ADVANCES IN Cancer IMMUNOTHERAPY™

Immunotherapy of Hematologic Malignancies

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ACCC Association of Community Cancer Centers

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Disclosures

- Research support: Kite, Merck, BMS, Cellectis, Poseida, Karus, Acerta
- Advisory Board: Kite, Merck, Celgene, Novartis

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Immune checkpoint blockade

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PD-L1 Expression in Lymphomas

	Lymphoma subtype	PD-L1 positive (% cases)
Aggressive B-cell NHL	Hodgkin (NS and MC)	89%
	PMBCL	100%
	EBV+ DLBCL	100%
	T-cell/histiocyte-rich B-cell	91%
	EBV+/- PTLD	60%
	ABC DLBCL	57%
	HHV8-associated PEL	50%
	Plasmablastic	44%
	DLBCL NOS	11%
T-cell NHL	ALK+ ALCL	100%
	PTCL	64%
	Extranodal NK/TCL	67%
Indolent B-cell NHL	NLP Hodgkin	13%
	FL, SLL, MZL, MCL, EBV+ BL	0%

PD-L1 / PD-L2 amplification and/or translocation in HL, PMBCL, PCNSL, and testicular lymphoma

Brown et al, J Immunol 2003; Marzec et al, PNAS, 2008; Xerri et al, Hum Pathol, 2008; Andorsky et al, Clin Cancer Res, 2011; Chen et al, Clin Cancer Res, 2013; Chapuy et al, Blood 2016

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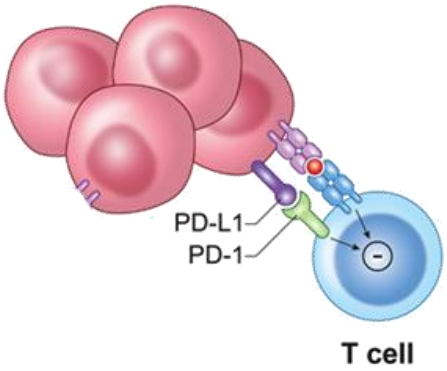

Anti-PD-1 in Hodgkin's Lymphoma

Table 3. Clinical Activity in Nivolumab-Treated Patients.*

Variable	All Patients (N=23)	Failure of Both Stem-Cell Transplantation and Brentuximab (N=15)	No Stem-Cell Transplantation and Failure of Brentuximab (N=3)	No Brentuximab Treatment (N=5)†
Best overall response — no. (%)				
Complete response	4 (17)	1 (7)	0	3 (60)
Partial response	16 (70)	12 (80)	3 (100)	1 (20)
Stable disease	3 (13)	2 (13)	0	1 (20)
Progressive disease	0	0	0	0
Objective response				
No. of patients	20	13	3	4
Percent of patients (95% CI)	87 (66–97)	87 (60–98)	100 (29–100)	80 (28–99)
Progression-free survival at 24 wk — % (95% CI)‡	86 (62–95)	85 (52–96)	NC§	80 (20–97)
Overall survival — wk				
Median	NR	NR	NR	NR
Range at data cutoff¶	21–75	21–75	32–55	30–50

* NC denotes not calculated, and NR not reached.
† In this group, two patients had undergone autologous stem-cell transplantation and three had not.
‡ Point estimates were derived from Kaplan–Meier analyses; 95% confidence intervals were derived from Greenwood's formula.
§ The estimate was not calculated when the percentage of data censoring was above 25%.
¶ Responses were ongoing in 11 patients.

Ansell SM et al. N Engl J Med 2015;372:311-319

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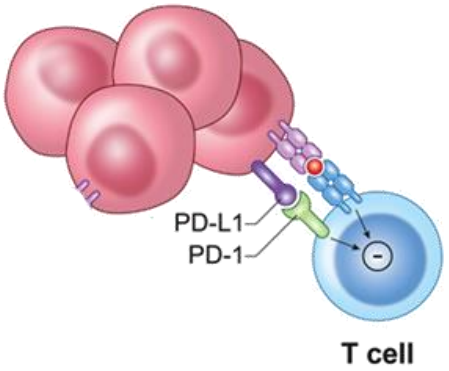

Anti-PD-1 in Hodgkin's Lymphoma

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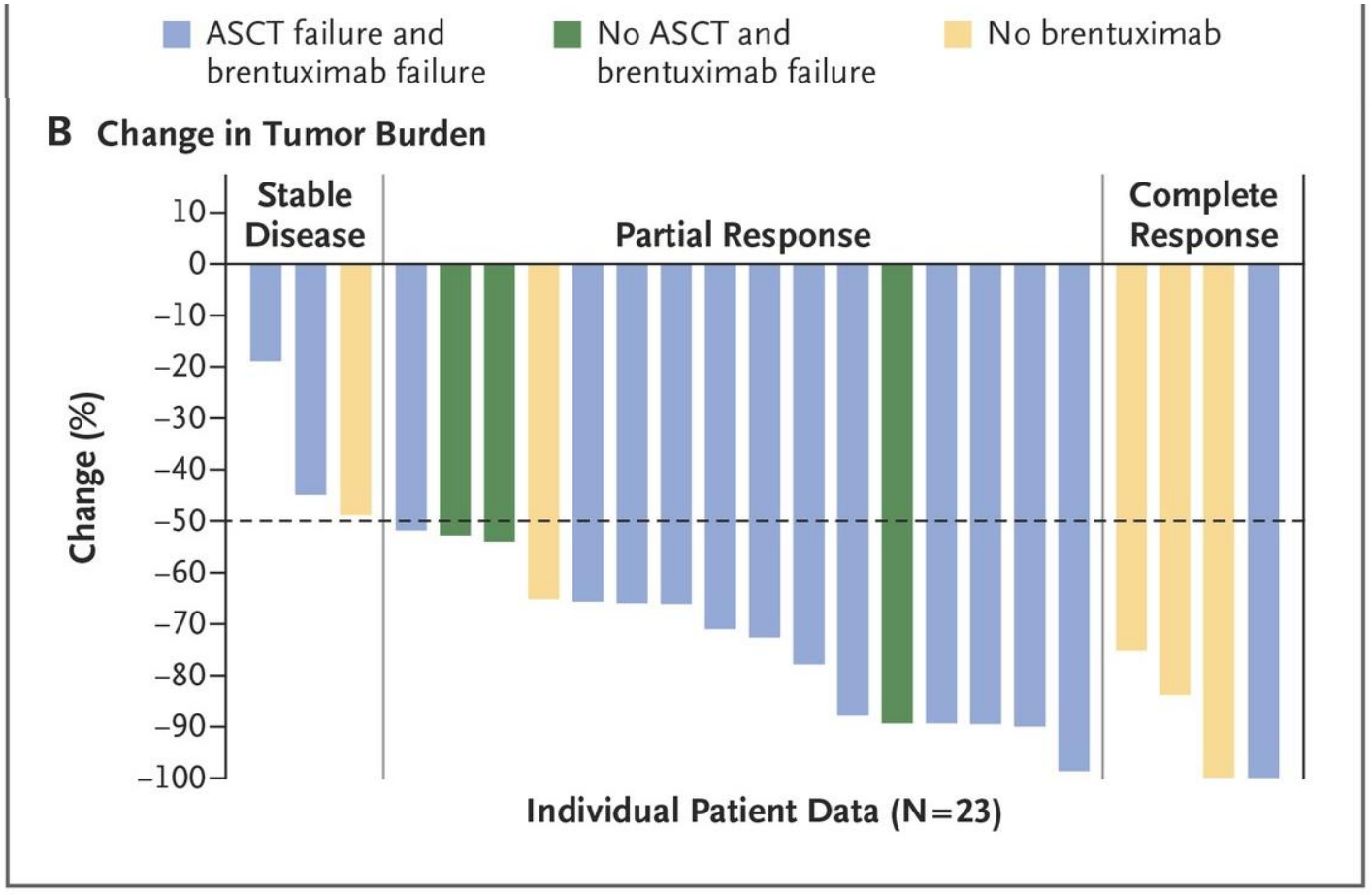

* NC de
† In this
‡ Point e
§ The estimate was not calculated when the percentage of data censoring was above 25%.
¶ Responses were ongoing in 11 patients.

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Nivolumab in R/R B Cell Malignancies: Efficacy

Types	N	ORR, n (%)	CR, n (%)	PR, n (%)	SD, n (%)
B cell lymphoma	29	8 (28)	2 (7)	6 (21)	14 (48)
DLBCL	11	4 (36)	1 (9)	3 (27)	3 (27)
FL	10	4 (40)	1 (10)	3 (30)	6 (60)
T cell lymphoma	23	4 (17)	0	4 (17)	10 (43)
Mycosis fungoides	13	2 (15)	0	2 (15)	9 (69)
PTCL	5	2 (40)	0	2 (40)	0
Multiple myeloma	27	0	0	0	18 (67)
Primary mediastinal B-cell lymphoma	2	0	0	0	2 (100)

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Pembolizumab in R/R PMBCL: Efficacy

Efficacy population (N = 29)	n	% (95% CI)
Overall response	12	41% (24 – 61)
Complete response	4	14% (4 - 32)
Partial response	8	28% (13 - 47)
Stable disease	3	10% (2 - 27)
Progressive disease	8	28% (13 - 47)
No assessment[a]	6	21% (8 - 49)

Zinzani et al, ICML 2017, Abstract 50

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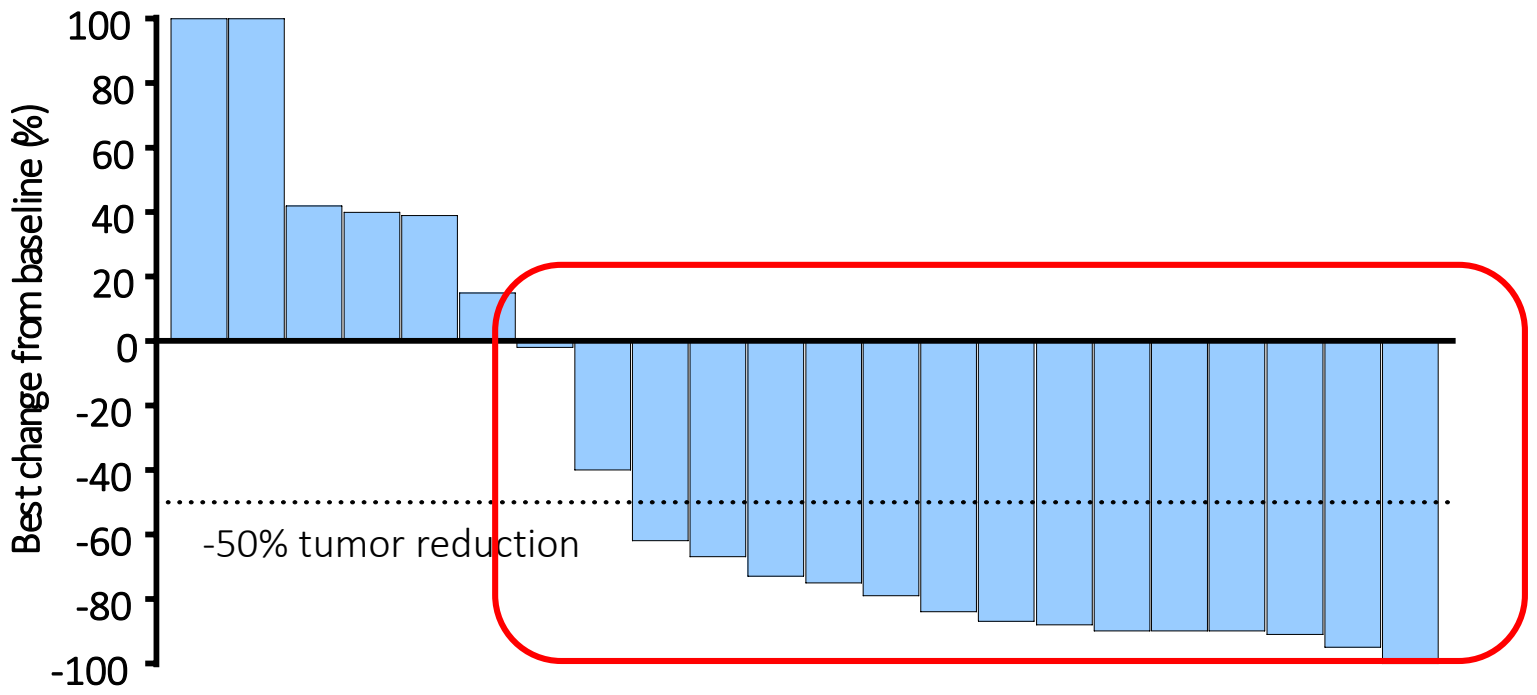
Pembolizumab in R/R PMBCL: Efficacy



73% of patients (16/22) had reduction in target lesions

Zinzani et al, ICML 2017, Abstract 50

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Pembolizumab in CLL and Richter's transformation: Efficacy

Response	RT (n=9)	CLL (n=16)	Total (n=25)
CR	1 (11%)	0	1 (4%)
PR	2 (22%)	0	2 (8%)
PMR	1 (11%)	0	1 (4%)
SD	4 (44%)	5 (31%)	9 (36%)
not evaluated*	0	3 (19%)	3 (12%)
PD#	1 (11%)	8 (50%)	9 (36%)
Median PFS (Months)	5.4	2.4	3.0
Median OS (95% CI)	10.7 (4.4 to NR)	11.2 (2.8 to NR)	10.7 (4.4 to NR)

RT – 44% ORR **CLL – 0% ORR**

Ding et al, Blood 2017; doi:10.1182/blood-2017-02-765685

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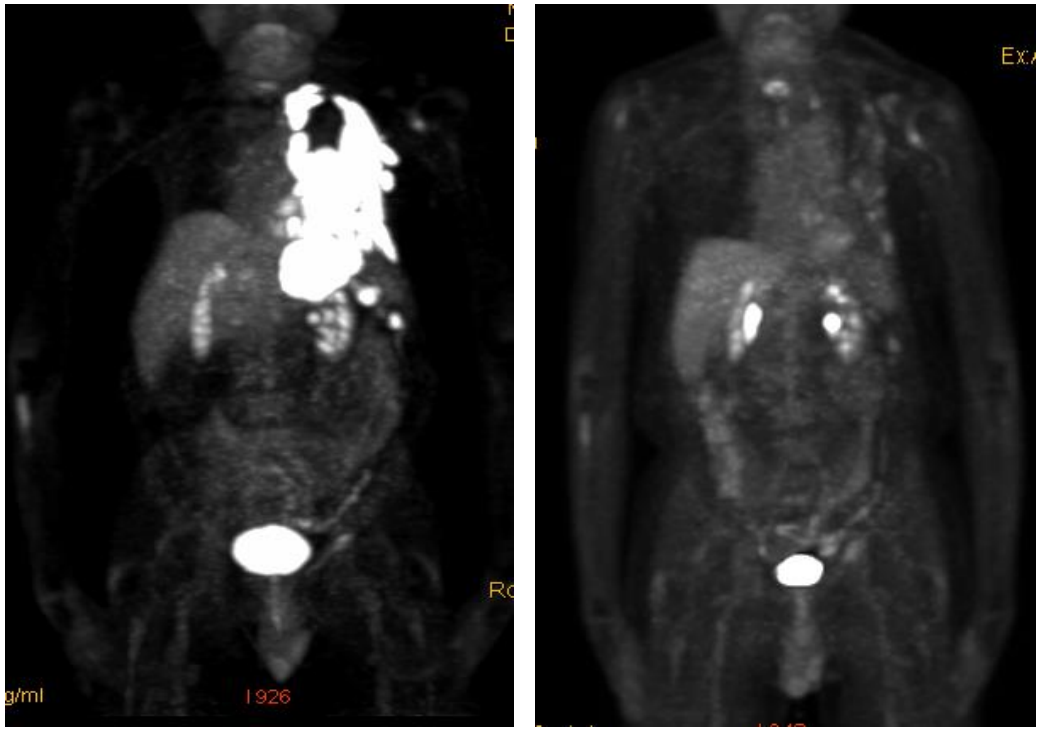
Pembolizumab in CLL and Richter's transformation: Efficacy

Prior therapies (2011-2015)

- PCR x 6 -2011
- RT, 10/2013 - RCHOP x 4, PR
- RICE X 3, 1/2014, no response
- RDHAP x 2, 4/2014, no response
- Local RT to nodal mass, 6/2014
- Ibrutinib, 8/2014 – 2/2015

Baseline | **Pembrolizumab x 2 cycles**

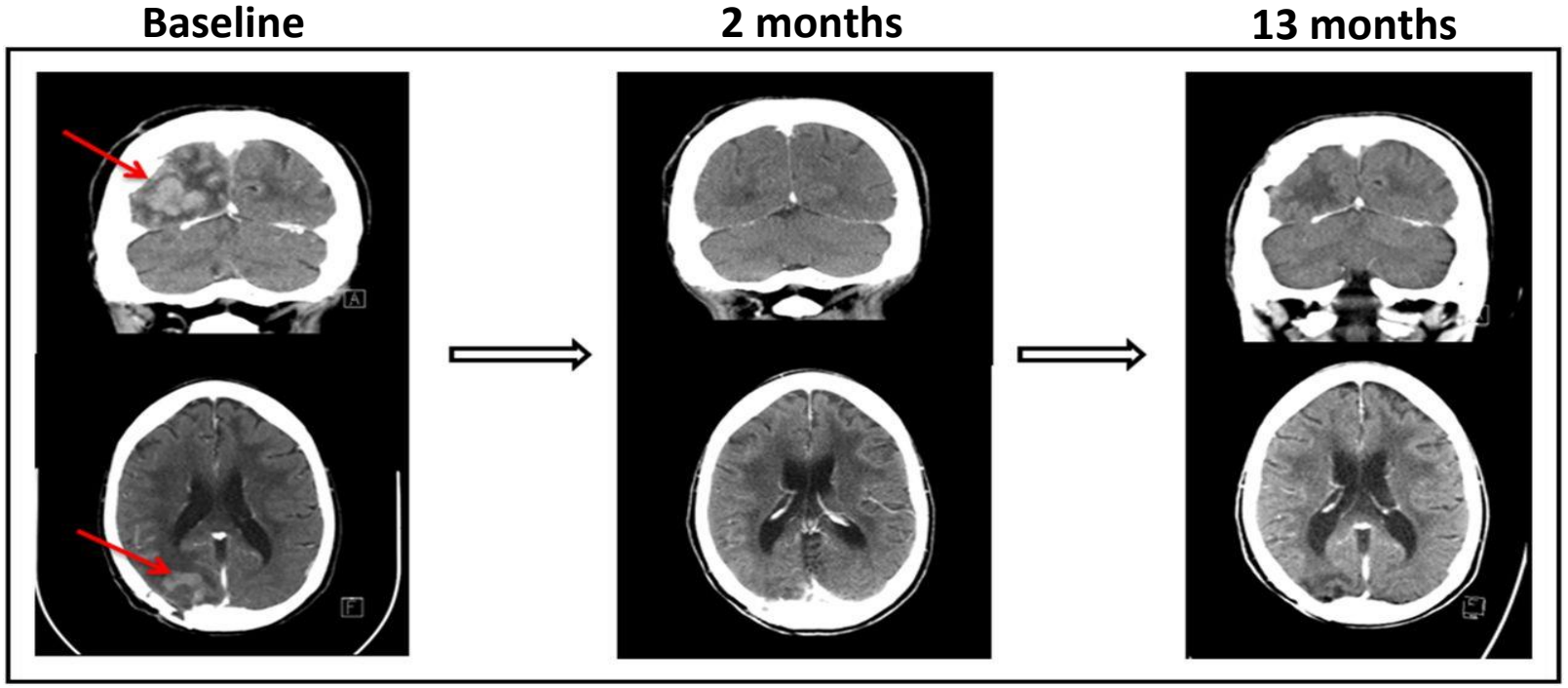


CR ongoing at 16 mos

Ding et al, Blood 2017; doi:10.1182/blood-2017-02-765685

Nivolumab in R/R CNS Lymphoma: Efficacy

- Frequent 9p24.1 copy-number alterations and increased expression of PD-L1 and PD-L2
- 5/5 patients responded; 4 CRs; 1 PR
- 3 remain progression-free at 13+, 14+, and 17+ months



Lakshmi Nayak et al. Blood 2017;129:3071-3073

Pembolizumab in R/R NK/T-cell Lymphoma: Efficacy

- N = 7 r/r NK/TCL
- Pembrolizumab 2 mg/kg every 3 weeks
- Prior therapies included SMILE (n=5), GELOX (n=1), m-BACOD (n=1); allo-SCT (n=2)

Efficacy

- All 7 responded; 5 CRs, 2 PRs
- All 5 CR patients remain in remission at median f/u of 6 mo (range 2-10 mo)
- PD-L1 expression was strong in 4 patients (3 achieving CR) and weak in 1 (achieving PR)

Yok-Lam Kwong et al. Blood 2017;129:2437-2442

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Re-directing T-cell specificity

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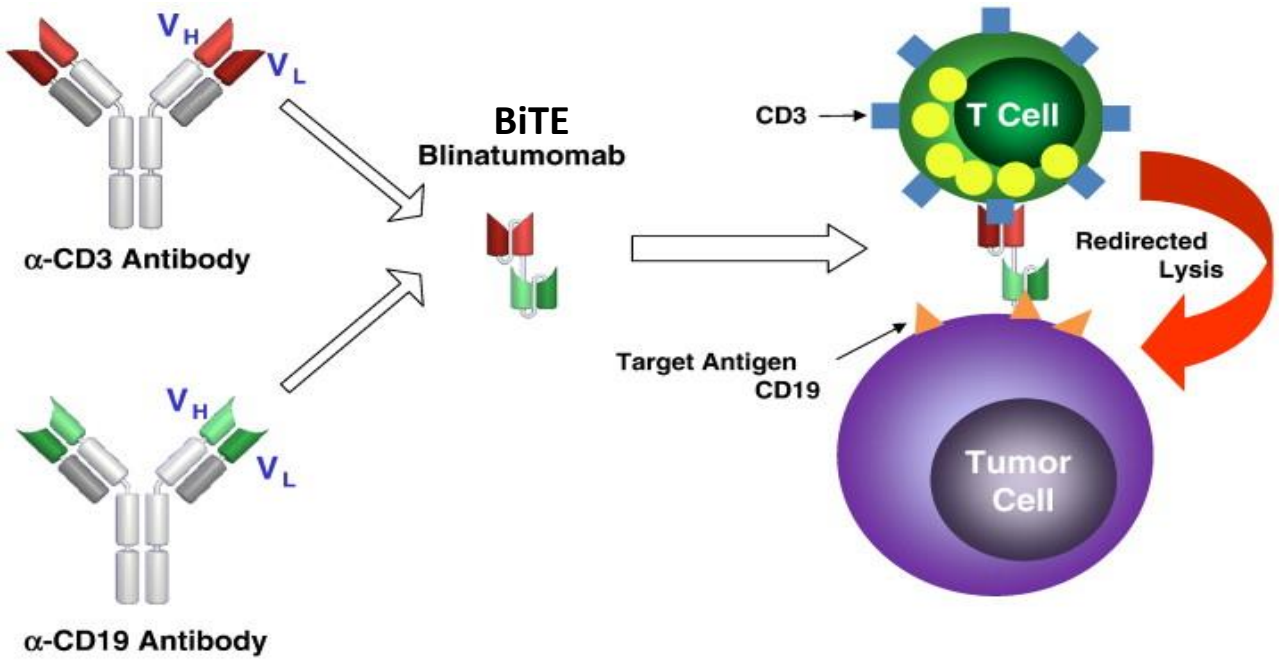
BiTE (Bi-specific T-cell Engager: Blinatumomab

- Combines the F(ab) of an antibody with an anti-CD3 F(ab); Lacks the Fc
  Requires continuous infusions
- Shown considerable activity in:
  - Follicular NHL
  - DLBCL
  - ALL



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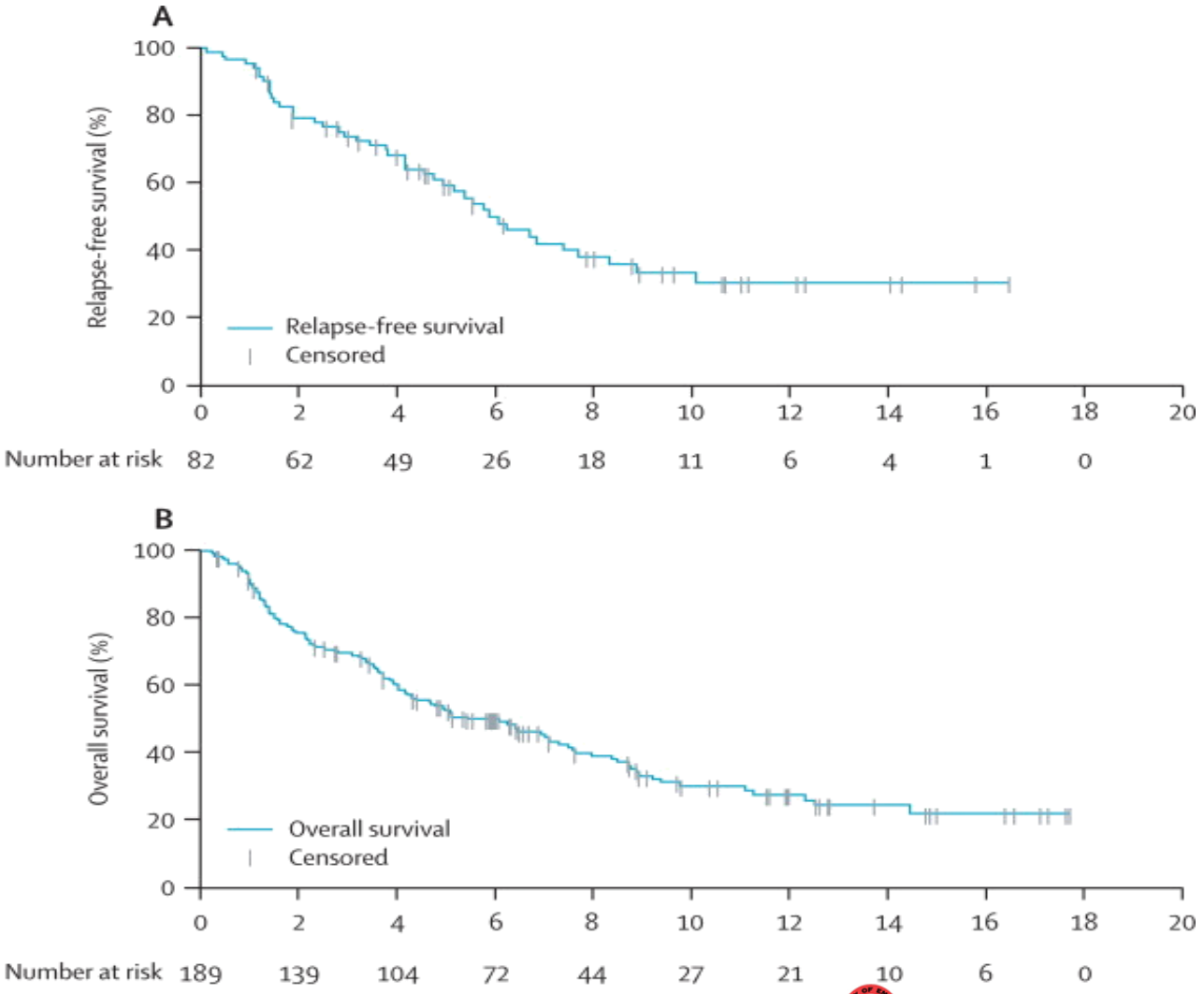
Blinatumomab in ALL



Topp, Max S et al., The Lancet Oncology , Volume 16 , Issue 1 , 57 - 66

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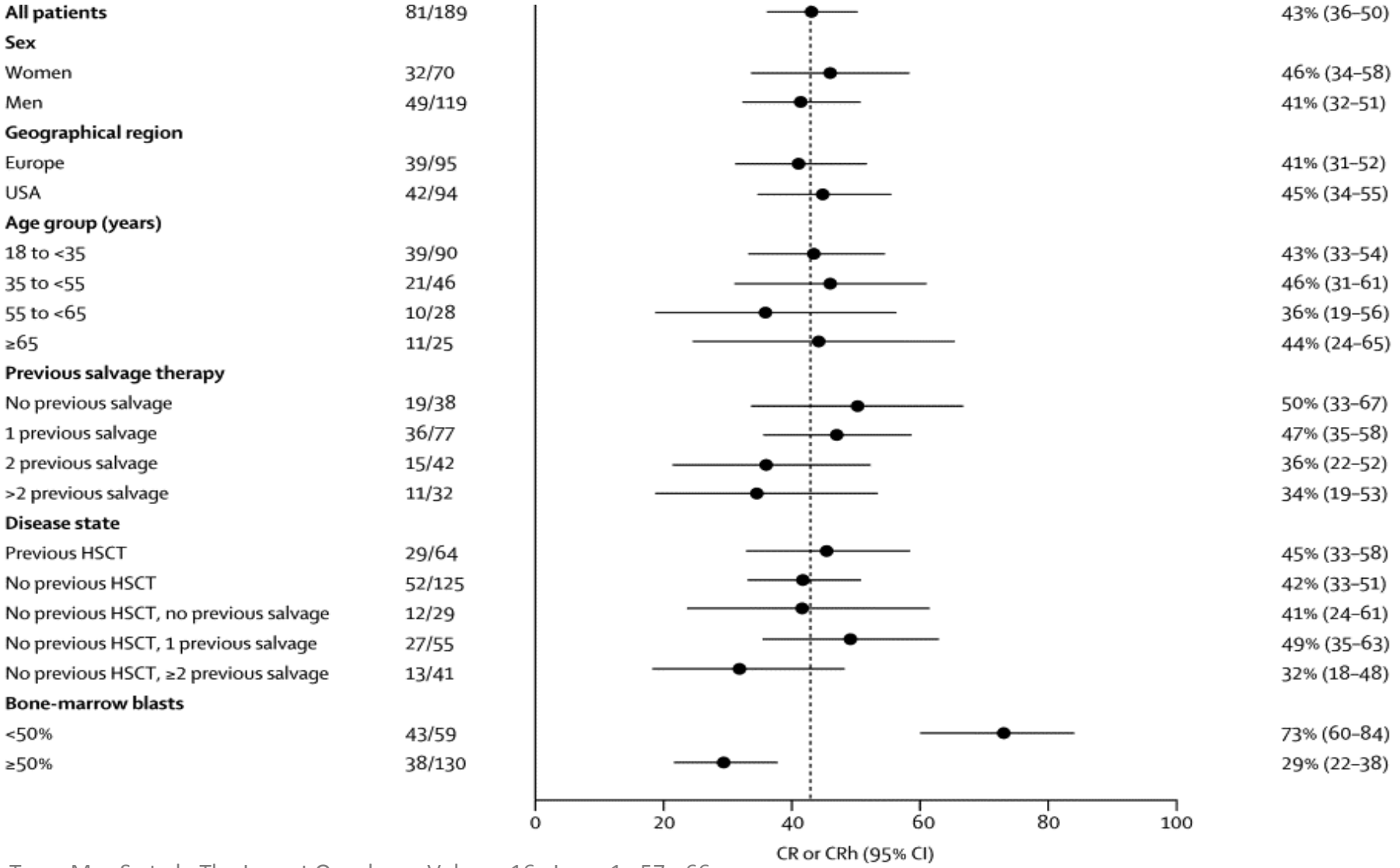
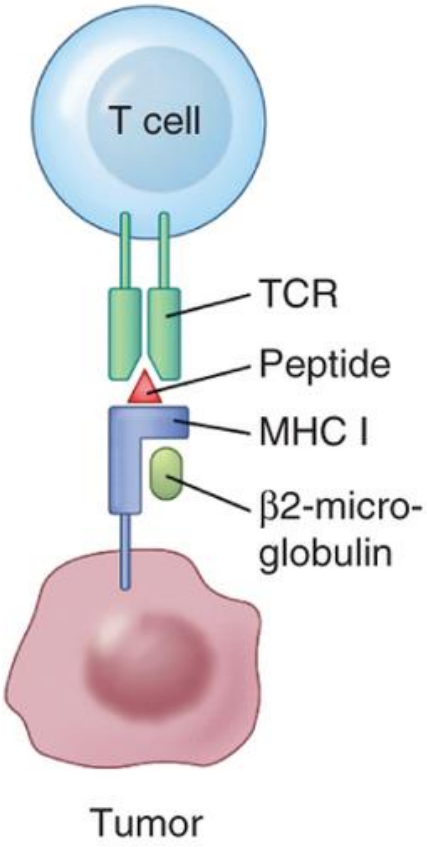
Blinatumomab in ALL: Efficacy across subgroups



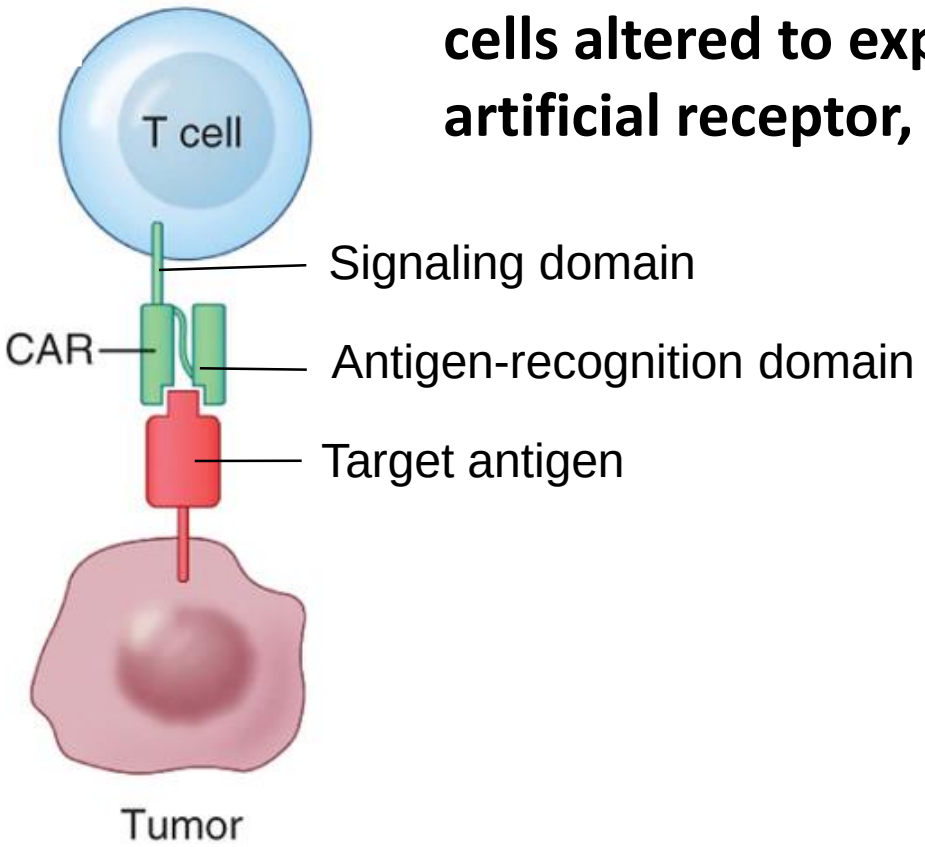
Topp, Max S et al., The Lancet Oncology , Volume 16 , Issue 1 , 57 - 66

Chimeric Antigen Receptor (CAR) Modified T cells

Normal T cell



CAR T cell



Genetically engineered T cells altered to express an artificial receptor, CAR

Adapted from Hinrichs & Restifo. Nat Biotech 2013

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CD19 CAR T products for ALL and NHL

	NCI	U Penn	FHCRC / SCH
CD19 Ab	FMC63	FMC63	FMC63
Hinge	CD28	CD8a	CD28
Transmembrane			
Signal 2	CD28	4-1BB	4-1BB
Signal 1	CD3ζ	CD3ζ	CD3ζ
Gene transfer	Retrovirus	Lentivirus	Lentivirus
	Kite Pharma	**Novartis**	**Juno Therapeutics**
	KTE-C19	**CTL-019**	**JCAR017**
	Axicabtagene ciloleucel	**Tisagenlecleucel**	**CD4:CD8 = 1:1**
	Axi-cel		

Adapted from van der Steegen et al. Nat Rev Drug Discov, 2015

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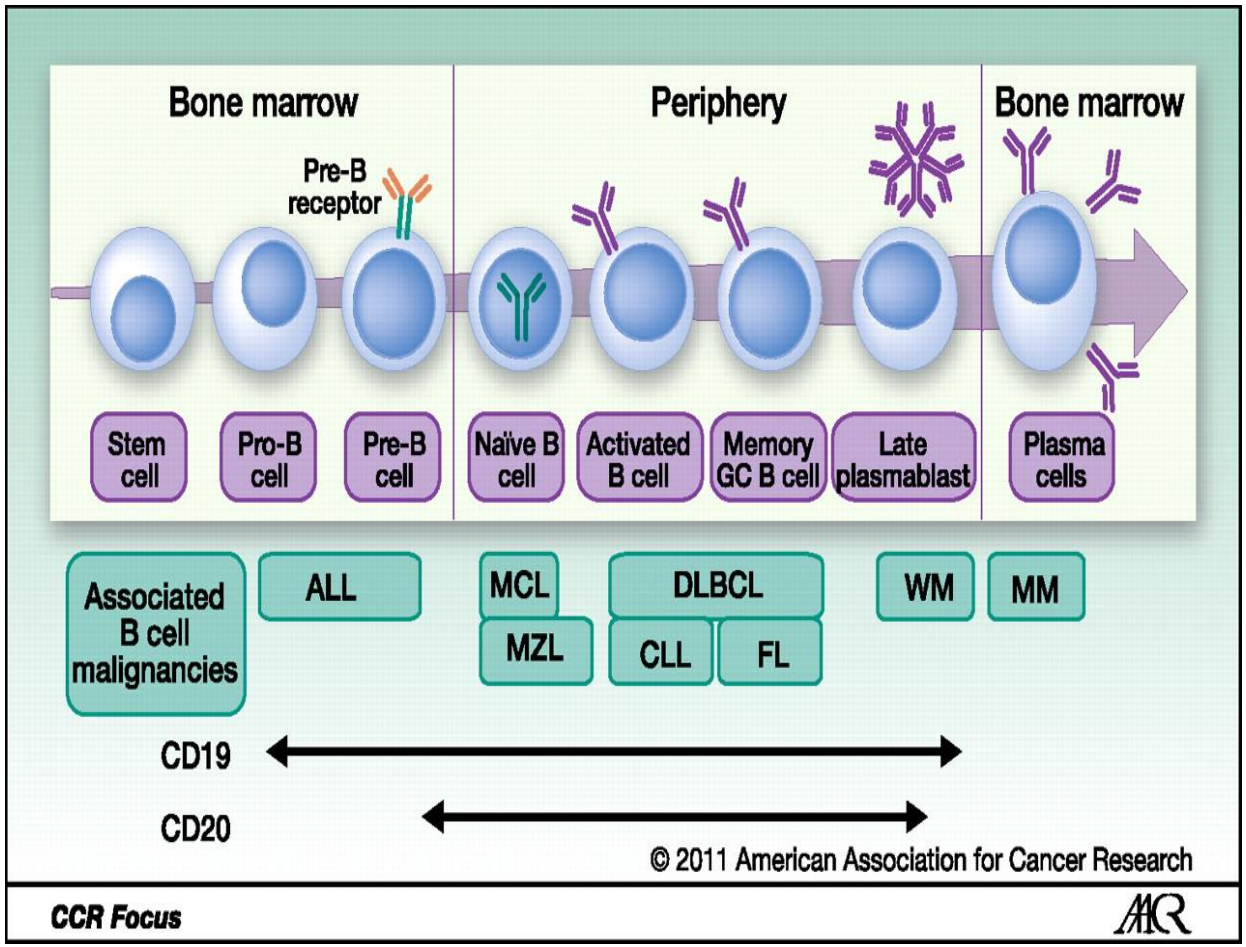
CD19 as a CAR T target



- CD19 is expressed on precursor and mature B cells
- Not expressed on BM stem cells or other tissues
- Rarely lost during neoplastic transformation
- Present on a wide range of B-cell malignancies

Adapted from Blanc et al. Clin Cancer Res 2011; 17:6448-6458

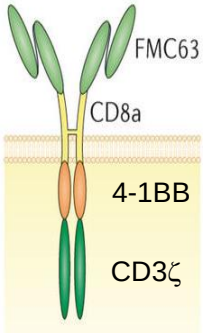
ELIANA: 1st multicenter trial of CD19 CAR T in R/R pediatric ALL

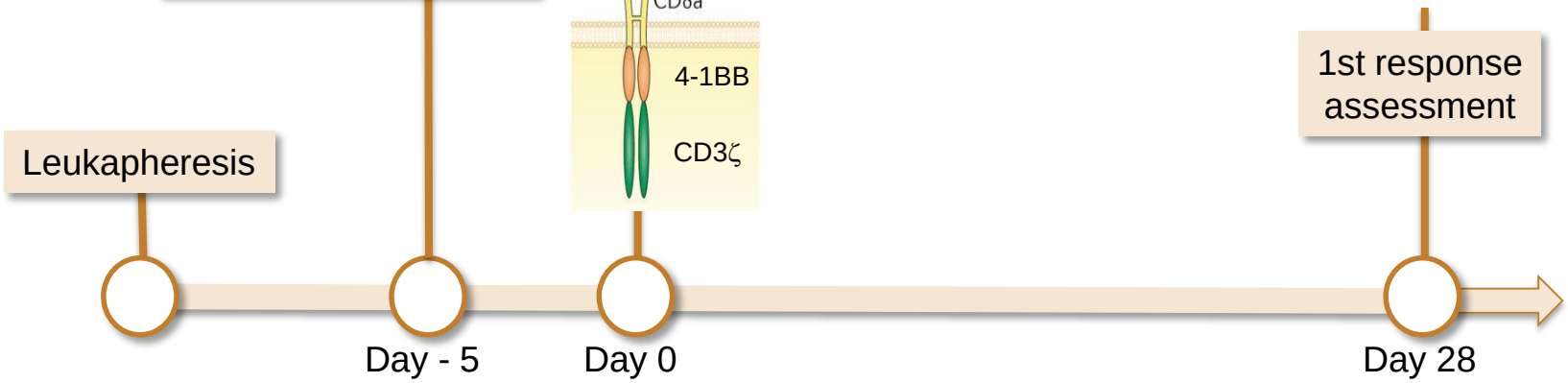
Tisagenlecleucel

- 0.2-5.0 x 10^6 /kg for patients ≤50 kg
- 0.1-2.5 x 10^8 for patients >50 kg

Conditioning

Cy – 500 mg/m^2/d x 2
Flu – 30 mg/m^2/d x 4





Eligibility

- r/r ALL with ≥5% lymphoblasts in BM
- Ages 3 yrs at screening to 21 yrs at initial diagnosis

Endpoints

- Primary: ORR within 3 months, 4-week maintenance of remission
- Secondary: MRD status, DOR, OS, cellular kinetics, safety

Grupp et al, ASH 2016, Abstract 221

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ELIANA: Patient Characteristics

Characteristic	N=68
Age (years), median (range)	12 (3-23)
Male, %	56
Prior therapies, median (range)	3 (1-8)
Prior stem cell transplant, %	59
Primary refractory, %	9
Blast count in BM, %, median (range)	73 (5-99)

Grupp et al, ASH 2016, Abstract 221
Updated ODAC meeting, July 2017

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ELIANA: Efficacy (N = 63)

	N (%)
ORR (CR+CRi) within 3 months	52 (83)*
CR	40 (63)
CRi	12 (19)
Day 28 response	53 (84)
CR or CRi with MRD negative bone marrow	52 (83)*

*$P < 0.0001$

- CR = Complete remission
- CRi = Complete remission with incomplete blood count recovery
- MRD negative = Flow cytometry of < 0.01%

Grupp et al, ASH 2016, Abstract 221
Updated ODAC meeting, July 2017

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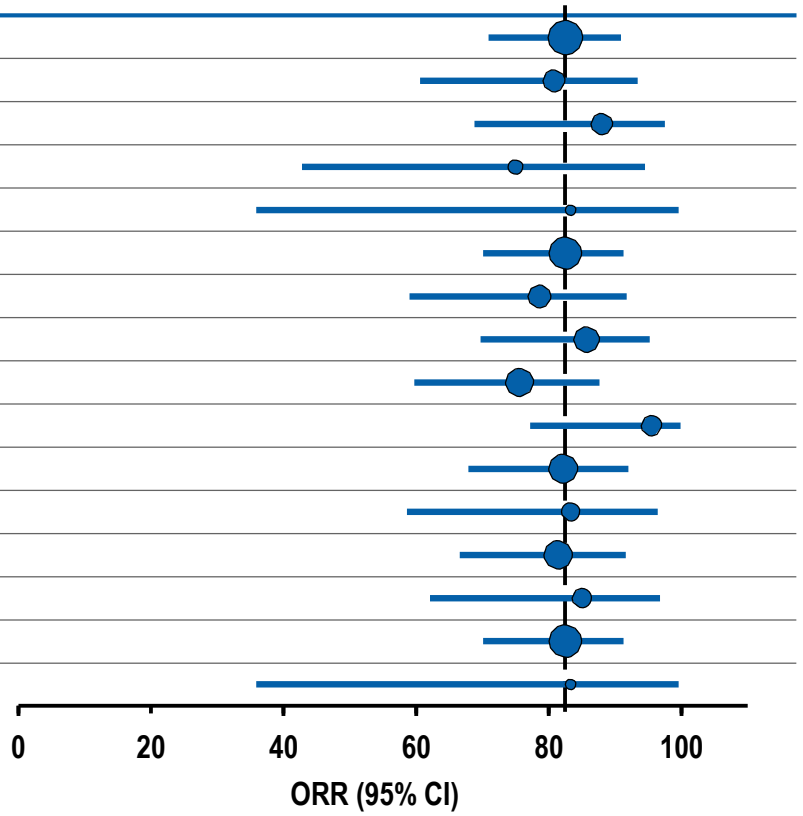
ELIANA: Efficacy across key subgroups

		n
Overall		63
Age	<10	26
	≥10- <18	25
	≥18	12
Response status at study entry	Primary refractory	6
	Relapsed disease	57
Prior SCT therapy	No	28
	Yes	35
Enrollment bone marrow tumor burden	High	41
	Low	22
Complex karyotypes (≥5 unrelated abnormalities)	No	45
	Yes	18
Any high-risk mutations	No	43
	Yes	20
Down syndrome	No	57
	Yes	6



Grupp et al, ASH 2016, Abstract 221
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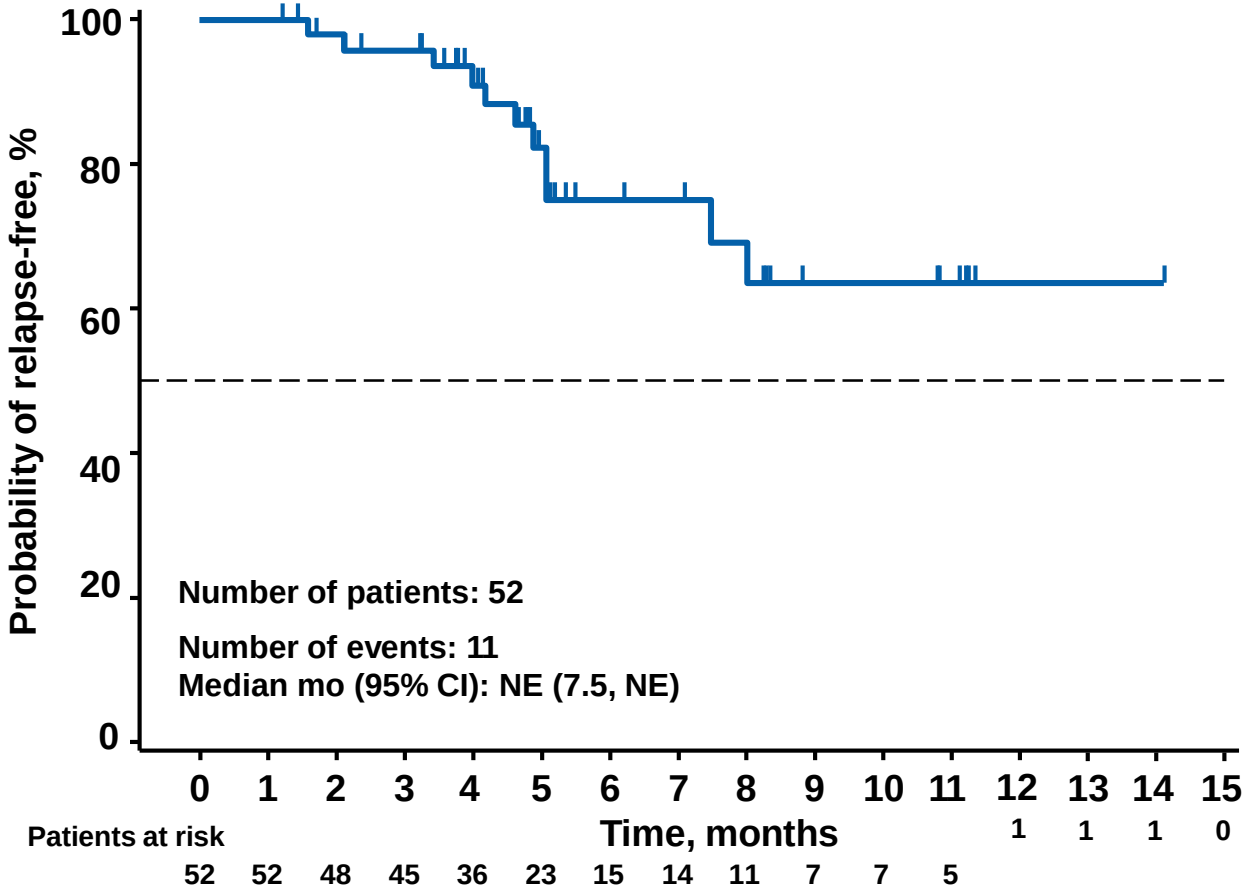
ELIANA: Duration of response



- Median duration of RFS and OS not reached
- 75% relapse-free at 6 months after onset of remission
- Probability of 6 and 12 mos OS 89% and 79%
- FDA approval of tisagenlecleucel (Kymriah) on August 30, 2017

Grupp et al, ASH 2016, Abstract 221
Updated ODAC meeting, July 2017

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ELIANA: Safety

Adverse Events (within 8 wks post-CAR T)	All grades (%)	Grade ≥3 (%)
Cytokine release syndrome (CRS)	79	48
Neurological events	45	15
Tumor lysis syndrome	5	5
Cytopenias not resolved by day 28	37	30
Infections	40	26

- 2 deaths within 30 days of CTL019 (1 ALL, 1 cerebral hemorrhage)
- All patients who achieved CR/CRi developed B-cell aplasia
- No deaths due to CRS
- No cases of cerebral edema
- No replication-competent lentivirus or insertional oncogenesis

Grupp et al, ASH 2016, Abstract 221
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Antigen-specific Approaches in ALL

Technology:	CART	ADC	BiTE
Example	CART-19	Inotuzumab (anti-CD22 + toxin)	Blinatumumab (anti-CD3/CD19)
Dosing	One infusion	Every 3 weeks	Continuous 28 days
Complete Response	90%	19%	66%
Survival	78% 6 mos OS	5-6 months median	9 mos median
Major toxicity	Cytokine release	Hepatotoxicity	Cytokine release
Antigen loss relapse?	Yes	No	Yes
Challenges	Complex manufacturing, individualized	Lower response rates	Burdensome infusion

Gill Immunol Rev Dec 2014

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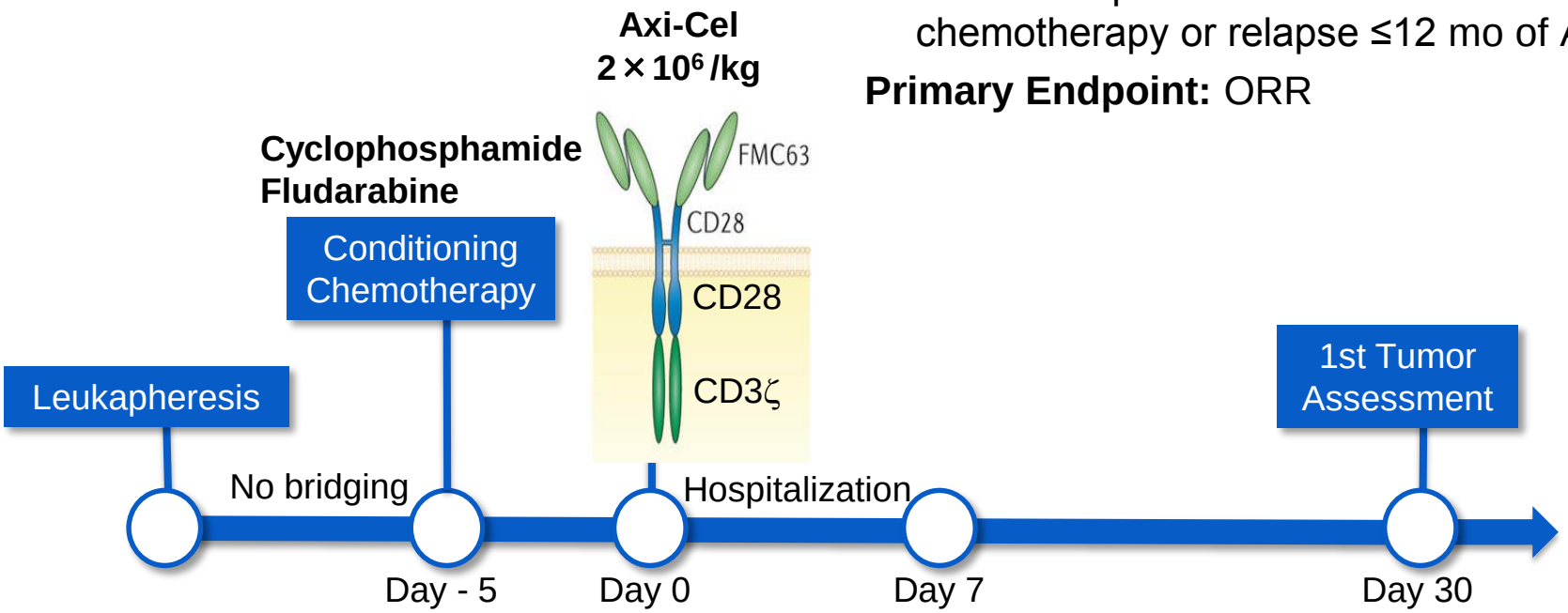
ZUMA1: 1st multicenter trial of CD19 CAR T in refractory aggressive NHL

Eligibility criteria

- DLBCL, PMBCL, TFL
- Chemotherapy-refractory disease: PD or SD as best response to most recent chemotherapy or relapse ≤12 mo of ASCT

Primary Endpoint: ORR



- 111 patients enrolled at 22 sites
- 99% (110/111) manufacturing success rate
- 17-day average turnaround time from apheresis to delivery to clinical site
- 91% (101/111) of enrolled patients received axi-cel

Neelapu et al. ICML 2017, Abstract 8

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ZUMA1: Patient Characteristics

Characteristic	DLBCL (n = 77)	PMBCL/TFL (n = 24)	All Patients (N = 101)
Median (range) age, y	58 (25–76)	57 (23–76)	58 (23–76)
≥65 y, n (%)	17 (22)	7 (29)	24 (24)
Men, n (%)	50 (65)	18 (75)	68 (67)
ECOG PS 1, n (%)	49 (64)	10 (42)	59 (58)
Disease stage III/IV, n (%)	67 (87)	19 (79)	86 (85)
IPI score 3-4, n (%)	37 (48)	11 (46)	47 (47)
≥3 prior therapies, n (%)	49 (64)	21 (88)	70 (69)
History of primary refractory disease, n (%)	23 (30)	3 (13)	26 (26)
History of refractory to 2 consecutive lines, n (%)	39 (51)	15 (63)	54 (54)
Response to last chemotherapy regimen, n (%)	10 (13)	4 (17)	14 (14)
Stable Disease	51 (66)	15 (63)	66 (65)
Refractory Subgroup Before Enrollment	**DLBCL (n = 77)**	**PMBCL/TFL (n = 24)**	All Patients (N = 101)
Refractory to second- or later-line therapy, n (%)	59 (77)	19 (79)	78 (77)
Relapse post-ASCT, n (%)	16 (21)	5 (21)	21 (21)

Neelapu, Locke et al. ICML 2017, Abstract 8

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ZUMA1: Efficacy

	DLBCL (N= 77)		PMBCL/TFL (N=24)		Combined (N=101)	
	ORR (%)	**CR (%)**	**ORR (%)**	**CR (%)**	**ORR (%)**	**CR (%)**
Best response	82	49	83	71	82	54
Med f/u 8.7 mo	36	31	67	63	44	39

- Study met primary endpoint for ORR ($p < 0.0001$) at primary analysis
- ORR and CR rate in SCHOLAR-1 study were 26% and 7% (Crump et al, Blood, 2017)

Neelapu, Locke et al. ICML 2017, Abstract 8

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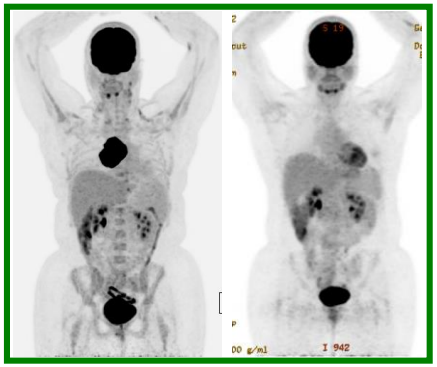
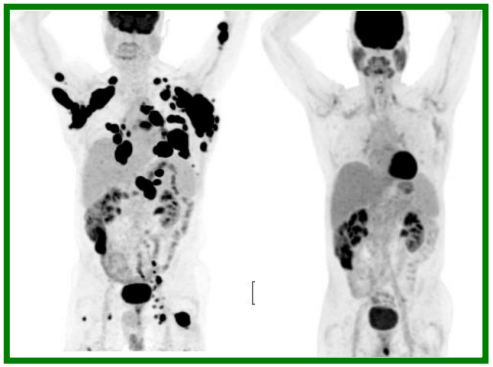
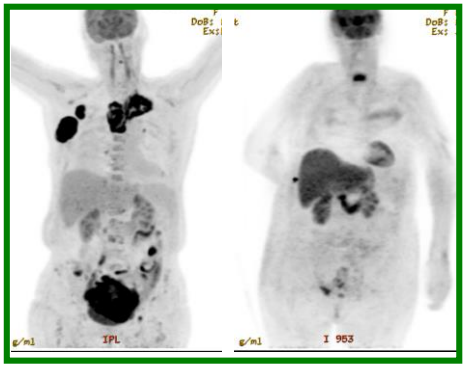
ZUMA1: CRs after axi-cel in NHL



28/F/PMBCL
- R-CHOP - SD
- R-ICE - PR
- R-DHAP - PD

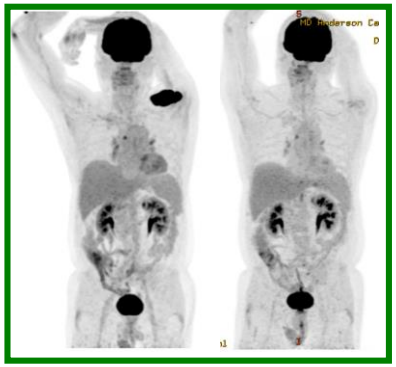


62/M/DLBCL
- R-CHOP - PR
- R-GDP - PD
- R-ICE - PD
- R-Rev - PD

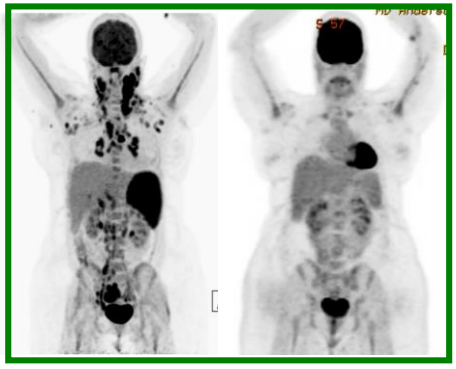


66/F/DLBCL
- R-CHOP - PR
- R-ICE - SD
- Ofat-Ibr - PD
- Idela - PD

R-EPOCH - PD
O-DHAP - PD

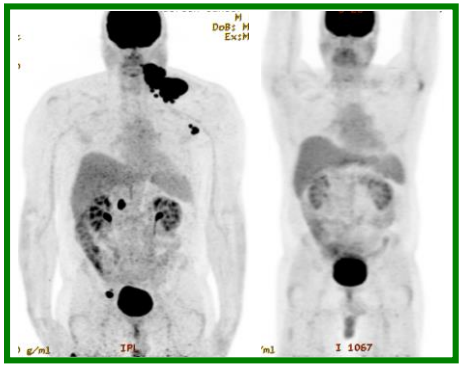


60/M/TFL
- R-Benda - CR
- R-EPOCH - PD
- R-HCVAD - PD

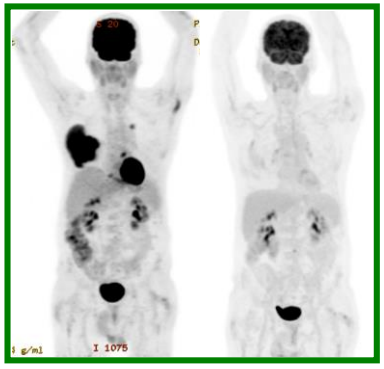


40/F/DLBCL
- R-CHOP - CR
- R-ICE - CR
- ASCT - CR

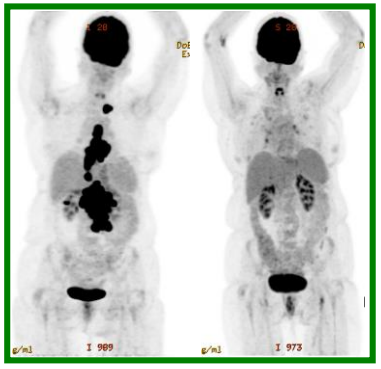
PNT2258 - PD
R-Gem-Ox - PD



59/M/DLBCL
- R-CHOP - CR
- R-ICE - PD



75/M/DLBCL
- R-EPOCH - PD
- R-Gem-Ox - PD



66/F/TFL
- R-CHOP - CR
- R-ICE - PD

Neelapu, Locke et al. ICML 2017, Abstract 8

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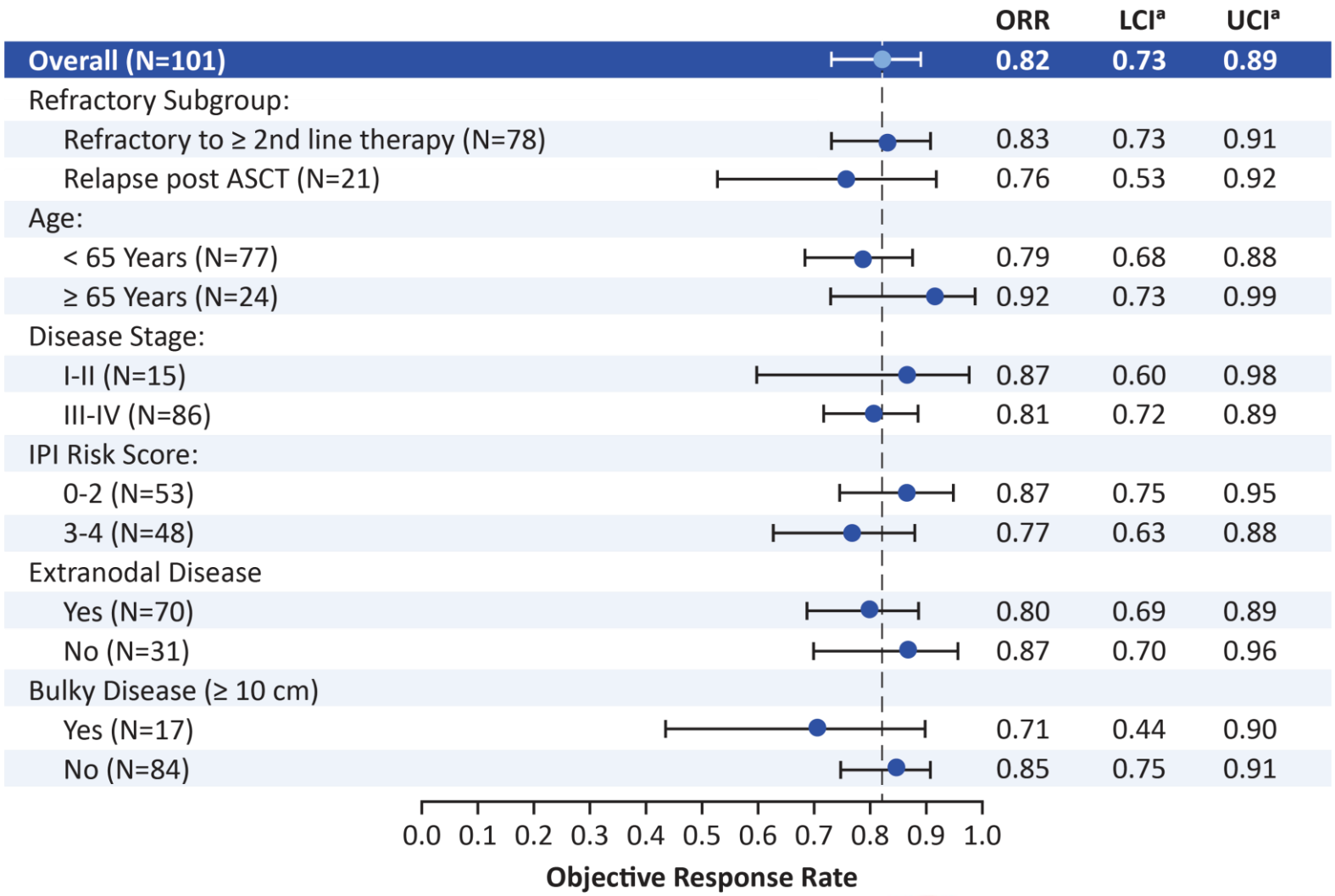
ZUMA1: Efficacy across key covariates



Neelapu, Locke et al. ICML 2017, Abstract 8

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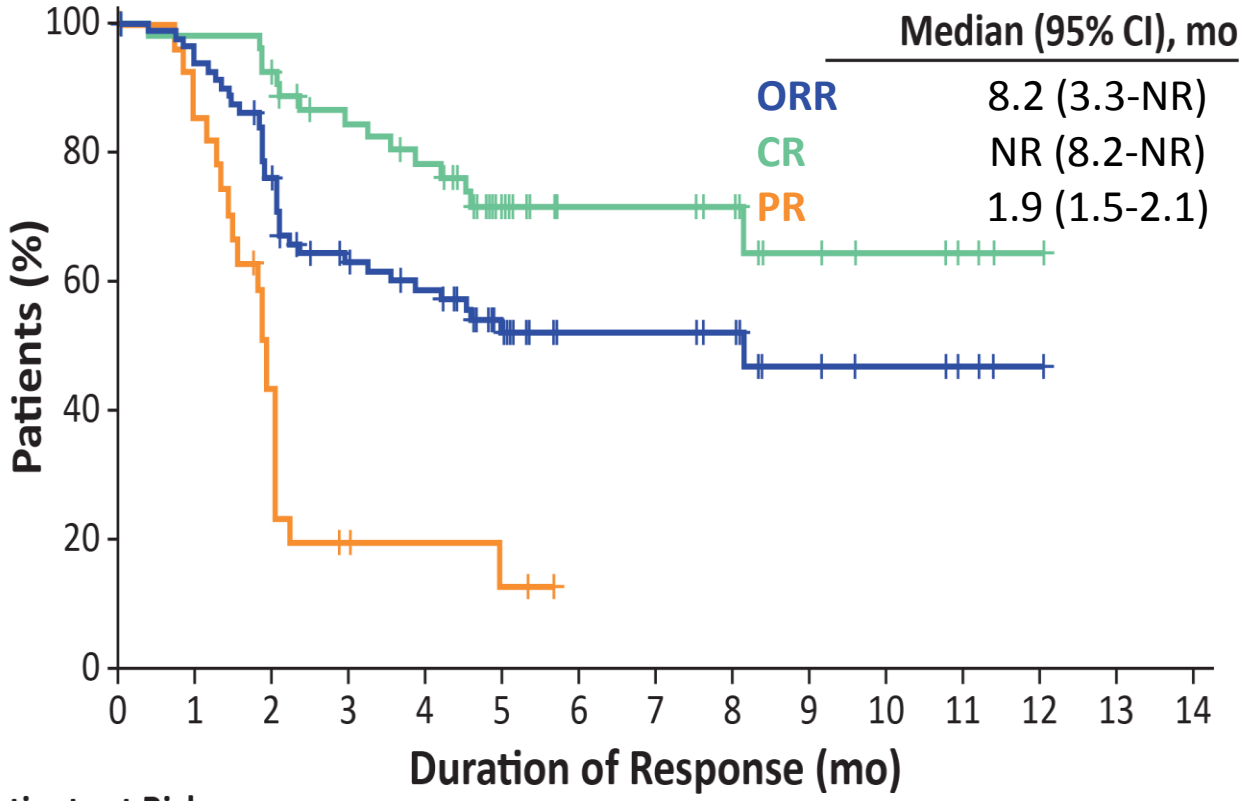
ZUMA1: Duration of response



Patients at Risk

ORR	83	75	60	45	40	26	14	14	12	7	5	3	1	0
CR	55	52	49	41	37	24	14	14	12	7	5	3	1	0
PR	28	23	11	4	3	2	0							

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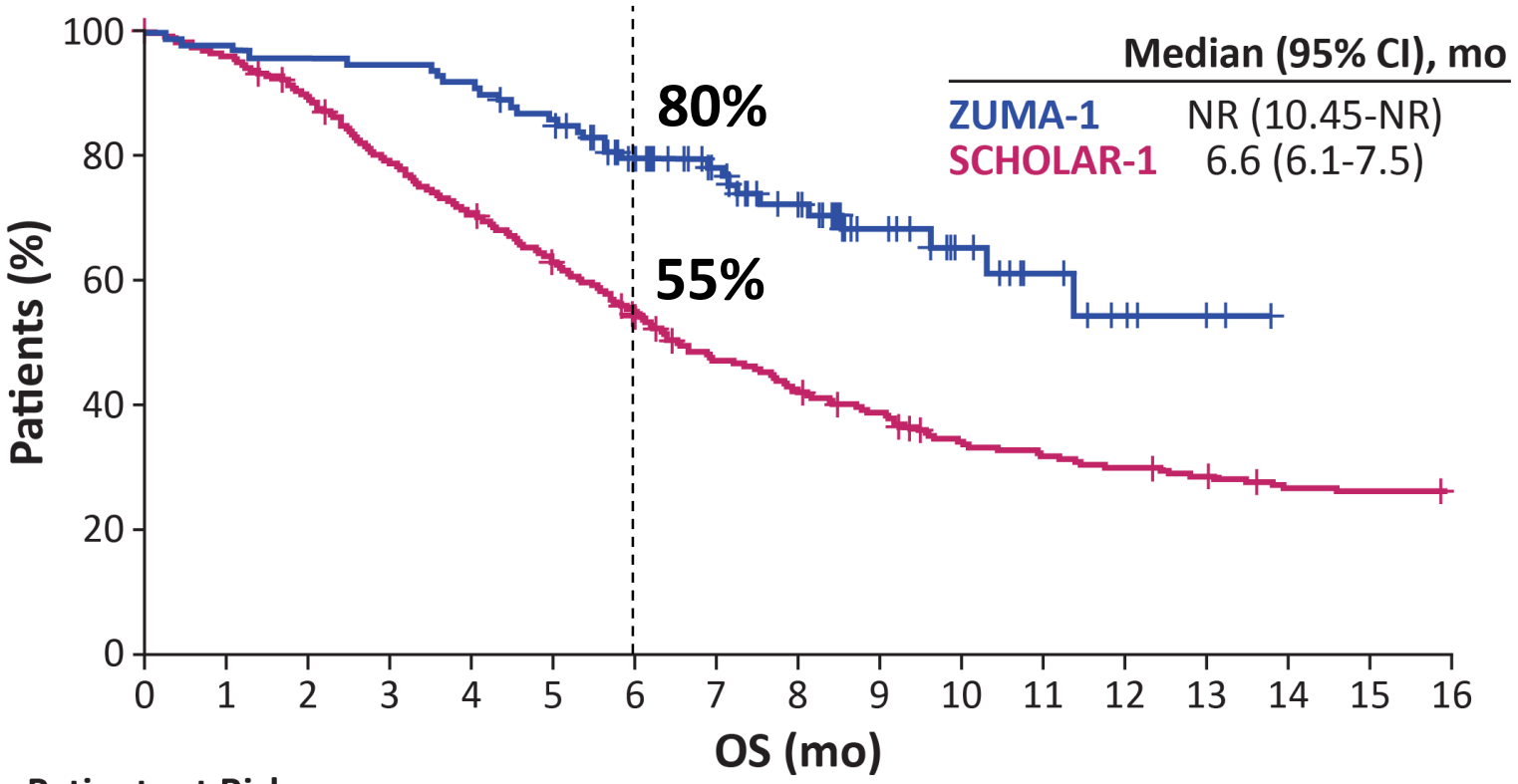
ZUMA1: Survival benefit



Patients at Risk

ZUMA-1	101	99	97	96	93	87	72	58	42	26	19	10	6	3	0		
SCHOLAR-1	635	594	555	487	436	392	337	286	259	233	202	191	177	167	156	151	151

- FDA approval of axicabtagene ciloleucel (Yescarta) on October 18, 2017

Neelapu, Locke et al. ICML 2017, Abstract 8

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ADVANCES IN Cancer IMMUNOTHERAPY™

CD19 CAR T in NHL: Efficacy in single and multicenter trials

Study/Sponsor	Product	Histology	N	ORR (%)	CR (%)	Ref
NCI	CD19/CD3ζ/CD28 with Cy/Flu (hi-dose)	DLBCL, iNHL, CLL	15	**80**	**53**	Kochenderfer et al, JCO 2015
NCI	CD19/CD3ζ/CD28 with Cy/Flu (lo-dose)	DLBCL, FL, MCL	22	**73**	**55**	Kochenderfer et al, JCO 2017
U Penn	CD19/CD3ζ/4-1BB variable conditioning	DLBCL, FL, MCL	28	**57**	**51**	Schuster et al, ASH 2015-16
Fred Hutch	CD19/CD3ζ/4-1BB with Cy/Flu	DLBCL, FL, MCL	18	**72**	**50**	Turtle et al, SciTranMed 2016
ZUMA1 / Kite	CD19/CD3ζ/CD28 with Cy/Flu	DLBCL, TFL, PMBCL	101	**82**	**54**	Neelapu et al, ICML 2017
JULIET / Novartis	CD19/CD3ζ/4-1BB with Cy/Flu	DLBCL	51	**59**	**43**	Schuster et al, ICML 2017
TRANSCEND / Juno	CD19/CD3ζ/4-1BB with Cy/Flu	DLBCL, MCL, PMBCL, FL	54	**76**	**52**	Abramson et al, ICML 2017

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ADVANCES IN Cancer IMMUNOTHERAPY™

CD19 CAR T in NHL: Efficacy in single and multicenter trials

Study/Sponsor	Product	N	CRS All Grades	CRS Grade ≥3	NT All Grades	NT Grade ≥3	Ref
ZUMA1 / Kite	CD19/CD3ζ/CD28	101	93%	13%	64%	28%	Neelapu et al, ICML 2017
JULIET / Novartis	CD19/CD3ζ/4-1BB	51	57%	26%	21%	13%	Schuster et al, ICML 2017
TRANSCEND / Juno	CD19/CD3ζ/4-1BB	55	35%	2%	22%	16%	Abramson et al, ICML 2017

- Majority of CRS and neurotoxicity AEs were grade 1 to 2
- Managed with anti-IL-6 therapy (tocilizumab) and/or streroids
- Use of tocilizumab and steroids did not impact efficacy in ZUMA1

CARTOX Guidelines

REVIEWS

Nat Rev Clin Oncol, Sep 2017

Chimeric antigen receptor T-cell therapy — assessment and management of toxicities

Sattva S. Neelapu[1], Sudhakar Tummala[2], Partow Kebriaei[3], William Wierda[4], Cristina Gutierrez[5], Frederick L. Locke[6], Krishna V. Komanduri[7], Yi Lin[8], Nitin Jain[4], Naval Daver[4], Jason Westin[1], Alison M. Gulbis[9], Monica E. Loghin[2], John F. de Groot[2], Sherry Adkins[1], Suzanne E. Davis[10], Katayoun Rezvani[3], Patrick Hwu[10], Elizabeth J. Shpall[3]

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Immunotherapy in Hematological Malignancies: Key Takeaways

- Anti-PD-1 antibody therapy is highly effective in r/r Hodgkin lymphoma
- Anti-PD-1 antibody therapy has modest activity in common NHLs such as FL and DLBCL
- Early data suggests moderate to high activity in certain less common NHL subtypes – PMBCL, PCNSL, Richter's, NK/TCL, MF
- Blinatumomab is highly effective in low-tumor burden ALL
- CD19 CAR T is highly effective in r/r pediatric ALL and adult NHL with ORR of >80%
- Durable remissions in ~65% of ALL patients and ~45% of NHL patients with CAR T
- Centralized manufacturing of CD19 CAR T is feasible with turnaround time of ~2-3 weeks
- Responding patients return to near-normal quality of life within 1-2 months after CAR T therapy

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