CAR T-cell Therapy:
The Past, The Present, and The Future

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LOUISIANA ONCOLOGY SOCIETY

Disclosure of Conflicts of Interest

Consultant – Janssen Biotech; CTI Biopharma

Learning Objectives

- Understand the current state of CAR T-cell therapy in hematologic malignancies
- Know what to expect for CART in the community
- Review future directions in the field of cellular therapy

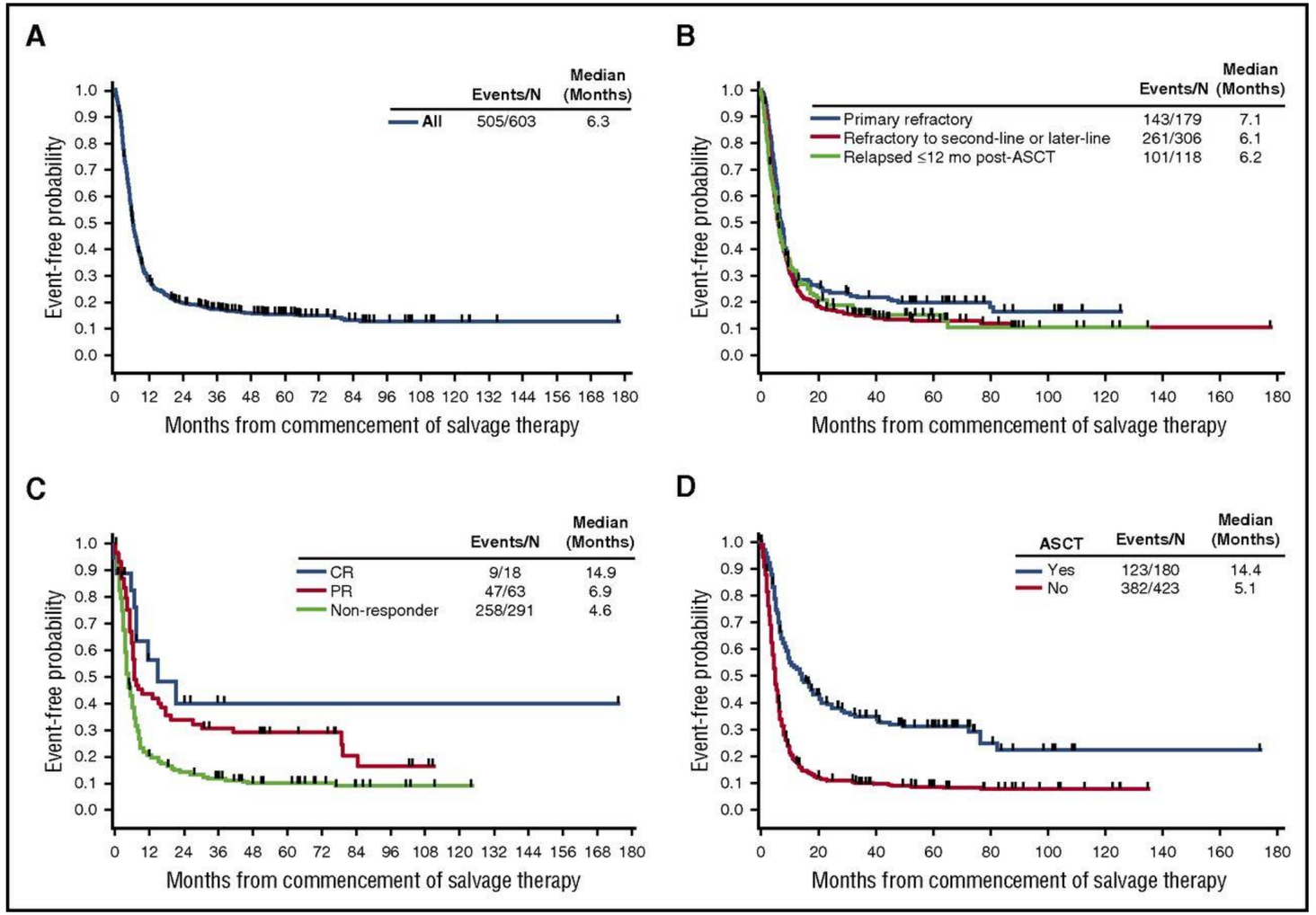
Outline

- History of CAR T-cell therapy
- Current commercial CART products
- Updated trials in CART
- CART in the community
- Future directions in cellular therapy

The Problem Prior to CAR T-Cell Therapy

Diffuse Large B-cell Lymphoma

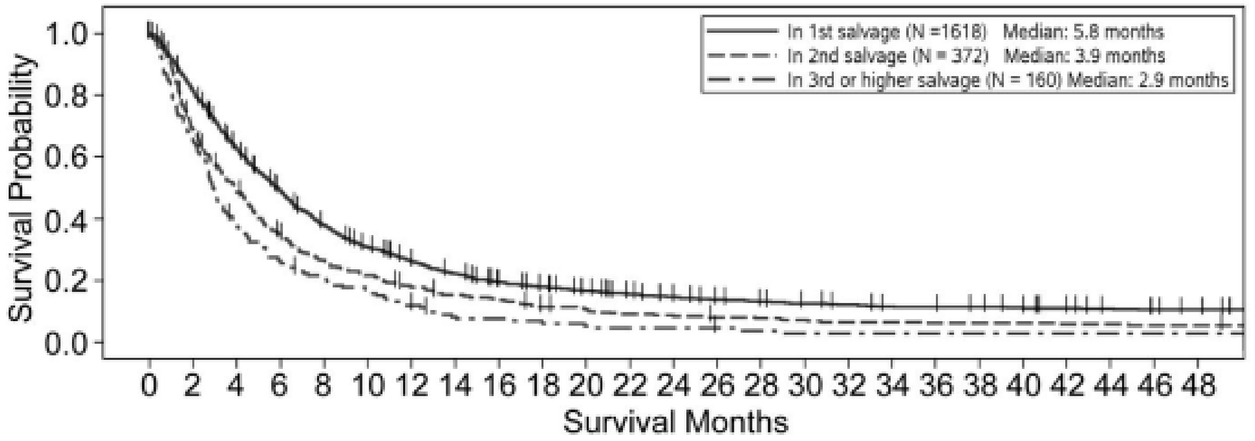
- **SCHOLAR-1:**
  - Multicenter, international, retrospective study with non-Hodgkin lymphoma with multiply relapsed or refractory disease (n=636) in the post-rituximab era (2000-2017).
  - Objective response rates 26%, complete response rate 7%, and median overall survival of 6.3 months.
  - Benchmark for CART trials.



Crump. Blood. 2017, Figure 3.

Acute Lymphoblastic Leukemia

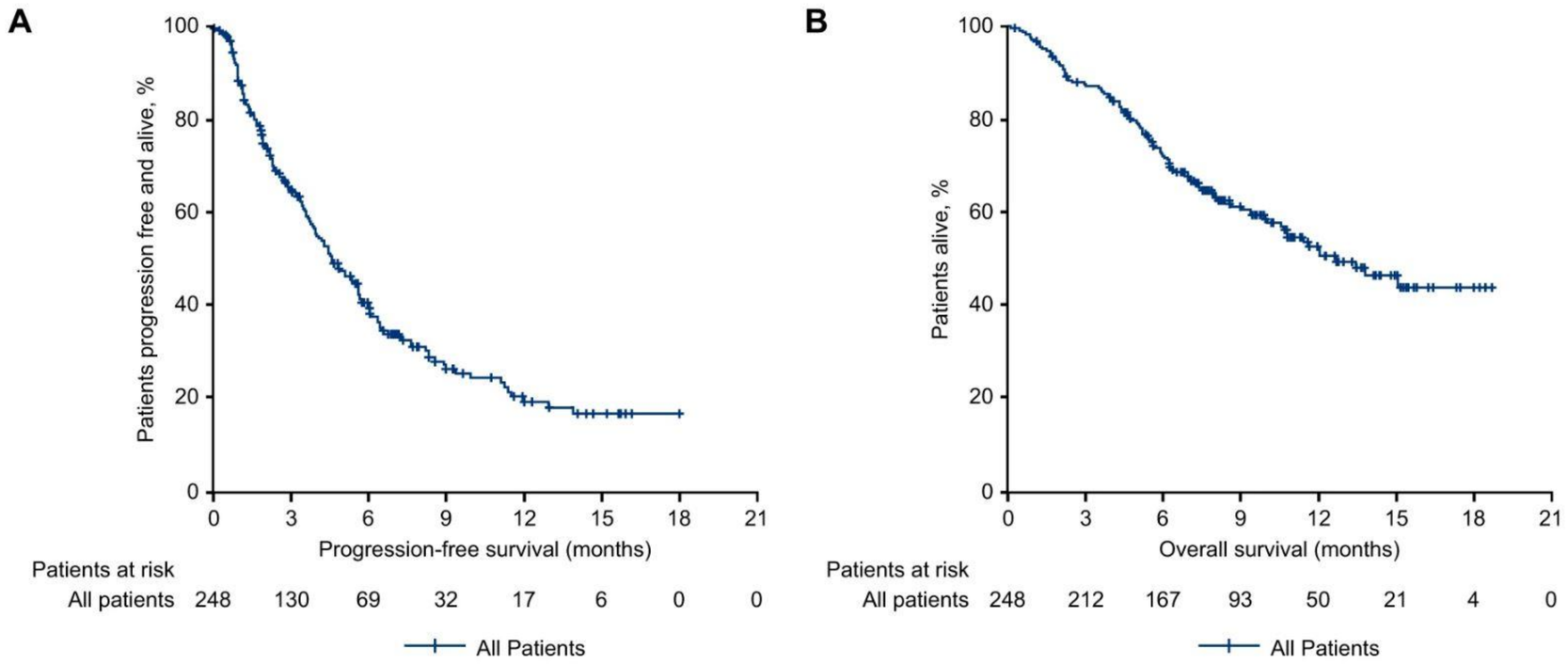
- Ph- acute lymphoblastic leukemia:
  - Initial CR rate = 90%
    - First salvage CR rate = 40%
    - Second salvage CR rate = 21%
    - Third and higher CR rate = 11%



Gökbuget. Haematologica. 2016: 1524-1533.

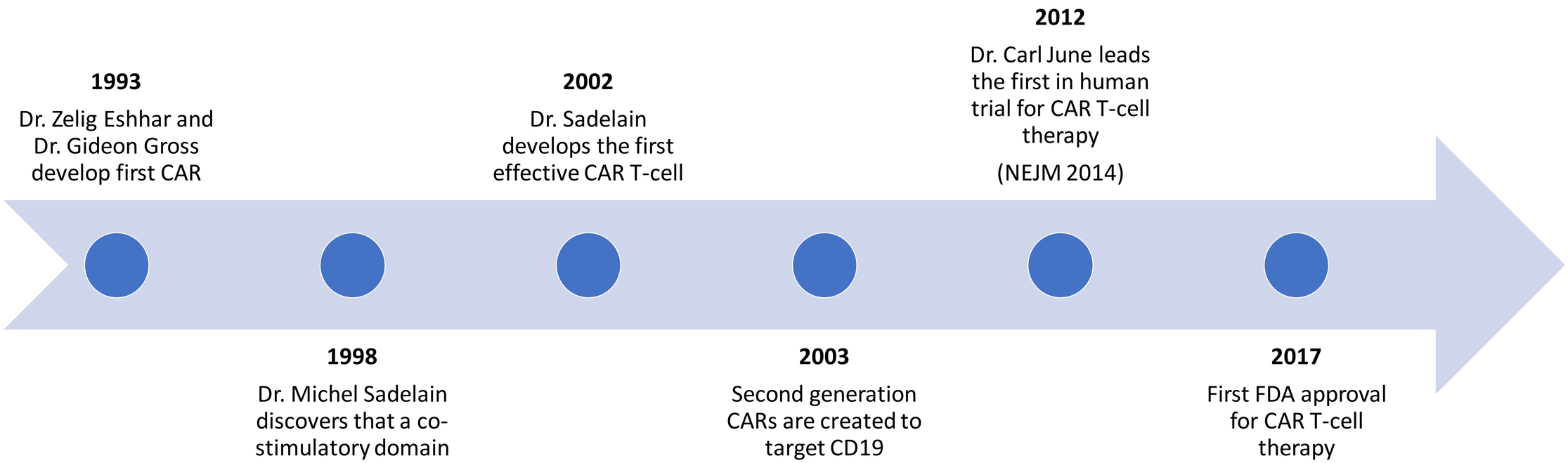
Multiple Myeloma

- **LocoMMotion Trial**
  - Triple class refractory (IMiD, PI, and anti-CD38 mAbs):
    - ORR 29.8%
    - mPFS 4.6 months
    - mOS 12.4 months



Mateos, MV. Leukemia 36, 1371–1376 (2022).

Along Comes CAR T-cell Therapy



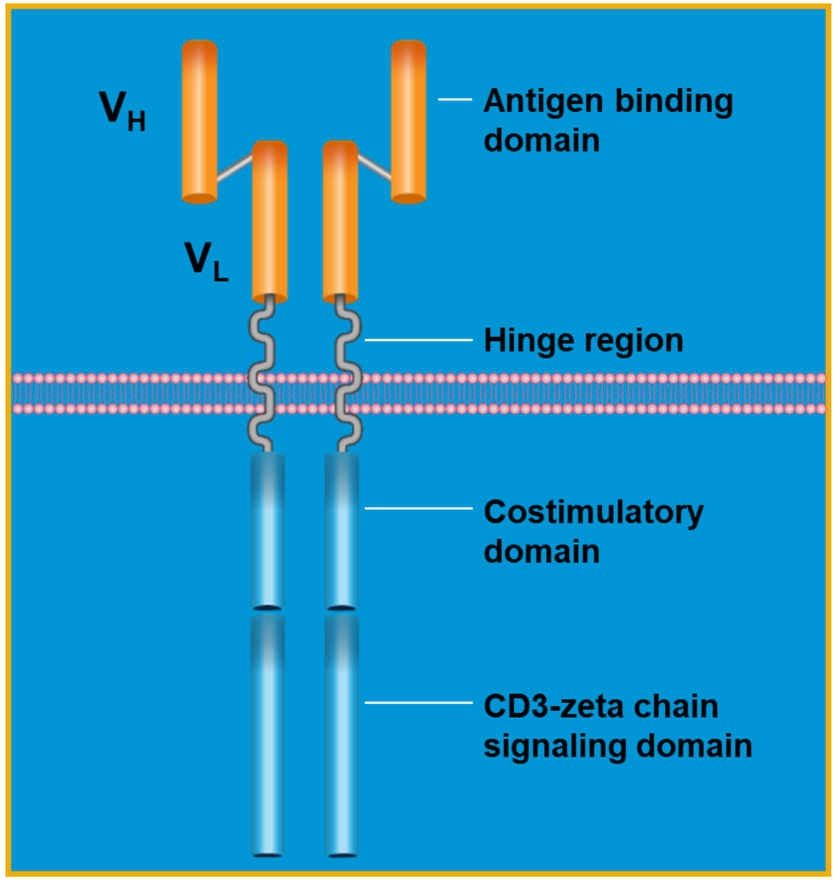
https://www.mskcc.org/timeline/car-t-timeline-progress

CAR T-cell Production

CAR T-cell Construct

Antigen Binding Domain

Activation Domains



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

Hinge region
Essential for optimal antigen binding

Costimulatory Domain: CD28 or 4-1BB
Enhances proliferation, cytotoxicity and persistence of CAR T cells

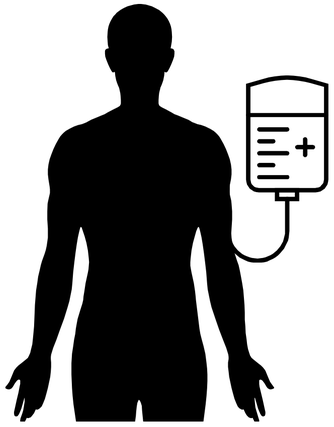
Signaling Domain: CD3ζ chain
Proliferation and activation of CAR T cells
CAR T-cell-mediated killing of tumor cells

Slide created by E Squared Communications
Courtesy of the CAR T Working Group

Autologous CAR T-Cell Therapy: Underlying Principles

Leukapheresis

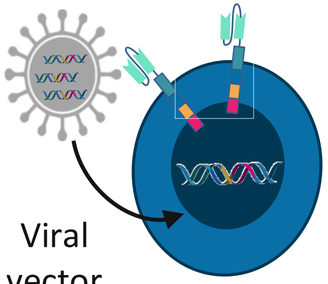
Collect patient's white blood cells

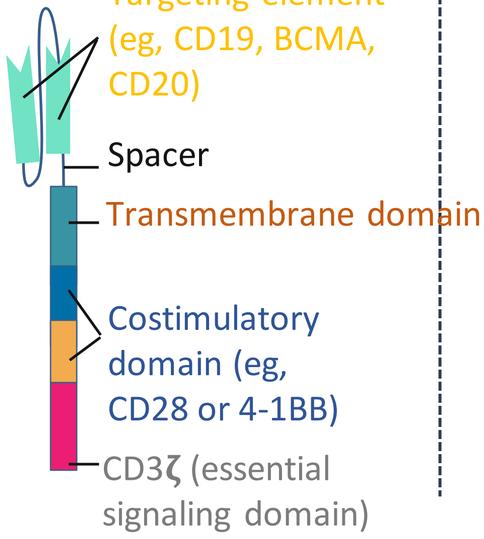


Manufacturing

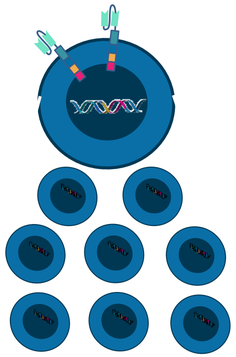
Isolate and activate T cells

Engineer T cells with CAR gene



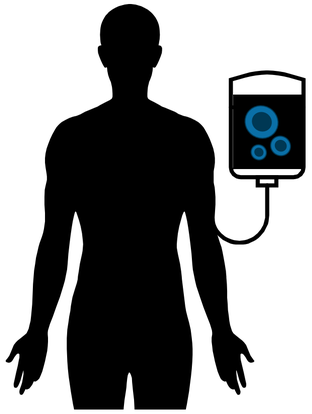


Expand CAR T cells

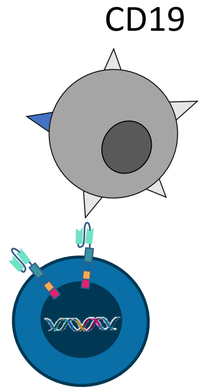


Infusion

Infuse same patient with CAR T cells



Activity



Median manufacturing time: 17-28 days

Patients undergo lymphodepleting (and possibly salvage/bridging) therapy

Majors. EHA 2018. Abstr PS1156. Lim. Cell. 2017;168:724. Sadelain. Nat Rev Cancer. 2003;3:35. Brentjens. Nat Med. 2003;9:279. Park. ASH 2015. Abstr 682. Axicabtagene ciloleucel PI. Tisagenlecleucel PI.

Current Commercial CAR T-cell Products

Non-Hodgkin Lymphoma

FDA Approved CAR T-cell Products

YESCARTA Axicabtagene ciloleucel	BREYANZI Lisocabtagene maraleucel
• Refractory DLBCL • 3L DBLCL • 3L PMBCL • 3L HGBCL • 3L transformed FL • 3L FL	• R/R DLBCL • R/R HGBCL • R/R PMBCL • R/R FL grade 3B
KYMRIAH **Tisagenlecleucel**	**TECARTUS** **Brexucabtagene autoleucel**
• 3L DLBCL • 3L HGBCL • 3L transformed FL • 3L FL	• Relapsed/refractory MCL

Key Trials of CD19 CAR T-cell Products in LBCL

ZUMA-1 Axicabtagene ciloleucel	**TRANSCEND** Lisocabtagene maraleucel	**JULIET** Tisagenlecleucel
• N=108 (119 enrolled) • Bridging therapy: N/A • Days to infusion: 17	• N=294 (344 enrolled) • Bridging therapy: 59% • Days to infusion: 37	• N=111 (165 enrolled) • Bridging therapy: 92% • Days to infusion: 54
• ORR: 74% • CR: 54% • mPFS: 5.9 months	• ORR: 73% • CR: 53% • mPFS: 7.2 months	• ORR: 52% • CR: 40% • mPFS: 35% at 1 year
• CRS, G3-4: 11% • Neurotox, G3-4: 32% • Infection, G3-4: 28%	• CRS, G3-4: 2% • Neurotox, G3-4: 10% • Infection, G3-4: 12%	• CRS, G3-4: 22% • Neurotox, G3-4: 12% • Infection, G3-4: 20%

Neelapu. NEJM. 2017;377:2531.
Abramson. Lancet. 2020;396:839.
Schuster. NEJM. 2019;380:45.

Key Trials of CD19 CAR T-cell Products in Other Lymphomas

ZUMA-2 Brexucabtagene autoleucel	ZUMA-5 Axicabtagene ciloleucel
• N=68 (74 enrolled) • Bridging therapy: 37% • Days to infusion: 16	• N=148 (124 FL, 24 MZL) • Bridging therapy: 4% • Days to infusion: 17
• ORR: 85% • CR: 59%	• ORR: 94% (FL) and 80% (MZL) • CR: 85% (FL) and 60% (MZL)
• CRS, G3-4: 15% • Neurotox, G3-4: 31% • Infections, G3-4: 32% • Cytopenias: 94%	• CRS, G3-4: 7% • Neurotox, G3-4: 19% • Infections, G3-4: 18% • Cytopenias: 70%

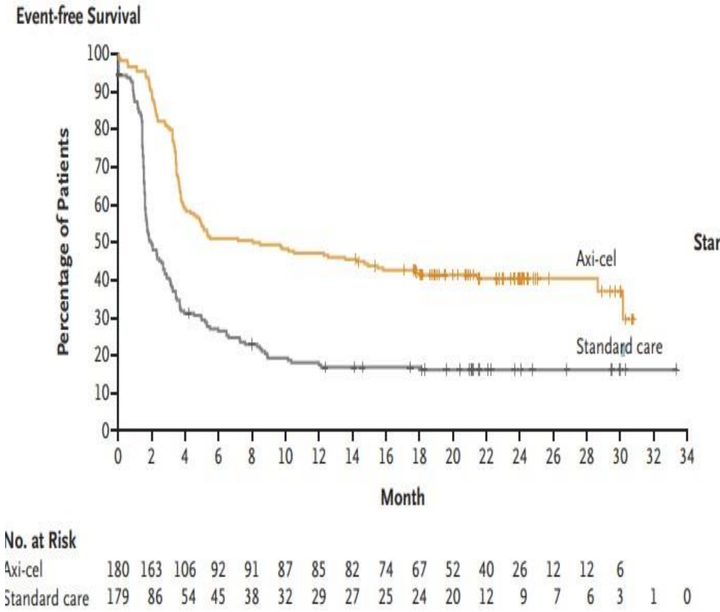
Wang. NEJM. 2020;382:1331.
Jacobson. Lancet Oncology. 2022; 91:103

Results from ASH 2021 Presentations

	ZUMA-7 Axicabtagene ciloleucel	TRANSFORM Lisocabtagene maraleucel	BELINDA Tisagenlecleucel
Event free-survival	8.3 months (vs. 2 months)	10.1 months (vs. 2.3 months)	3 months (vs. 3 months)
Overall response rate	83% (vs. 50%)	86% (vs. 48%)	46% (vs. 43%)
Complete response rate	65% (vs. 32%)	66% (vs. 39%)	28% (vs. 28%)
Overall survival	Not reached (vs. 35 months)	Not reached	"Immature at data cutoff"

Locke. NEJM. 2022; 386:640-654.
Kamdar. Lancet. 2022; 2294-2308.
Bishop. NEJM. 2022; 386:629-639

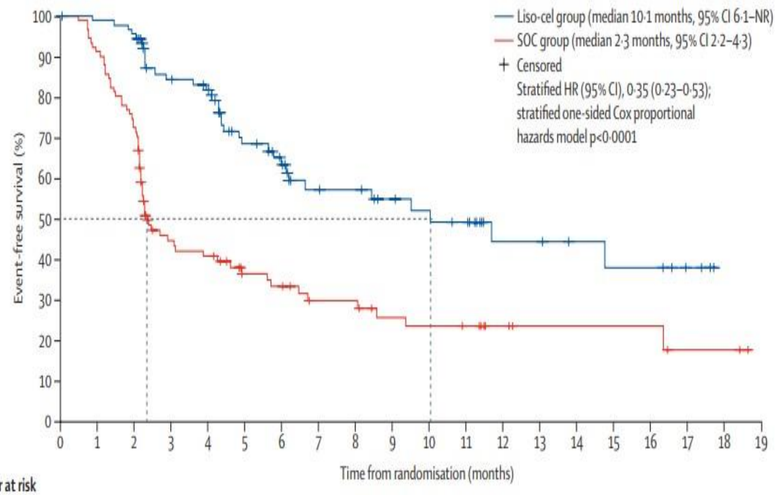
Results from ASH 2021 Presentations



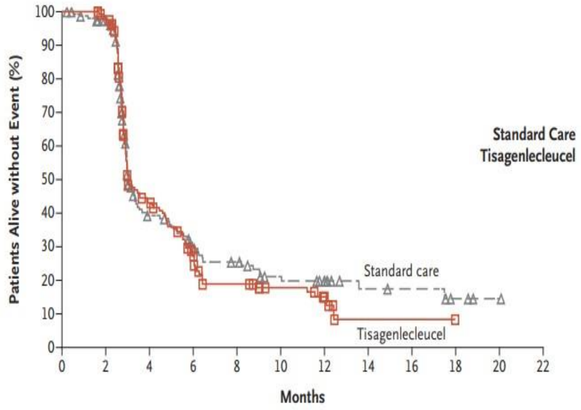
	No. of Patients	Median Event-free Survival (95% CI)
		mo
Axi-cel	180	8.3 (4.5–15.8)
Standard Care	179	2.0 (1.6–2.8)

Stratified hazard ratio for event or death, 0.40 (95% CI, 0.31–0.51)
P<0.001

No. at Risk																
Axi-cel	180	163	106	92	91	87	85	82	74	67	52	40	26	12	12	6
Standard care	179	86	54	45	38	32	29	27	25	24	20	12	9	7	6	3	1	0



Number at risk																							
umber censored)																							
Liso-cel group	92 (0)	89 (2)	86 (2)	66 (13)	62 (15)	43 (25)	36 (29)	27 (35)	26 (36)	21 (40)	19 (41)	17 (42)	9 (49)	9 (49)	7 (51)	6 (51)	6 (51)	4 (53)	0 (57)	- (57)			
SOC group	92 (0)	83 (1)	66 (1)	35 (8)	32 (8)	23 (14)	21 (14)	16 (17)	16 (17)	12 (19)	11 (19)	10 (20)	6 (24)	4 (26)	4 (26)	4 (26)	4 (26)	2 (27)	2 (27)	0 (29)			



	No. of Patients	No. of Events	Median Event-free Survival (95% CI)
			mo
Standard Care	160	104	3.0 (3.0–3.5)
Tisagenlecleucel	162	117	3.0 (2.9–4.2)

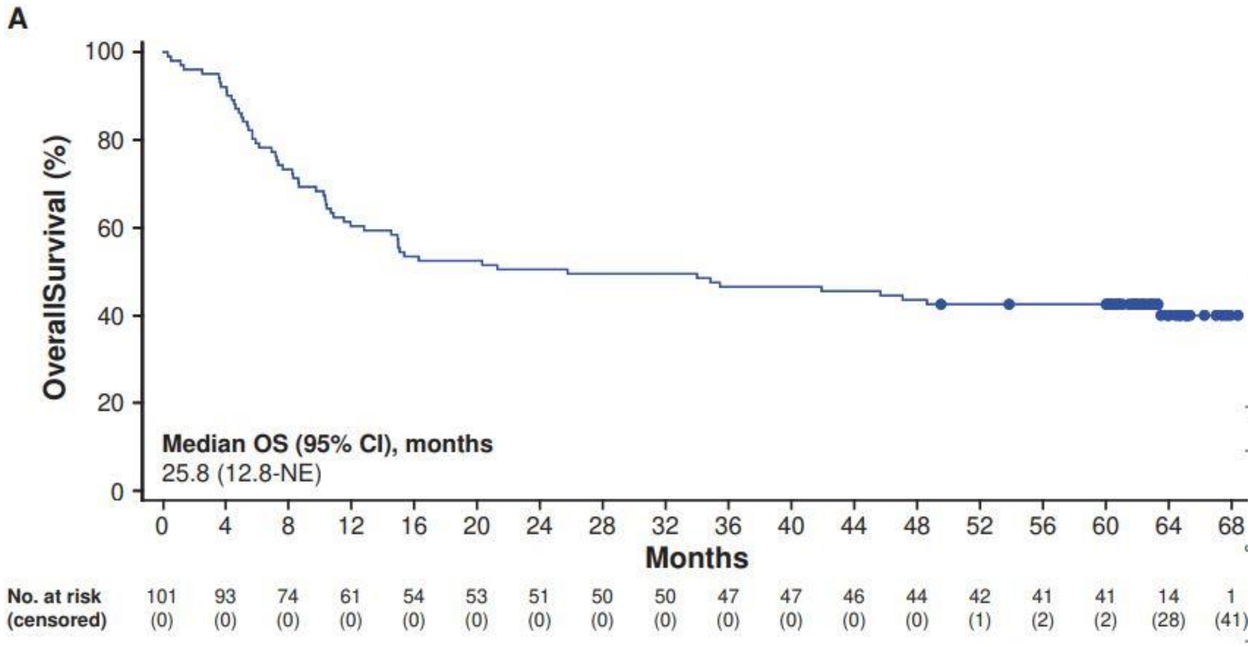
Hazard ratio for event or death (tisagenlecleucel vs. standard care), 1.07 (95% CI, 0.82–1.40)
P=0.61

No. at Risk												
Standard care	160	148	45	31	25	17	12	7	6	3	1	0
Tisagenlecleucel	162	156	57	32	19	13	6	1	1	0	0	0

Locke. NEJM. 2022; 386:640-654.
Kamdar. Lancet. 2022; 2294-2308.
Bishop. NEJM. 2022; 386:629-639

Long-Term Follow Up

- 5 year analysis of data from ZUMA-1:
  - ORR 83%
  - Median OS 25.8 months
  - Estimated 5-year OS 42.6%
  - No new long-term adverse events reported



Neelapu. Blood. 2022018893. 23 Feb. 2023.

Long-Term Follow Up

Press Releases

March 21, 2023

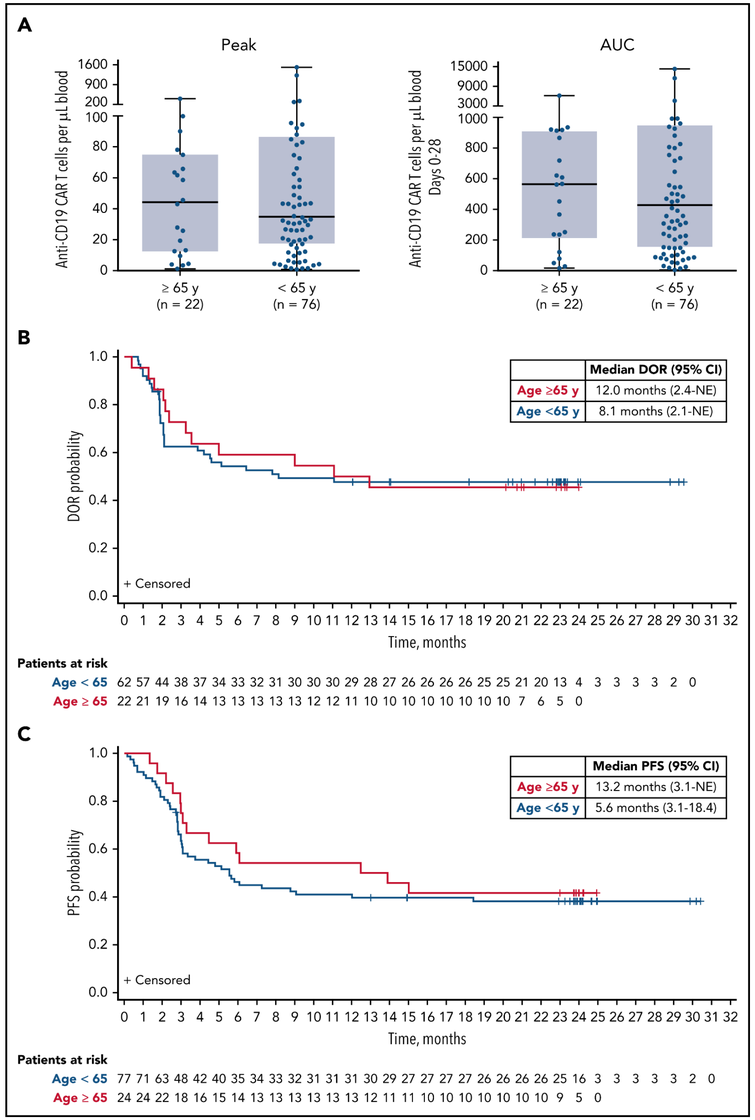
Kite's Yescarta® CAR T-cell Therapy Demonstrates a Statistically Significant Improvement in Overall Survival for Initial Treatment of Relapsed/Refractory Large B-cell Lymphoma

-- First and Only Treatment in Nearly 30 Years to Show Statistically Significant Improvement in OS for Initial Treatment of R/R LBCL Patients Versus Historical Standard of Care in Curative Setting --

-- Landmark ZUMA-7 Study OS Data Reach Maturity Per Protocol, 5 Years After 1st Patient Randomized --

CART in Older Patients

- Subgroup analysis of ZUMA-1:
  - Response rates similar (ORR 92%, CR 75%)
  - No increase in adverse events
    - G3-4 CRS: 7%
    - G3-4 neurotox: 44%
    - G3-4 infections: 19%
  - Outcomes were better compared to SCHOLAR-1

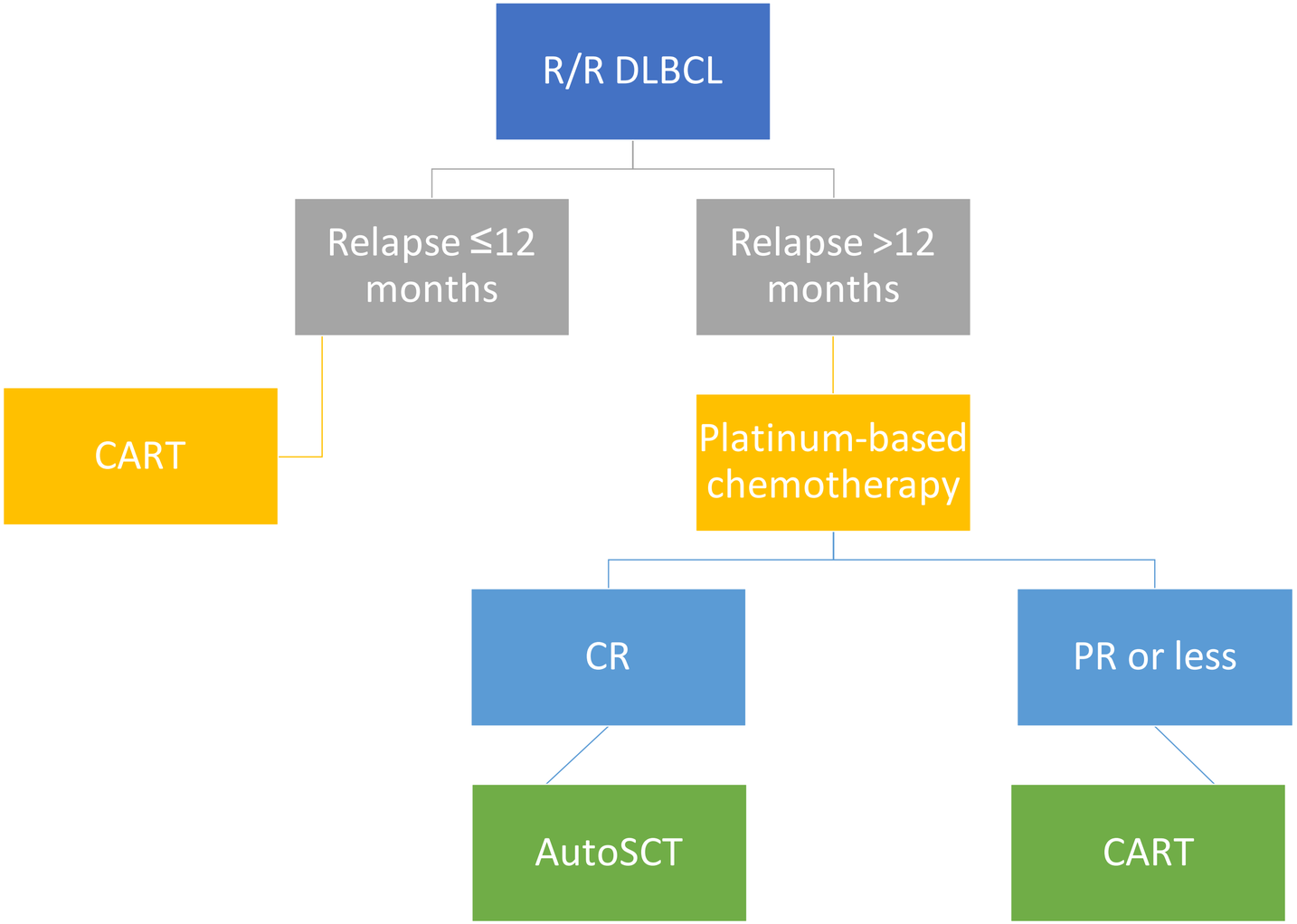


Neelapu. Blood. 2020: 2106-2109.

Take Home Points

- CAR T-cell therapy is very effective and durable in patients with relapsed large cell lymphomas, MCL, and FL/MZL.
- In primary refractory DLBCL, CAR T-cell therapy is the new standard of care.
- CAR T-cell therapy is an option for patients >65.

My Approach


R/R DLBCL
Relapse ≤12 months
Relapse >12 months
CART
Platinum-based chemotherapy
CR
PR or less
AutoSCT
CART

Acute Lymphoblastic Leukemia

FDA Approved CAR T-cell Products

KYMRIAH Tisagenlecleucel	TECARTUS Brexucabtagene autoleucel
• Young adults up to age 25 with R/R ALL	• Adults with R/R ALL

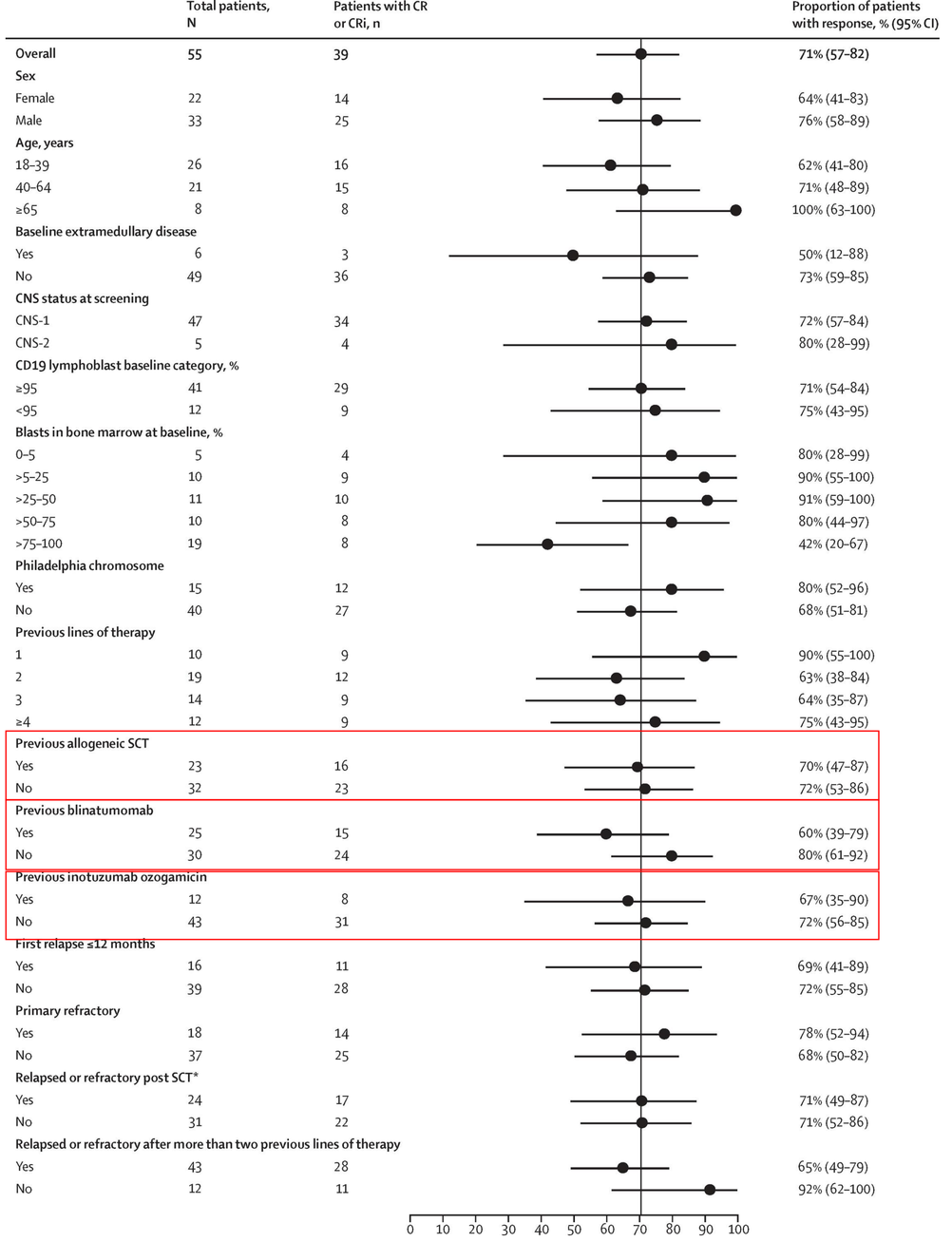
Key Trials of CD19 CAR T-cell Products in ALL

ELIANA Tisagenlecleucel	**ZUMA-3** Brexucabtagene autoleucel
• N=79 (Peds/AYA) • CR/CRi: 82% (all MRD negative) • 6 mo EFS: 73% • 6 mo OS: 90% • 5 yr EFS: 36% • 5 yr OS: 55%	• N=54 (adults) • 45% prior blinatumomab • CR: 71% (38/39 MRD negative) • DOR: 14.6 months
• CRS, G3-4: 49% • Neurotox, G3: 13% (no G4)	• CRS, G3-4: 24% • Neurotox, G3-4: 25%

Maude. NEJM. 2018:439-448.
Shah. Lancet. 2021: 491-502.
Shah. JCO. 2022: 7010-7010

What about prior treatment?

- ZUMA-3:
  - 45% of patients had prior **blinatumomab** exposure
    - Lower rates of CR/CRi (60% vs 80%)
    - No change in OS and RFS
  - 22% of patients had prior **inotuzumab** exposure
  - 42% of patients had prior **allogeneic SCT**



	Total patients, N	Patients with CR or CRi, n	Proportion of patients with response, % (95% CI)
Overall	**55**	**39**	**71% (57–82)**
Sex			
Female	22	14	64% (41–83)
Male	33	25	76% (58–89)
Age, years			
18–39	26	16	62% (41–80)
40–64	21	15	71% (48–89)
≥65	8	8	100% (63–100)
Baseline extramedullary disease			
Yes	6	3	50% (12–88)
No	49	36	73% (59–85)
CNS status at screening			
CNS-1	47	34	72% (57–84)
CNS-2	5	4	80% (28–99)
CD19 lymphoblast baseline category, %			
≥95	41	29	71% (54–84)
<95	12	9	75% (43–95)
Blasts in bone marrow at baseline, %			
0–5	5	4	80% (28–99)
>5–25	10	9	90% (55–100)
>25–50	11	10	91% (59–100)
>50–75	10	8	80% (44–97)
>75–100	19	8	42% (20–67)
Philadelphia chromosome			
Yes	15	12	80% (52–96)
No	40	27	68% (51–81)
Previous lines of therapy			
1	10	9	90% (55–100)
2	19	12	63% (38–84)
3	14	9	64% (35–87)
≥4	12	9	75% (43–95)
Previous allogeneic SCT			
Yes	23	16	70% (47–87)
No	32	23	72% (53–86)
Previous blinatumomab			
Yes	25	15	60% (39–79)
No	30	24	80% (61–92)
Previous inotuzumab ozogamicin			
Yes	12	8	67% (35–90)
No	43	31	72% (56–85)
First relapse ≤12 months			
Yes	16	11	69% (41–89)
No	39	28	72% (55–85)
Primary refractory			
Yes	18	14	78% (52–94)
No	37	25	68% (50–82)
Relapsed or refractory post SCT*			
Yes	24	17	71% (49–87)
No	31	22	71% (52–86)
Relapsed or refractory after more than two previous lines of therapy			
Yes	43	28	65% (49–79)
No	12	11	92% (62–100)

Shah. Lancet. 2021: 491-502.

Take Home Points

- CAR T-cell therapy can provide long-term disease control in ALL.
- Prior blinatumomab exposure does not limit survival data.

Multiple Myeloma

FDA Approved CAR T-cell Products

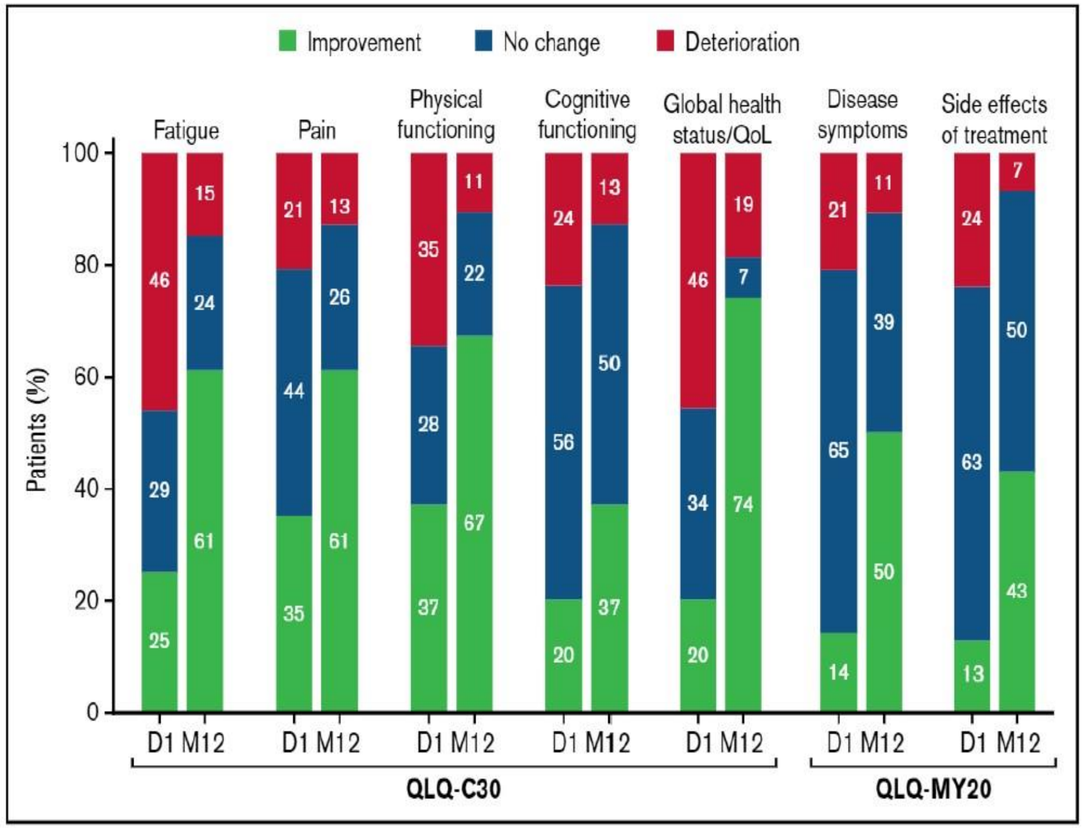
CARVYKTI Ciltacabtagene autoleucel	**ABECMA** Idecabtagene vicleucel
• Adults with R/R multiple myeloma after >4 lines of therapy (including IMiD, PI, anti-CD38 MA)	• Adults with R/R multiple myeloma after >4 lines of therapy (including IMiD, PI, anti-CD38 MA)

Key Trials of BCMA CAR T-cell Products in Multiple Myeloma

CARTITUDE-1 Ciltacabtagene autoleucel	**KarMMa-3** Idecabtagene vicleucel
• N=97 patients (6 prior therapies) • ORR: 97% • sCR: 83% • mPFS: NR • mOS: NR	• N=128 (triple class refractory) • ORR: 73% • CR: 33% (79% MRD negative) • mPFS: 8.8 months
• CRS, G3-4: 4% • Neurotox, G3-4: 9%	• CRS, G3-4: 5% • Neurotox, G3-4: 3%

Martin. JCO. 2022: 1265-1274.
Munshi. NEJM. 2021: 384:705-716

CAR T-cell Therapy Improves HRQoL



- 128 patients who received ide-cel.
- Measured by EORTC-QoL C30 and EuroQoL 5-dimension 5-level instrument.
- Pre-treatment, patients with RRMM had worse symptoms and QoL than general population.
- After ide-cel, there were improvements in fatigue, pain, functioning, and QoL.
  - Median time to improvement: 4 months
  - Improvements sustained for 15-18 months

Delforge. Blood Advances. 2022: 1309-1318.

Take Home Points

- We have another effective treatment option in multiple myeloma – CART!
- CART can improve quality of life in patients with RRMM.
- CART slots are limited.

Monitoring CART Patients in the Community

Long-Term Toxicities

- **Cytopenias**
  - Prolonged cytopenias can be very troublesome.
  - May be related to G3-4 CRS and ICANS.
  - Monitor/transfuse as needed.
  - GCSF and other supportive measures OK.
- **Infections**
  - Monitor closely for infections post-CART.
  - Prophylactic antimicrobials as needed.
- **B-cell aplasia**
  - Occurred in approximately 15% of patients treated with axi-cel, brexu-cel, and tisa-cel.
  - If IgG <400, consider IVIG.

Jain. Blood Advances. 2020: 3776-3787.
Chakraborty. Transplant Cell Therapy. 2021: 222-229.

Long-Term Toxicities

- **Delayed-onset neurotoxicity**
  - No driving for 8 weeks post-CART infusion.
  - Rare in BCMA CARs.
- **Secondary malignancies**
  - Rare (1 patient in ZUMA-1) but probably more common.

Chakraborty. Transplant Cell Therapy. 2021: 222-229.

Referral for CART

- Refer early for CAR T-cell therapy to allow time for evaluation, collection, and planning.
- Consider referral for any relapsed/refractory large B-cell lymphoma, mantle cell lymphoma, acute lymphoblastic leukemia, and multiple myeloma.
- No age limit for referral.

Future Directions in Cellular Therapy

New Targets for CAR T-cell Therapy

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

GPRC5D-Targeted CAR T Cells for Myeloma

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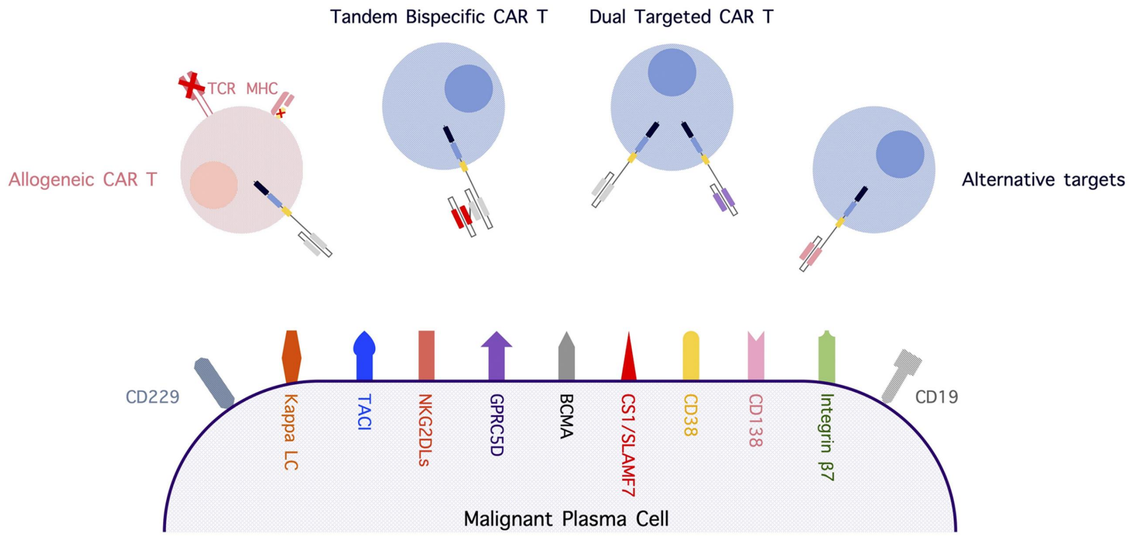
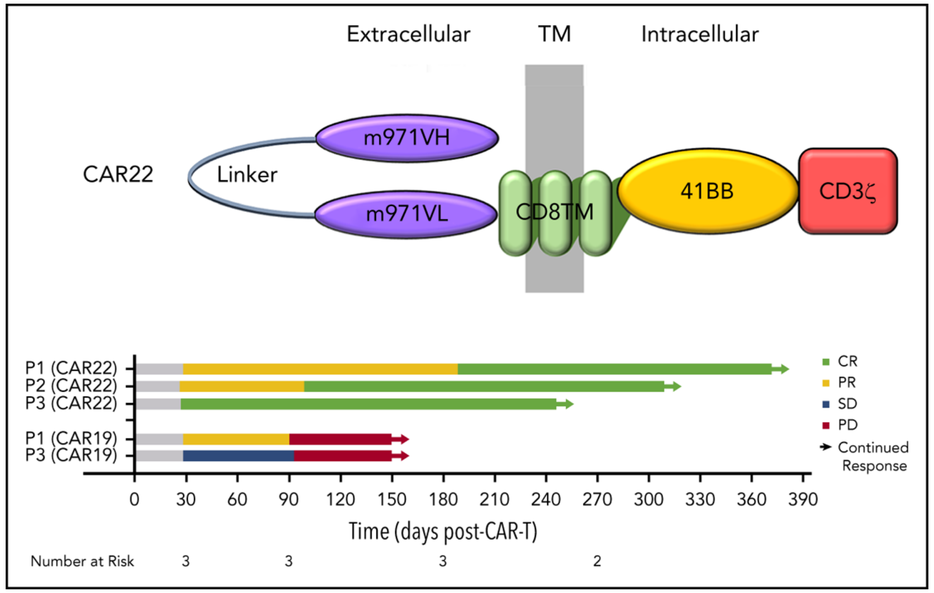
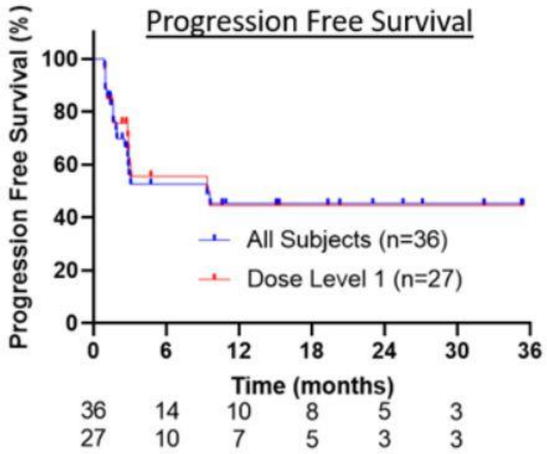


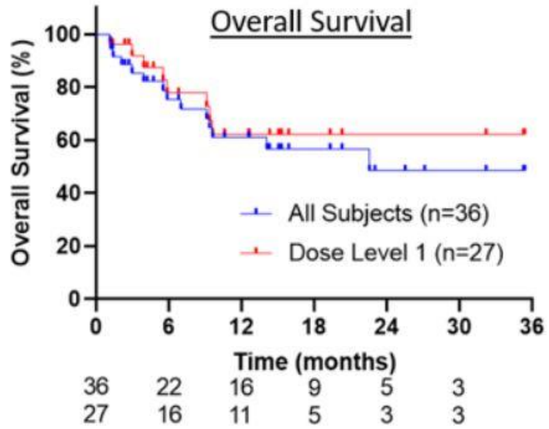
Wudhikarn K et al, ASH Education Program 2020

New Targets for CAR T-cell Therapy



Baird. Blood. 2021: 2321-2325.





- 37 of 39 patients to date
- Median follow up 15.7 months
- ORR 72%
- CR 53%
- Only 1 of 19 who achieved CR relapsed

Frank. CD22 CAR T Cell Therapy Induces Durable Remissions in Patients with Large B Cell Lymphoma Who Relapse after CD19 CAR T Cell Therapy. Tandem 2023.

Dual Target and Tandem CAR T-cells

nature medicine

ARTICLES

https://doi.org/10.1038/s41591-021-01436-0

Check for updates

OPEN

CAR T cells with dual targeting of CD19 and CD22 in adult patients with recurrent or refractory B cell malignancies: a phase 1 trial

Jay Y. Spiegel[1,13], Shabnum Patel[2,13], Lori Muffly[1,2,13], Nasheed M. Hossain[3], Jean Oak[4], John H. Baird[1], Matthew J. Frank[1], Parveen Shiraz[1], Bita Sahaf[2], Juliana Craig[1], Maria Iglesias[1], Sheren Younes[4], Yasodha Natkunam[4], Michael G. Ozawa[4], Eric Yang[4], John Tamaresis[5], Harshini Chinnasamy[2], Zach Ehlinger[2], Warren Reynolds[2], Rachel Lynn[2,12], Maria Caterina Rotiroti[6], Nikolaos Gkitsas[2], Sally Arai[1], Laura Johnston[1], Robert Lowsky[1], Robbie G. Majzner[2,6], Everett Meyer[1], Robert S. Negrin[1], Andrew R. Rezvani[1], Surbhi Sidana[1], Judith Shizuru[1], Wen-Kai Weng[1], Chelsea Mullins[7], Allison Jacob[7], Ilan Kirsch[7], Magali Bazzano[8], Jing Zhou[8], Sean Mackay[8], Scott J. Bornheimer[9], Liora Schultz[2,6,10], Sneha Ramakrishna[2,6], Kara L. Davis[2,6], Katherine A. Kong[2], Nirali N. Shah[10], Haiying Qin[10], Terry Fry[10,11], Steven Feldman[2,14], Crystal L. Mackall[2,6,14] ✉ and David B. Miklos[1,2,14] ✉

653.MYELOMA: THERAPY, EXCLUDING TRANSPLANTATION | NOVEMBER 13, 2019

A Bcma and CD19 Bispecific CAR-T for Relapsed and Refractory Multiple Myeloma

Hua Zhang, Lei Gao, Li Liu, Jishi Wang, PhD, Sanbin Wang, Li Gao, Cheng Zhang, MD PhD, Yao Liu, Peiyan Kong, Jia Liu, Jiaping He, Yu Han, Hua Shi, Yan He, Xun Ye, Yi Zhao, Wei Cao, Lianjun Shen, Xi Zhang

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Blood (2019) 134 (Supplement_1): 3147.

https://doi.org/10.1182/blood-2019-131056

Allogeneic CAR T-cells

- No delays for cell processing.
- Repeat dosing can be given if need be.
- No complex logistics.
- Less product variability.

ADI-001: Allogeneic gamma delta CAR T-cell Therapy for CD20

- 9 patients with LBCL (5 DLBCL, 2 HGBCL with DH/TH, 1 HGBCL NOS, 1 MCL)
  - 4 patients with prior CD19 CAR
- Minimal CRS/ICANS – only grade 1 and 2
- ORR 78%, CR 78%

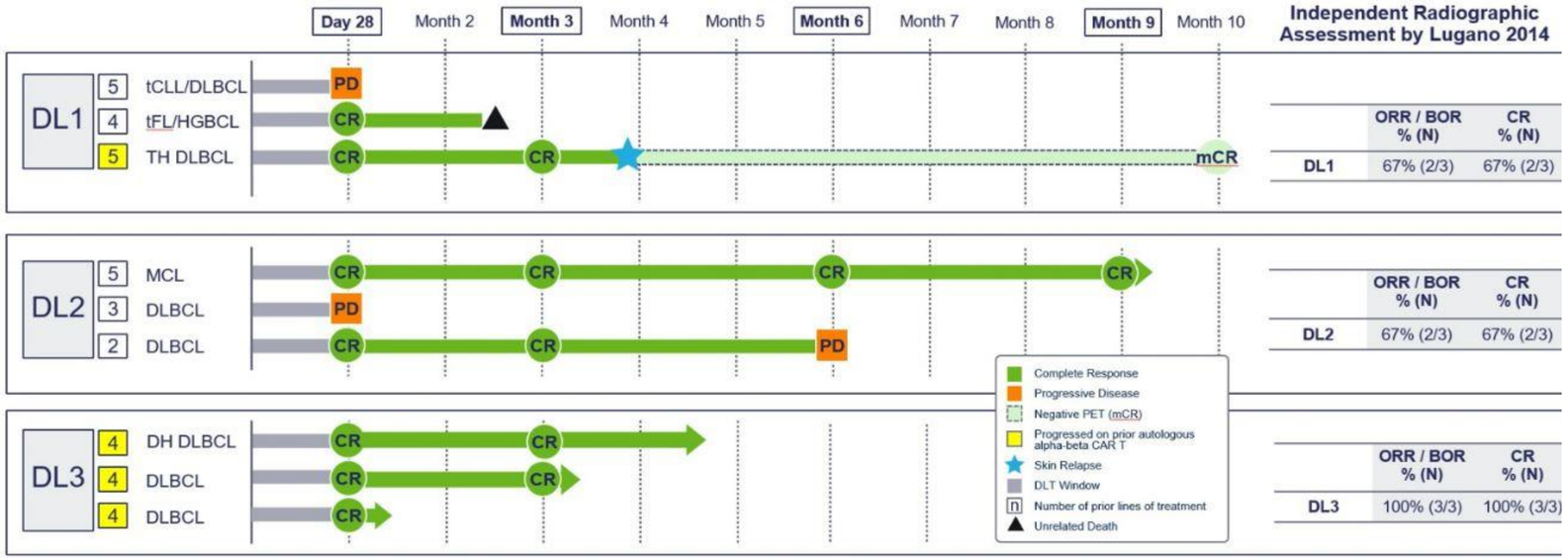

Fig1. Waterfall plot, data cut-off 15 July

Neelapu. A Phase 1 Study of ADI-001: Anti-CD20 CAR-Engineered Allogeneic Gamma Delta1 (γδ) T Cells in Adults with B-Cell Malignancies. Tandem 2023.

CAR T-cell Therapy for Autoimmune Conditions

ARTICLES
https://doi.org/10.1038/s41591-022-02017-5
nature medicine
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Anti-CD19 CAR T cell therapy for refractory systemic lupus erythematosus

Andreas Mackensen[1,2,8], Fabian Müller[1,2,8], Dimitrios Mougiakakos[1,2,3,8], Sebastian Böltz[2,4], Artur Wilhelm[2,4], Michael Aigner[1,2], Simon Völkl[1,2], David Simon[2,4], Arnd Kleyer[2,4], Luis Munoz[2,4], Sascha Kretschmann[1,2], Soraya Kharboutli[1,2], Regina Gary[1,2], Hannah Reimann[1,2], Wolf Rösler[1,2], Stefan Uderhardt[2,4], Holger Bang[5], Martin Herrmann[2,4], Arif Bülent Ekici[6], Christian Buettner[6], Katharina Marie Habenicht[7], Thomas H. Winkler[7], Gerhard Krönke[2,4,8] and Georg Schett[2,4,8] ✉

Systemic lupus erythematosus (SLE) is a life-threatening autoimmune disease characterized by adaptive immune system activation, formation of double-stranded DNA autoantibodies and organ inflammation. Five patients with SLE (four women and one man) with a median (range) age of 22 (6) years, median (range) disease duration of 4 (8) years and active disease (median (range) SLE disease activity index Systemic Lupus Erythematosus Disease Activity Index: 16 (8)) refractory to several immunosuppressive drug treatments were enrolled in a compassionate-use chimeric antigen receptor (CAR) T cell program. Autologous T cells from patients with SLE were transduced with a lentiviral anti-CD19 CAR vector, expanded and reinfused at a dose of 1×10^6 CAR T cells per kg body weight into the patients after lymphodepletion with fludarabine and cyclophosphamide. CAR T cells expanded in vivo, led to deep depletion of B cells, improvement of clinical symptoms and normalization of laboratory parameters including seroconversion of anti-double-stranded DNA antibodies. Remission of SLE according to DORIS criteria was achieved in all five patients after 3 months and the median (range) Systemic Lupus Erythematosus Disease Activity Index score after 3 months was 0 (2). Drug-free remission was maintained during longer follow-up (median (range) of 8 (12) months after CAR T cell administration) and even after the reappearance of B cells, which was observed after a mean (±s.d.) of 110 ± 32 d after CAR T cell treatment. Reappearing B cells were naïve and showed non-class-switched B cell receptors. CAR T cell treatment was well tolerated with only mild cytokine-release syndrome. These data suggest that CD19 CAR T cell transfer is feasible, tolerable and highly effective in SLE.

CAR T-cell Therapy Frontline

- ZUMA-23 (NCT05605899)
  - Axicabtagene ciloleucel vs SOC (R-CHOP or DA-EPOCH-R)
  - Currently enrolling

Emily Whitehead

https://emilywhiteheadfoundation.org/

Thank you!

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