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Immune Effector Cell Therapy for Lymphoid Malignancies: What to Do and Know in Community Oncology Practice.

Disclosures

- Research Support
  - Abbvie, Bayer, BMS, Genentech
- Advisory Board
  - Abbvie, ADC Therapeutics, AstraZeneca, Bayer, Beigene, BMS, Genmab, Genentech, Gilead, Eli Lily, Epizyme, Incyte, Pharmacyclics, TG Therapeutics, Seattle Genetics
- Strategic Counsel
  - Epizyme, Genmab
- Scientific Board
  - Genentech, Merck, Genmab

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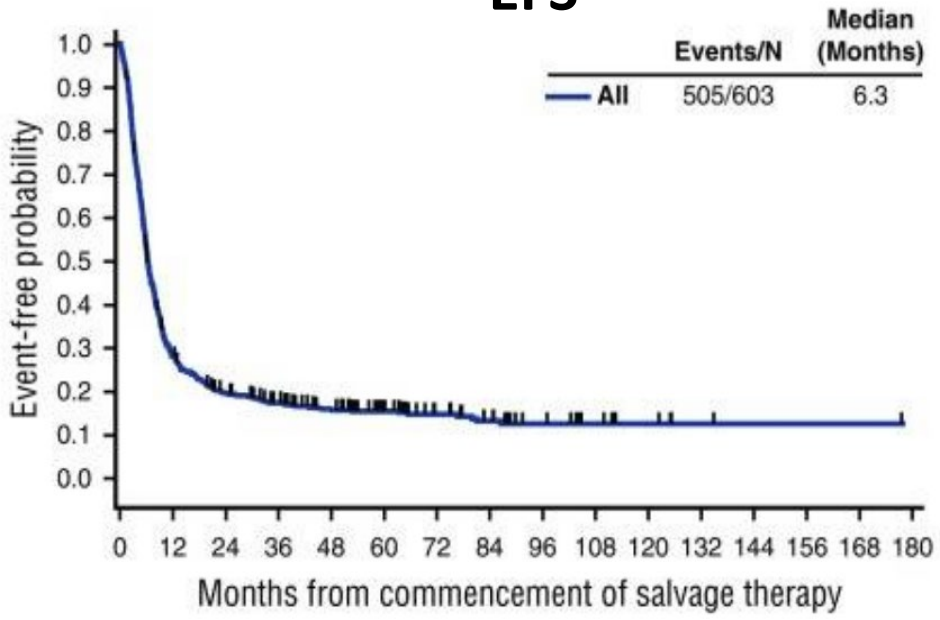
Treatment of NHL 2024

- Treatment paradigm has shifted considerably in the last 5 years
  - DLBCL – CAR-T has moved and replaced ASCT as SOC for 2L patients
  - FL – multiple options but PI3Ki no longer options
  - MCL – 3rd generation BTKi but biggest improvement in R/R remains CAR-T
  - CLL – 1st glimpse of CAR-T in R/R setting

Chemotherapy-refractory DLBCL has a poor prognosis

- Patients refractory to chemotherapy or relapsing ≤12 months after ASCT have low response rates to next therapy and an OS of 6 months

EFS



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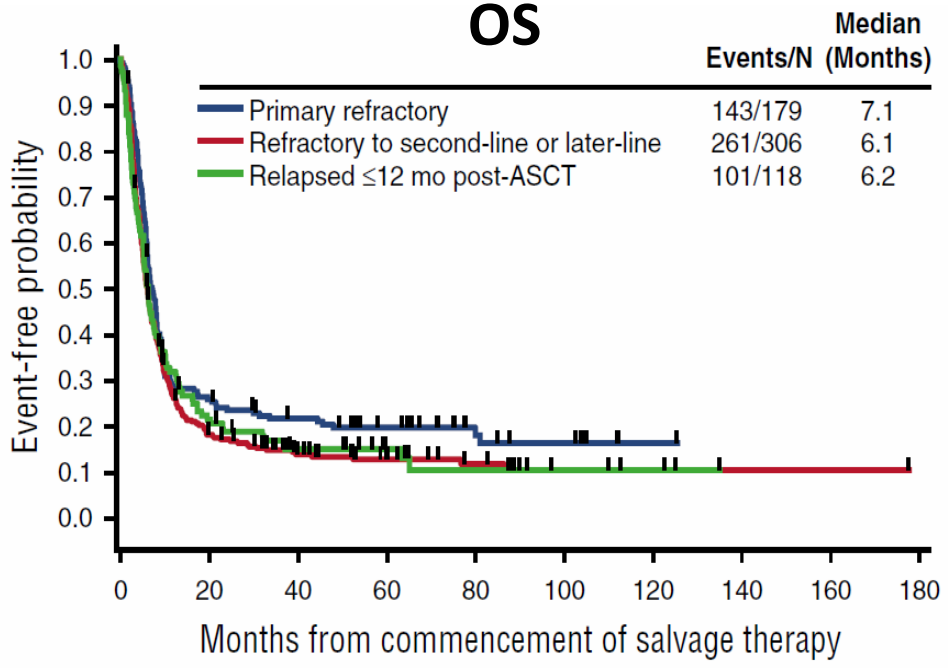

- ASCT, autologous stem cell transplantation; DLBCL, diffuse large B-cell lymphoma OS, overall survival.
  Crump M, et al. Blood. 2017;130:1800-8.

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Three Major anti-CD19 CAR T-cell Products for DLBCL

	Axicabtagene Ciloleucel	Lisocabtagene Maraleucel	Tisagenlecleucel
Construct	antiCD19-CD28tm-**CD28**-CD3z	antiCD19-CD28tm-**41BB**-CD3z	antiCD19-CD8αtm-**41BB**-CD3z
Vector	Retrovirus	Lentivirus	Lentivirus
T-cell manufacturing	Bulk	Defined doses CD4, CD8	Bulk
Dose	2 × 10^6/kg (max 2 x 10^8)	1.0 x 10^8	0.6 to 6.0 x 10^8
Lymphodepletion	Flu/Cy 500/30 x 3d	Flu/Cy 300/30 x 3d	Flu/Cy 250/25 x 3d, or Benda 90 x 2d

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CART-2L – Deeper Dive

Product	Bridging	Cross-Over	PFS benefit	OS benefit	Approved
Axi-cel	N	N	Y	Y	Y
Tisa-cel	Y	Y	N	N	N
Liso-cel	Y	Y	Y	N/A	Y

- Little dispute about CAR-T in 2L setting.
  - Few if any CAR-T ineligible patients
  - Choice of agents mainly driven by Brain to Vein Time (Matt Lunning-ism)
  - Only question is what to do with those who respond to chemotherapy as some data suggests those patients do as well with ASCT (retrospective).
    - Patients who relapse within 9-12 months?

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CAR-T in 3L+ DLBCL

Product	N	Follow Up	ORR	CR	PFS (median)	OS (median)
Axi-cel	101	27.1 m	83%	58%	5.9 m	NR
Tisa-cel	111	14 m	52%	40%	NR (responders)	12 m
Liso-cel	255	18.8 m	73%	53%	6.8 m	21.1 m

EPCORE NHL-1: LBCL Expansion Cohort

Dose escalation

Dose expansion data cutoff: January 31, 2022
Median follow-up: 10.7 mo

B-NHL:

- ✓ No DLTs
- ✓ MTD not reached
- ✓ RP2D identified
- ✓ Manageable safety profile
- ✓ Encouraging antitumor activity

Key inclusion criteria:

- R/R CD20+ mature B-cell neoplasm
- ECOG PS 0–2
- ≥2 prior lines of antineoplastic therapy, including ≥1 anti-CD20 mAb
- FDG PET–avid and measurable disease by CT/MRI
- Prior CAR T allowed

Step-up dosing[a]

Epcoritamab SC RP2D 48 mg
QW C1–3,
Q2W C4–9,
Q4W C10+

→

Treatment until PD[b,c] or unacceptable toxicity

→

LBCL Cohort N=157
DLBCL, HGBCL, PMBCL, and FL Gr3B

- To ensure patient safety and better characterize CRS, inpatient monitoring was required at first full dose for 24 h in this part of the study
- **Primary endpoint:** ORR by independent review committee (IRC)
- **Key secondary endpoints:** DOR, TTR, PFS, OS, CR rate, and safety/tolerability

[a]Step-up dosing (priming 0.16 mg and intermediate 0.8 mg dosing before first full dose) and corticosteroid prophylaxis were used to mitigate CRS. [b]Radiographic disease evaluation was performed every 6 wk for the first 24 wk (6, 12, 18, and 24 wk), then every 12 wk (36 and 48 wk), and every 6 mo thereafter. [c]Measurable disease with CT or MRI scan with involvement of ≥2 lesions/nodes with a long axis >1.5 cm and short axis >1.0 cm (or 1 lesion/node with a long axis >2.0 cm and short axis ≥1.0 cm) and FDG PET scan that demonstrates positive lesion(s) compatible with CT-defined (or MRI-defined) anatomical tumor sites for FDG-avid lymphomas. ClinicalTrials.gov: NCT03625037. EudraCT: 2017-001748-36.

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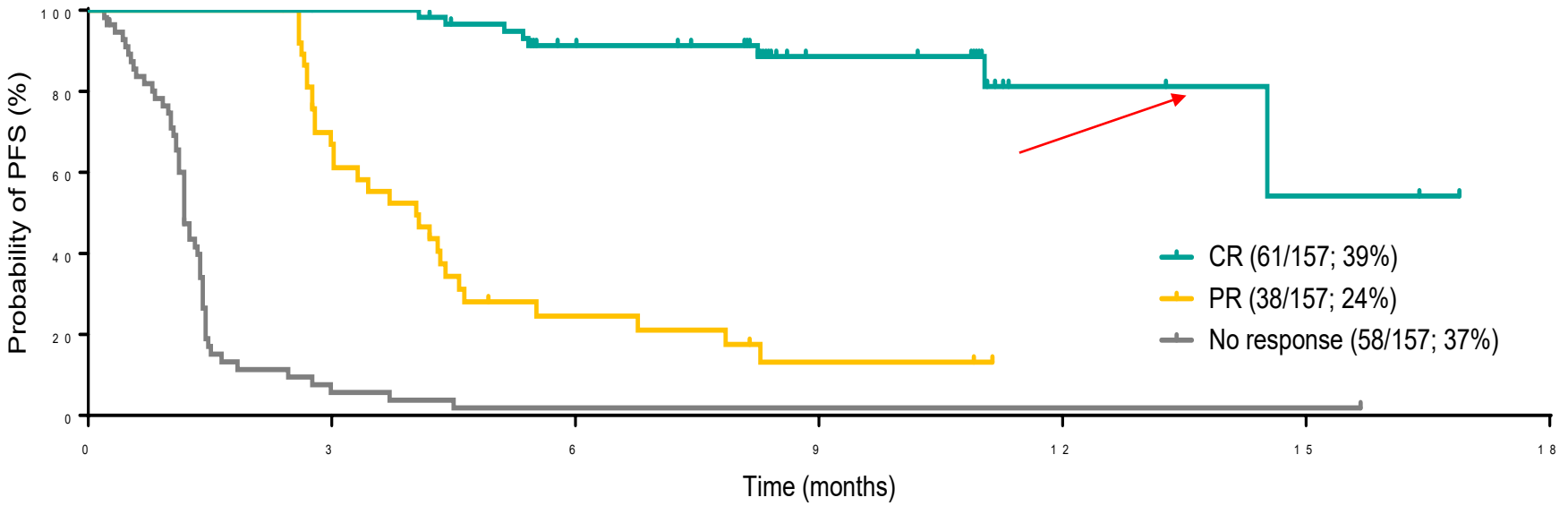
PFS by Best Response per IRC



Patients at risk

61	60	43	24	4	2	0
38	23	7	3	0	0	0
58	3	1	1	1	1	0

Kaplan–Meier Estimate	
Median PFS for complete responders	**Not reached**
Complete responders remaining in complete response at 9 mo	**89%**
Median PFS, mo (95% CI)	4.4 (3.0–7.9)
PFS at 6 mo, % (95% CI)	43.9 (35.7–51.7)

Response Characteristics, mo (range)	
Median time to response	1.4 (1.0–8.4)
Median time to CR	2.7 (1.2–11.1)
Median duration of response[a]	12 (0+ to 15.5+)
Median duration of response for patients in CR	Not reached

KM estimates. Based on IRC assessment and Lugano criteria.

- Majority of CRs were achieved by the first or second assessment
- Some conversions from PR to CR were still observed at ≥36 weeks

A correlation between depth of response and PFS was observed

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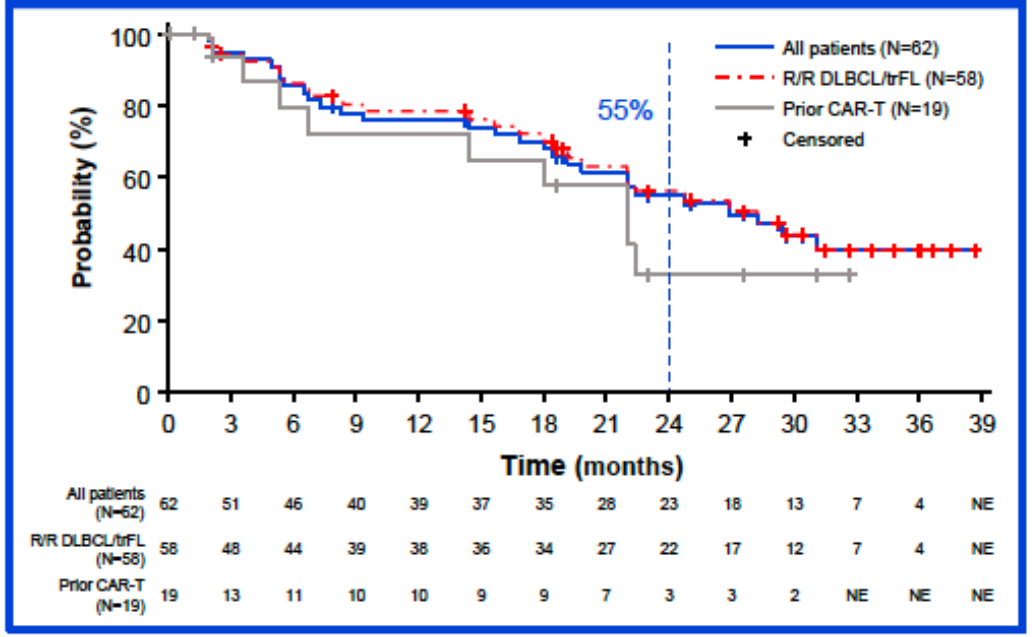
Response rates and DoCR

	All patients (N=155)*	R/R DLBCL/ trFL (N=132)†‡	Prior CAR-T (N=52)†
ORR, n (%) [95% CI]	80 (52) [43.5–59.7]	74 (56) [47.2–64.7]	26 (50) [35.8–64.2]
CR rate, n (%) [95% CI]	62 (40) [32.2–48.2]	58 (44) [35.3–52.8]	19 (37) [23.6–51.0]
Median DoCR, months (95% CI)	26.9 (19.8–NR)	28.3 (19.8–NR)	22.0 (6.7–NR)
24-month DoCR, % (95% CI)	55.0 (41.1–68.8)	56.2 (41.9–70.4)	33.1 (7.2–59.0)
Median CR follow-up, months (range)	29.6 (0–39)	29.6 (0–39)	23.0 (0–33)
Ongoing CRs, n/N (%)	34/62 (55)	32/58 (55)	10/19 (53)

DoCR by IRC



- Median time on study: 32.1 months (range: 0–43)

With 32 months median follow-up, glofitamab showed high response rates and durable remissions across subgroups

*Intent-to-treat population (DLBCL, trFL, HGBCL, and PMBCL); †Patients in this subgroup had similar baseline characteristics to the overall population; ‡Primary efficacy population reported in the glofitamab USPI, all patients received at least one dose of glofitamab. CI, confidence interval; NE, not estimable; NR, not reached; USPI, United States prescribing information.

1. COLUMVI USPI. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761309s000lbl.pdf.

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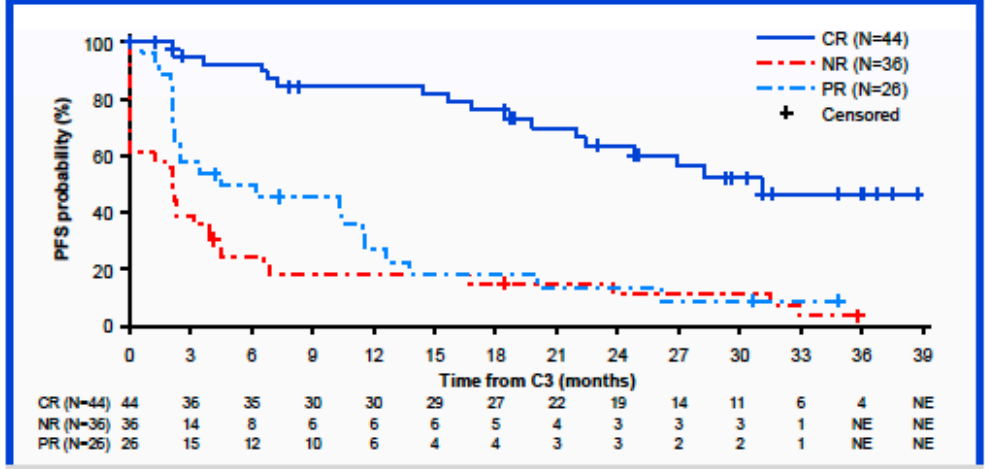
Landmark analysis by response at Cycle 3

PFS



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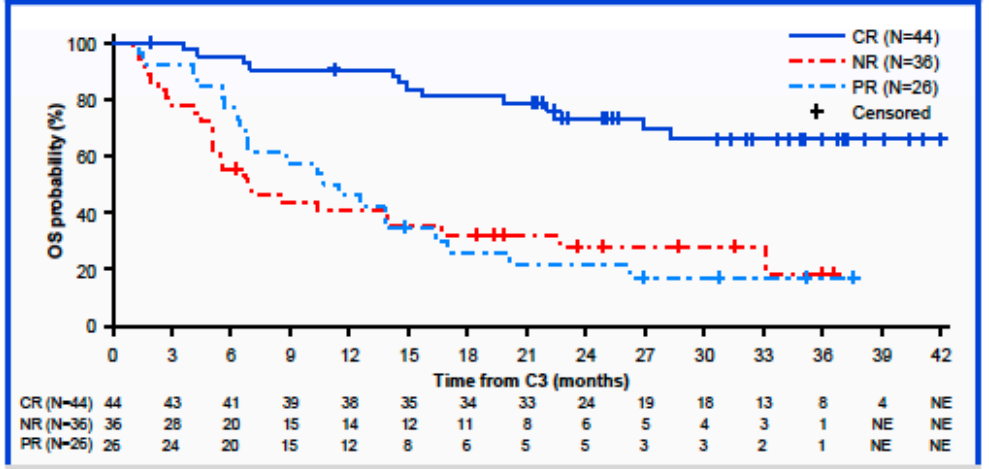

Landmark PFS from C3 in patients with CR at C3*	N=44
Median PFS, months (95% CI)	31.1 (22.4–NE)
24-month PFS rate, % (95% CI)	63.5 (47.5–79.6)

Landmark OS from C3 in patients with CR at C3*	N=44
Median OS, months (95% CI)	NE (NE)
24-month OS rate, % (95% CI)	73.4 (59.9–87.0)

A high proportion of patients with a CR at C3 remained progression-free and alive after 24 months

*KM estimates. NR, no response.

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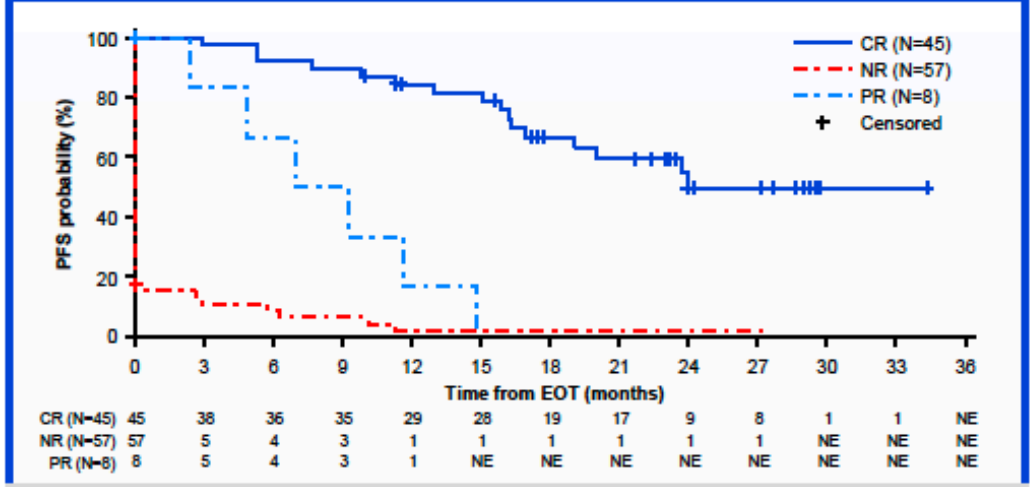
Landmark analysis by response at EOT

PFS



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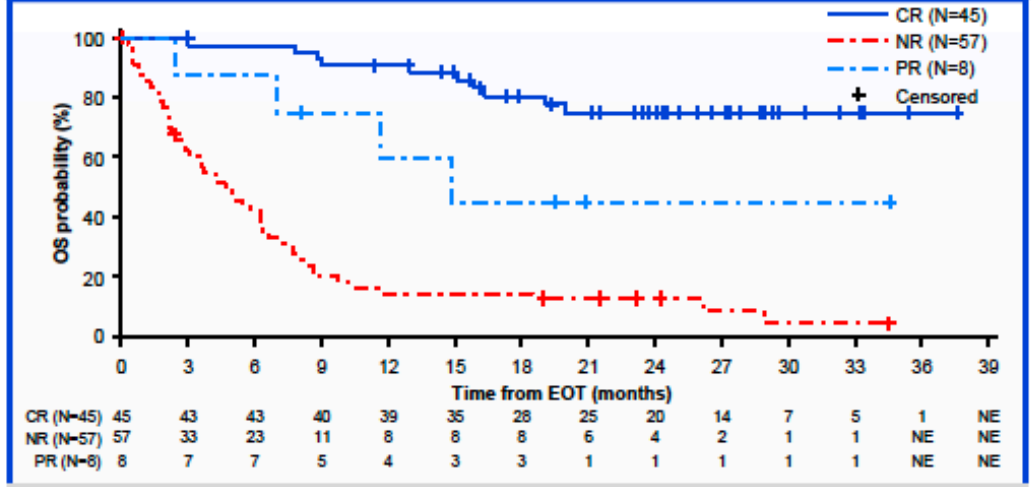

Landmark PFS from EOT in patients with CR at EOT*	N=45
Median PFS, months (95% CI)	24.0 (19.1–NE)
18-month PFS rate, % (95% CI)	66.6 (51.0–82.2)

Landmark OS from EOT in patients with CR at EOT*	N=45
Median OS, months (95% CI)	NE (NE)
18-month OS rate, % (95% CI)	80.7 (68.6–92.8)

Majority of patients with a CR at EOT remained progression-free and alive at 18 months after EOT

*KM estimates.
EOT, end-of-treatment; NR, no response.

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Efficacy DLBCL

Drug	N	ORR	CR	PFS (median)	DOR	Approved
Epcoritamab	157	63%	39%	4.4 m	15.6 m	Yes
Glofitamab	291	52.6%	35%	4.9 m*	18.4 m	Yes
Odronextamab	130	49.2%*	30.8%*	4.4 m	10.2 m	No

Week 12 response assessment by independent central review	1/20 step-up regimen N=67	0.7/4/20 step-up regimen N=63
ORR	46.3% [95% CI: 34.0–58.9%]	42.9% [95% CI: 30.5–56.0%]
Complete response	26.9%	20.6%

- Median opportunity of follow-up: 21.3 months (range 2.6–29.8)

Drug	post CAR-T patients	Refractory (*R*)	ORR	CR	CR (*R*)
Epcoritamab	61	46	54%	34%	28%
Glofitamab	52	N/A	N/A	35%	N/A
Odronextamab	31		48.4%*	32.3%	N/A

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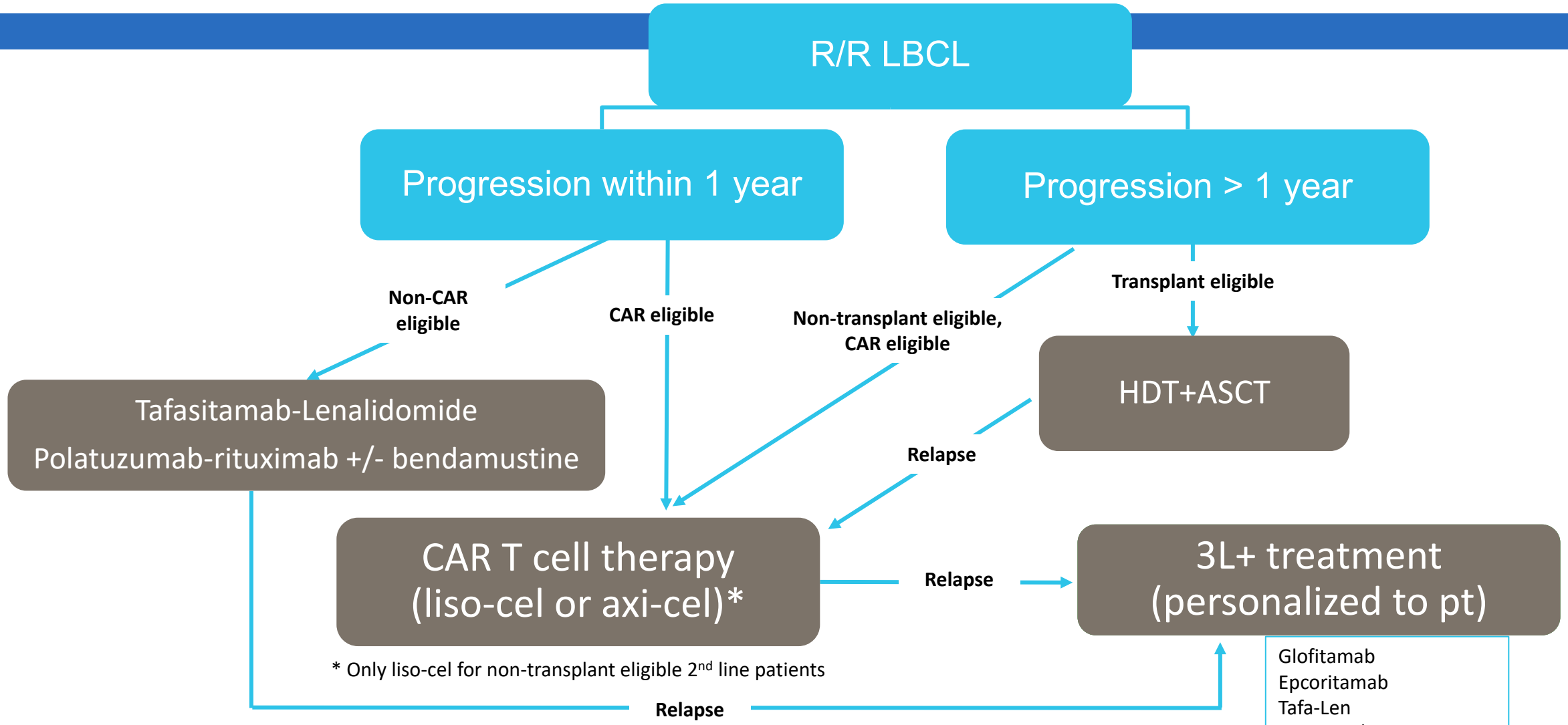
My Current Approach to Relapsed/Refractory DLBCL



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CAR T-cells vs. Bispecific Antibodies for Relapsed/Refractory LBCL

- CAR T-cells are proven to be curative for DLBCL in the 3rd line or later setting with over 5 years of follow-up.
- Hope is bispecifics will lead to cure in some patients, but it is still too early to know
- Bispecifics will certainly be preferred 3rd line therapy if CAR T-cells are not accessible
  - For most community sites the key to these options are early referral to CAR-T sites and/or if no plans for CAR-T to establish infrastructure that will allow patients to get bispecifics in community
  - Team→Plan (where to treat/monitor, do you have Toci (likely not needed for majority of patients, who is going to take calls, where will you admit patients if needed during SUD).

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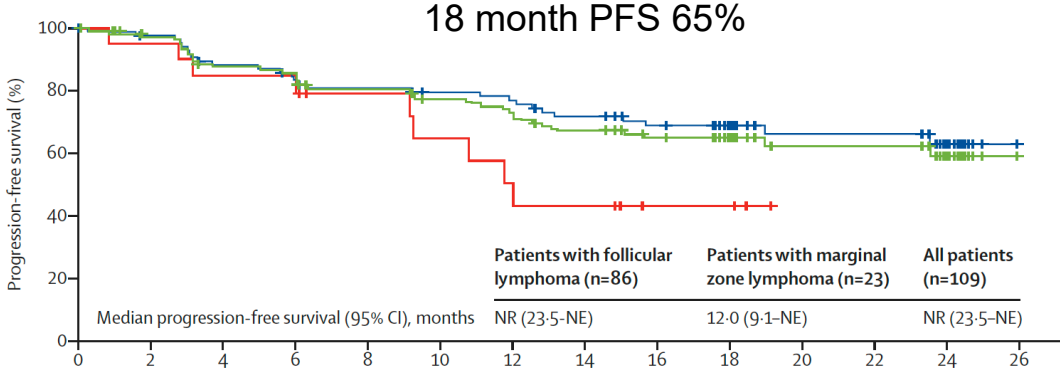
ZUMA-5 Study of Axi-cel in relapsed/refractory FL and MZL

Characteristic	FL n=124	MZL N=24	All Patients N=148
Median age (range)	60 (53-67)	65 (61-72)	61 (53-68)
FLIPI 3-5	54 (44%)	N/A	N/A
High tumor burden (GELF)	64 (52%)	10 (42%)	74 (50%)
Median prior tx (IQR)	3 (2-4)	3 (2-5)	3 (2-5)
Refractory to last tx	84 (68%)	18 (75%)	102 (69%)
POD24	68 (55%)	13 (57%)	81 (55%)

Progression-free survival

18 month PFS 65%



	All patients (n=109)	FL (n=86)	MZL (n=23)
ORR	92%	94%	83%
CRR	76%	79%	65%

AEs of Special Interest (n=148)	
Cytokine Release Syndrome	
Any grade	82%
Grade ≥ 3	7%
Neurologic Events	
Any grade	59%
Grade ≥ 3	19%

13 FL and 11 MZL retreated after response at median 11 months. ORR 100%, CRR 77%. 46% had ongoing response at median of 11 months f/u

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Jacobson, et al. Lancet Onc 2022.

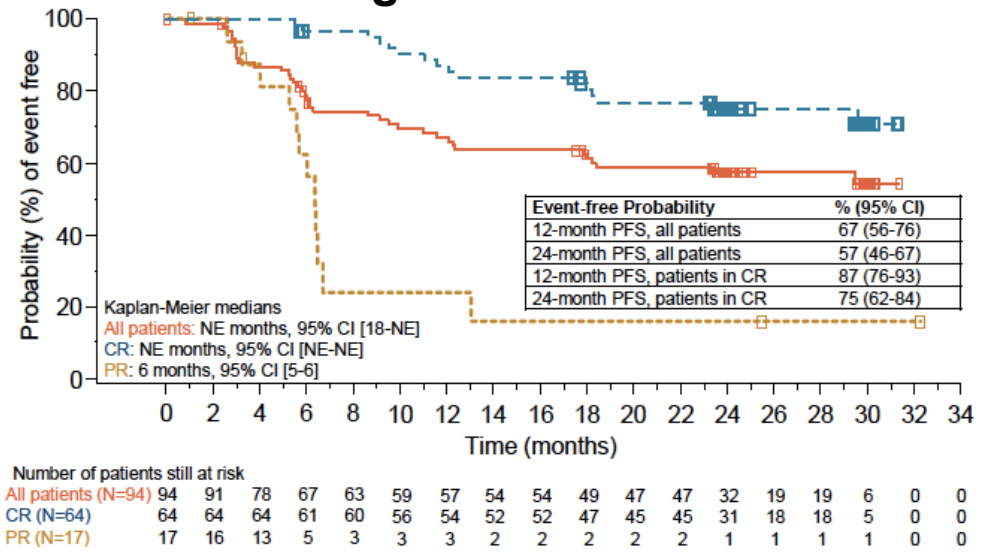
ELARA Study of Tisa-cel in relapsed/refractory FL

Characteristic	n=97
Median age (range)	57 (29-73)
Median prior tx (range)	4 (2-13)
Refractory	78%
POD24	60%

	All patients n=94
ORR	**86%**
CRR	**68%**

AEs of Special Interest (n=97)	
Cytokine Release Syndrome	
Any grade	49%
Grade ≥ 3	0%
ICANS	
Any grade	4%
Grade ≥ 3	1%

Progression-free survival



Median PFS not reached
24-month PFS 57.0% (46-67)

Dreyling, at al. Proc ASH 2022
Fowler, et al. Nat Med 2022.

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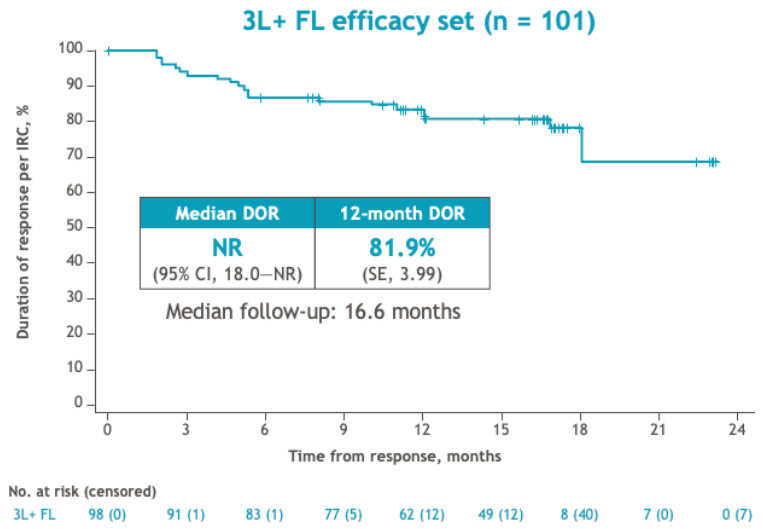
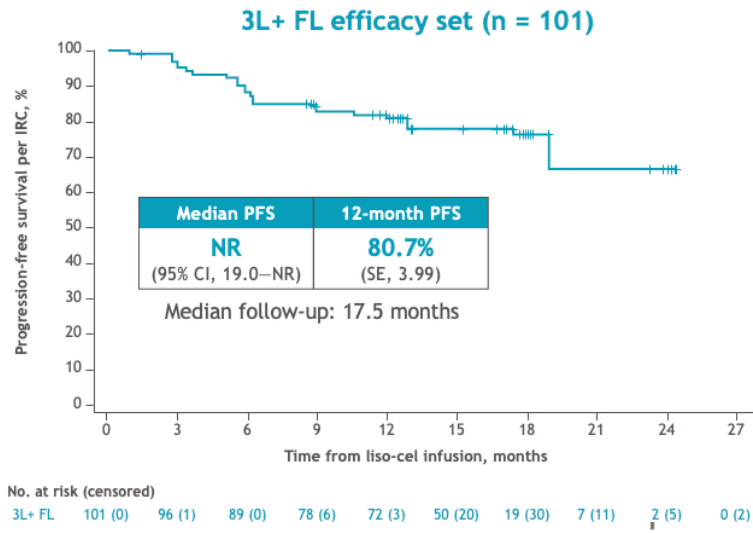
TRANSCEND FL: Phase 2 study results of lisocabtagene maraleucel (liso-cel) in patients with relapsed/refractory follicular lymphoma

Baseline characteristics for 3L+ FL	N=107
Median age	62 (34-80)
Median prior therapies	3 (2-10)
FLIPI high risk	57%
Prior ASCT	31%
Elevated LDH	44%
Chemorefractory	67%
POD24	54%

Response	N=101
Overall response	97%
Complete response	94%

CRS and ICANS	N=130
CRS	
Any grade	58%
Grade ≥3	1%
ICANS	
Any grade	15%
Grade ≥3	2%



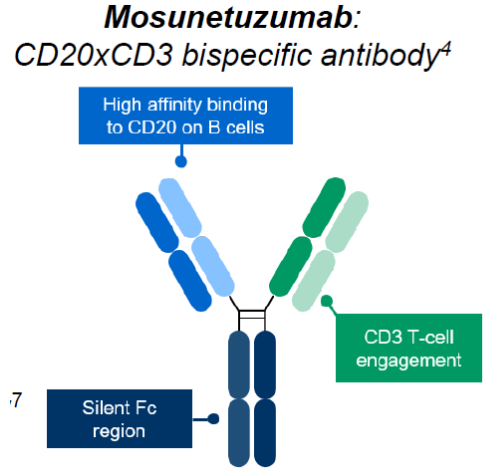


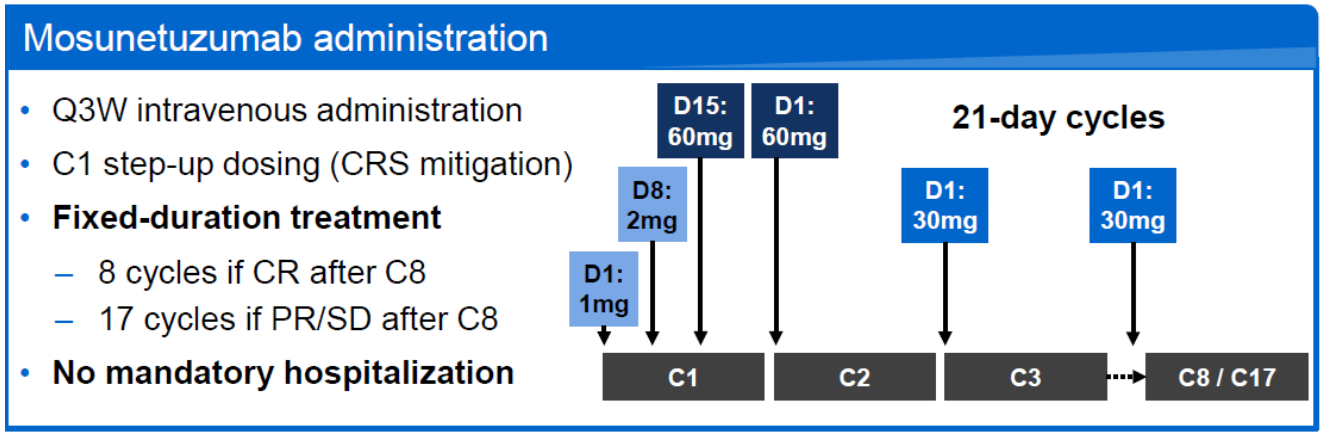
Morschhauser, et al. Proc ICML 2023, #LBA4

Mosunetuzumab

- Recent approval for 3L beyond FL based on study by Budde et al.
  - CD20/CD3 bispecific antibody
  - Original study with IV but now exploring SQ injections

		N=90
Median number of prior lines, n (range)		3 (2–10)
Prior systemic therapy	Anti-CD20 therapy	90 (100%)
	Alkylator therapy	90 (100%)
	PI3K inhibitor	17 (18.9%)
	IMiD	13 (14.4%)
	CAR-T	3 (3.3%)
Prior ASCT		19 (21.1%)
Refractory to last prior therapy		62 (68.9%)
Refractory to any prior aCD20 therapy		71 (78.9%)
Refractory to any prior aCD20 therapy and alkylator therapy (double refractory)		48 (53.3%)
POD24		47 (52.2%)





SQ dosing 5 mg (C1D1), 45 mg (C1D8), 45 mg C1D15 until EOT

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Mosunetuzumab

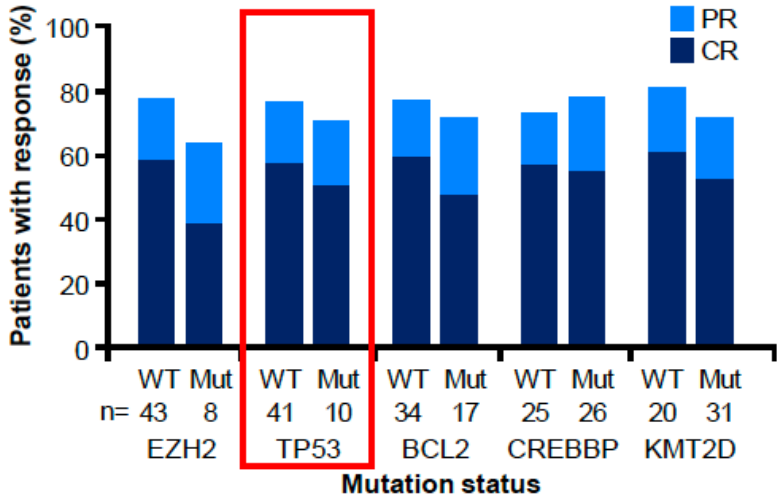
Response rates

Efficacy endpoint in the overall population by investigator assessment; % (95% CI)	N=90
ORR	**78%** (68–86)
CR	**60%** (49–70)

Time to first response (median [range]): **1.4 months** (1.0–11)
Time to first CR (median [range]): **3.0 months** (1.0–19)

High ORR and CR rate were consistent with published results[1]

Response by mutation status



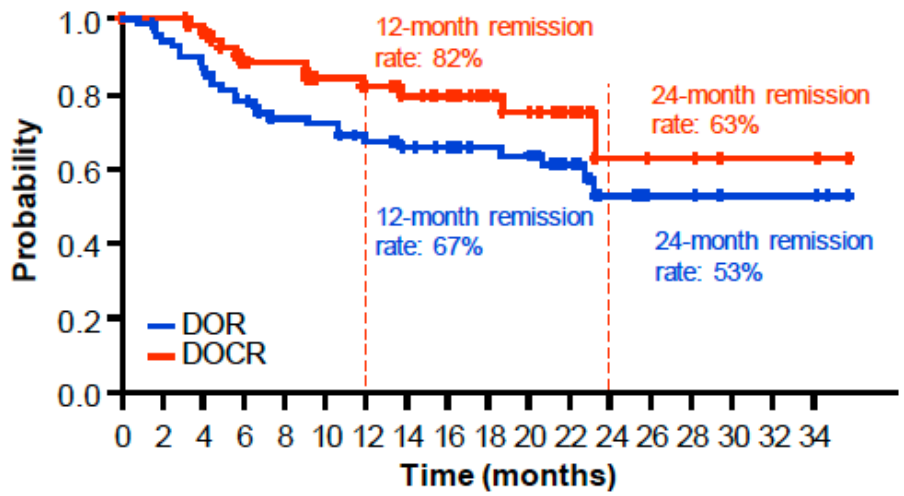
1. Budde LE, et al. Lancet Oncol 2022;23(8):1055–1065

Mosunetuzumab

Durability of responses

Efficacy endpoint by investigator assessment	N=90
Median DOR, months (range), n=70	NR (21–NR)
24-month DOR (95% CI)	53% (38–68)
Median DOCR, months (range), n=54	NR (23–NR)
24-month DOCR (95% CI)	63% (38–88)
Median PFS, months (range)	24 (12–NR)
24-month PFS (95% CI)	48% (36–60)
Median TTNT, months (range)	NR (18–NR)
24-month TTNT (95% CI)	56% (45–67)
Median OS, months (range)	NR (NR–NR)
24-month OS (95% CI)	87% (80–94)

DOR and DOCR



Durable responses: majority of patients in remission after 2 years

DOCR, duration of complete response; TTNT, time-to-next therapy.

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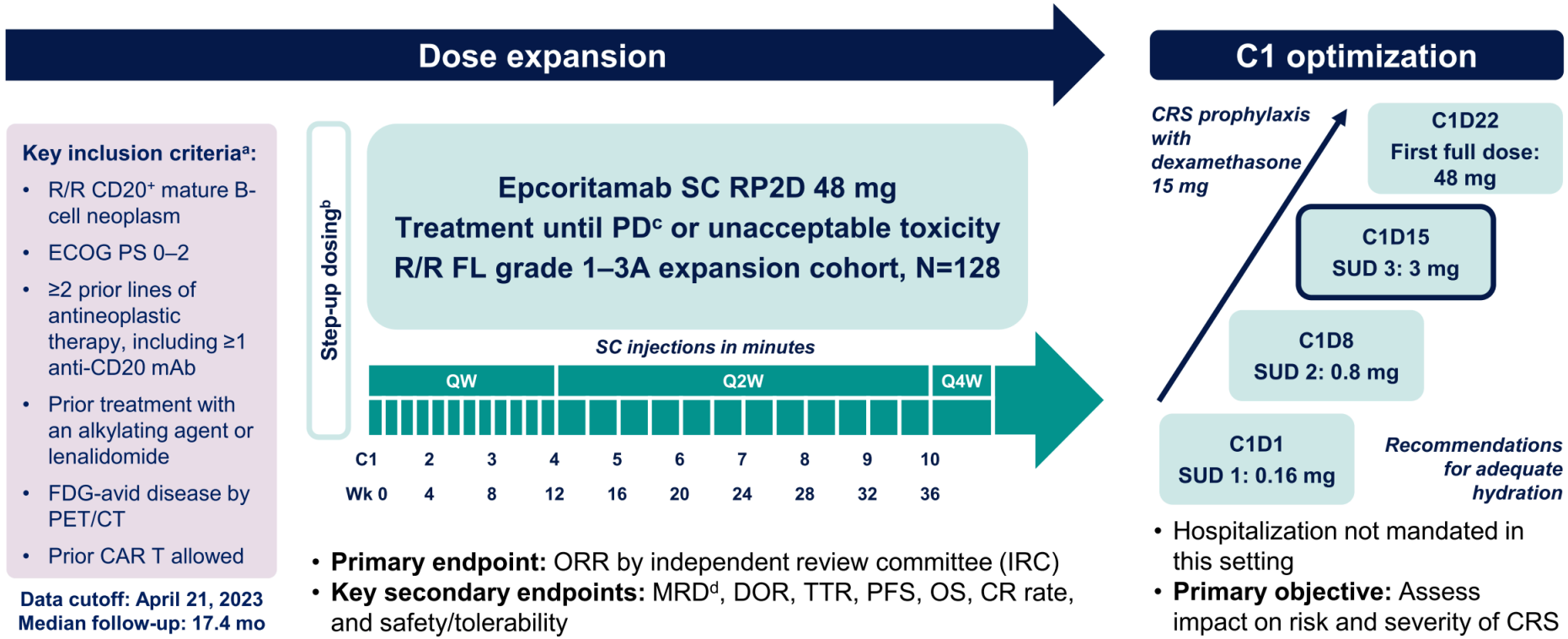
Epcoritamab

Trial Design: Pivotal EPCORE™ NHL-1 Study



Phase 1/2 trial. [a]Patients enrolled in this trial (and excluded from trials of other T-cell–engaging therapies) included those with worse anemia, lymphopenia, and/or renal function. [b]Step-up dosing (SUD; priming [SUD 1] 0.16 mg and intermediate [SUD 2] 0.8 mg dosing before first full dose) and corticosteroid prophylaxis were used to mitigate CRS. [c]≥2 measurable (by CT/MRI) and FDG PET–positive lesions; radiographic disease evaluation was performed every 6 wk for the first 24 wk (6, 12, 18, and 24 wk), then every 12 wk (36 and 48 wk), and every 6 mo thereafter. [d]MRD was assessed in peripheral blood using the clonoSEQ® (Adaptive Biotechnologies, Seattle, WA) next-generation sequencing assay. ClinicalTrials.gov: NCT03625037; EudraCT: 2017-001748-36.

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Baseline Characteristics and Prior Treatments

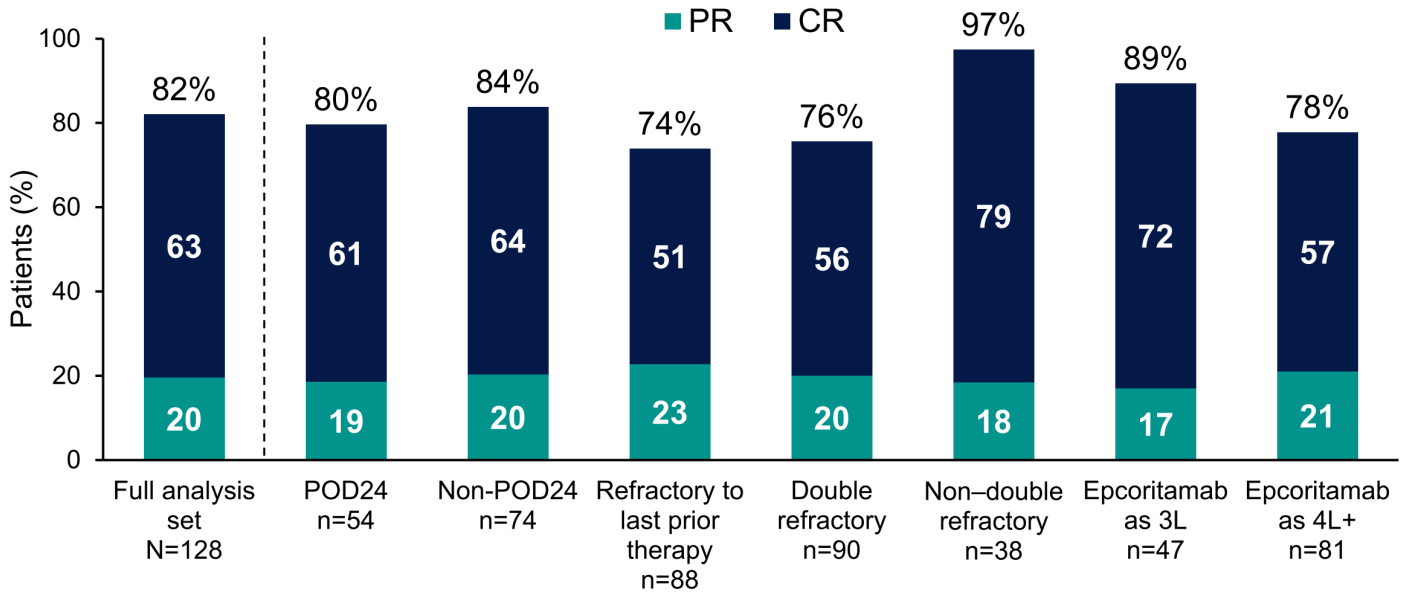
Demographics	N=128
Median age, y (range)	65 (39–84)
Male, n (%)	79 (62)
Ann Arbor stage, n (%)[a]	
III	32 (25)
IV	77 (60)
FLIPI, n (%)[b]	
2	31 (24)
3–5	78 (61)
Beta-2 microglobulin, n (%)[c]	
High	79 (62)

Treatment History	N=128
Median time from diagnosis to first dose, y (range)	5.8 (0.6–35)
Median time from end of last line of therapy to first dose, mo (range)	5.2 (1–105)
Median time from end of last anti-CD20 therapy to first dose, mo (range)	10.3 (1–159)
Median number of prior lines of therapy (range)	3 (2–9)
≥3 prior lines, n (%)	81 (63)
≥4 prior lines, n (%)	40 (31)
POD24,[d] n (%)	54 (42)
Double refractory,[e,f] n (%)	90 (70)
Primary refractory,[e] n (%)	69 (54)
Refractory[e] to last prior systemic therapy, n (%)	88 (69)

- All patients had prior treatment with an anti-CD20 mAb and an alkylating agent
  - Other prior systemic treatments included anthracyclines (77%), bendamustine (63%), nucleotides (48%), topoisomerase inhibitors (36%), IMiDs (31%), PI3K inhibitors (23%), and CAR T-cell therapy (5%)

[a]Ann Arbor stage was I–II in 19 patients. [b]FLIPI was 0–1 in 17 patients, unknown for 1 patient, and not applicable for 1 patient. FLIPI was prior to first dose on study. [c]Beta-2 microglobulin was normal in 45 patients and missing for 4 patients. [d]Progression within 2 y of initiating first-line chemoimmunotherapy. [e]Refractory: No response or relapse within 6 mo after therapy. [f]Double refractory: Refractory to both anti-CD20 and an alkylating agent.

ORRs and CR Rates Were High Regardless of Subgroup



Efficacy Parameters	N=128
Median time to response, mo (range)	1.4 (1.0–3.0)
Median time to complete response, mo (range)	1.5 (1.2–11.1)
Median duration of response, mo (95% CI)[a]	NR (13.7–NR)
Median duration of complete response, mo (95% CI)[a]	NR (21.4–NR)
MRD negativity, n (%)[b]	61 (67)
Median progression-free survival, mo (95% CI)[a]	
Overall (N=128)	15.4 (10.9–NR)
Complete responders (n=80)	NR (22.8–NR)
MRD-negative patients (n=61)	NR (22.8–NR)
Median overall survival, mo (95% CI)[a]	NR (NR–NR)
Median time to next therapy, mo (range)[a]	NR (0.2+ to 30.0+)

MRD, minimal residual disease; NR, not reached. [a]Based on Kaplan–Meier estimate. [b]Based on MRD-evaluable set (n=91) per clonoSEQ® PBMC assay with 10^{-6} cutoff.

Summary of Response FL

Drug	N	ORR	CR	PFS 24 m	OS 24 m	mDOR
Mosunetuzumab	90	78%	60%	48%	87%	NR
Epcoritamab	128	82%	63%	15.4 m (17 m f/u)	NR	NR
Odronextamab	121	81.8%	75.2%	55.3%*	N/A	20.5 m

*18 months

Drug	DOR 12 m	DOCR 12 m	DOR 24 m	DOCR 24 m
Mosunetuzumab	67%	82%	53%*	63%
Eporitamab	NR	NR	N/A	N/A
Odronextamab	68.8%	72.2%	55%*	59.1%*

*18 months

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Considerations in choosing between mosunetuzumab and CAR T-cells in FL

CAR T-cells	Mosunetuzumab
Excellent efficacy with longer follow up	Excellent efficacy, but with shorter follow up
Requires 3-4 weeks of manufacturing	Off the shelf
Logistically more complex	Logistically less complex
”One and done” for life at this time.	8-17 cycles (can be repeated)
Needs lymphodepleting chemo	No lymphodepleting chemo
Higher risk of CRS and neurotoxicity (tisa-cel better than axi-cel)	Lower risk of CRS and neurotoxicity
Usually inpatient	Usually outpatient

- They are not mutually exclusive, though we do not have data on optimal sequencing
- Decision will be personalized for most patients between Mosunutuzemab and CAR
- CAR T-cells for those with concern of tDLBCL

kim, at al.Proc ASH. 2022

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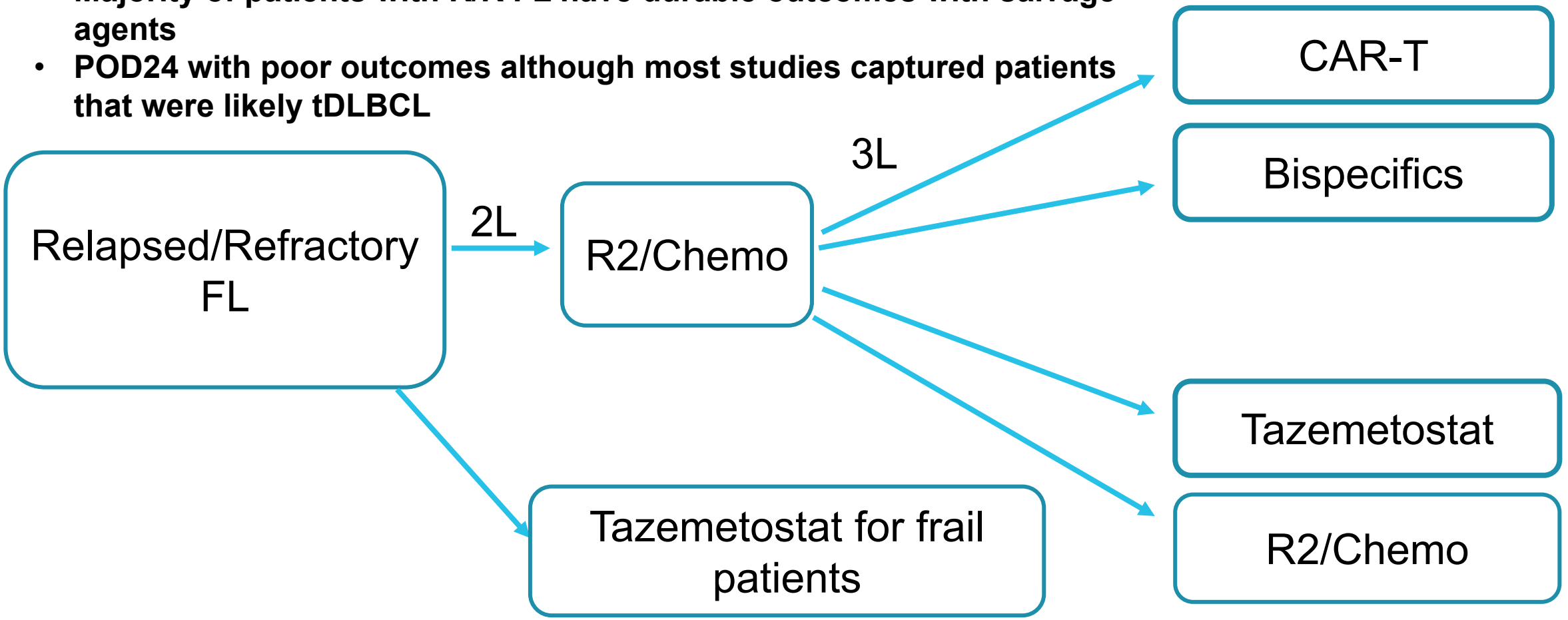
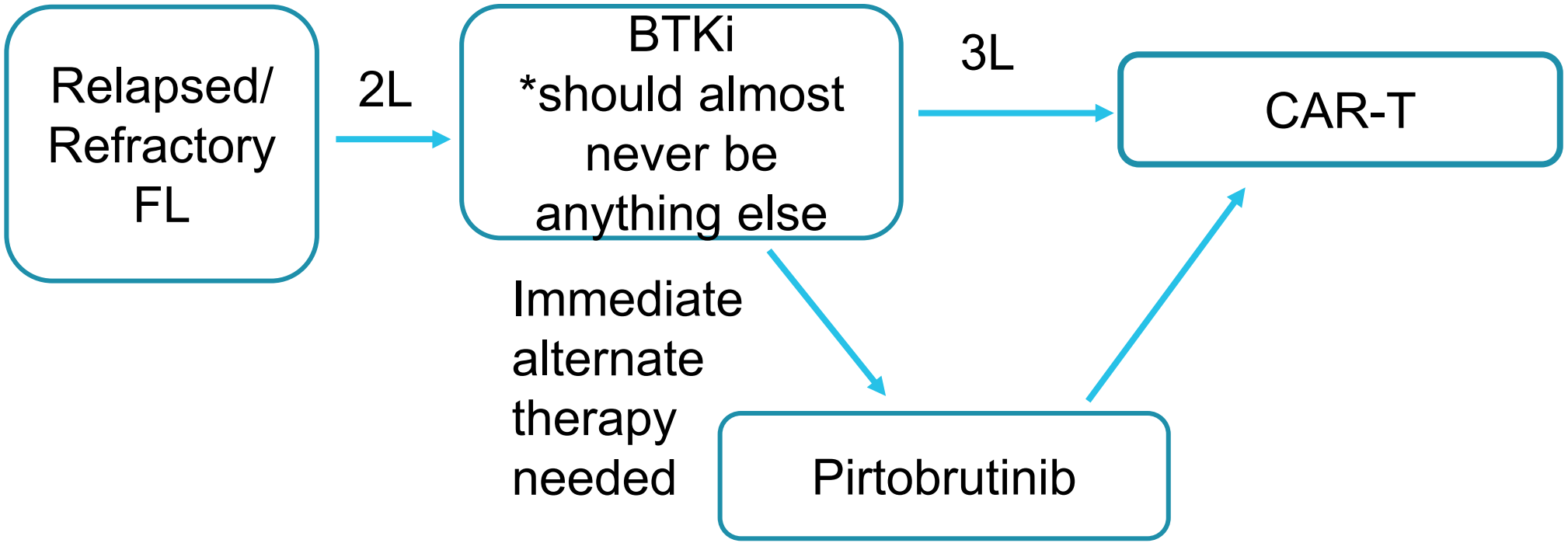
R/R FL

- **Majority of patients with R/R FL have durable outcomes with salvage agents**
- **POD24 with poor outcomes although most studies captured patients that were likely tDLBCL**



R/R MCL

- **Outcomes in R/R MCL remain poor especially after BTKi failure**



Study design: Phase II dose expansion

Study design: Phase II dose expansion

Key inclusion criteria

- R/R MCL
- ECOG PS 0–2
- ≥2 prior therapies (including an anti-CD20 antibody, anthracycline or bendamustine therapy, and BTKi)

Objectives

- Primary: efficacy of mosun-pola (best ORR[1] by IRC)
- Secondary: efficacy by INV, durability of response, and safety

Mosun-pola fixed duration administration (NCT03671018)

Mosun

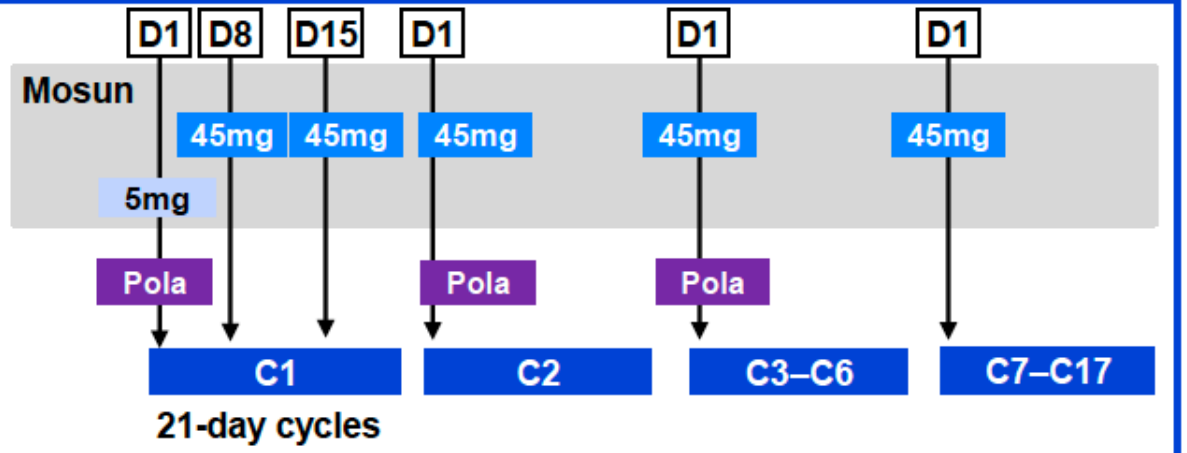
- SC administered in 21-day cycles with step-up dosing in Cycle (C) 1; total of 17 cycles

Pola

- 1.8mg/kg IV on Day [D],1 of C1–6

No mandatory hospitalization

All patients received corticosteroid premedication prior to each dose in C1*



*From C2 and beyond, premedication was optional for patients who did not experience CRS in the previous cycle; corticosteroid premedication consisted of 20mg of dexamethasone or 80mg of methylprednisolone, either IV or orally.

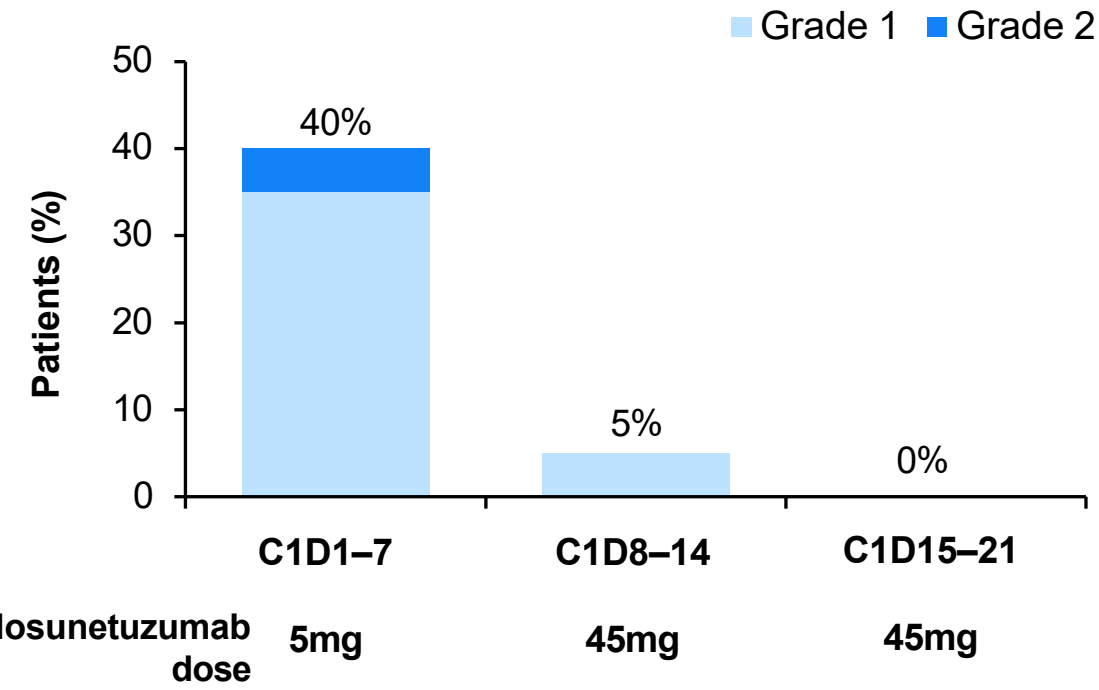
1. Cheson BD, et al. J Clin Oncol 2014;32:3059–68.

*From C
premedication consisted of 20mg of dexamethasone or 80mg of methylprednisolone, either IV or orally.
1. Cheson BD, et al. J Clin Oncol 2014;32:3059–68.

CRS summary

CRS by ASTCT criteria[1]	N=20
Any grade, n (%)	9 (45)
Grade 1	8 (40)
Grade 2*	1 (5)
Grade 3+	0
Median time to first CRS onset relative to last dose, days (range)	1 (0–2)
Median CRS duration, days (range)	3 (1–9)
CRS management, n (%)	
Corticosteroids	1 (5)
Tocilizumab	1 (5)
Low-flow oxygen	1 (5)

CRS by cycle and grade



All CRS events were low grade and resolved within C1

Clinical cut-off date: July 6, 2023. *This patient experienced Grade 2 fever, confusion, and hypoxia on D3; management included tocilizumab, low-flow oxygen, acetaminophen, and broad-spectrum antibiotics.
ASTCT, American Society for Transplantation and Cellular Therapy

1. Lee DW, et al. Biol Blood Marrow Transplant 2019;25:625–38.

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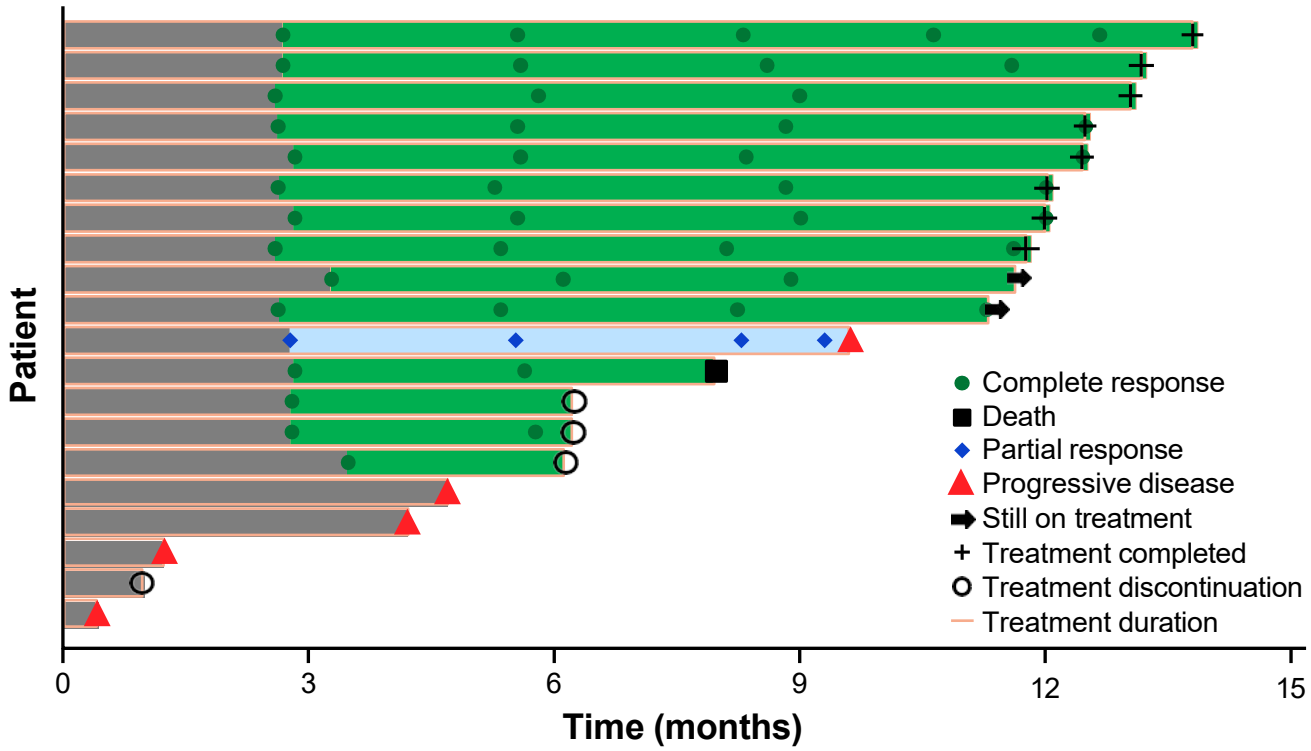
Durability of response

Swimlane plot



- Median follow-up:
  15.8 months (range: 0–25)
- Median time to first response:
  2.8 months (range: 2.6–3.4)
- Of 14 patients with CR, 11 remain in remission*

Complete remission was achieved early and remained durable

Clinical cut-off date: July 6, 2023. *Out of the three patients who were not in remission, 1 patient had progressive disease, and two died from non-lymphoma causes.

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Conclusions

- DLBCL
  - CAR-T approved in both 2L+ (primary refractory) and 3L+
    - Provides another curative option for patients
    - Recent data indicates that in 2L setting CAR-T has an OS benefit
  - Data on bispecifics is still maturing but provides option to give in community
- FL with two CAR-T and soon two bispecifics available for R/R patients
  - Responses durable but cure unlikely as such more debate on which should be given first.
- MCL more difficult space given increased AE and no hint that treatment is curative.
  - Currently only CAR-T is available but potentially Mosun-Pola might be an option for community especially given rates of CRS

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Questions

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