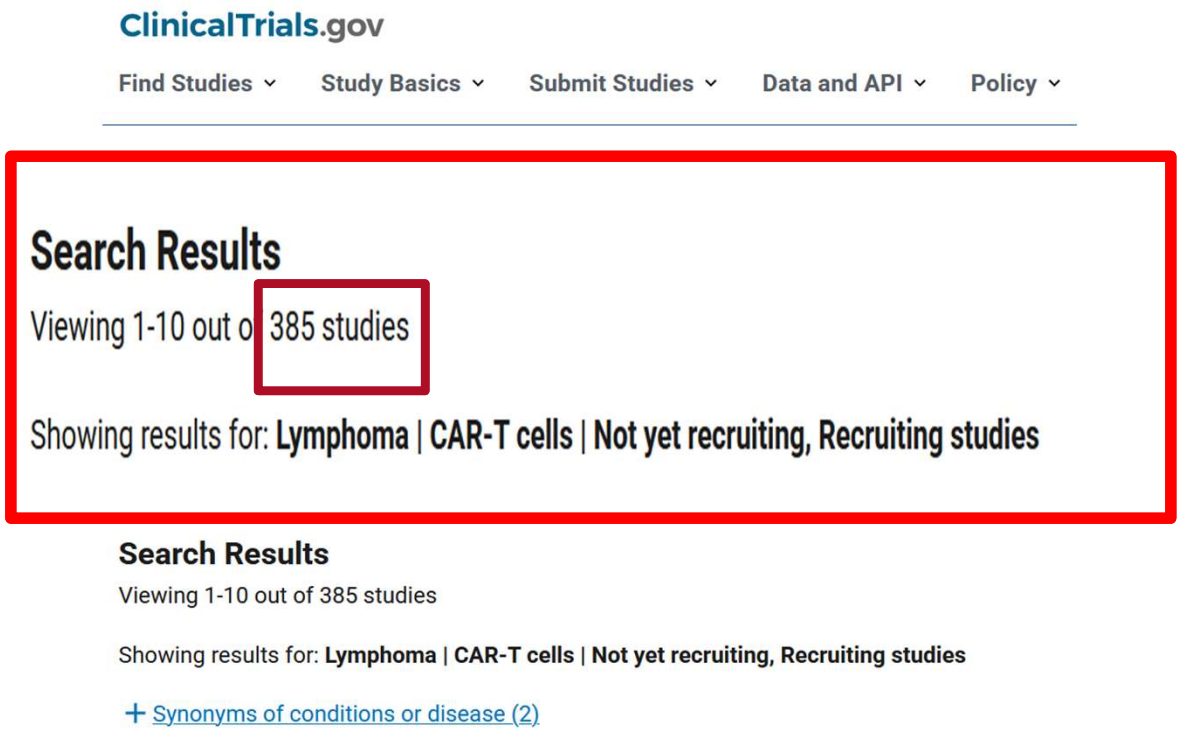
NCCN 2025 Oncology Fellows Program: New Horizons in Quality Cancer Care™



Christopher D'Angelo, MD
Assistant Professor, Hematology/Oncology
University of Nebraska Medical Center

University of Nebraska Medical Center

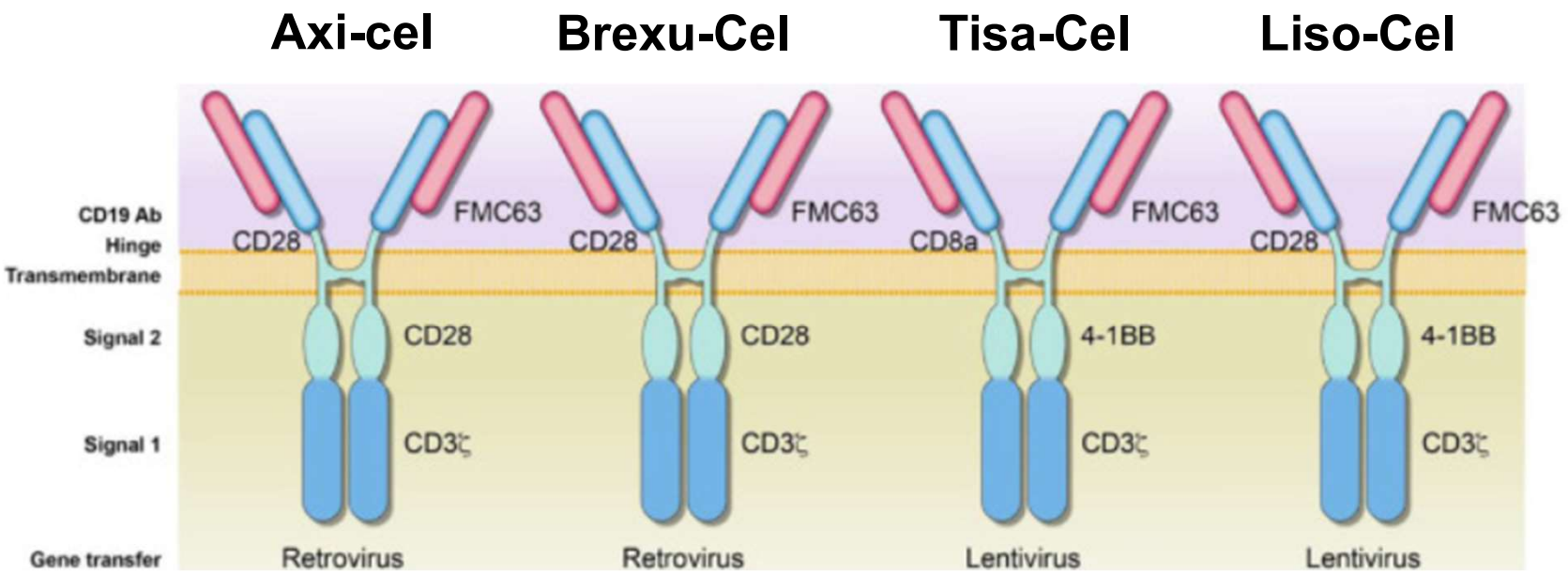
Challenge: Accepted



Content Outline

- Review the current landscape and challenges
  - Lymphoma and myeloma
- Discuss the blueprint for advances
  - Innovation opportunities
- Highlight emerging successes

CAR T: CD19 for B-cell NHL

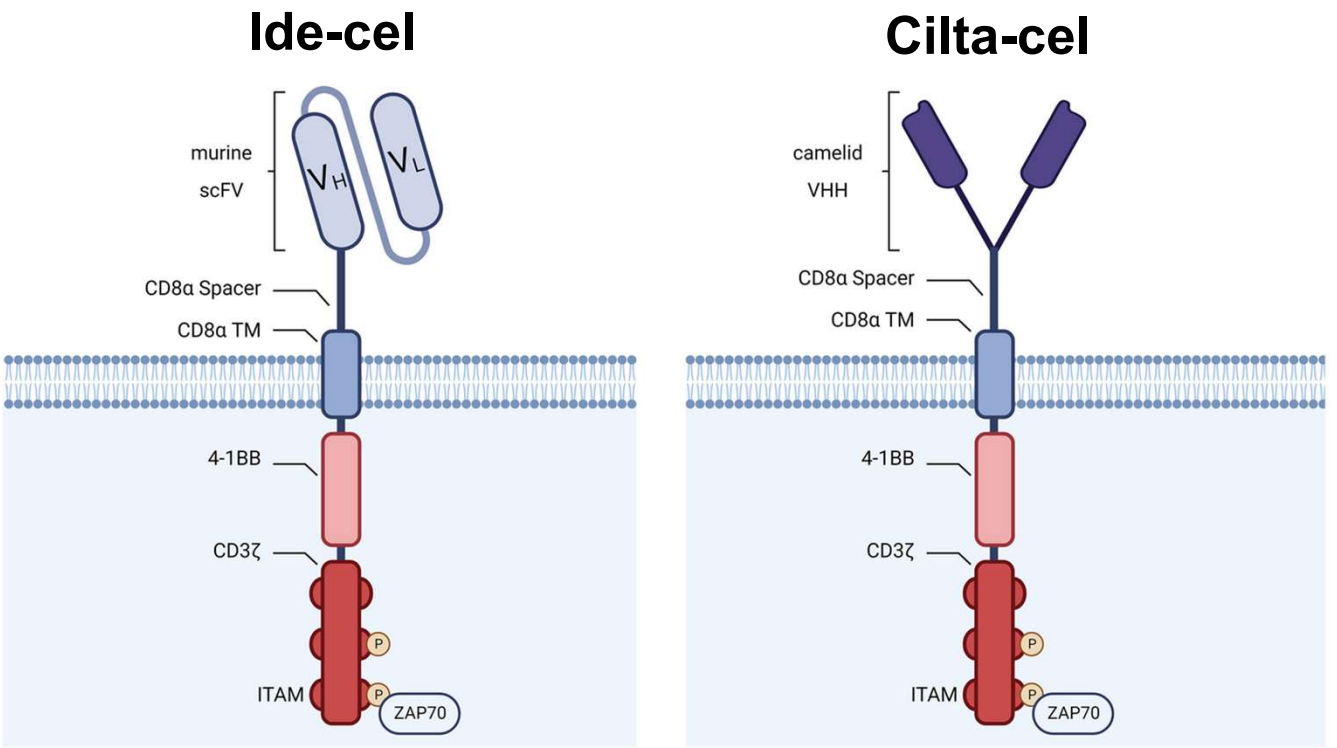


Berger et al, Gene and Cellular Immunotherapy 2022

Lymphoma Indications

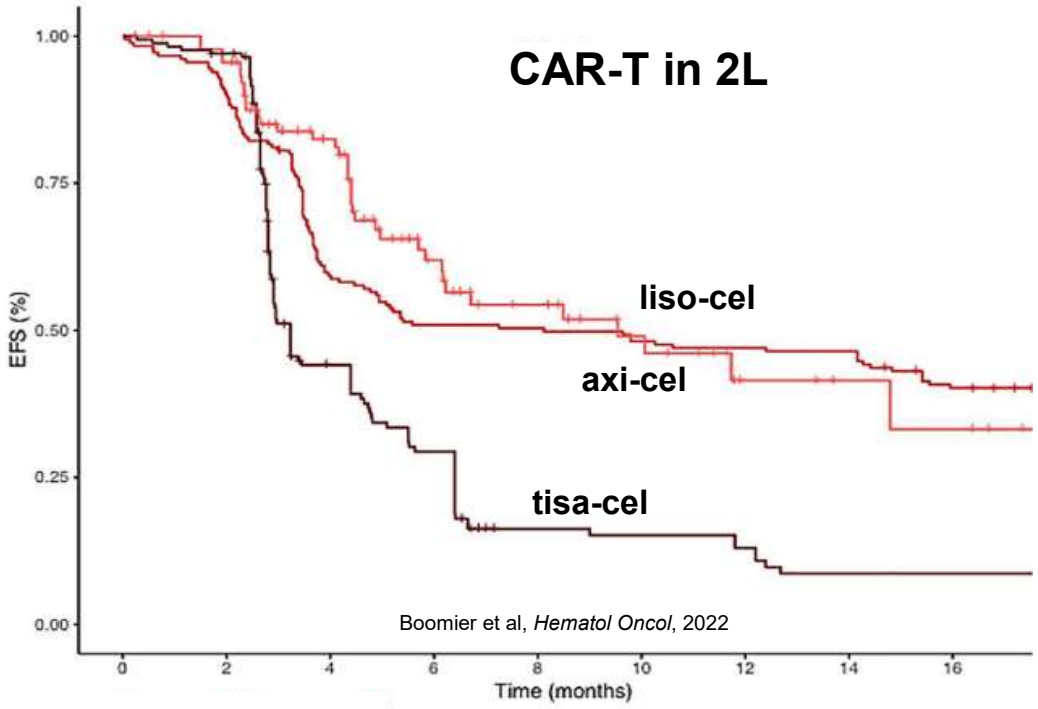
- Liso-cel
  - Diffuse Large B-cell lymphoma
  - Follicular Lymphoma
  - Mantle Cell lymphoma
- Axi-cel
  - DLBCL
  - Follicular lymphoma
- Brexu-cel
  - Mantle Cell lymphoma

CAR T: BCMA in Multiple Myeloma



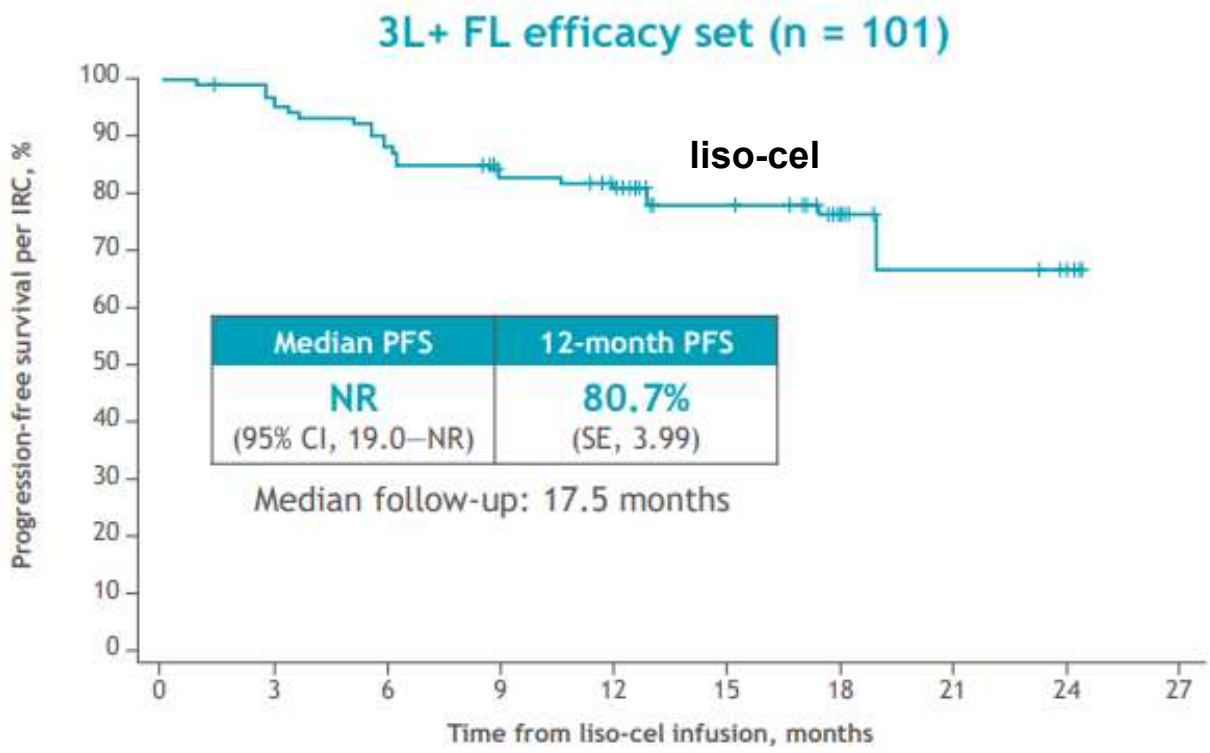
Scheller et al, Leukemia & Lymphoma 2023

Problem: most DLBCL patients will relapse post CAR T



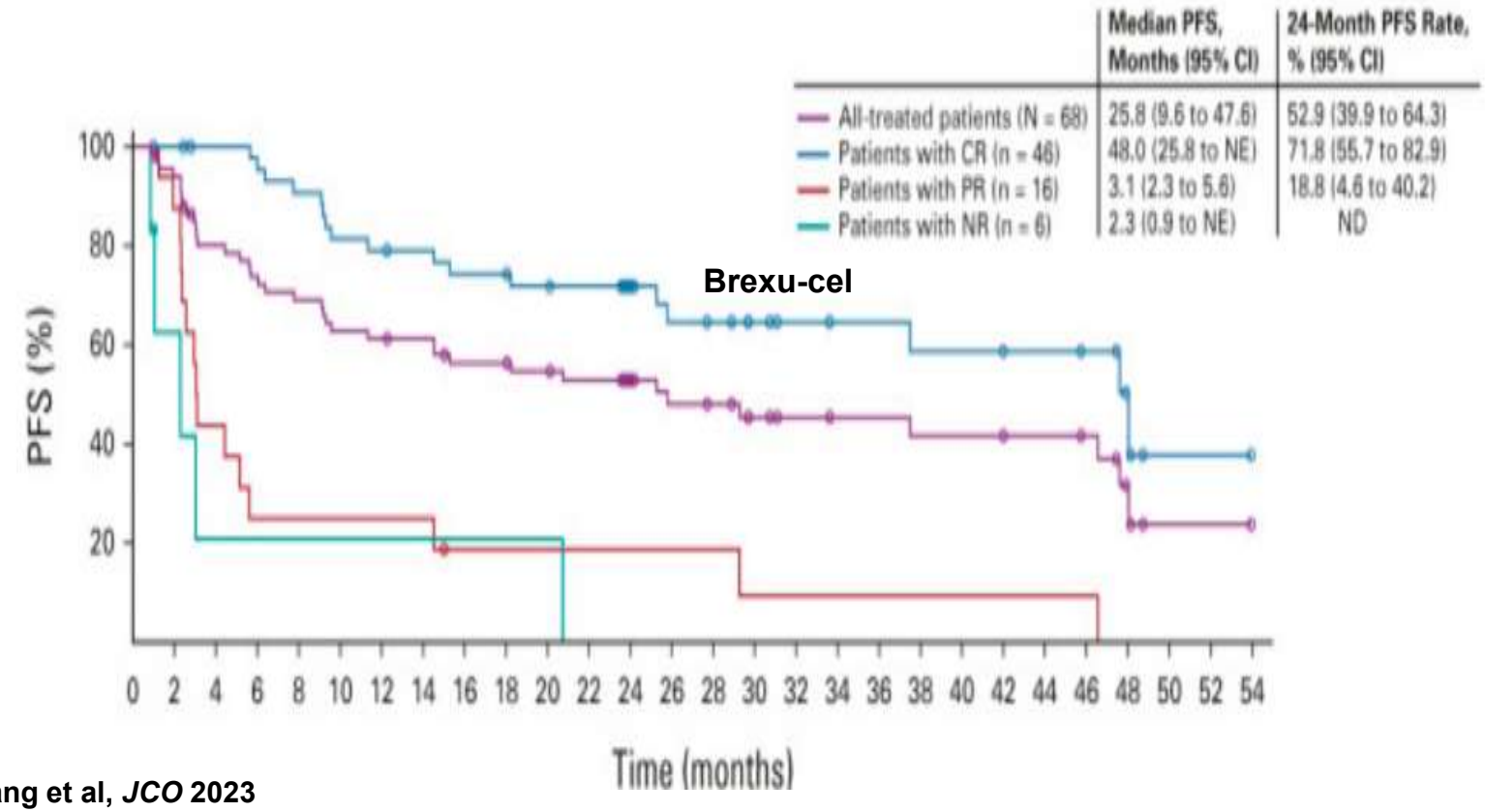
Boomier et al, *Hematol Oncol*, 2022

Problem: FL patients will relapse post CAR T



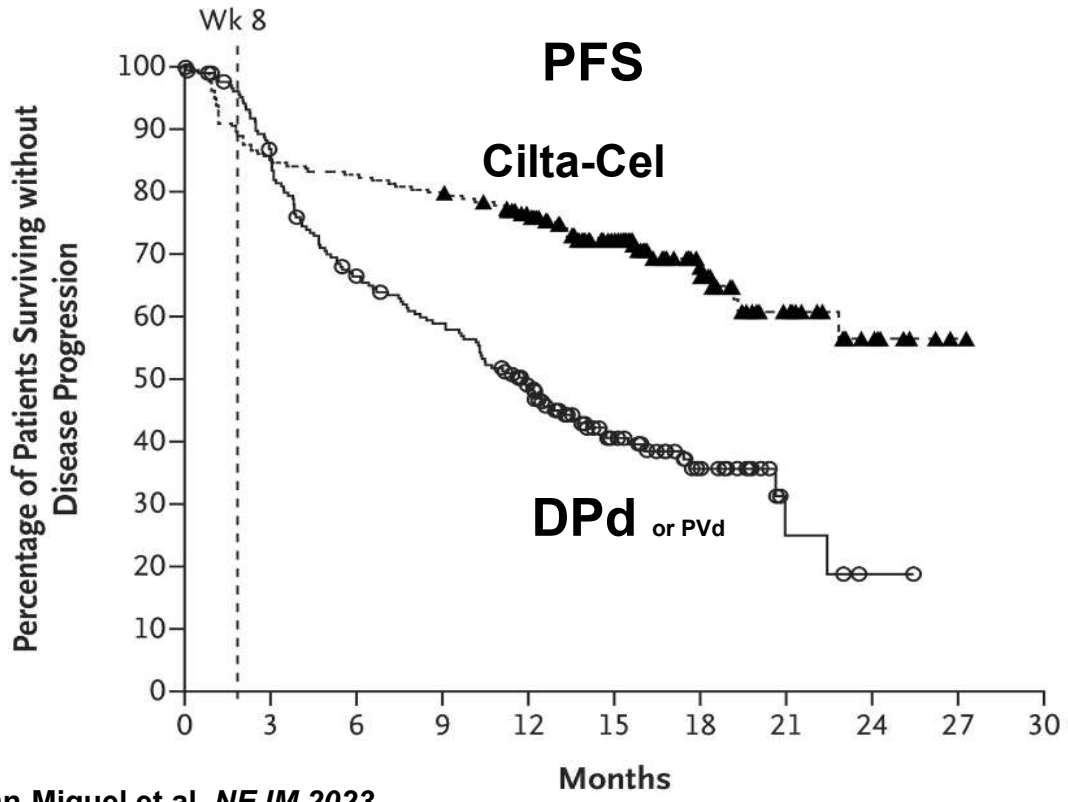
Morschhauser et al, *ICML 2023 LBA4* 6/2023

Problem: MCL patients will relapse post CAR T



Wang et al, *JCO* 2023

Problem: Myeloma is Incurable



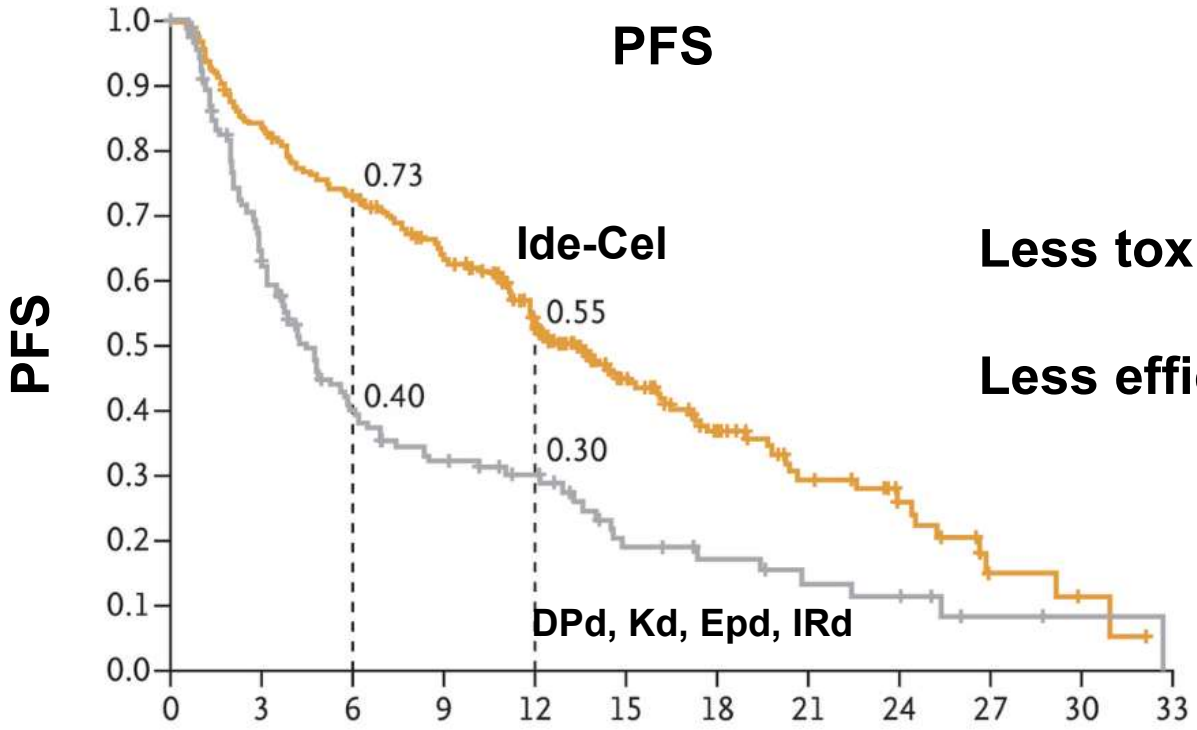
San-Miguel et al, *NEJM 2023*

Neurotoxicity

Infection

IEC-HLH

Problem: Myeloma is Incurable



Less toxicity

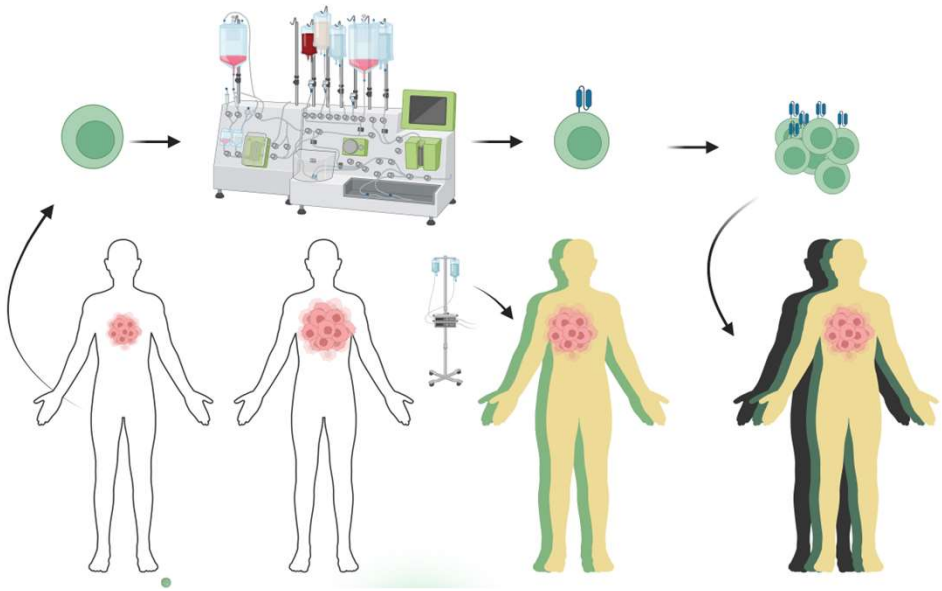
Less efficacy

Rodriguez-Otero, *NEJM 2023*

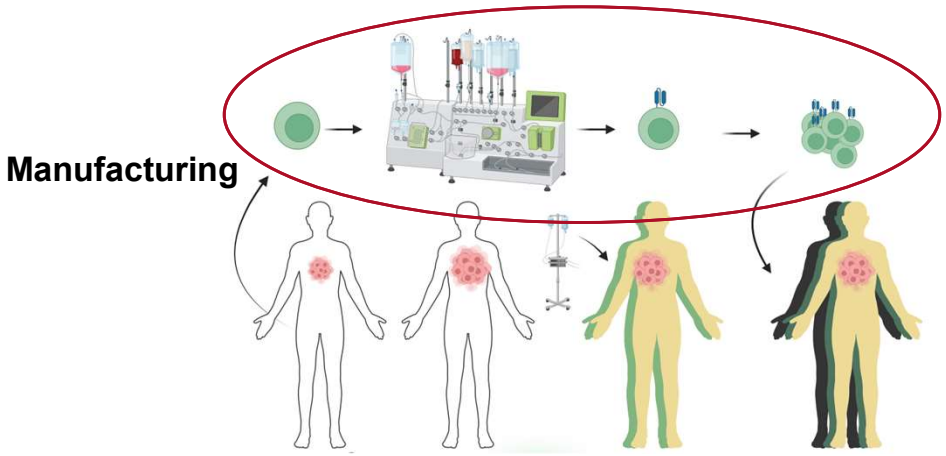
Problem: Toxicity

- Cytokine Release Syndrome manageable with tocilizumab
- ICANS: immune effector cell associated neurotoxicity
  - More difficult to treat
  - More success with higher doses of anakinra
- IEC-HS: immune effector cell hemophagocytic syndrome
  - Requires early recognition, prompt immunosuppression
- ICAHT: immune effector cell associated hematologic toxicity
  - Early vs late
  - Severity based on degree of neutropenia
- Infection
  - Prophylaxis is key
    - Esp with BCMA CAR T
- Delayed Neurotoxicity
  - Rare, disabling, fatal
  - ICANS may lead to more subtle chronic neurocognition issues

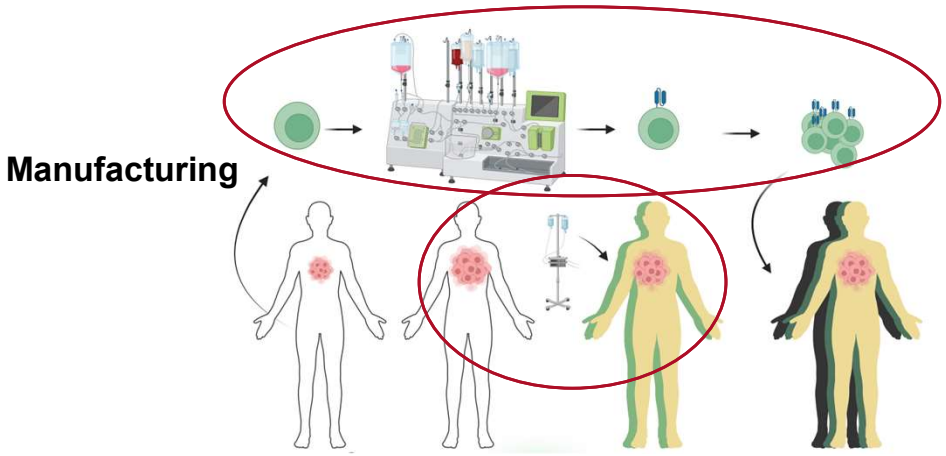
How We Can Improve



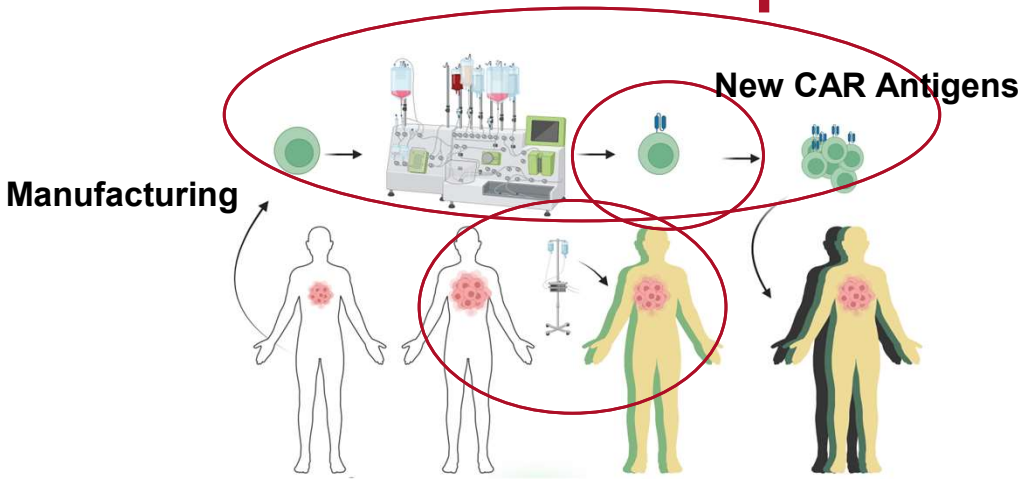
How We Can Improve



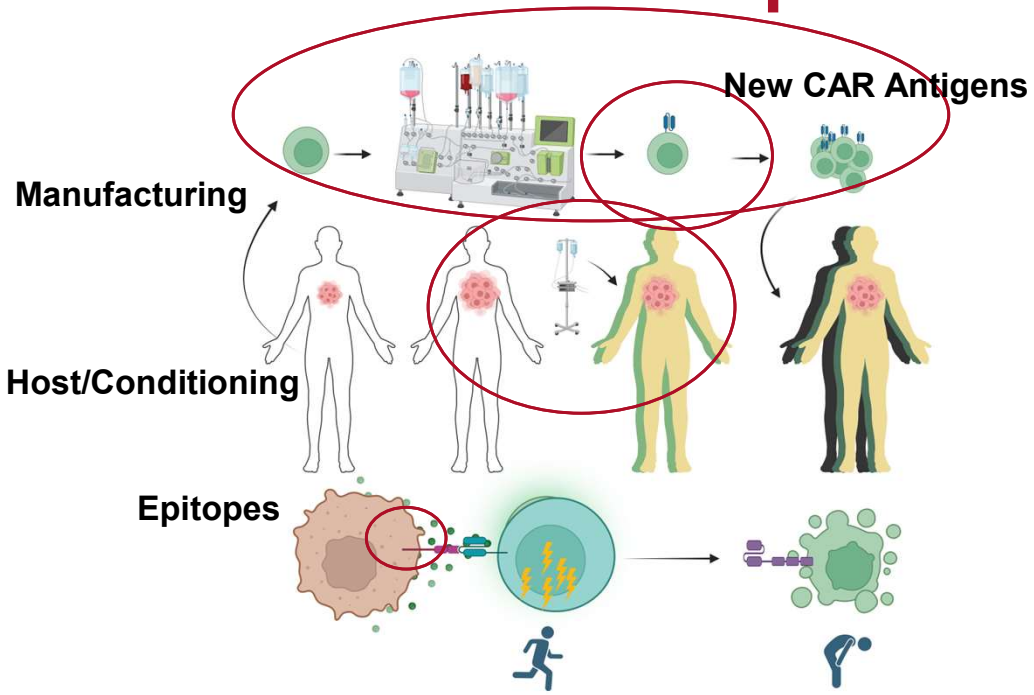
How We Can Improve



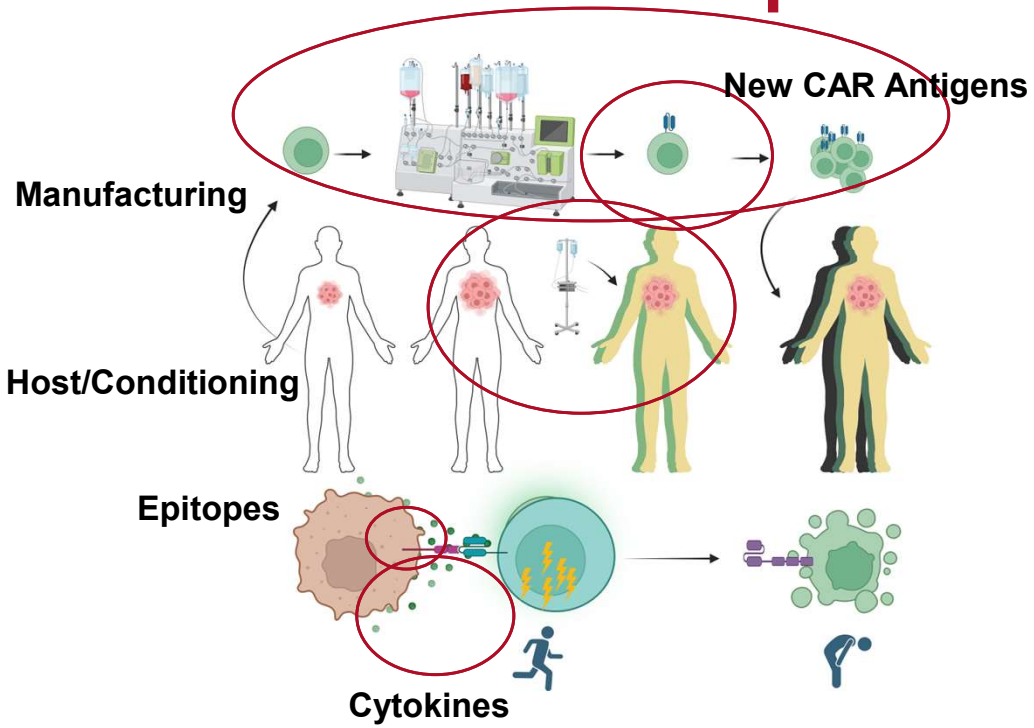
How We Can Improve



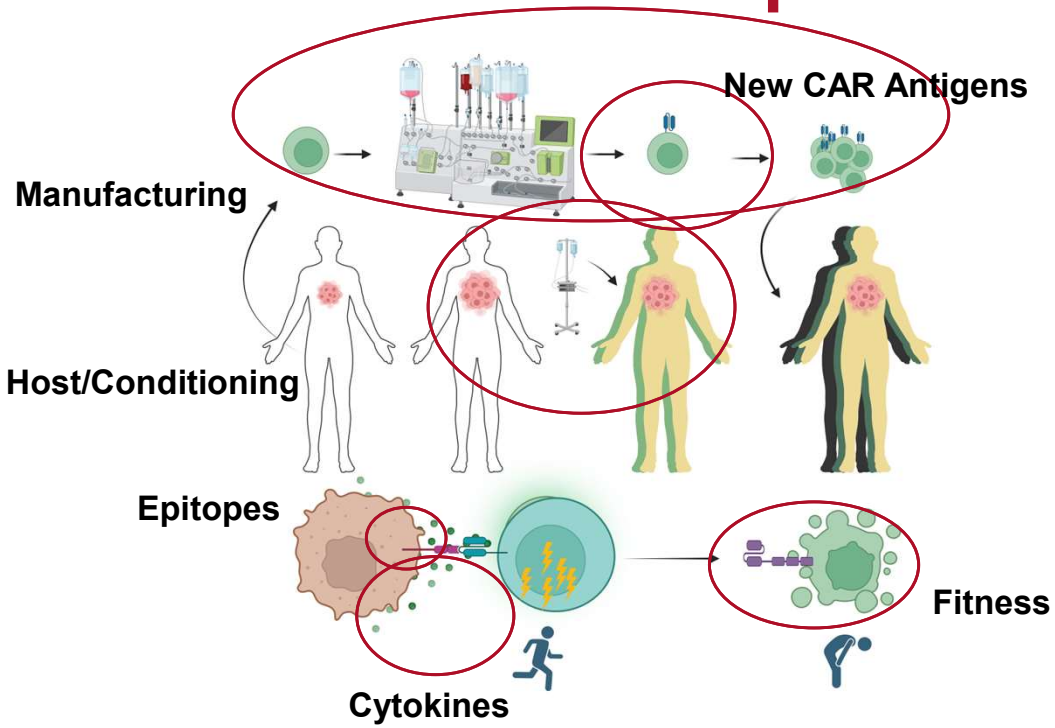
How We Can Improve



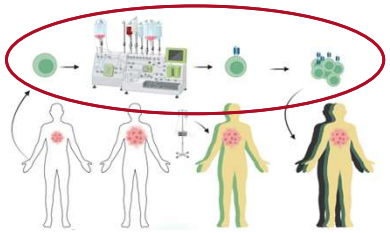
How We Can Improve



How We Can Improve



Manufacturing



- Liso-cel vein to vein: 36 days!
- Cilta-cel : 70 days!

blood®

ISSUES FIRST EDITION ABSTRACTS COLLECTIONS

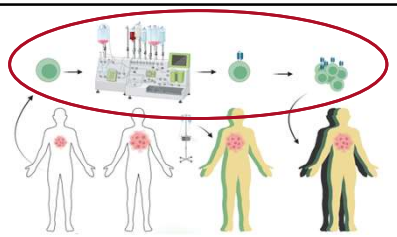
628.AGGRESSIVE LYMPHOMAS: CELLULAR THERAPIES | NOVEMBER 5, 2024

Interim Results from a Phase 2 Pivotal Study (DALY II USA) of Tandem CD20-CD19-Directed Non-Cryopreserved CAR-T Cells - Zamtocabtagene Autoleucel (Zamto-Cel) in Patients with Relapsed/Refractory Diffuse Large B Cell Lymphoma

Nirav N. Shah, Richard T. Maziarz, Caron A. Jacobson, Patrick B. Johnston, Sunil Abhyankar, Iris Isufi, Miguel Angel Perales,

Shah et al, ASH 2024

Manufacturing

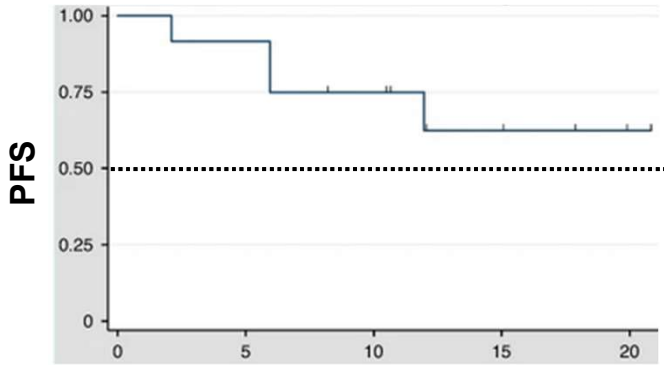


Zamto-cel

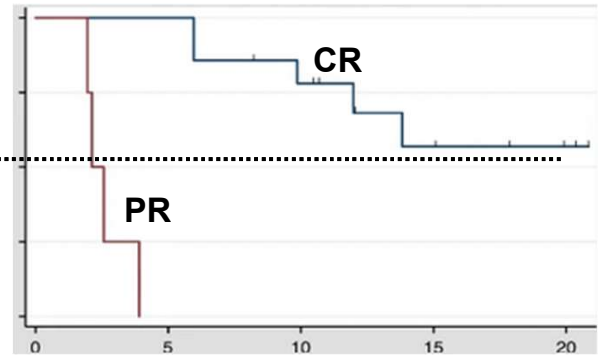
vein to vein **14 days**
CD19/CD20 dual targeting
fresh (not cryopreserved)
on-site manufacture

Phase 2 ASH 2024,
n=66
CR: 50%
1 yr PFS: 42%

PFS from Phase 1 n=12



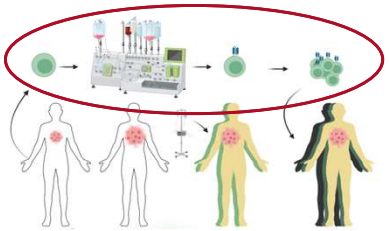
Duration of Response from Phase 1



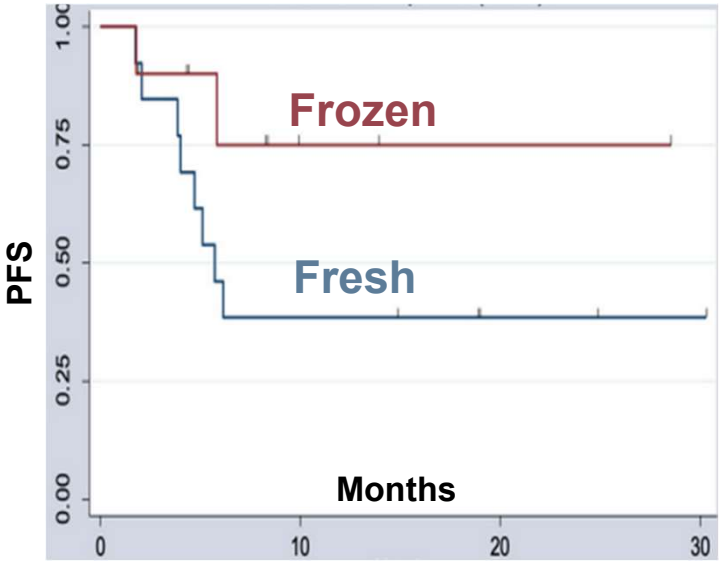
Shah et al, Nature Med, 2020

Manufacturing

Fresh vs Frozen, better T-cells?

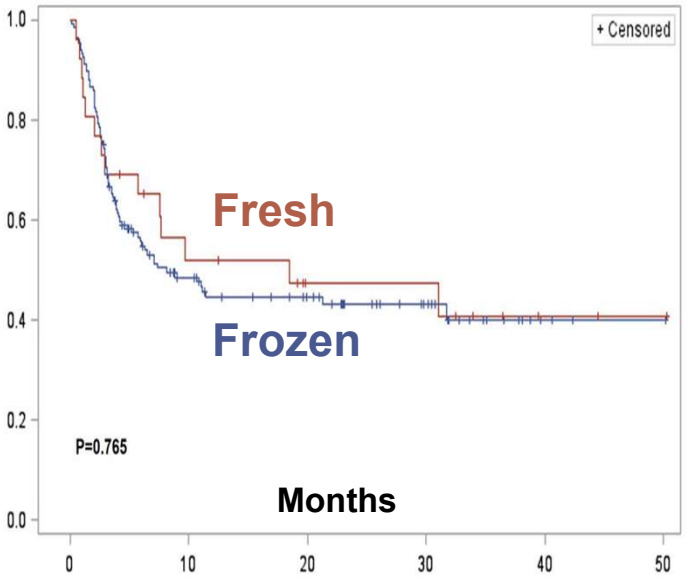


Zamto-cel PFS



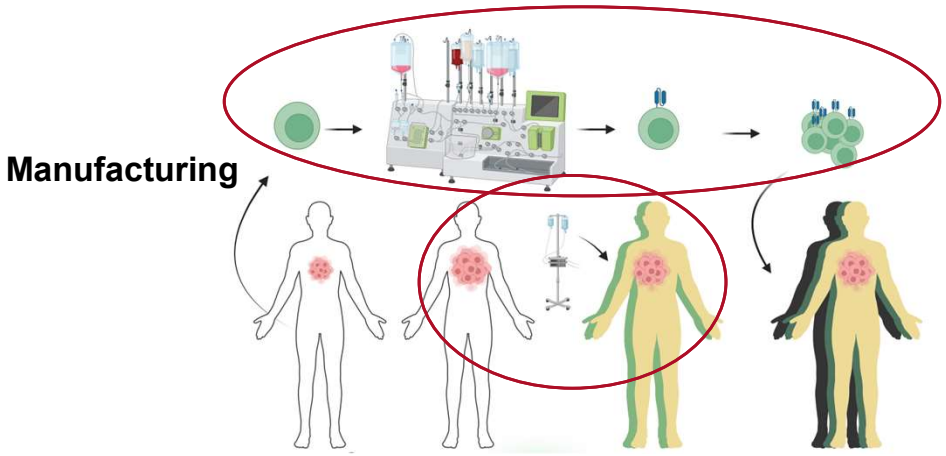
Furqan et al, TCT 2024

Retrospective PFS CD19/41BB



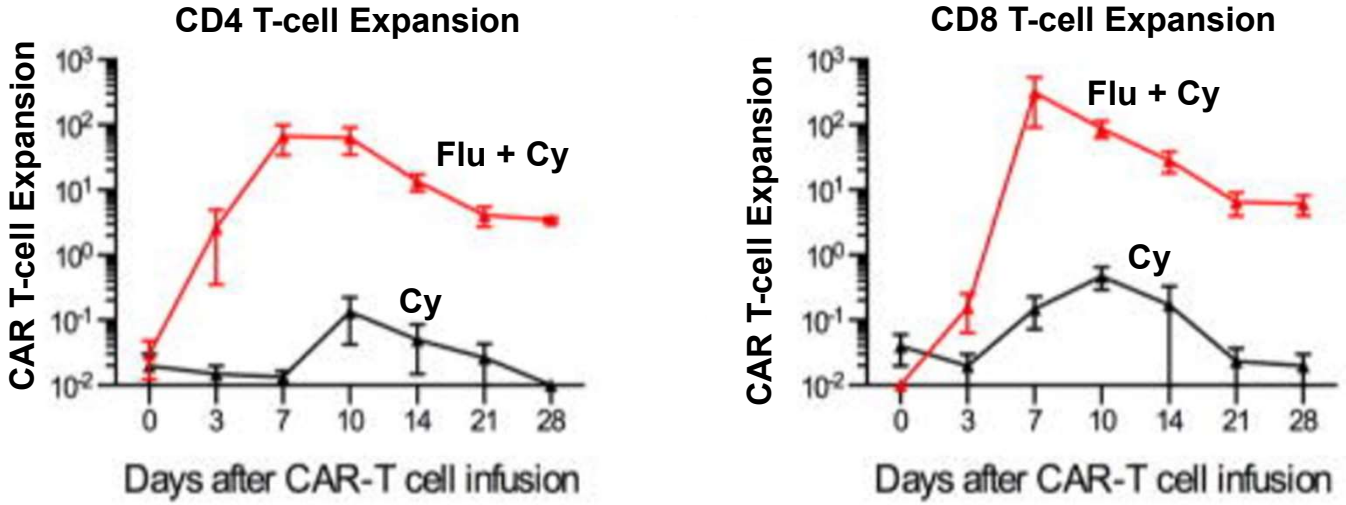
Xu et al, ASH 2023

How We Can Improve



Conditioning: immunology

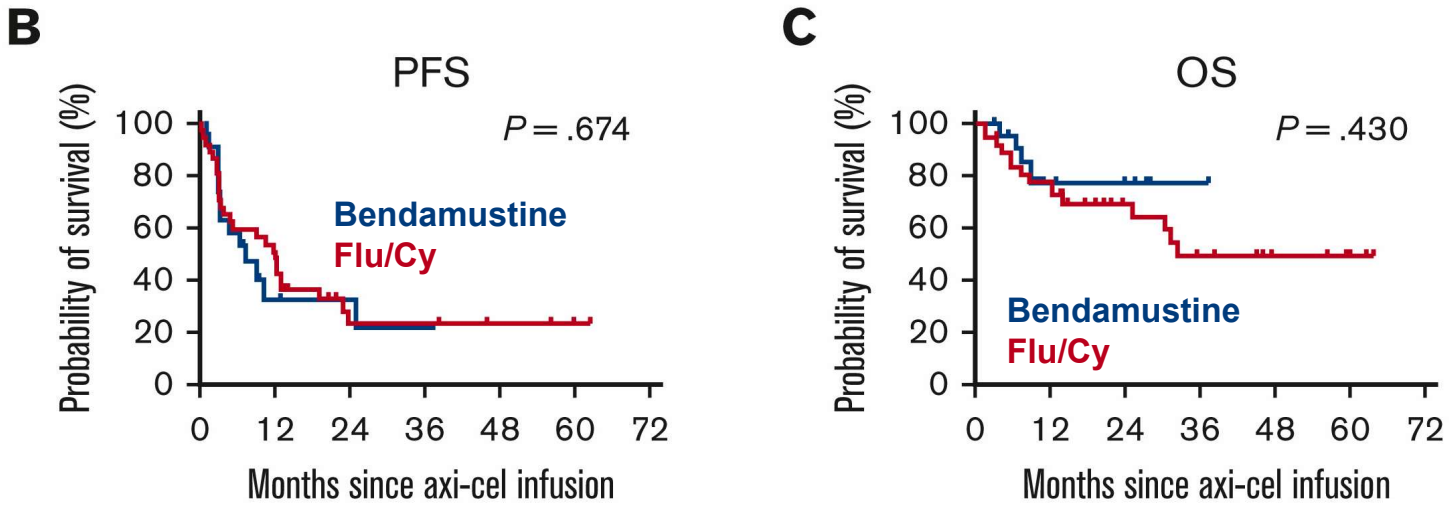
- Lymphodepletion: historic, iterative testing
- Decrease host immune response to murine CAR
- Cytokine wave post chemo:
- Flu/Cy: CR **50%**, Cy: **8%**



Brentjens et al, *Blood* 2011, Turtle et al, *Science Trans Med,* 2017

Conditioning

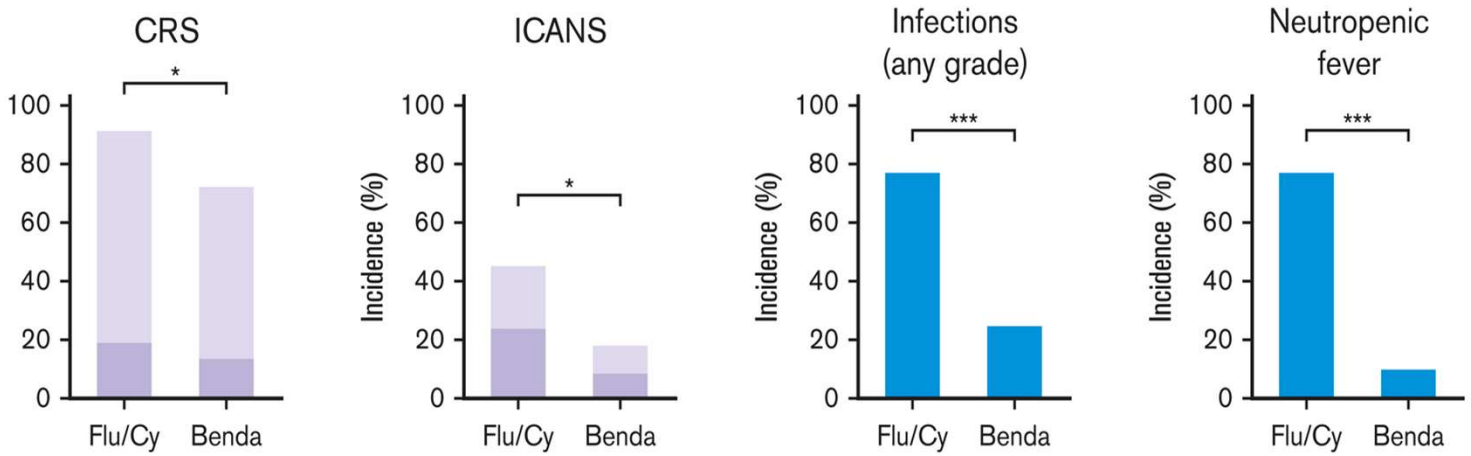
- Flu/Cy vs bendamustine
- Retrospective, n= 60



Ghilardi et al, *Blood Advances,* 2024

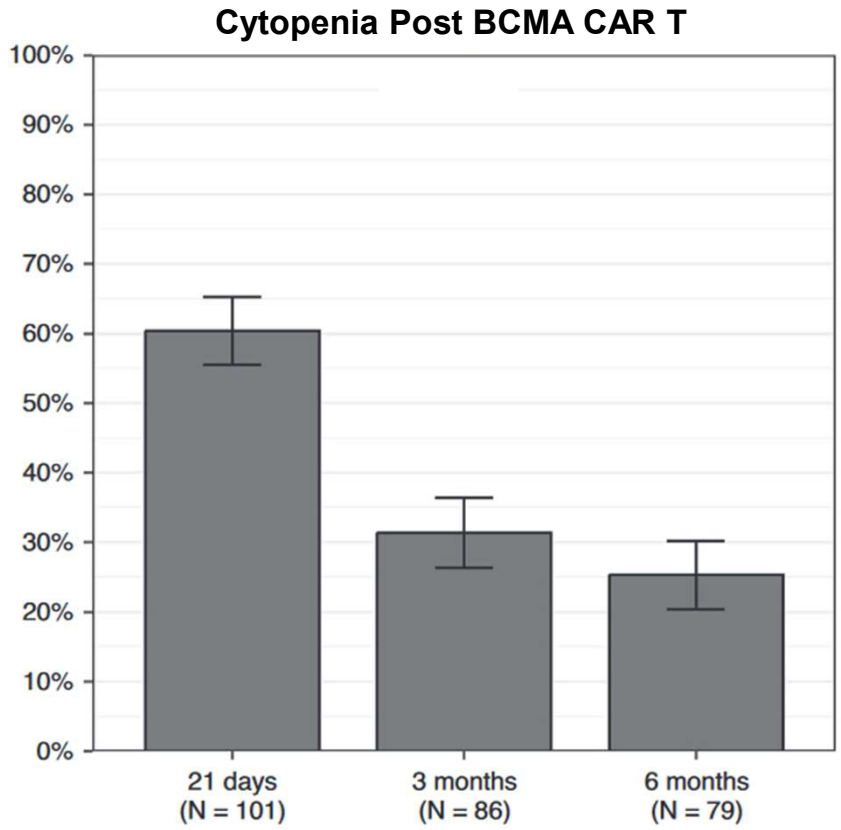
Conditioning

- Flu/Cy vs bendamustine
- Retrospective, n= 60



Ghilardi et al, *Blood Advances,* 2024

Toxicity: ICAHT



Mohan et al, Bone Marrow Transplant, 2024

ICAHT

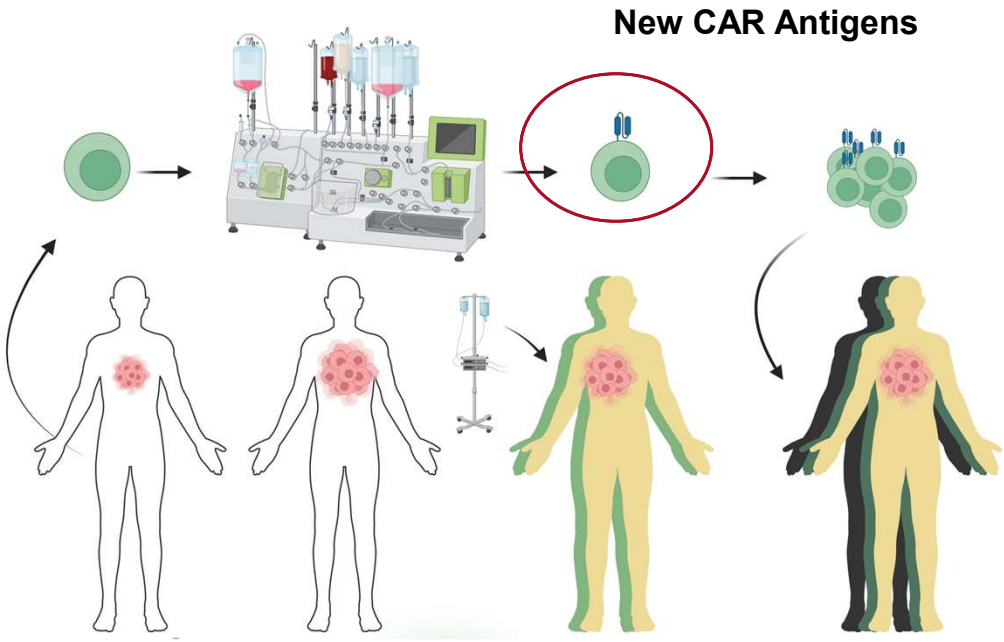
Effect of Stem Cell Boost

	Pre	Post (3mo)	*P*
ANC	720	3000	***
Plt	30K	127K	**
Hgb	8.8	11	***

N =14
P *** <0.001, ** 0.001
Median CD34+ boost: 3.84 x10^6 (1.0 -9)

Mohan et al, Bone Marrow Transplant, 2024

How We Can Improve



New Targets: CD22

- **Specific** to B-cells
- **Expressed** broadly on B-cell cancers
- **Efficacy** of targeted ADCs

CD22-directed CAR T-cell therapy for large B-cell lymphomas progressing after CD19-directed CAR T-cell therapy: a dose-finding phase 1 study

Matthew J Frank, John H Baird*, Anne Marijn Kramer*, Hrishikesh K Srinagesh, Shabnum Patel, Annie Kathleen Brown, Jean S Oak, Sheren F Younes, Yasodha Natkunam, Mark P Hamilton, Yi-Jiun Su, Neha Agarwal, Harshini Chinnasamy, Emily Egeler, Sharon Mavroukakis, Steven A Feldman, Bita Sahaf, Crystal L Mackall, Lori Muffly, David B Miklos, on behalf of the CARdinal-22 Investigator group†*

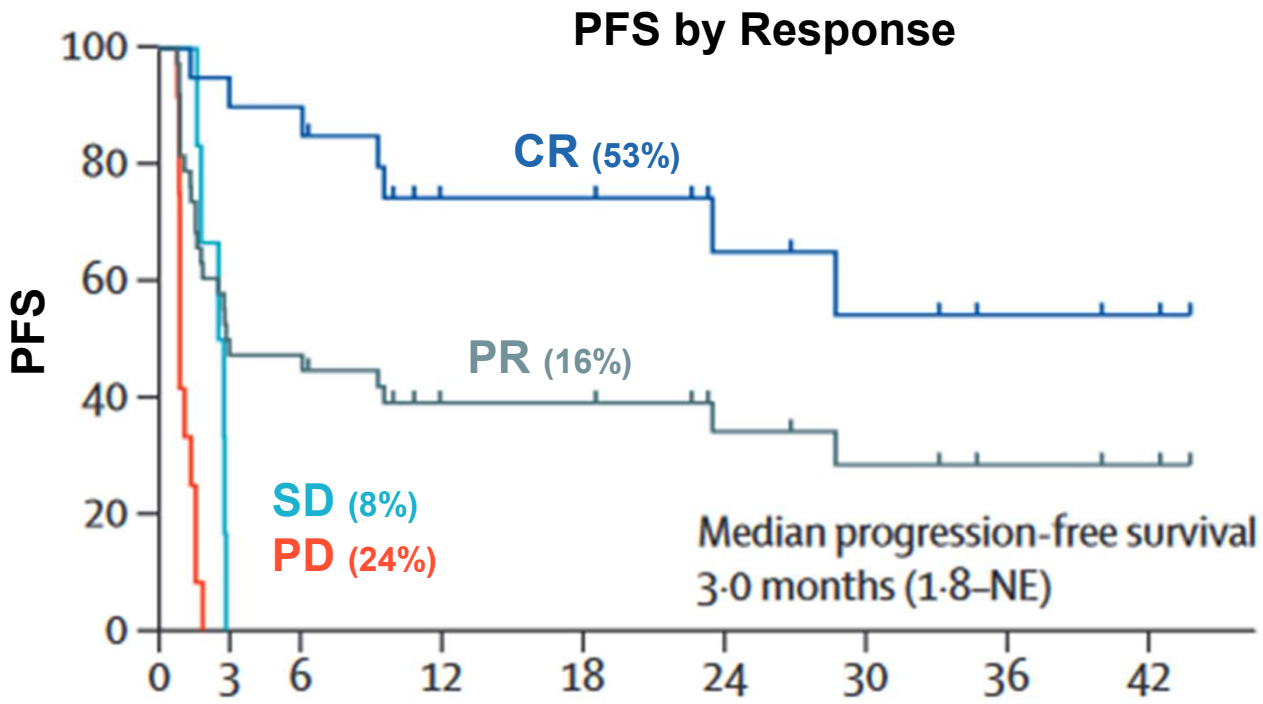
Frank et al, *Lancet,* 2024

New Targets: CD22

- Phase 1 N= 41
- 95%+ aggressive B-cell lymphoma
- 97% prior CD19 CAR T
- CD22, 41BB, fully humanized
- Vein to vein 18 days
- Successfully made and infused 95%
- Median prior CAR response: 3 months

Frank et al, *Lancet,* 2024

New Targets: CD22



Frank et al, *Lancet,* 2024

New Targets: CD22

Toxicity	All n=38	Grade 3+
CRS	95%	3%
ICANS	11%	0%
Infection	42%	5%
HLH	13%	1%

Frank et al, *Lancet,* 2024

New Targets: GPRC5D

- **Some** expression on skin
- **Unknown** function
- **Expressed** broadly on plasma cells
- **Efficacy** of targeted BsAb

ORIGINAL ARTICLE

GPRC5D-Targeted CAR T Cells for Myeloma

Authors: Sham Mailankody, M.B., B.S., Sean M. Devlin, Ph.D., Jonathan Landa, D.O., Karthik Nath, M.B., B.S., Ph.D., Claudia Diamonte, B.S.N., R.N., O.C.N., Elizabeth J. Carstens, M.D., Douglas Russo, M.S., Romany Auclair, M.D., Lisa Fitzgerald, M.S.N., Briana Cadzin, B.S.N., R.N., Xiuyan Wang, Ph.D., Devanjan Sikder, Ph.D., Brigitte Senechal, Ph.D., Vladimir P. Bermudez, Ph.D., Terence J. Purdon, M.S., Kinga Hosszu, Ph.D., Devin P. McAvoy, B.S., Tasmin Farzana, M.P.H., Elena Mead, M.D., Jessica A. Wilcox, M.D., Bianca D. Santomasso, M.D., Ph.D., Gunjan L. Shah, M.D., Urvi A. Shah, M.D., Neha Korde, M.D., Alexander Lesokhin, M.D., Carlyn R. Tan, M.D., Malin Hultcrantz, M.D., Ph.D., Hani Hassoun, M.D., Mikhail Roshal, M.D., Filiz Sen, M.D., Ahmet Dogan, M.D., Ph.D., Ola Landgren, M.D., Ph.D., Sergio A. Giralt, M.D., Jae H. Park, M.D., Saad Z. Usmani, M.D., Isabelle Rivière, Ph.D., Renier J. Brentjens, M.D., Ph.D., and Eric L. Smith, M.D., Ph.D. -30 Author Info & Affiliations

Published September 28, 2022 | N Engl J Med 2022;387:1196-1206 | DOI: 10.1056/NEJMoa2209900

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New Targets: GPRC5D

- **Phase 1 n = 17**
- **Humanized scvf, 41BB, second gen**
- **Prior CAR 47%**
- **Extramedullary dz 47%**
- **High risk cytogenetics: 76%**
  - Included 1q gain

Mailankody et al, *NEJM,* 2022

New Targets: GPRC5D

Median DOR: 8 months

Response	All dose lvls (n=17)
≥ PR	71%
≥ VGPR	59%
≥ CR	35%
MRD undetect	47%

Mailankody et al, *NEJM,* 2022

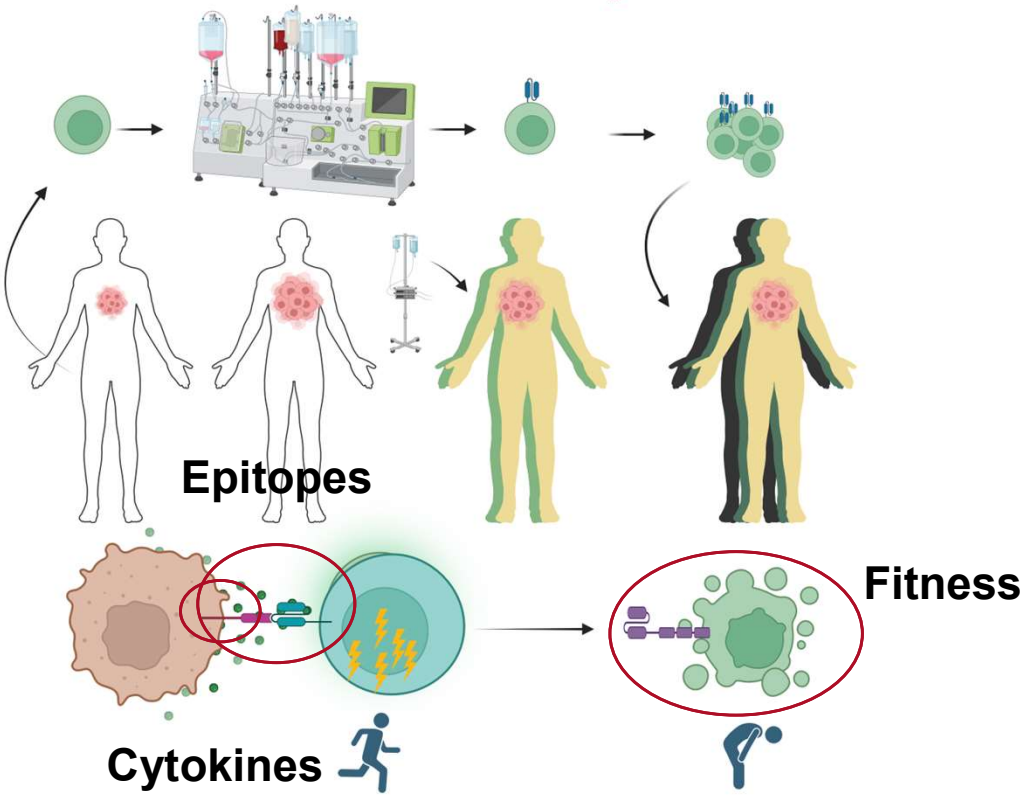
New Targets: GPRC5D

Toxicity	All n=17	Grade 3+
CRS	88%	6%
ICANS	6%	6%
Dysgeusia	12%	0%
Skin/Nail	65%	1%
Cerebellar*	12%	12%

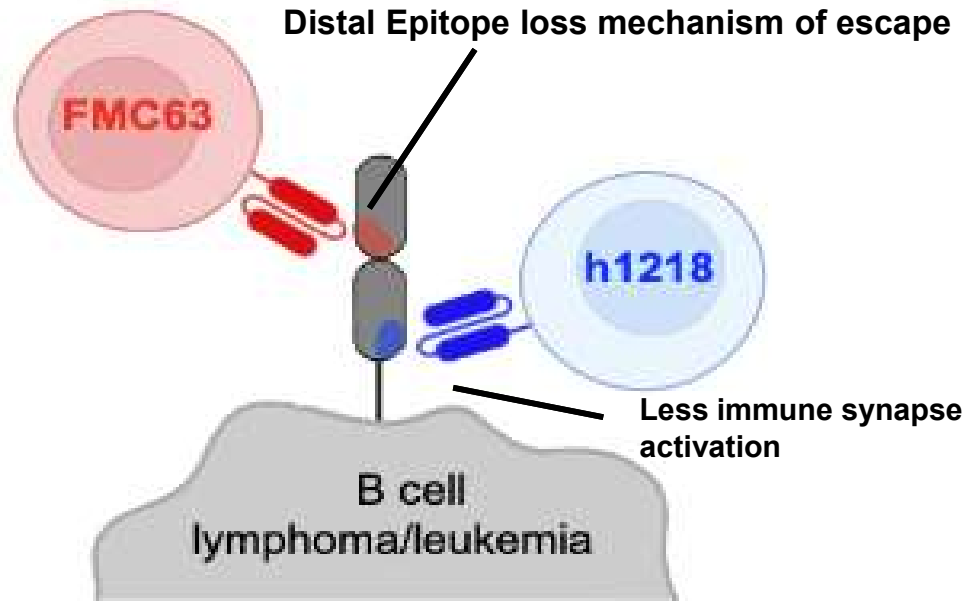
*** Only observed at high dose (450 x10^6)**

Mailankody et al, *NEJM,* 2022

How We Can Improve



New Epitope target

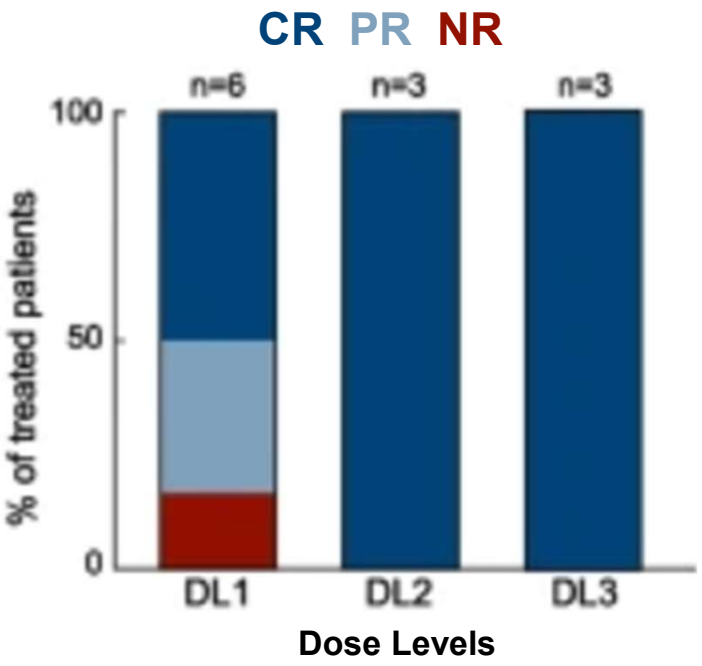


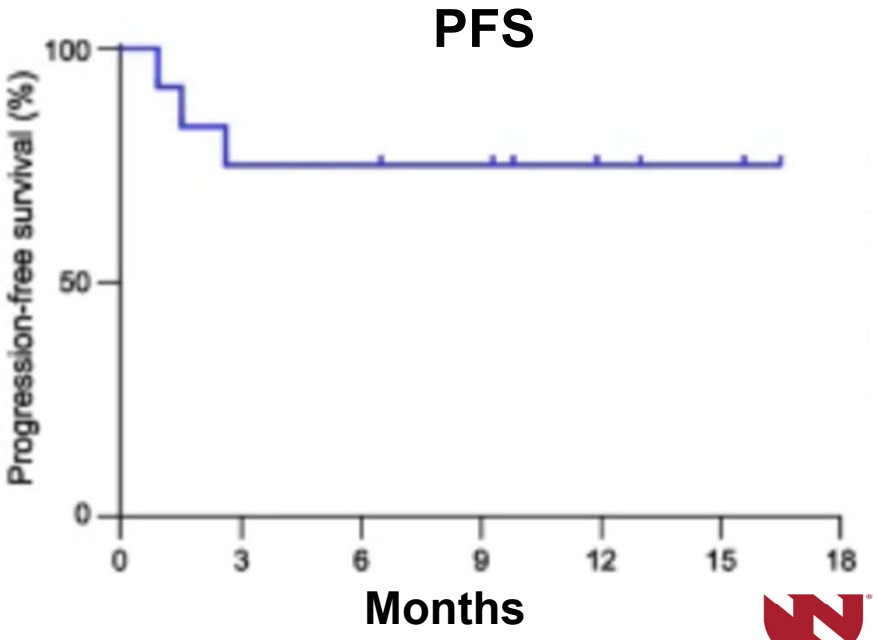
Better on/off kinetics
Less activation-induced cell death
Better CAR T fitness = better efficacy

Zhang et al, Abstract 2096, ASH 2023

New Epitope Target

N= 12
Prior CAR T Excluded



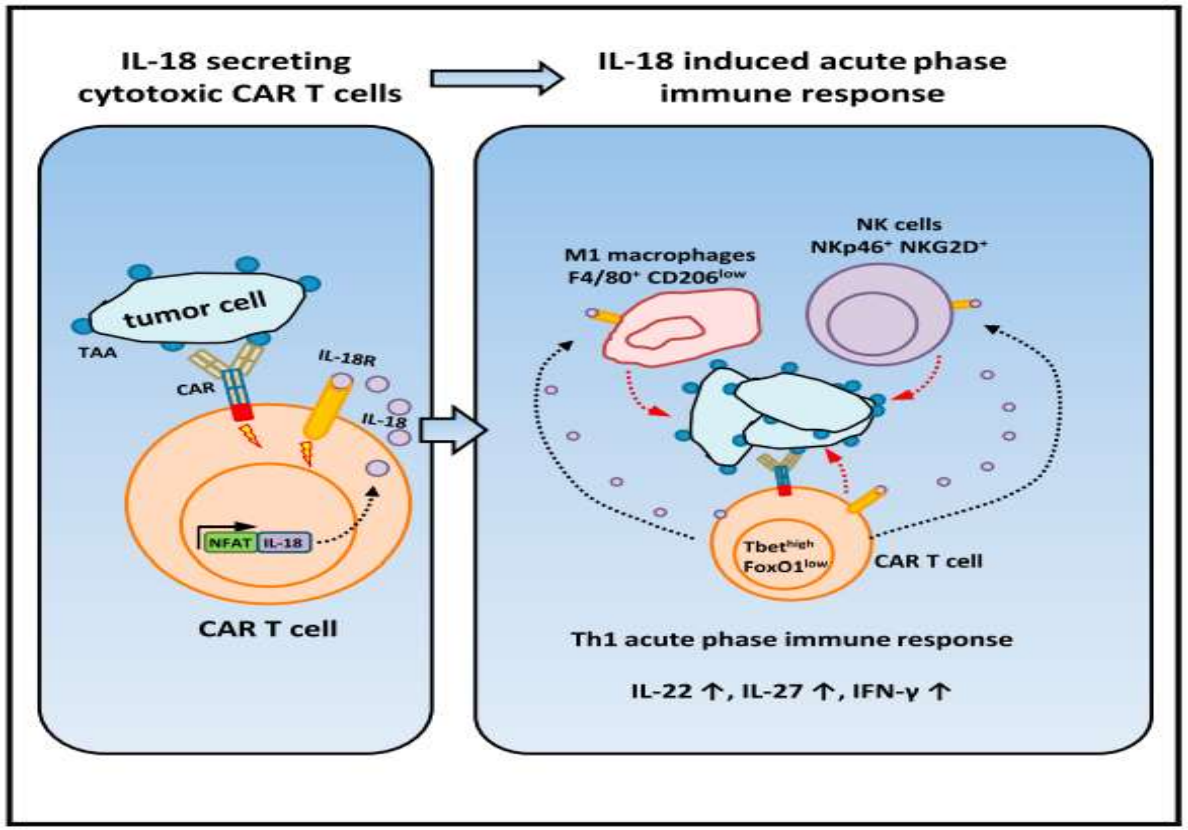


Zhang et al, *Molecular Cancer*, 2023

Novel Cell Therapy Approaches

- 4th generation: TRUCKS
  - CD19CAR + cytokine production
- Allo CAR T-cell products
  - Responses seen, ?durability

Trucks: T-cells Redirected for Universal Cytokine Killing



Chmielewski M et al. Cell Rep. 2017

Trucks: a hematologists depiction

huCART19-IL18

A TRUCK

Humanized antibody domain, targeting CD19, producing IL-18

Relapsed B-cell lymphoma n=13

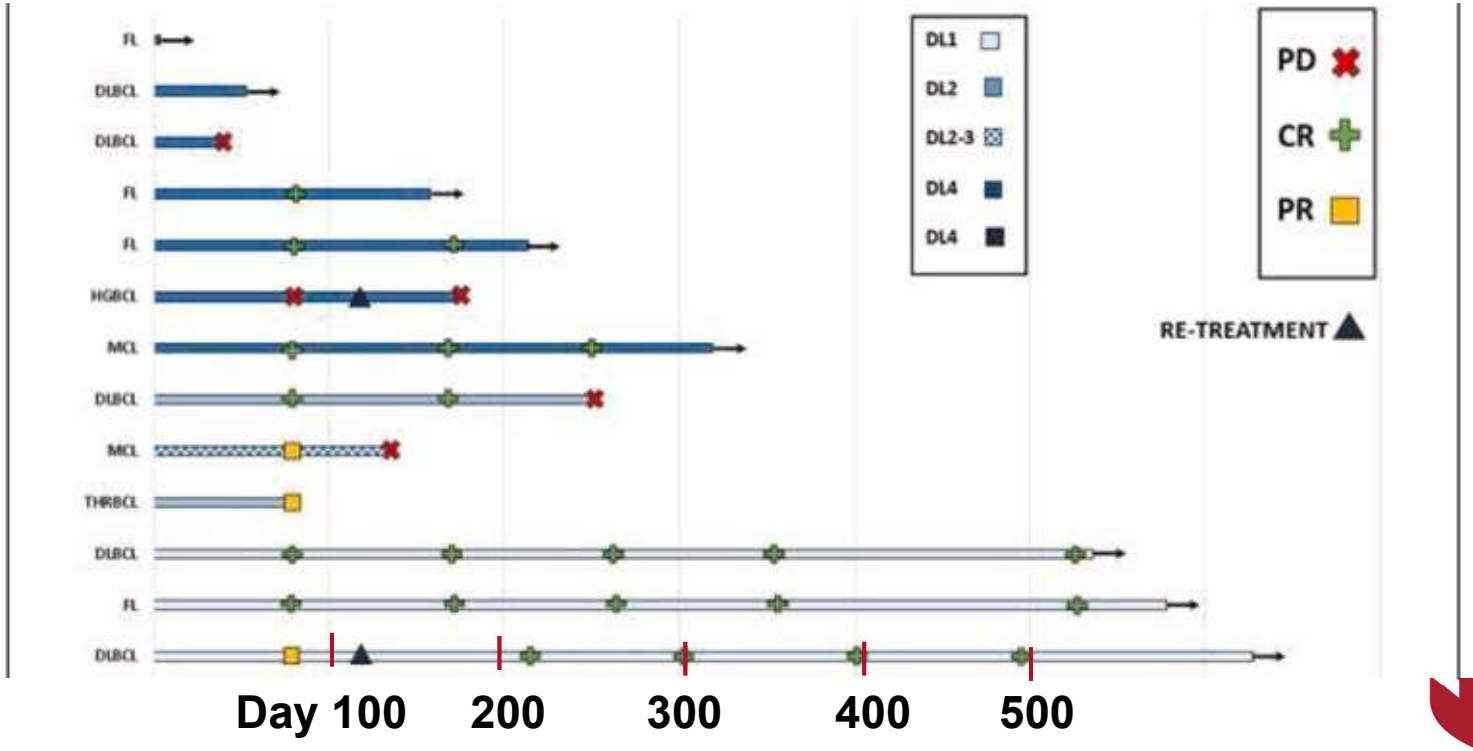
Relapse post commercial CD19 CAR T

Rapid ex-vivo manufacture 3 days
Vein to vein still at 47 days

Svoboda et al, ICML 6/2023,Hematol Oncol Vol 41, Issue S2

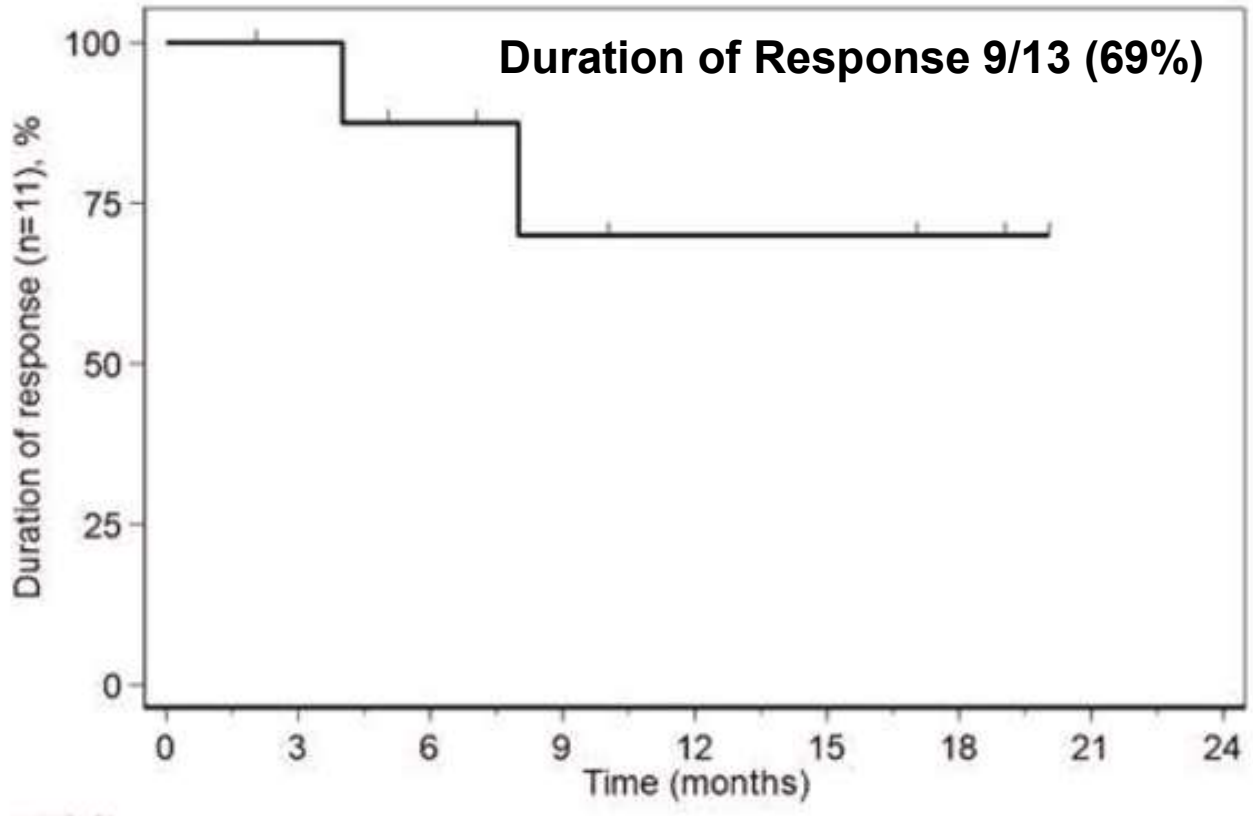
huCART19-IL18

Response to huCART19-18 CAR T Infusion



Svoboda et al, ICML 6/2023,Hematol Oncol Vol 41, Issue S2

huCART19-IL18



Svoboda et al, ICML 6/2023,Hematol Oncol Vol 41, Issue S2

Allogeneic CAR-T

Advantages

- “off-the-shelf” offers rapid turnaround
- Addresses issue of host T-cell performance
- Multi-dosing

Concerns

- GvHD
- Persistence (risk of graft rejection)
- Off target editing/rearrangements

Allo-501: Allo CAR T

- CD19, human derived allo-CAR
- Administered with anti-CD52 mAb (to suppress host T-cells and prevent rejection
- CD52 knockout of CAR (so the mAb won't affect)
- Ph1 results in a **CAR T naïve** relapsed/refractory DLBCL population

Journal of Clinical Oncology®
An American Society of Clinical Oncology Journal

CURR

OPEN ACCESS | ORIGINAL REPORTS | February 13, 2025

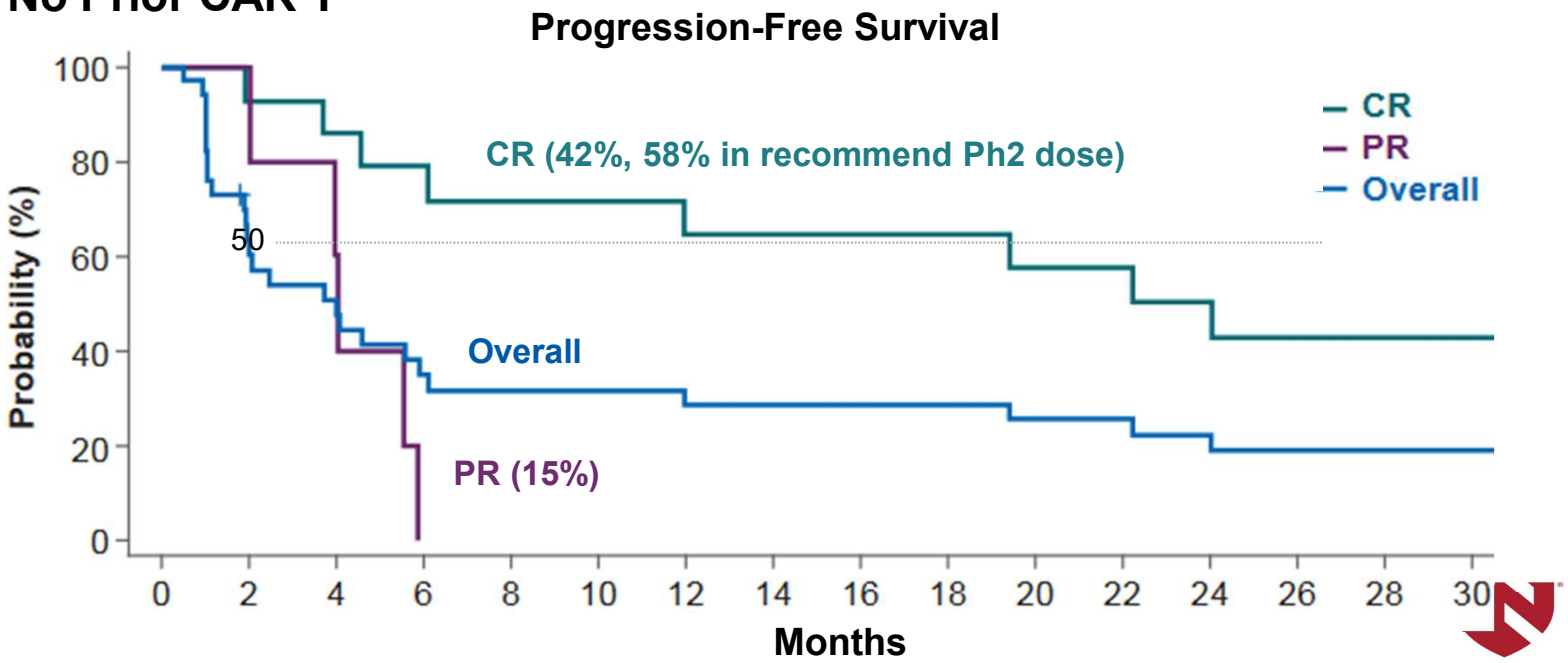
Allogeneic CAR T Cell Products Cemacabtagene Ansegedleucel/ALLO-501 in Relapsed/Refractory Large B-Cell Lymphoma: Phase 1 Experience From the ALPHA2/ALPHA Clinical Studies

Authors: Frederick L. Locke, Javier L. Munoz, Michael T. Tees, Lazaros J. Lekakis, Sven de Vos, Rajneesh Nath, Don A. Stevens, ... SHOW ALL ..., and Sattva S. Neelapu | AUTHORS INFO & AFFILIATIONS

Locke et al, *JCO,* 2025

Allo-501: Allo CAR T

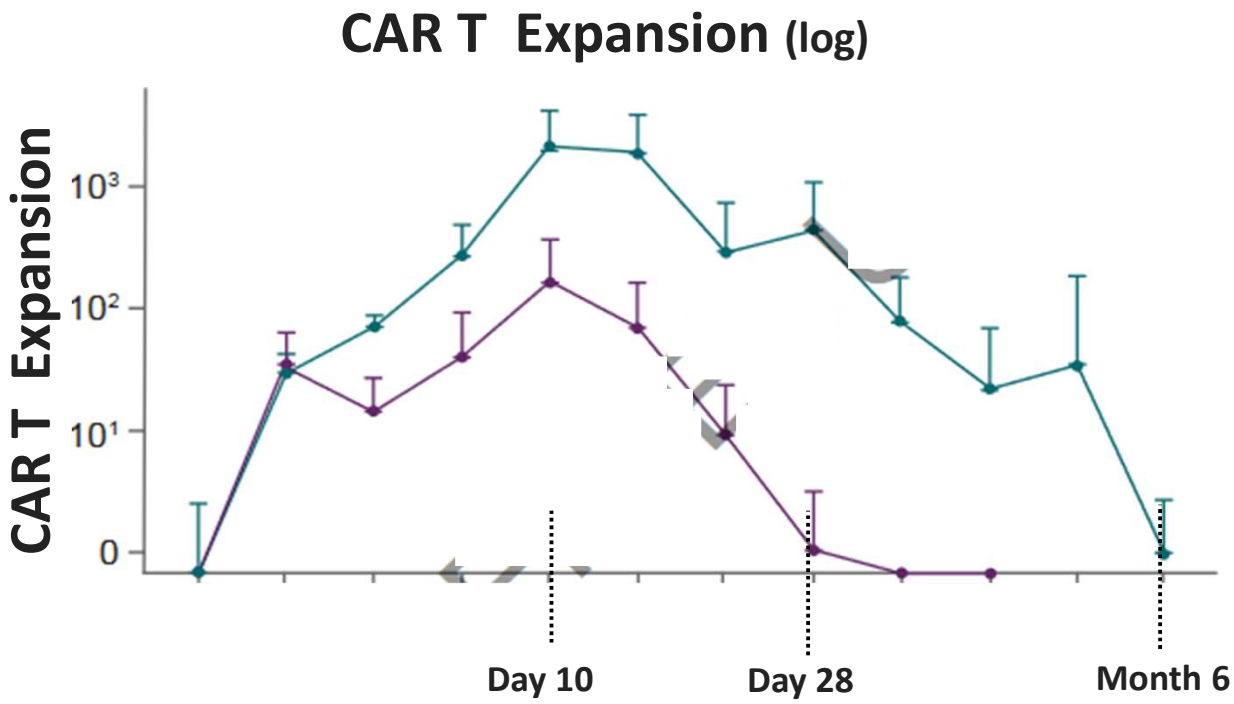
N=33
DLBCL med 3 prior lines (2-8)
No Prior CAR T



Locke et al, *JCO,* 2025

(Median follow up 10 months)

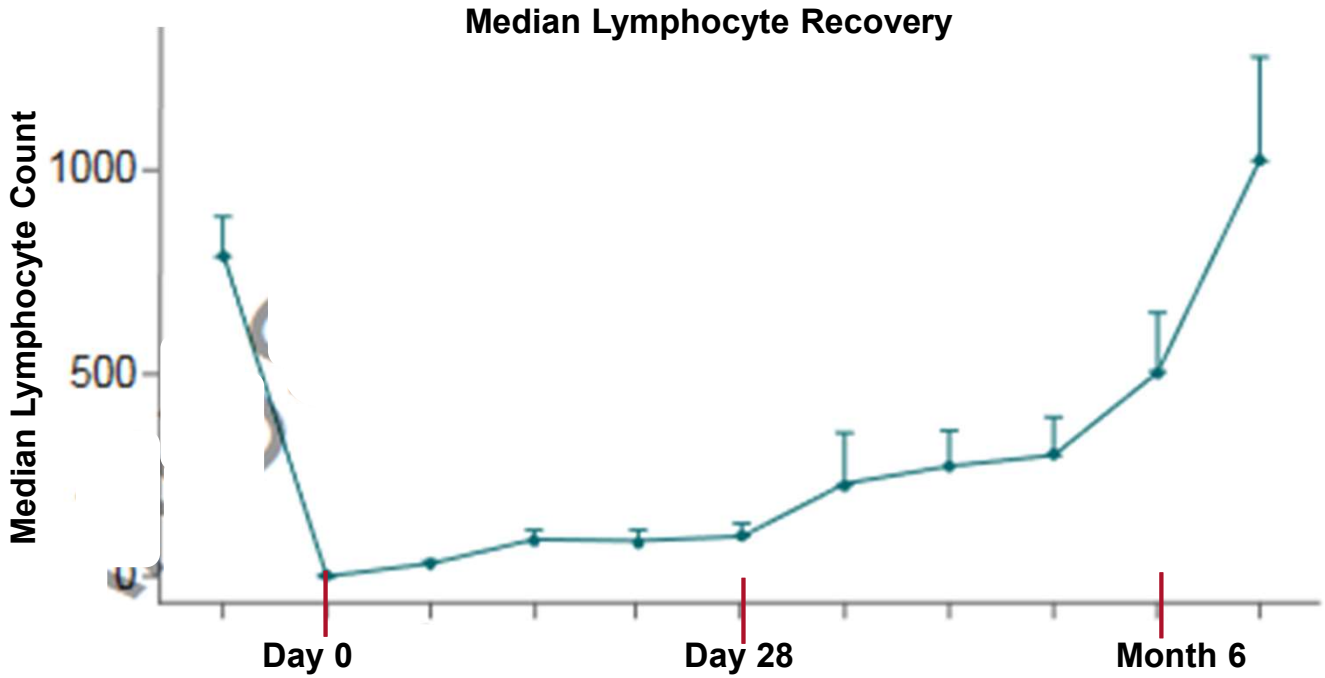
Allo-501: Allo CAR T



CD edited figure for presentation**

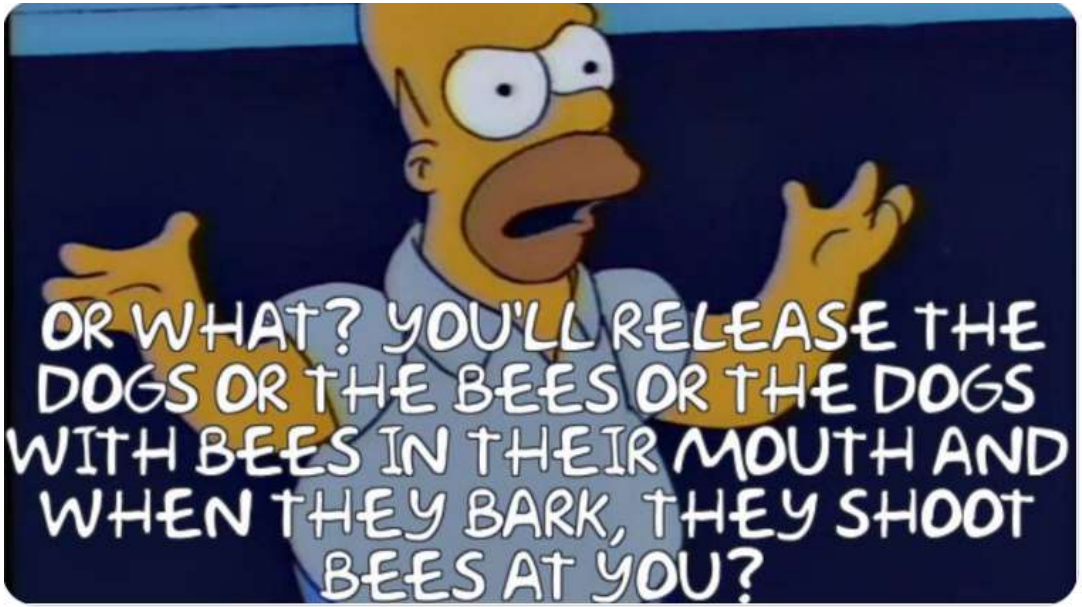
Locke et al, *JCO*, 2025

Allo-501: Allo CAR T

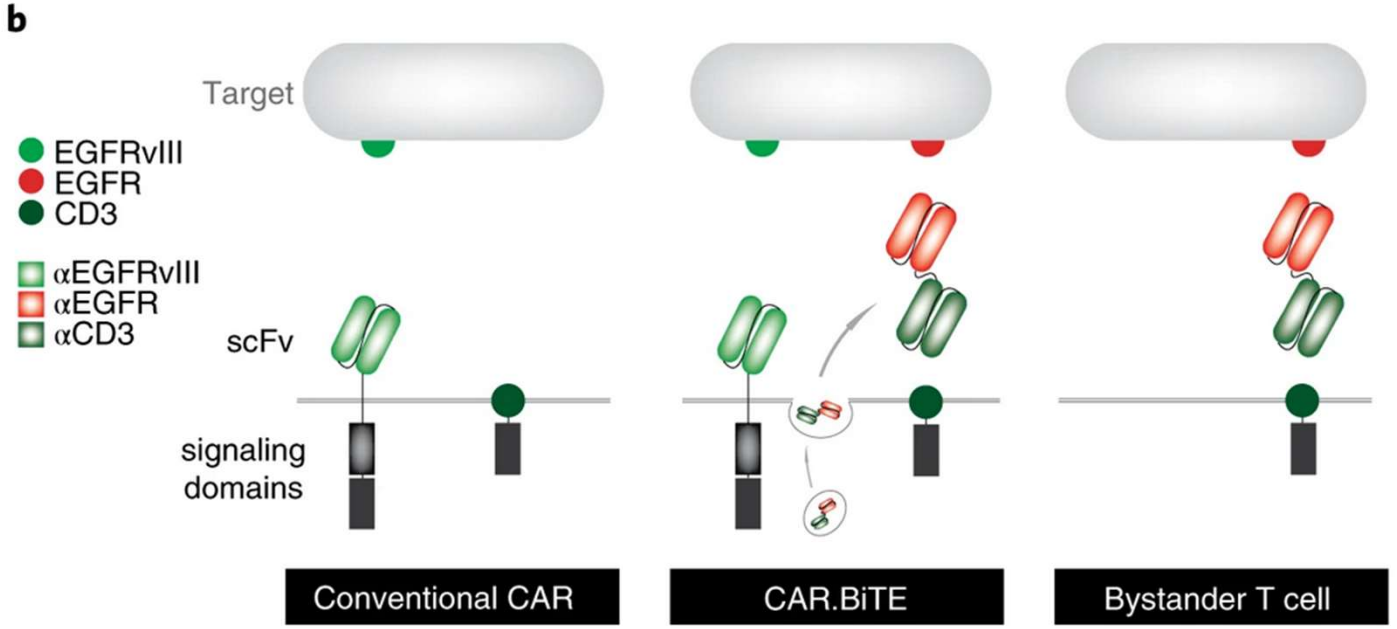


CD edited figure for presentation**
Locke et al, *JCO,* 2025

Future: CAR T or Bispecific antibodies?



CAR-T that secrete bispecific antibodies



Choi BD, et al. Nat Biotechnol. 2019

Summary:

- Opportunity to improve and innovate at every step of CAR T process
- Next generation products clearly safer
- New targets open cell therapy for new diseases
  - Work in progress
- Will the next generation be allo-T?, NK
  - Auto products are robust

Thank you!
Christopher.Dangelo@unmc.edu

Emerging Cellular Therapies for Solid Tumors

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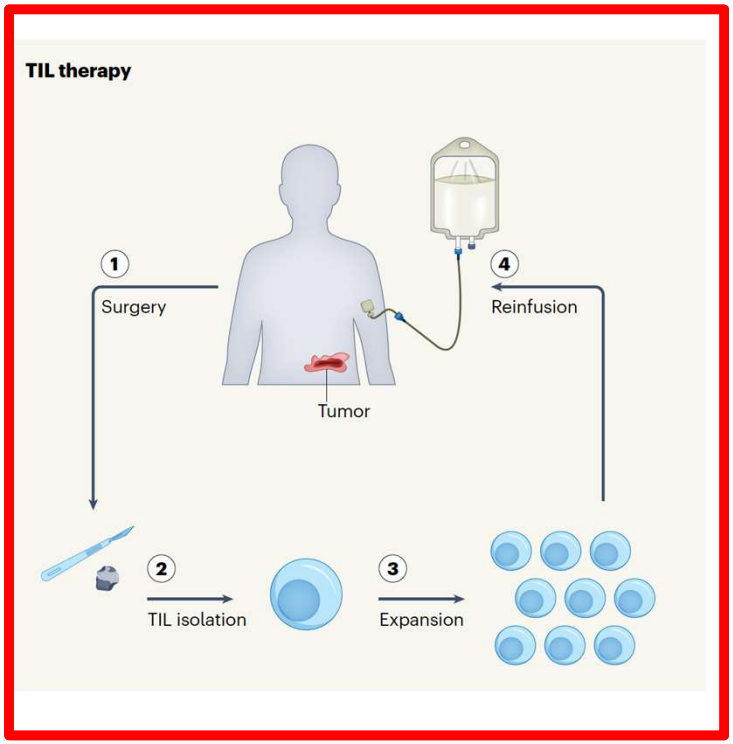
University of Washington
Fred Hutchinson Cancer Center, Seattle, WA

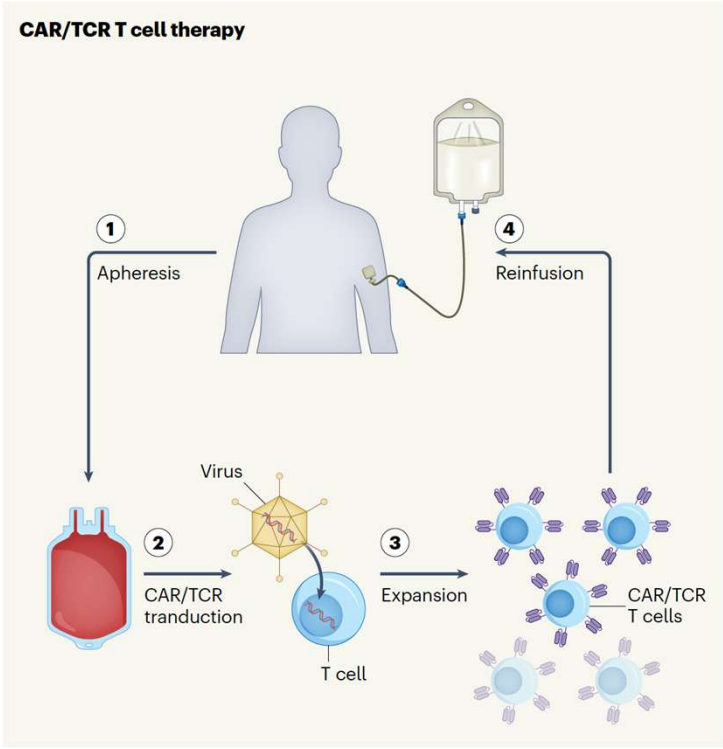
Mar 27th, 2025

Learning Objectives

- Describe the existing and emerging cellular therapies in the solid tumor space.
- Understand the benefits and implications of using different types of cellular therapies in the clinic.
- Discuss multidisciplinary strategies to utilize these cell-based therapies and address toxicity in treatment planning.

Adoptive T Cell Therapy Approaches

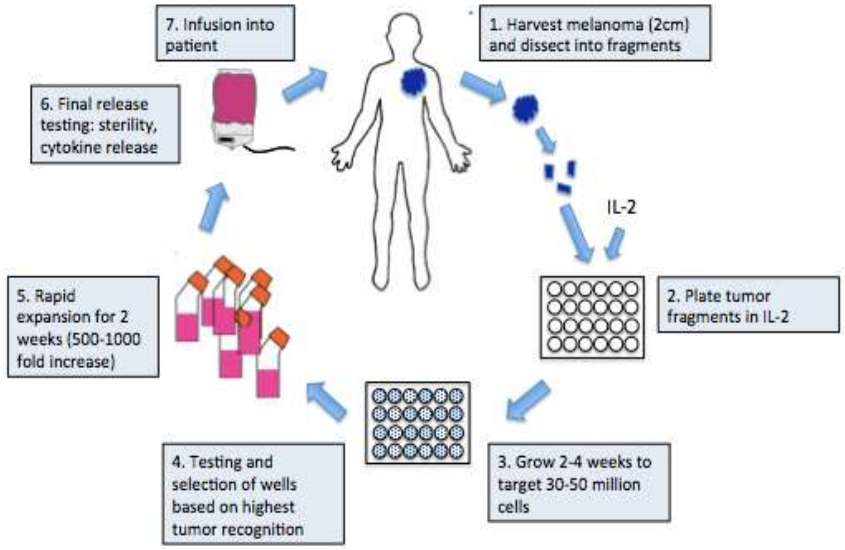


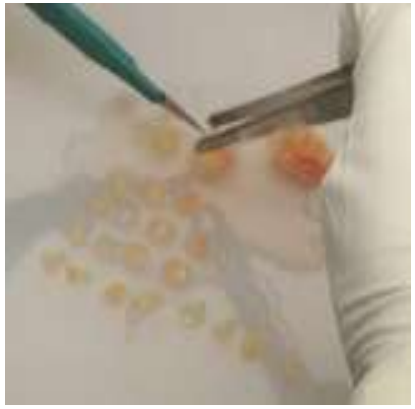


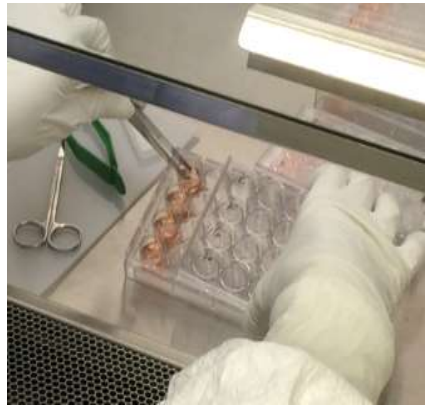
{Uslu U, June CH. *Nat Biotech*. 2024}

Tumor Infiltrating Lymphocytes (TILs)

Pioneered at NCI by **Steven Rosenberg** and team

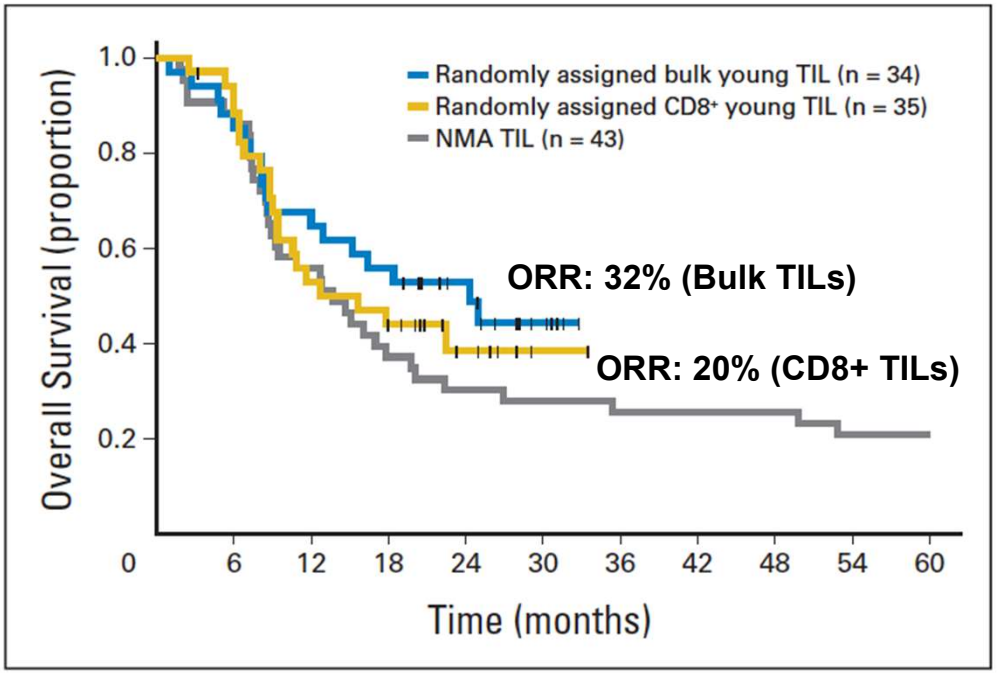






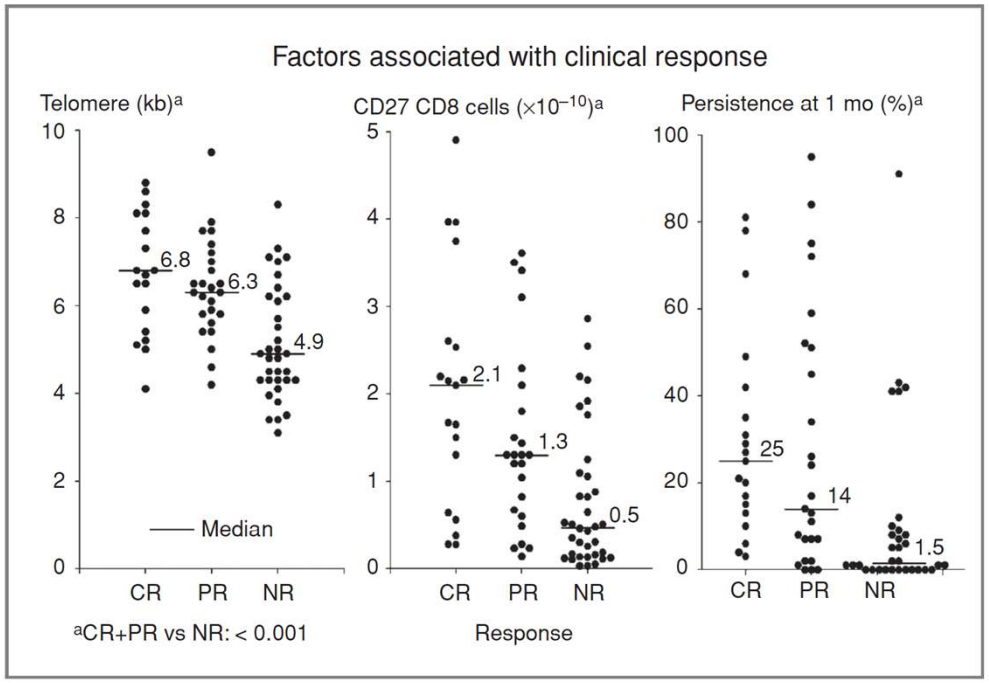
{Lee S, *Curr Oncol Rep*, 2012}

Enriching TILs for CD8+ T cells didn't enhance responses



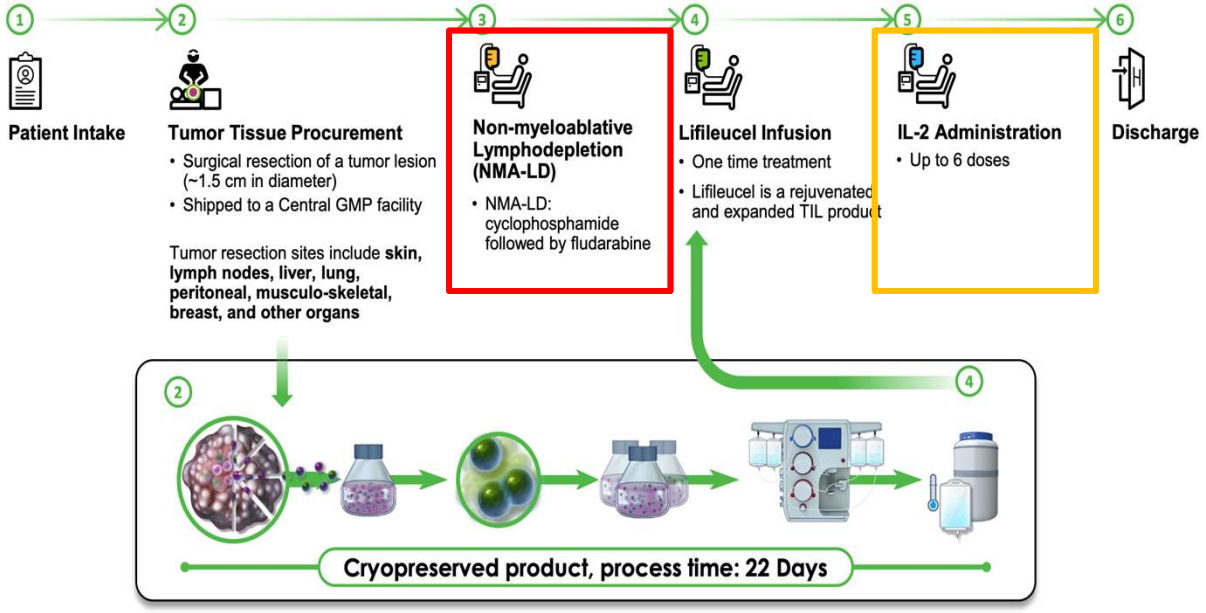
{Dudley ME et al. *JCO* 2013}

Younger, less-differentiated TILs may be better



{Rosenberg SA et al. *CCR* 2011}

Lifileucel: TILs for melanoma
(FDA-approved in Feb 2024)



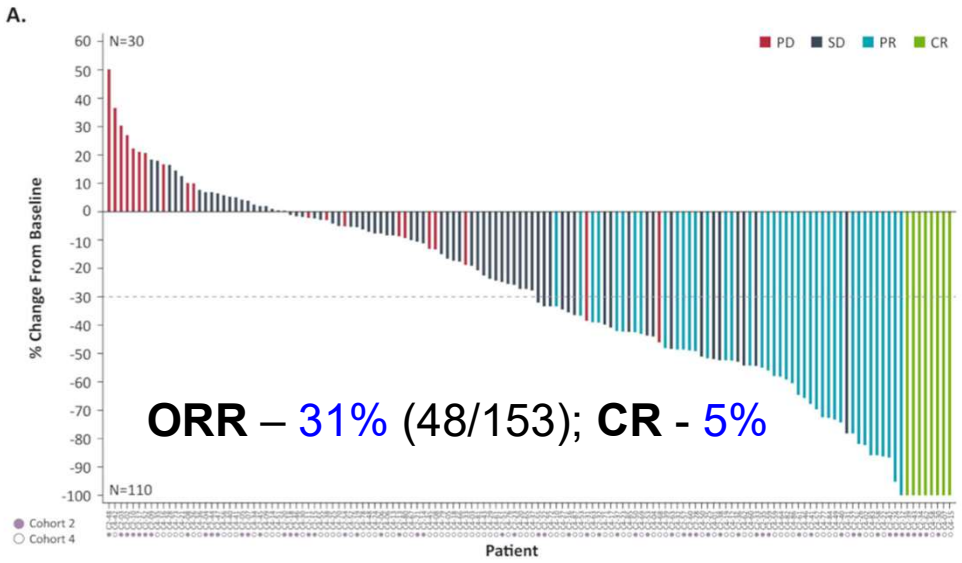
Cyclophosphamide 60 mg/kg for 2 days
Fludarabine 25 mg/m2 daily for 5 days

IL-2 (aldesleukin) at 600,000 IU/kg
every 8 to 12 hours for up to 6 doses

{Chesney J et al; AACR, 2021; Lifileucel package insert}

Lifileucel: Responses in refractory melanoma patients

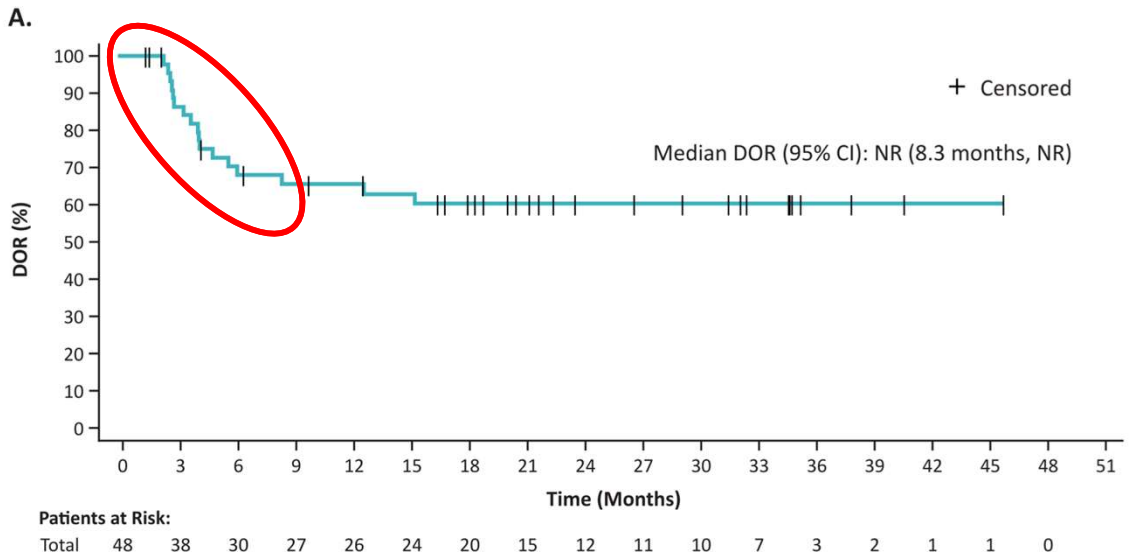
Median age: 56 [20-79]; **ECOG** 0/1
Median prior therapies: 3 [1-9]; Prior anti-PD-1 (100%)



ORR – 31% (48/153); **CR** - 5%

{Chesney J, *JITC*, 2022}

Lifileucel: Responses can be durable!



{Chesney J, *JITC*, 2022}

Lymphodepletion: A double-edged sword!

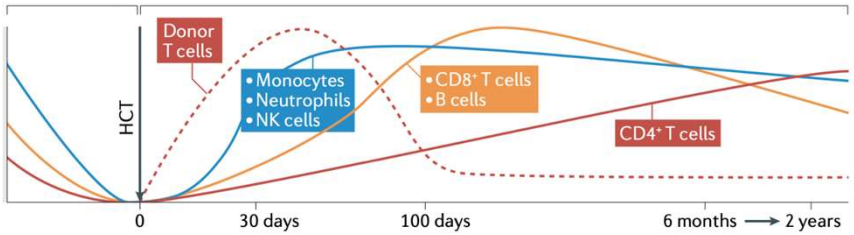
Cyclophosphamide 60 mg/kg for 2 days
Fludarabine 25 mg/m2 daily for 5 days

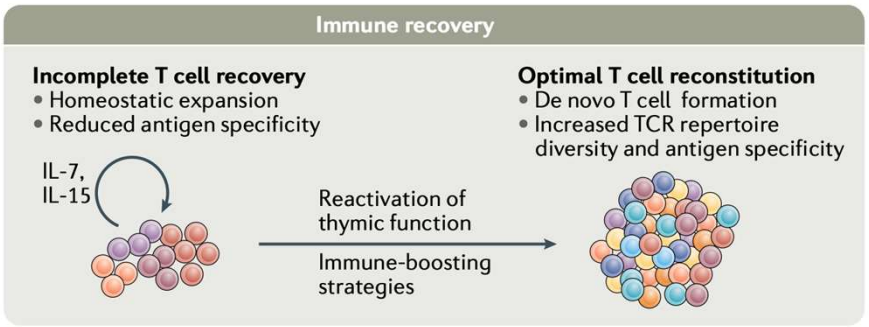
Potential mechanisms of efficacy:

- Elimination of suppressor T cells.
- Decreased competition by endogenous lymphocytes for homeostatic regulatory cytokines like IL-7 or IL-15.

{Dudley ME et al. *JCO* 2005}

Delayed kinetics of immune reconstitution!

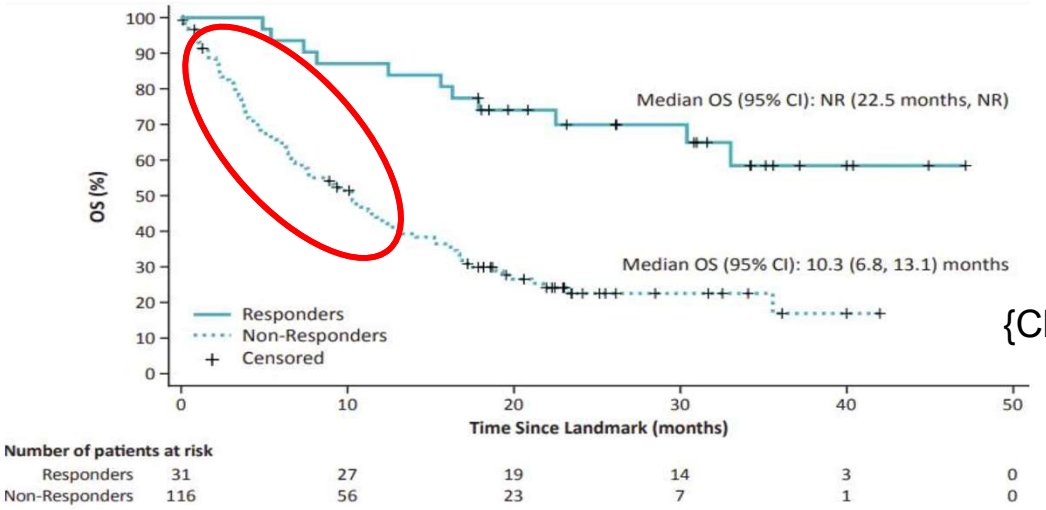




{Velardi E et al. 2021 *Nat Rev Immunol*}

Lifileucel: Poor OS in non-responders (?Immunosuppression related to Lymphodepletion)

Supplementary Figure 4. Overall Survival, by Response Status at 1.5 Months After Lifileucel Infusion



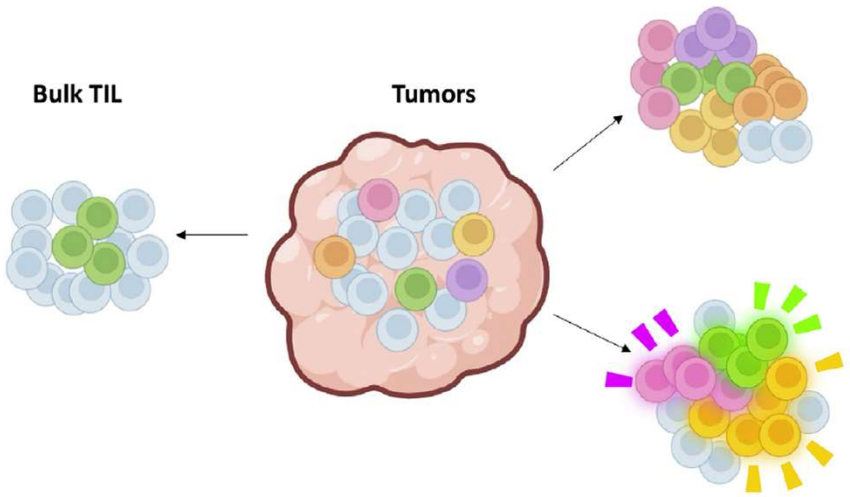
Number of patients at risk

Responders	31	27	19	14	3	0
Non-Responders	116	56	23	7	1	0

{Chesney J, *JITC*, 2022}

CAUTION: Use of TILs in earlier settings may compromise responses to subsequent IO!

Next Generation TIL therapy



Enhanced specificity

- CD39/CD103 selection
- Selection of T cells recognizing mutation associated neoantigens
- Selection of T cells recognizing clonal neoantigens

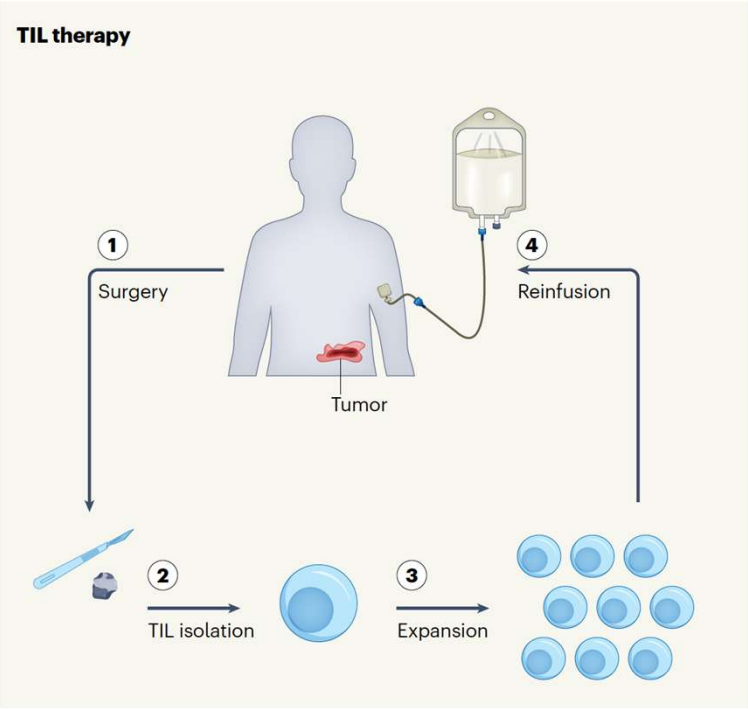
Enhanced function

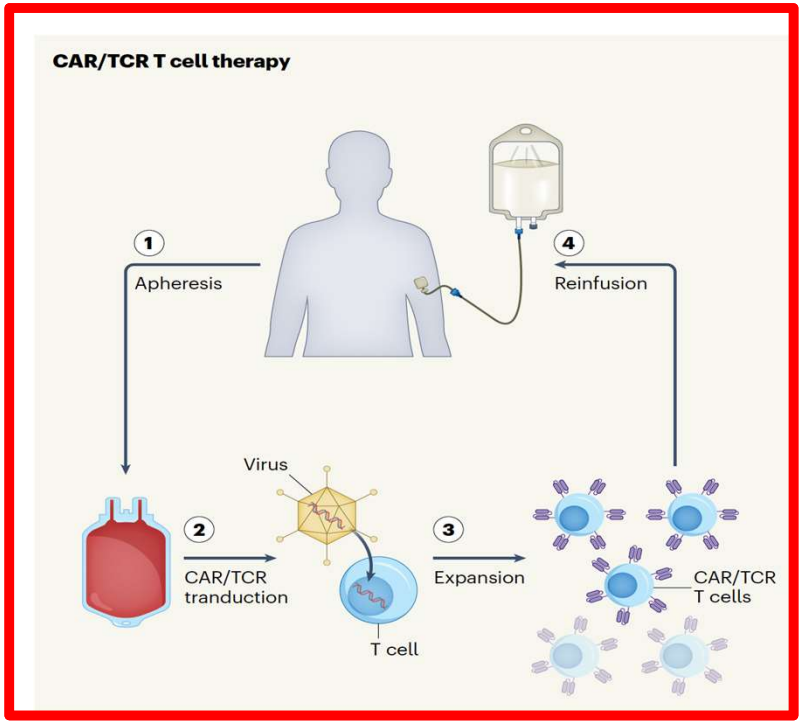
- Engineered costimulatory receptor
- Knock out/down *PDCD-1* or novel inhibitors of T cell function
- Promote stem-like CD8 T cells through epigenetic reprogramming
- Genetic engineering to promote IL-2 independent expansion/persistence

Figure 1. Strategies for next-generation TIL therapy.

{Tseng D, Lee SM. *JTCT* 2025}

Adoptive T Cell Therapy Approaches



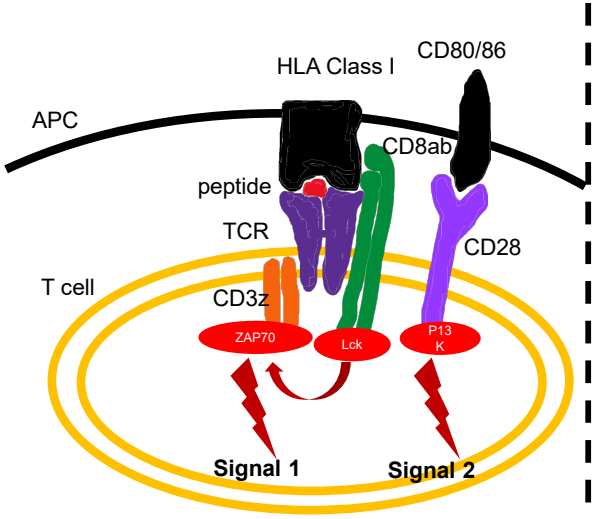


{Uslu U, June CH. *Nat Biotech*. 2024}

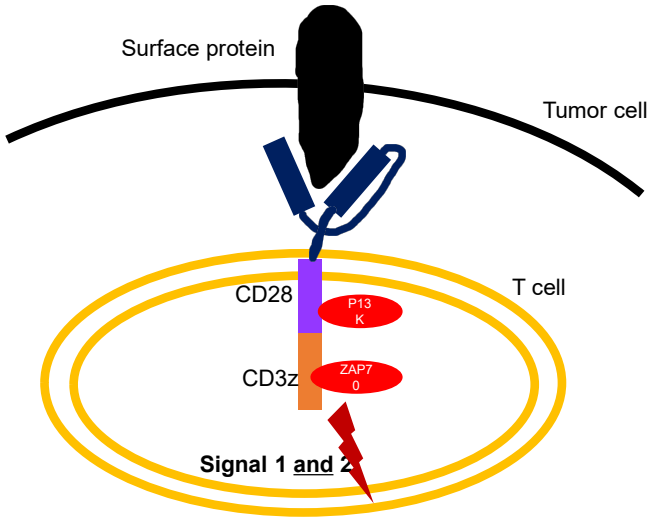
TCRs and CARs

Aude Chapuis, MD

T cell receptor

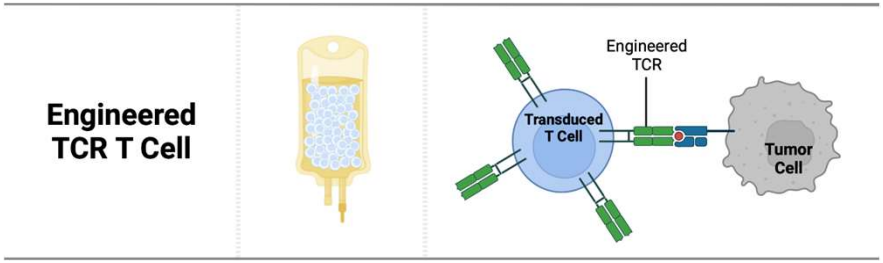


2nd generation CAR (chimeric Ag receptor)



APC = antigen-presenting cell: can be a dendritic cell, a tumor cell, a virally infected cell etc.

Engineered TCR T Cells



- Requires knowledge of target antigen and associated TCR sequence
  - No thymic selection: allows for targets beyond cancer-specific neoantigens
  - Examples: driver mutations, antigens arising from virally-encoded genes, cancer germline antigens, melanoma differentiation antigens
- Allows for targeting of **intracellular** proteins; potentially better for solid tumors
- High potential for on-target, off-tumor toxicity (due to shared epitopes between tumor and normal tissues)
- **HLA genotype must match TCR**

Afami-cel: Engineered TCR targeting HLA-A*02 Restricted MAGE-A4

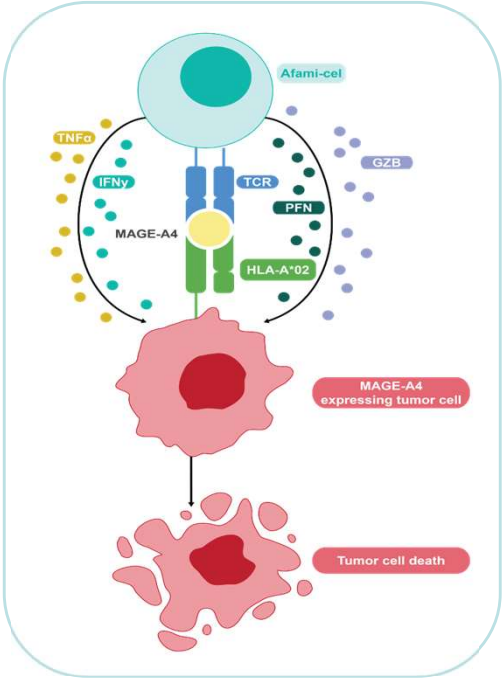


Figure courtesy of Sandra D'Angelo, MSKCC

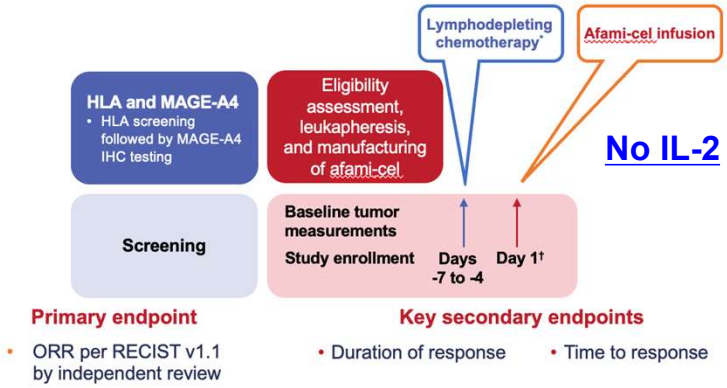
August 2024: US FDA accelerated approval for unresectable/metastatic Synovial Sarcoma who have:

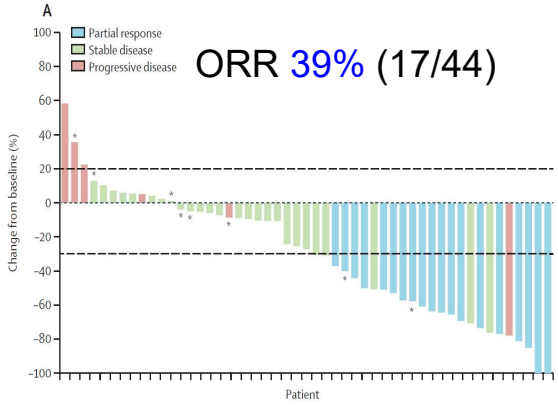
1) received prior chemotherapy

2) are HLA-A*02:01P, -A*02:02P, A*02:03P, or -A*02:06P positive

3) whose tumor expresses the MAGE-A4 antigen.

Afami-cel: Impressive efficacy in a subset of pts with Synovial Sarcoma

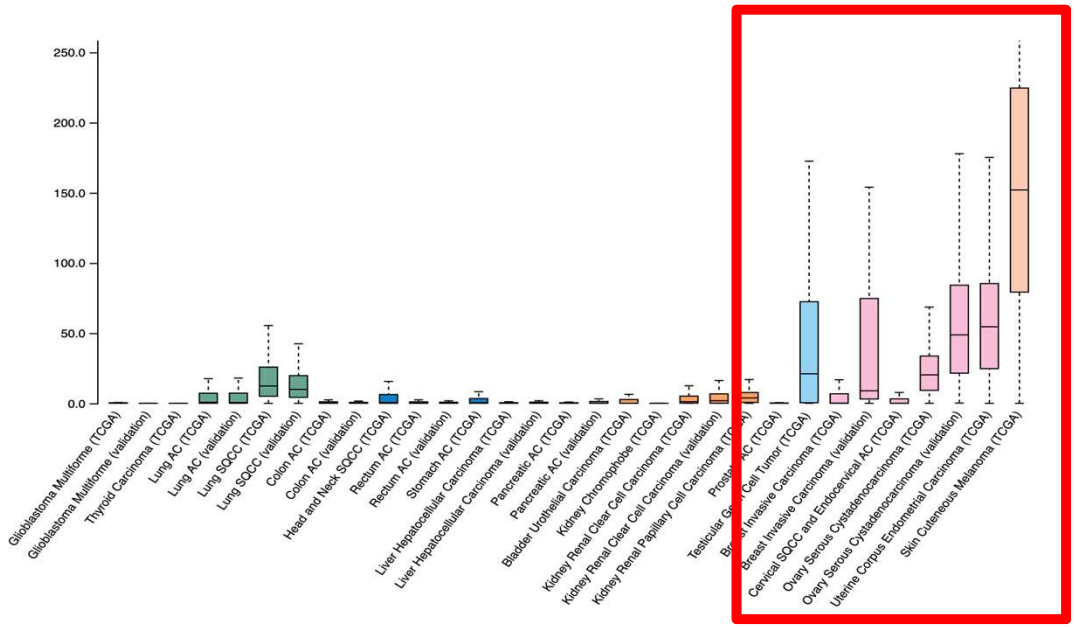




CRS occurred in 75% (33/44) patients, including **Grade ≥3 in 2%** (1/44) of patients

{D'Angelo SP et al. *Lancet* 2024}

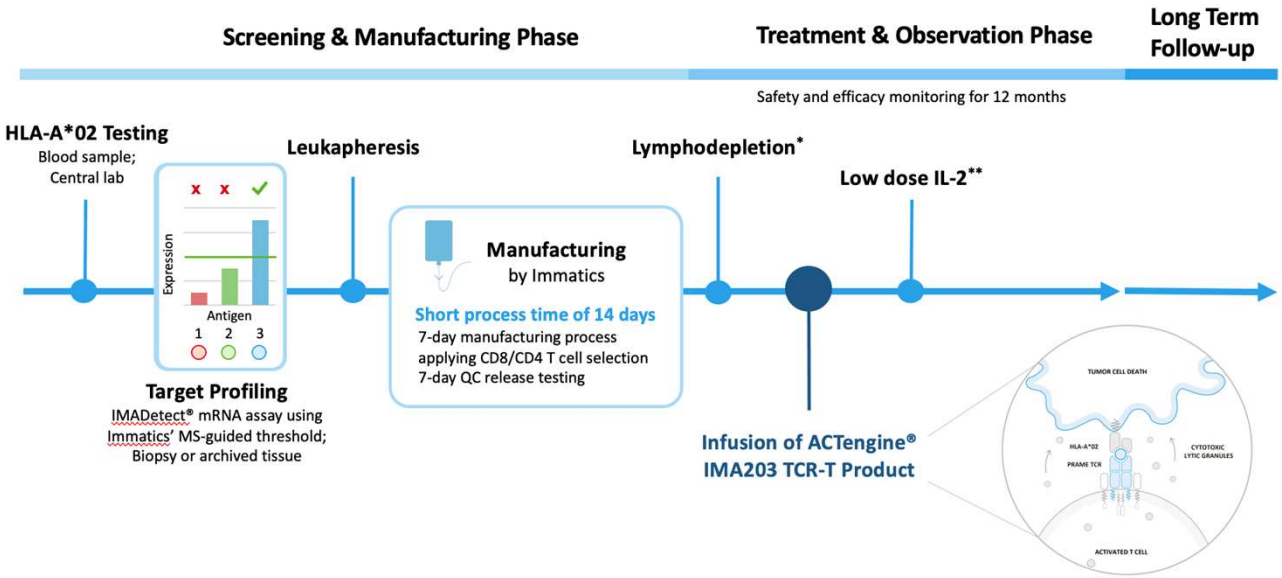
PRAME (Preferentially Expressed Antigen in Melanoma): An attractive target beyond melanoma



Melanoma (including uveal)
Ovarian (serous type)
Cervical
Endometrial
Germ cell tumors
Breast
Sarcomas

{https://www.proteinatlas.org}

IMA203: TCR-T targeting PRAME HLA-A*02:01

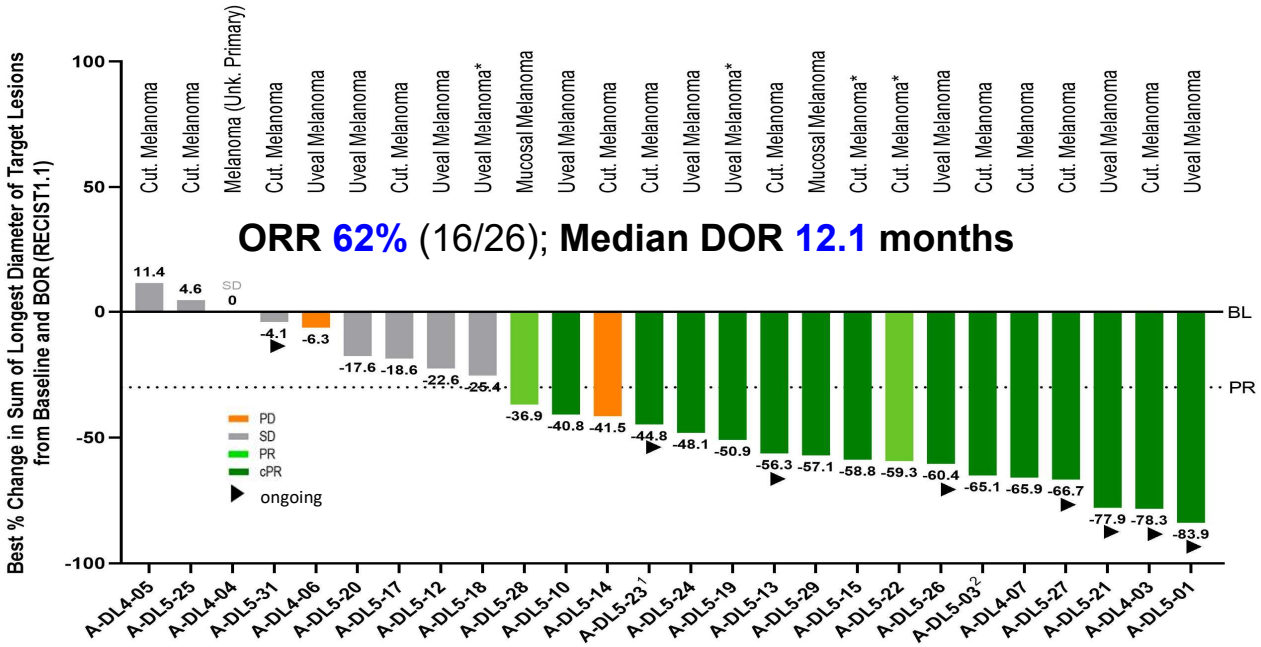


*30 mg/m^2 Fludarabine and 500 mg/m^2 Cyclophosphamide for **4** days

**__1m IU daily__ days 1-5 and twice daily days 6-10

{Wermke M et al; SMR, 2024}

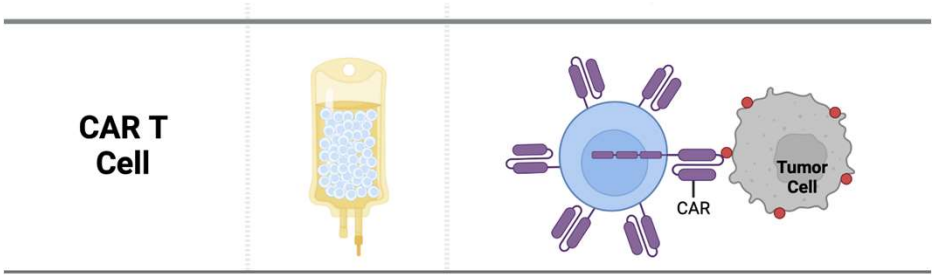
IMA203: TCR-T targeting PRAME HLA-A*02:01



Phase 3 trial ongoing in Refractory Melanoma

{Wermke M et al; SMR, 2024}

CAR T Cells



- Requires knowledge and consistent expression of target antigen
- Can only target extracellular antigens
- High potential for on-target, off-tumor toxicity
- No HLA restriction

nature biotechnology

Perspective

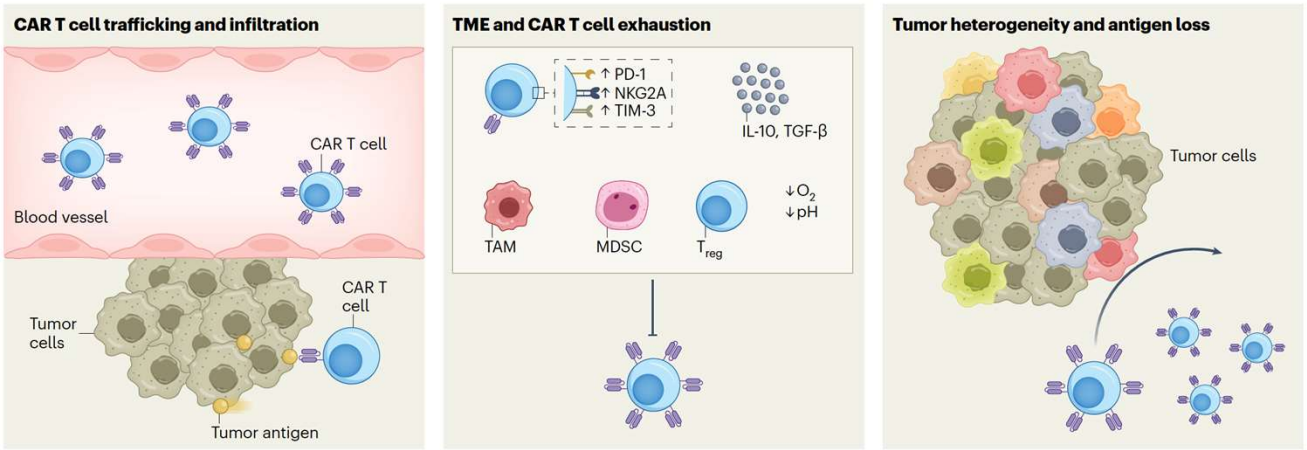
https://doi.org/10.1038/s41587-024-02446-2

Beyond the blood: expanding CAR T cell therapy to solid tumors

Received: 1 June 2024

Accepted: 23 September 2024

Ugur Uslu[1,2,3] & Carl H. June[1,2,3]

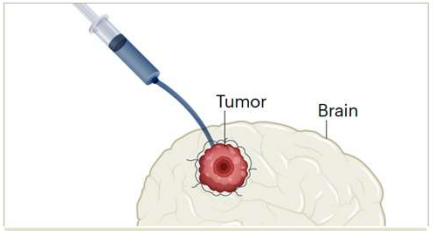


{Uslu U, June CH. *Nat Biotech*. 2024}

Table 1 | Recent publications on clinical trials reporting responses using CAR T cells in solid tumors

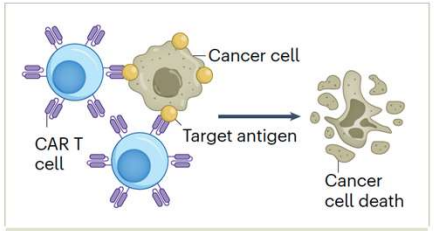
	Qi et al.[14]	Hegde et al.[15]	Choi et al.[16]	Bagley et al.[17]	Brown et al.[18]	Del Bufalo et al.[19]	Mackensen et al.[20]	Majzner et al.[21]	Adusumilli et al.[22]
Trial identifier	NCT03874897	NCT00902044	NCT05660369	NCT05168423	NCT02208362	NCT03373097	NCT04503278	NCT04196413	NCT02414269
Tumor entity	GI cancers	Advanced sarcoma	Glioblastoma	Glioblastoma	High-grade glioma	Neuroblastoma	CLDN6$^+$ solid tumors	Glioma	Malignant pleural diseases
Number of patients	98	13 in 14 enrollments	3 (ongoing)	6 (ongoing)	65	27	22 (ongoing)	4 (ongoing)	27
CAR target	CLDN18.2	HER2	EGFRvIII	EGFR, IL-13Rα2	IL-13Rα2	GD2	CLDN6	GD2	Mesothelin
CAR construct	2nd-gen. CAR (CD28; lentiv.)	2nd-gen. CAR (CD28; retrov.)	2nd-gen. CAR (4-1BB) secreting CD3/EGFR TEAM (lentiv.)	3rd-gen. (2×4-1BB) bicistronic CAR (4-1BB; lentiv.)	2nd-gen. CAR (4-1BB; lentiv.)	3rd-gen. CAR (CD28, 4-1BB) with iCasp9 gene (retrov.)	2nd-gen. CAR (4-1BB; retrov.)	2nd-gen. CAR (4-1BB) with iCasp9 gene (retrov.)	2nd-gen. CAR (CD28) with iCasp9 gene (retrov.)
CAR T dose	2.5×, 3.75×, 5× or 10×10^8	1×10^8 per m^2	10×10^6	1×10^7 or 2.5×10^7	$2–100\times10^6$ within 9 dose levels total	3×, 6× or 10×10^6 per kg	1×10^7 or 1×10^8	1×10^6 per kg	0.3×10^6–60×10^6 per kg
Route of CAR T infusion	i.v.	i.v.	Intraventricular	Intrathecal	Intratumoral, intraventricular or both	i.v.	i.v.	i.v. and intracerebro-ventricular	Intrapleural
Number of CAR T infusions	Up to 3 infusions	Up to 8 infusions	Up to 2 infusions	1 infusion	3 infusions (more allowed)	Up to 4 infusions	1 infusion (more allowed)+RNA vaccine	Up to 1 infusion per route	1 infusion (more allowed)+pembrolizumab
Overall response	38.8%	50%	100%	100%	50%	63%	67%	75%	54%
Lymphodepletion	flu+cyc+nabp/gem	flu only or flu+cyc	–	–	–	flu+cyc	flu+cyc	flu+cyc	cyc

CAR T, CAR T cell; gen., generation; iCasp9, inducible caspase 9; lentiv., lentiviral vector; retrov., retroviral vector; GI, gastrointestinal; flu, fludarabine; cyc, cyclophosphamide; nabp, nab-paclitaxel; gem, gemcitabine.



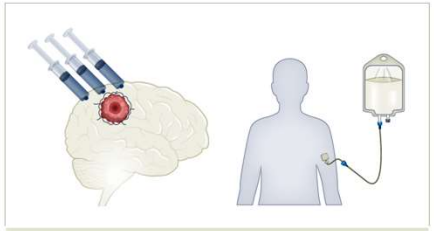
Locoregional delivery

- Intratumoral
- Intrathecal
- Intracerebroventricular (Ommaya reservoir)



Multi-targeting

- Bicistronic CARs
- TEAM-secreting CARs

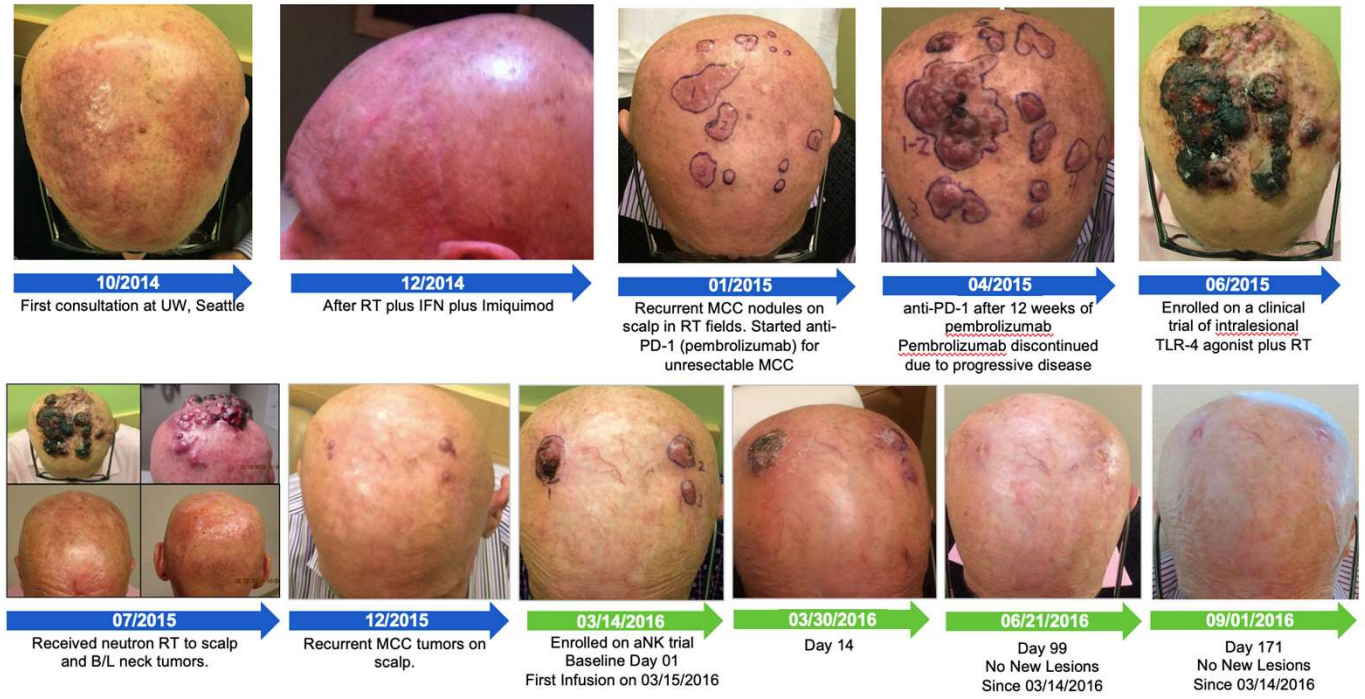


Enhancing persistence

- Repeated CAR T cell infusions
- Lymphodepleting chemotherapy

{Uslu U, June CH. *Nat Biotech*. 2024}

Cell therapy is more than T-cells!



Durable (7+ years) CR with **aNK cells** in a patient with refractory MCC

{Bhatia S *et al*; *Annual SITC meeting; 2019*}

Conclusions

- Cellular immunotherapy is feasible and efficacious in solid tumors!
- Unique hurdles posed by solid tumors are being addressed through creative strategies!
- Possible impact of lymphodepletion on subsequent IO needs to be studied carefully and may impact sequencing of therapies
- Do we have the infrastructure to meet the cell therapy tsunami for solid tumors?

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