Cases from the Community: Investigators Discuss the Application of Available Research in the Care of Patients with Diffuse Large B-Cell Lymphoma

A CME Satellite Symposium During the Society of Hematologic Oncology 2023 Annual Meeting

Friday, September 8, 2023
11:37 AM – 12:37 PM CT

Faculty

Matthew Lunning, DO
Laurie H Sehn, MD, MPH

Moderator

Christopher R Flowers, MD, MS

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Faculty

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Associate Vice Chair of Research
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Clinical Professor of Medicine
Division of Medical Oncology
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Podcast Editor, *Blood*
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Moderator

Christopher R Flowers, MD, MS
Chair ad Interim, Division of Cancer Medicine
Professor, Department of Lymphoma/Myeloma
The University of Texas
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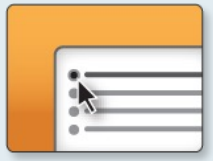
Clinicians in the Meeting Room

Access program slides using the URL included in the program syllabus.



Please take a moment to complete the pre- and postmeeting surveys. Instructions are included in the handout with the syllabus.

To ask a question, please email DrNeilLove@ResearchToPractice.com. We will aim to address as many questions as possible throughout the meeting.

To complete your course evaluation and receive CME credit, please follow the instructions included in the program syllabus.

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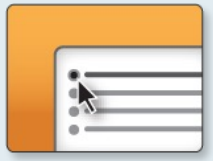
Clinicians Attending via Zoom

Review Program Slides: A link to the program slides will be posted in the chat room at the start of the program.



Answer Survey Questions: Complete the pre- and postmeeting surveys.

Ask a Question: Submit a challenging case or question for discussion using the Zoom chat room.

Get CME Credit: A CME credit link will be provided in the chat room at the conclusion of the program.

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About the Enduring Program

- The live meeting is being video and audio recorded.
- The proceedings from today will be edited and developed into an enduring web-based video/PowerPoint program.
  An email will be sent to all attendees when the activity is available.
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Advocate Aurora Health
Park Ridge, Illinois

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Florida Cancer Specialists
Lake Worth, Florida

Kimberly Ku, MD
Oncologist
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Neil Morganstein, MD
Atlantic Health System
Summit, New Jersey

Priya Rudolph, MD
Georgia Cancer Specialists
Athens, Georgia

Erik Rupard, MD
Drexel University College of Medicine
West Reading, Pennsylvania

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Agenda

Module 1 – Up-Front Management of Diffuse Large B-Cell Lymphoma (DLBCL) — Dr Flowers

Module 2 – Selection and Sequencing of Therapy for Relapsed/Refractory (R/R) DLBCL — Dr Lunning

Module 3 – Role of CD20 x CD3 Bispecific Antibodies in the Management of DLBCL — Dr Sehn

Agenda

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Module 3 – Role of CD20 x CD3 Bispecific Antibodies in the Management of DLBCL — Dr Sehn

Spencer Henick Bachow, MD
Boca Raton, Florida

Kimberly Ku, MD
Bloomington, Illinois

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Spencer Henick Bachow, MD

33-year-old woman: Pelvic pain, high CA-125; T-cell/histiocyte-rich DLBCL; polatuzumab vedotin/R-CHP

Kimberly Ku, MD

43-year-old woman: Extensive-stage DLBCL (GCB: MYC and Bcl-2 rearrangements)

Questions for the Faculty

Have you observed elevated CA-125 in DLBCL? (? Peritoneal involvement or compression from adenopathy)

Role of polatuzumab vedotin/R-CHP in extensive-stage disease based on disease subtype?

- *GCB vs ABC*
- *Double-hit*
- *T-cell rich*

Indications for CNS prophylaxis? What method do you generally use?

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Shams Bufalino, MD
Park Ridge, Illinois

Erik Rupard, MD
West Reading, Pennsylvania

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Shams Bufalino, MD

52-year-old man: Stage II GCB-type DLBCL

Erik Rupard, MD

70-year-old man: Wobbly teeth due to DLBCL in jaw; R-CHOP x 6 cycles

Questions for the Faculty

Duration of R-chemotherapy in limited-stage disease? Role of radiation therapy?

Do you have any experience with mandibular DLBCL?

What trials are ongoing in limited-stage disease?

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Up-Front Management of Diffuse Large B-Cell Lymphoma (DLBCL)

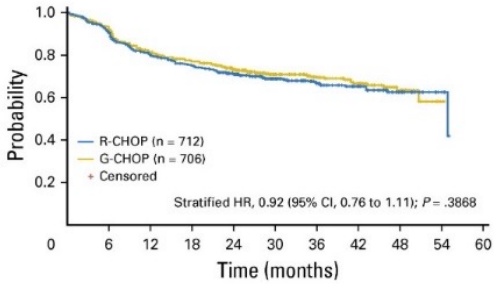
Christopher Flowers, MD, MS, FASCO

Chair, Professor Department of Lymphoma/Myeloma

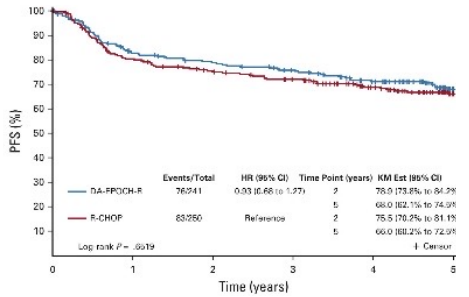
Division Head, Division of Cancer Medicine

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

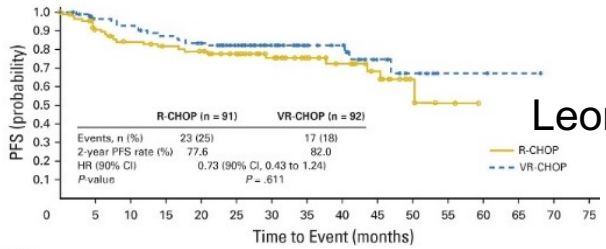
Trial	Comparison	Result
GOYA	R-CHOP vs. G-CHOP (n=1,418)	Negative
CALGB 50303	R-CHOP vs. R-DA-EPOCH (n=524)	Negative
PYRAMID (non-GCB)	R-CHOP vs. Bortezomib+R-CHOP (n=206)	Negative
REMoDL-B	R-CHOP vs. Bortezomib+R-CHOP (n=1,085)	Negative
LYM-2034 (non-GCB)	R-CHOP vs. Bortezomib+R-CHP (n=164)	Negative
PHOENIX (ABC)	R-CHOP vs. Ibrutinib+R-CHOP (n=838)	Negative
ECOG 1412	R-CHOP vs. Lenalidomide+R-CHOP (n=345)	*?Positive*
ROBUST (non-GCB)	R-CHOP vs. Lenalidomide+R-CHOP (n=570)	*Negative*



Vitolo *J Clin Oncol* 2017

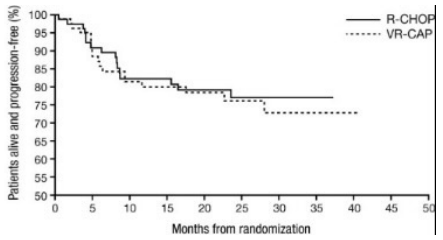


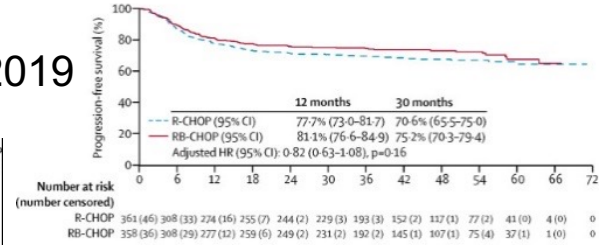
Bartlett *J Clin Oncol* 2019



Leonard *J Clin Oncol* 2017

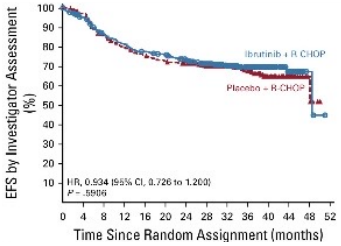
Davies Lancet Onc 2019





Offner *Blood* 2015

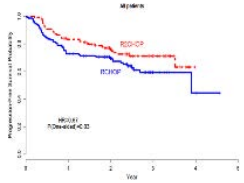
Younnes *J Clin Oncol* 2019



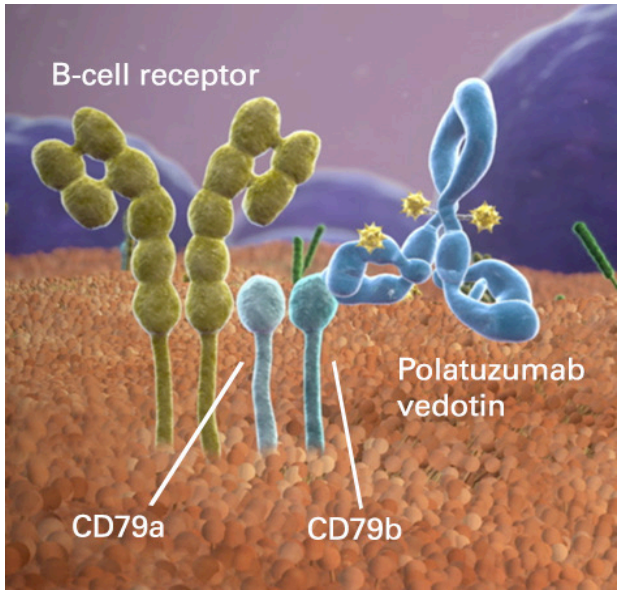
2-year OS: 87% Ien/R-CHOP
80% R-CHOP

Nowakowski *ICML* 2019

Johnson *ASH* 2019



POLARIX: 1L DLBCL Phase 3



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Polatuzumab Vedotin in Previously Untreated Diffuse Large B-Cell Lymphoma

H. Tilly, F. Morschhauser, L.H. Sehn, J.W. Friedberg, M. Trněný, J.P. Sharman, C. Herbaux, J.M. Burke, M. Matasar, S. Rai, K. Izutsu, N. Mehta-Shah, L. Oberic, A. Chauchet, W. Jurczak, Y. Song, R. Greil, L. Mykhalska, J.M. Bergua-Burgués, M.C. Cheung, A. Pinto, H.-J. Shin, G. Hapgood, E. Munhoz, P. Abrisqueta, J.-P. Gau, J. Hirata, Y. Jiang, M. Yan, C. Lee, C.R. Flowers, and G. Salles

Patients

- Previously untreated DLBCL
- Age 18–80 years
- IPI 2–5
- ECOG PS 0–2

Stratification factors

- IPI score (2 vs 3–5)
- Bulky disease (<7.5 vs ≥7.5cm)
- Geographic region (Western Europe, US, Canada, & Australia vs Asia vs rest of world)

R 1:1

Pola-R-CHP

Polatuzumab vedotin (1.8mg/kg)* + **R-CHP + vincristine placebo**

Cycles 1–6
(1 cycle=21 days)

R-CHOP

R-CHOP† + **polatuzumab vedotin placebo**

Rituximab
375mg/m^2

Cycles 7 & 8

Primary endpoint

Progression-free survival (Investigator-assessed)

Secondary endpoints

- Event-free survival
- Complete response rate at end of treatment (PET/CT, IRC-assessed)
- Disease-free survival
- Overall survival

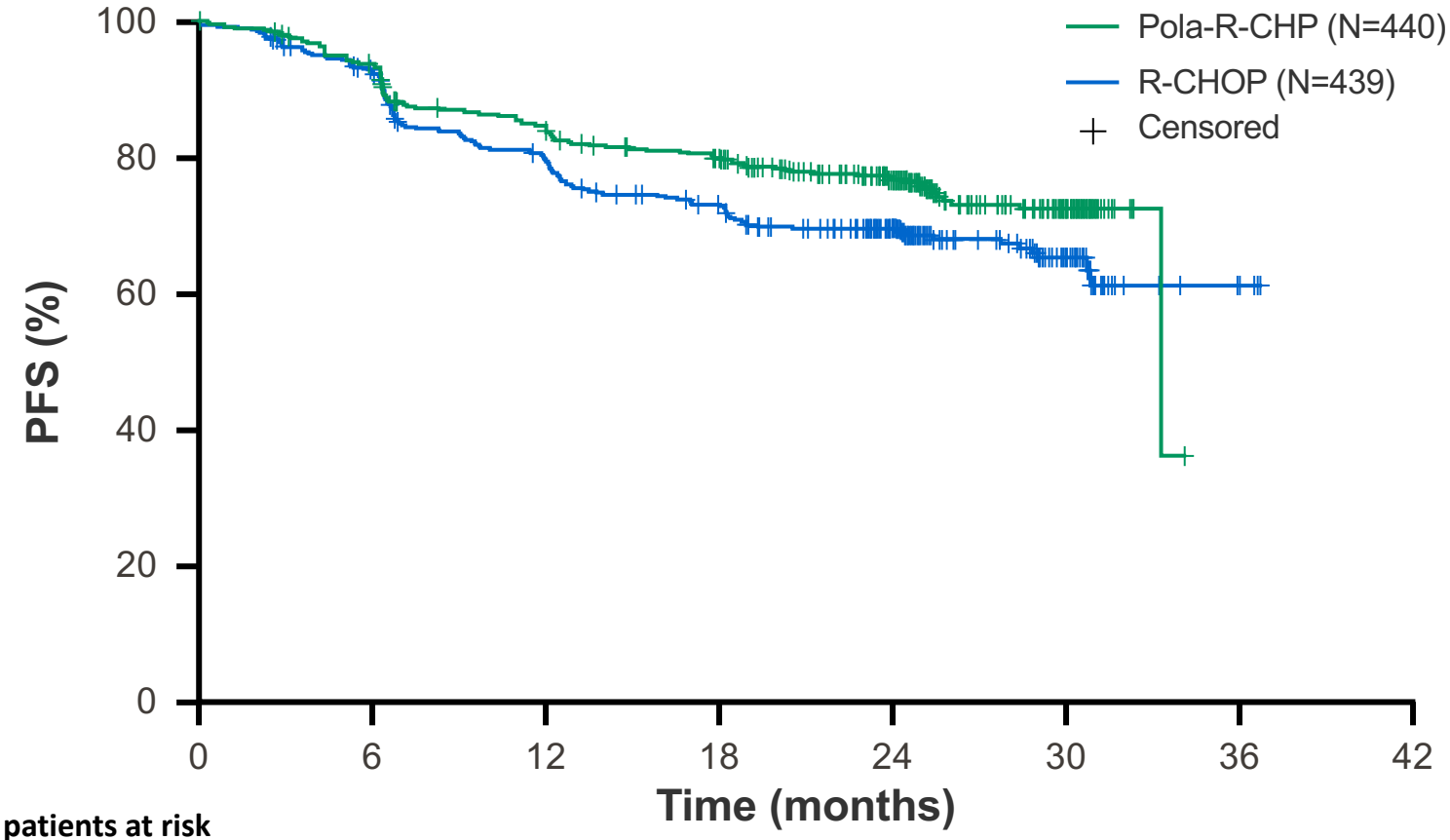
Safety endpoints

Incidence, nature, and severity of adverse events

Tilly et al. *NEJM* 2022

Primary endpoint: Progression-free survival

Pola-R-CHP significantly improved PFS vs R-CHOP



No. of patients at risk

Pola-R-CHP	440	404	353	327	246	78	NE	NE
R-CHOP	439	389	330	296	220	78	3	NE

HR 0.73 **(P=0.02)**

95% CI: 0.57, 0.95

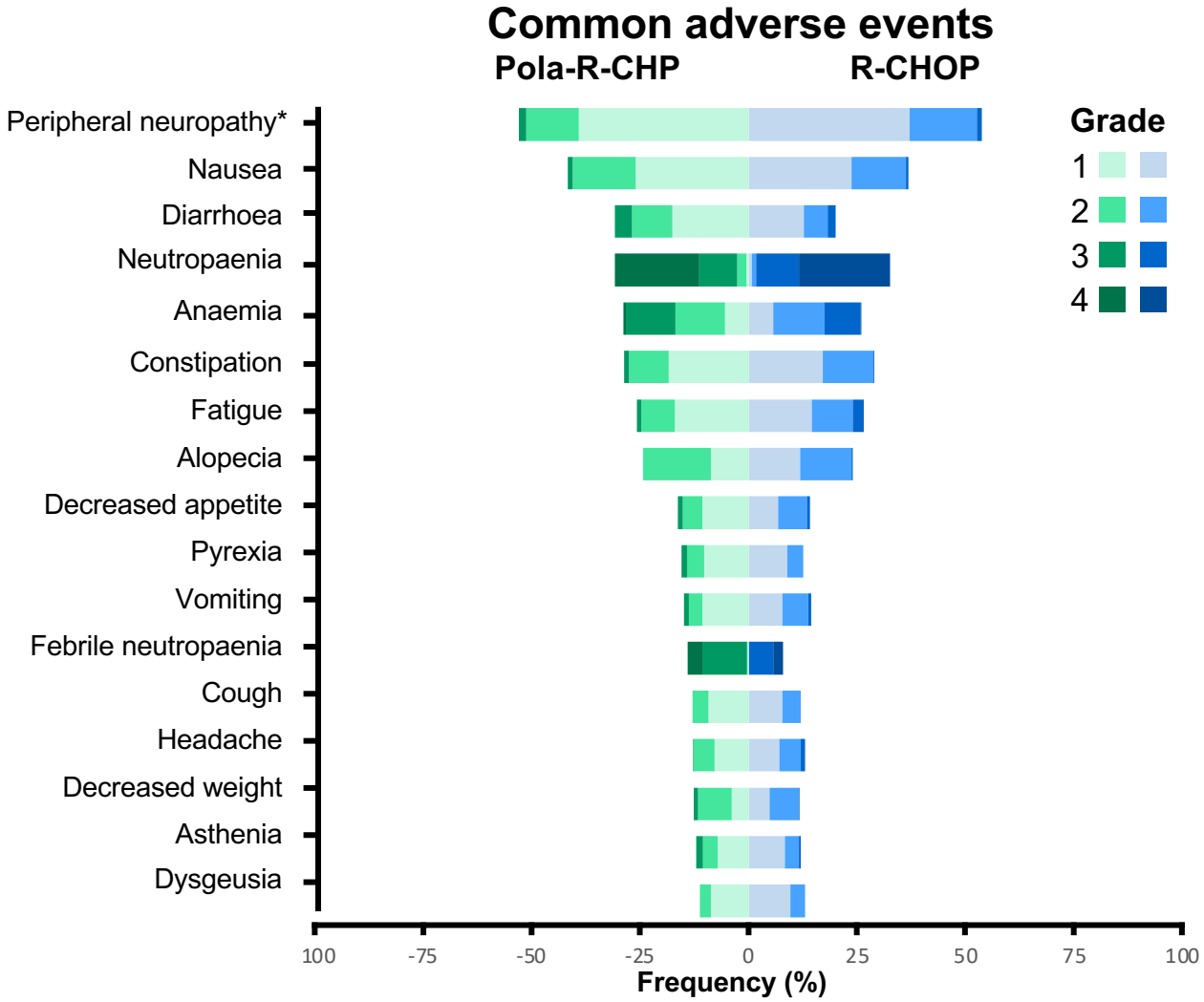
- Pola-R-CHP demonstrated a **27% reduction in the relative risk of disease progression, relapse, or death** vs R-CHOP
- **24-month PFS:** 76.7% with Pola-R-CHP vs 70.2% with R-CHOP (Δ**=6.5%**)

Tilly et al. *NEJM* 2022

Safety summary

Safety profiles were similar with Pola-R-CHP and R-CHOP

n (%)	Pola-R-CHP (N=435)	R-CHOP (N=438)
Any-grade adverse events	426 (97.9)	431 (98.4)
Grade 3–4	251 (57.7)	252 (57.5)
Grade 5	13 (3.0)	10 (2.3)
Serious adverse events	148 (34.0)	134 (30.6)
Adverse events leading to:		
Discontinuation of any study drug	27 (6.2)	29 (6.6)
Polatuzumab vedotin / vincristine	19 (4.4)	22 (5.0)
Dose reduction of any study drug	40 (9.2)	57 (13.0)



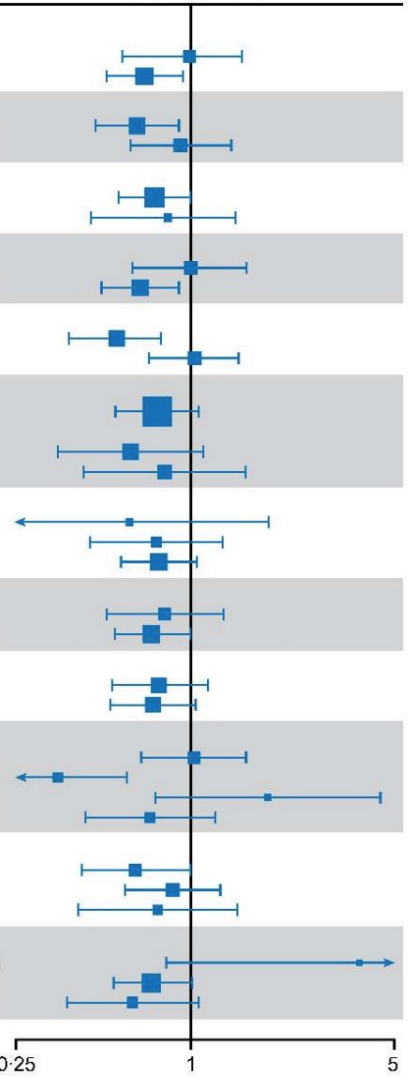
- ITT population. Data cut-off: June 28, 2021; median 28.2 months' follow-up.
  CI, confidence interval; HR, hazard ratio; NE, not evaluable; PFS, progression-free survival.

Tilly et al. *NEJM* 2022

Forest Plot by Subtypes

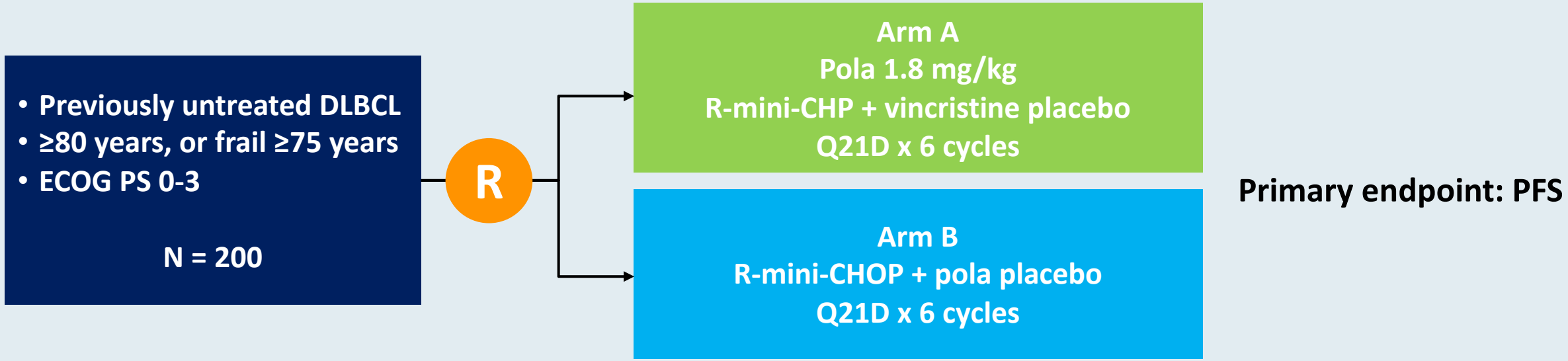
PFS: Pola-R-CHP vs R-CHOP

Baseline Risk Factors	Total N	Pola-R-CHP (N=440) n	Pola-R-CHP (N=440) 2-year Rate	R-CHOP (N=439) n	R-CHOP (N=439) 2-year Rate	Hazard Ratio	95% Wald CI
Age group							
≤60	271	140	74·1	131	71·9	0·9	(0·6 to 1·5)
>60	608	300	77·9	308	69·5	0·7	(0·5 to 0·9)
Sex							
Male	473	239	75·9	234	65·9	0·7	(0·5 to 0·9)
Female	406	201	77·7	205	75·2	0·9	(0·6 to 1·4)
ECOG PS							
0–1	737	374	78·4	363	71·2	0·8	(0·6 to 1·0)
2	141	66	67·2	75	65·0	0·8	(0·5 to 1·4)
IPI score							
IPI 2	334	167	79·3	167	78·5	1·0	(0·6 to 1·6)
IPI 3–5	545	273	75·2	272	65·1	0·7	(0·5 to 0·9)
Bulky disease							
Absent	494	247	82·7	247	70·7	0·6	(0·4 to 0·8)
Present	385	193	69·0	192	69·7	1·0	(0·7 to 1·5)
Geographic region							
Western Europe, United States, Canada, and Australia	603	302	78.6	301	72.0	0.8	(0·6 to 1·1)
Asia	160	81	74.3	79	65.6	0.6	(0·4 to 1·5)
Rest of world	116	57	70.8	59	67.3	0.9	(0·6 to 1·5)
Ann Arbor stage							
I–II	99	47	89·1	52	85·5	0·6	(0·2 to 1·8)
III	232	124	80·7	108	73·6	0·8	(0·5 to 1·3)
IV	548	269	72·6	279	66·1	0·8	(0·6 to 1·1)
Baseline LDH							
≤ULN	300	146	78·9	154	75·6	0·8	(0·5 to 1·3)
>ULN	575	291	75·4	284	67·2	0·7	(0·5 to 1·0)
No. of extranodal sites							
0–1	453	227	80·2	226	74·5	0·8	(0·5 to 1·1)
≥2	426	213	73·0	213	65·8	0·7	(0·5 to 1·0)
Cell-of-origin							
GCB	352	184	75·1	168	76·9	1·0	(0·7 to 1·5)
ABC	221	102	83·9	119	58·8	0·4	(0·2 to 0·6)
Unclassified	95	44	73·0	51	86·2	1·9	(0·8 to 4·5)
Unknown	211	110	73·8	101	64·3	0·7	(0·4 to 1·2)
Double expressor by IHC							
DEL	290	139	75·5	151	63·1	0·6	(0·4 to 1·0)
Non DEL	438	223	77·7	215	75·7	0·9	(0·6 to 1·3)
Unknown	151	78	76·0	73	69·8	0·8	(0·4 to 1·5)
Double- or triple-hit lymphoma							
Yes	45	26	69·0	19	88·9	3·8	(0·8 to 17·6)
No	620	305	76·8	315	70·3	0·7	(0·5 to 1·0)
Unknown	214	109	78·5	105	66·4	0·6	(0·4 to 1·1)



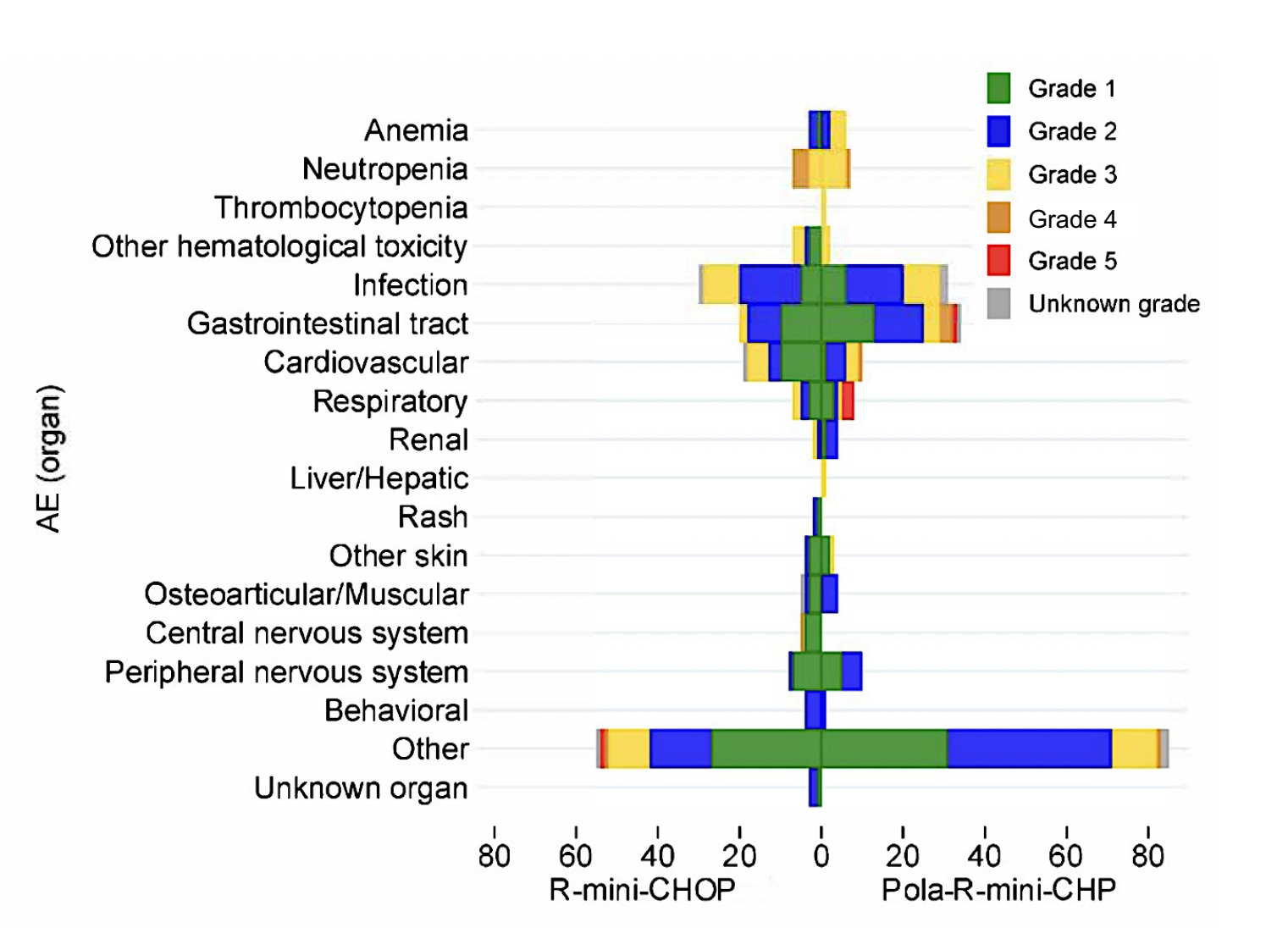
Tilly et al. *NEJM* 2022

POLAR BEAR Study Design: Adding Polatuzumab Vedotin to R-Mini-CHOP as Initial Therapy for Older Patients with DLBCL



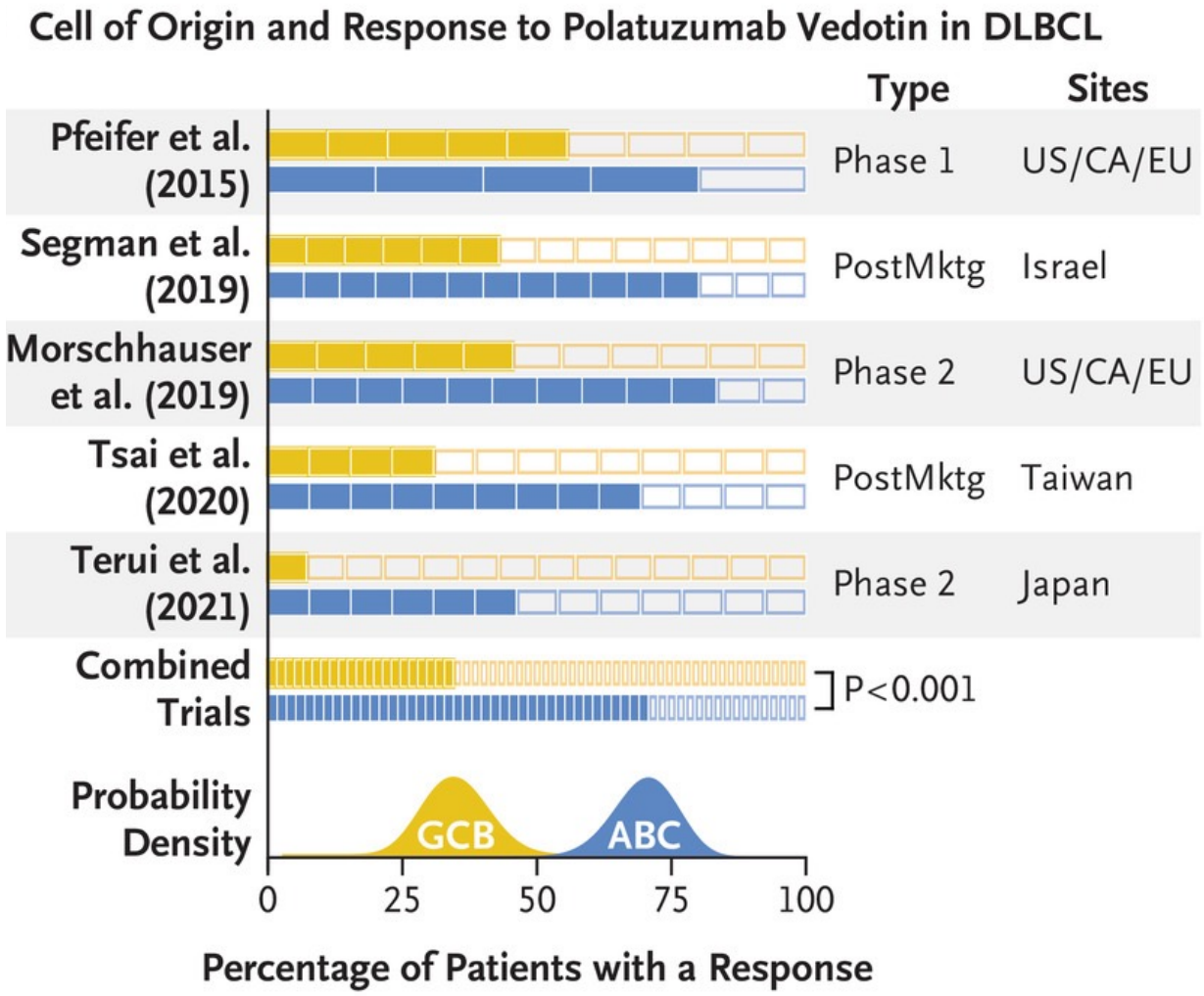
www.clinicaltrials.gov. NCT04332822. Accessed August 2022.

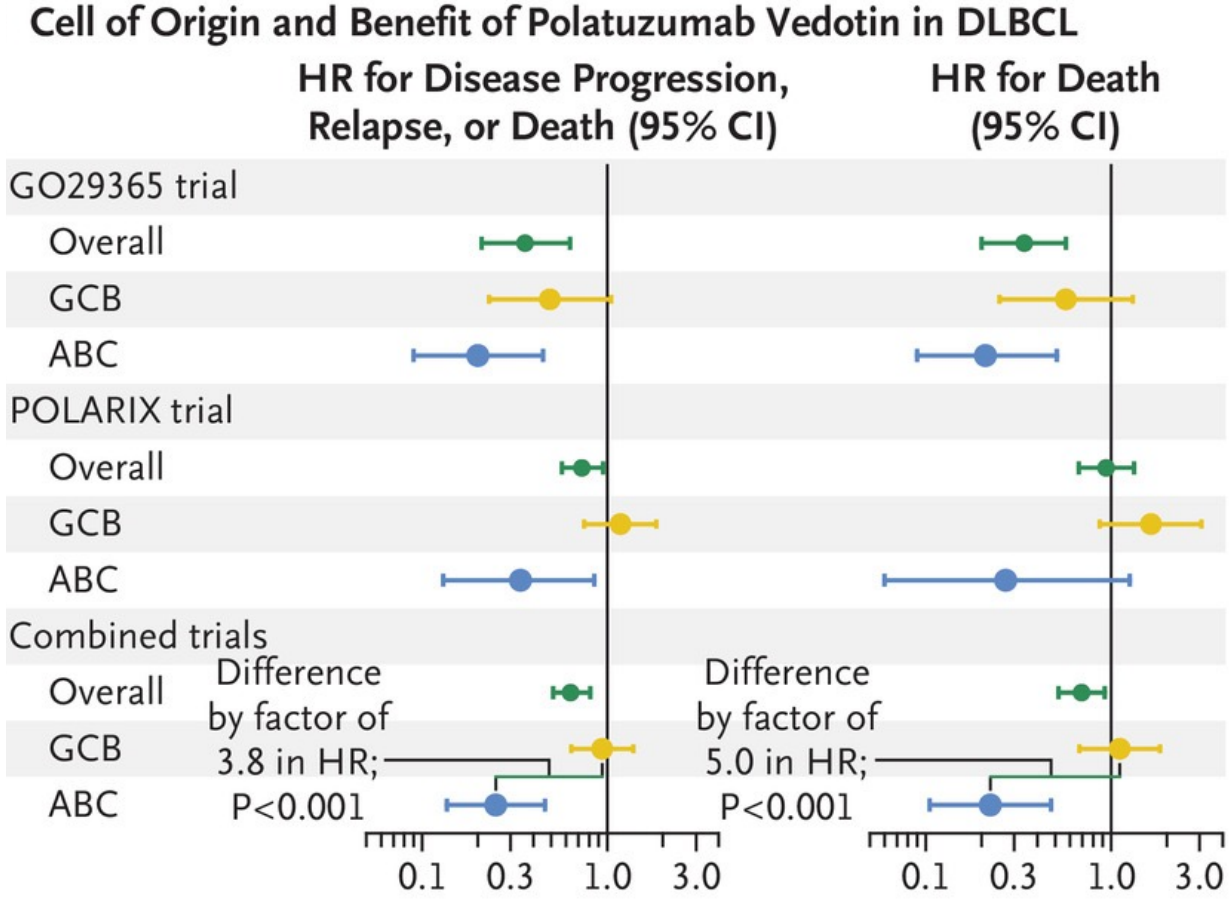
POLAR BEAR: Phase III Trial in Older or Frail Patients with DLBCL Comparing R-POLA-MINI-CHP to R-MINI-CHOP



Jerkeman M et al. EHA 2023;Abstract S227.

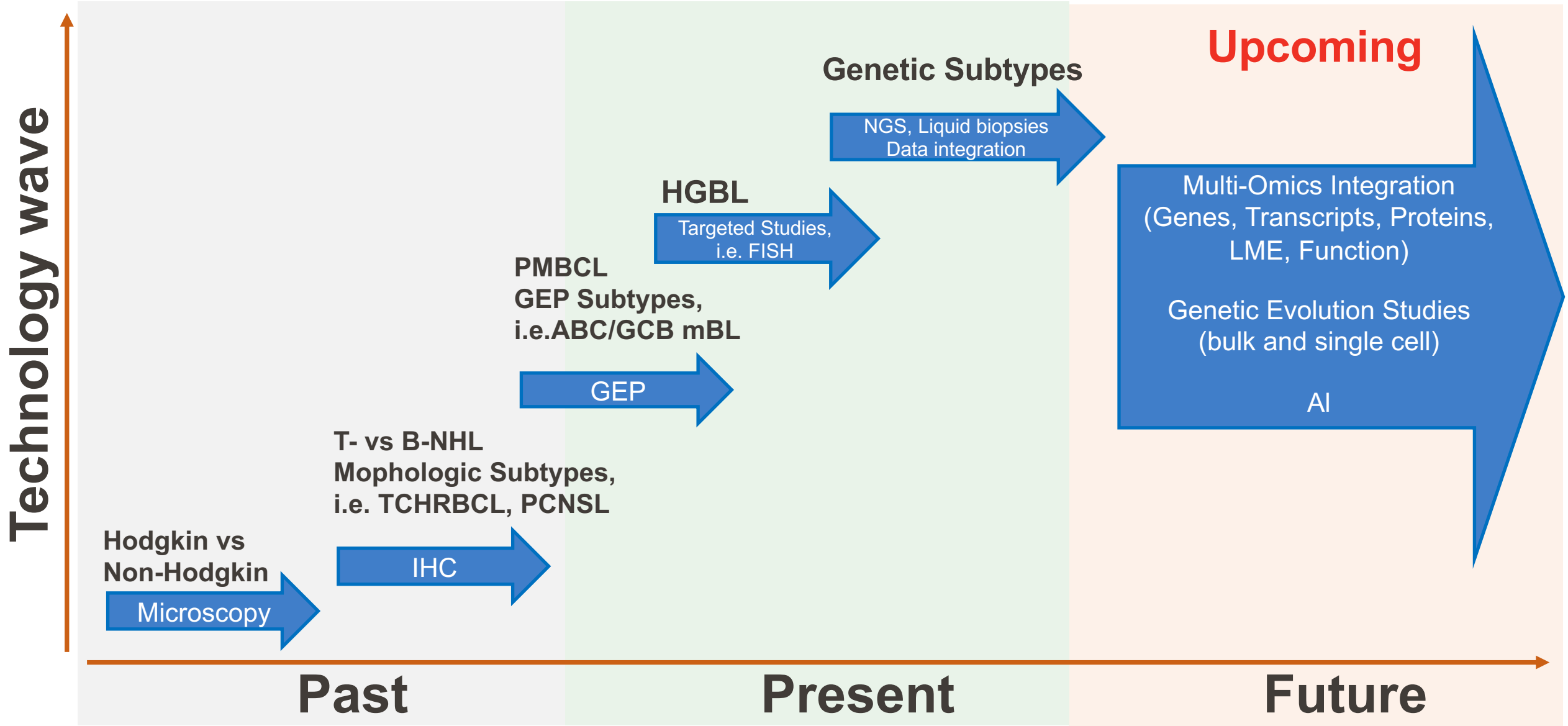
Polatuzumab Vedotin Efficacy in DLBCL Subtypes





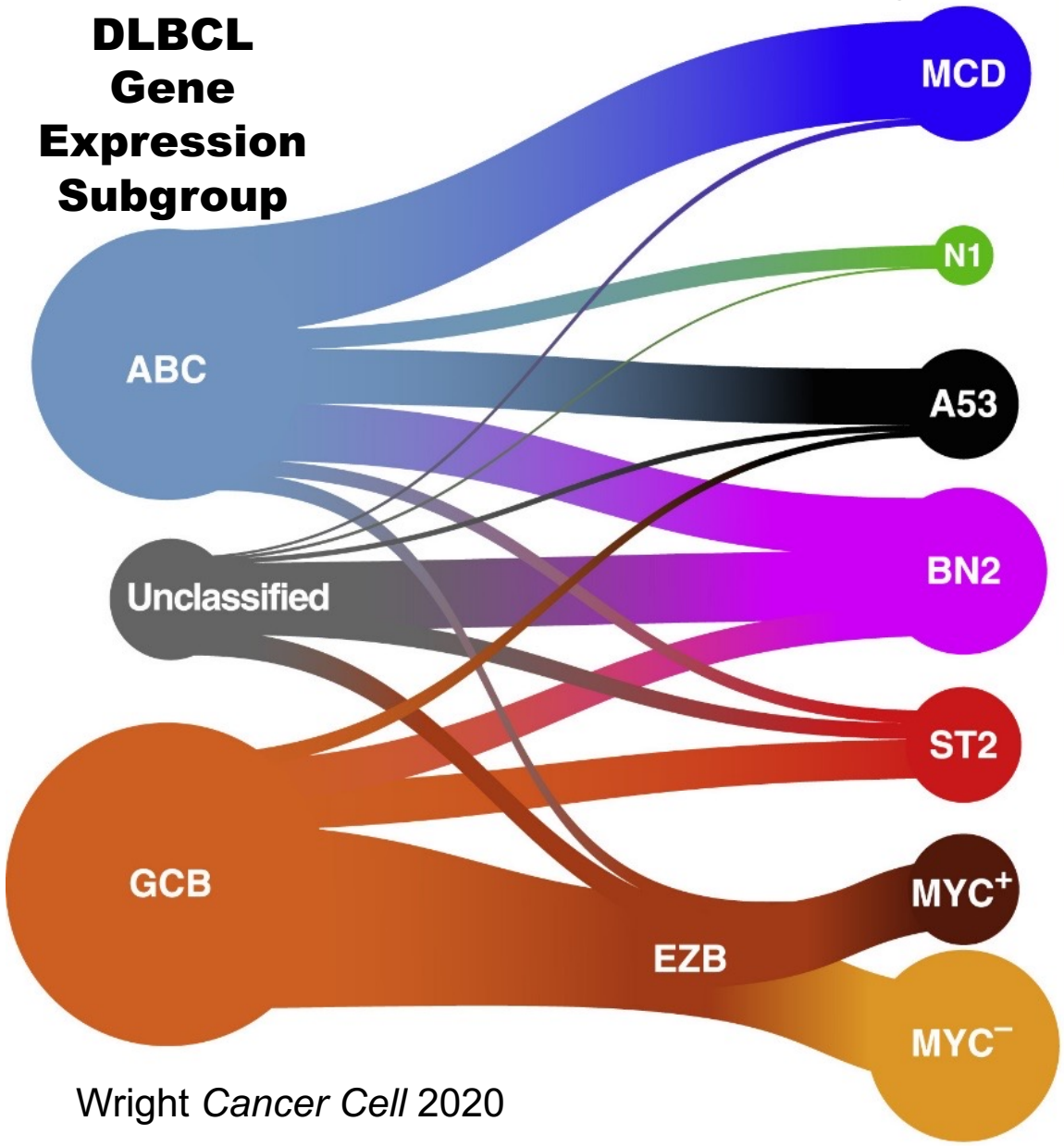
Palmer et al. *NEJM* 2023

Evolving Molecular Classification with Technology

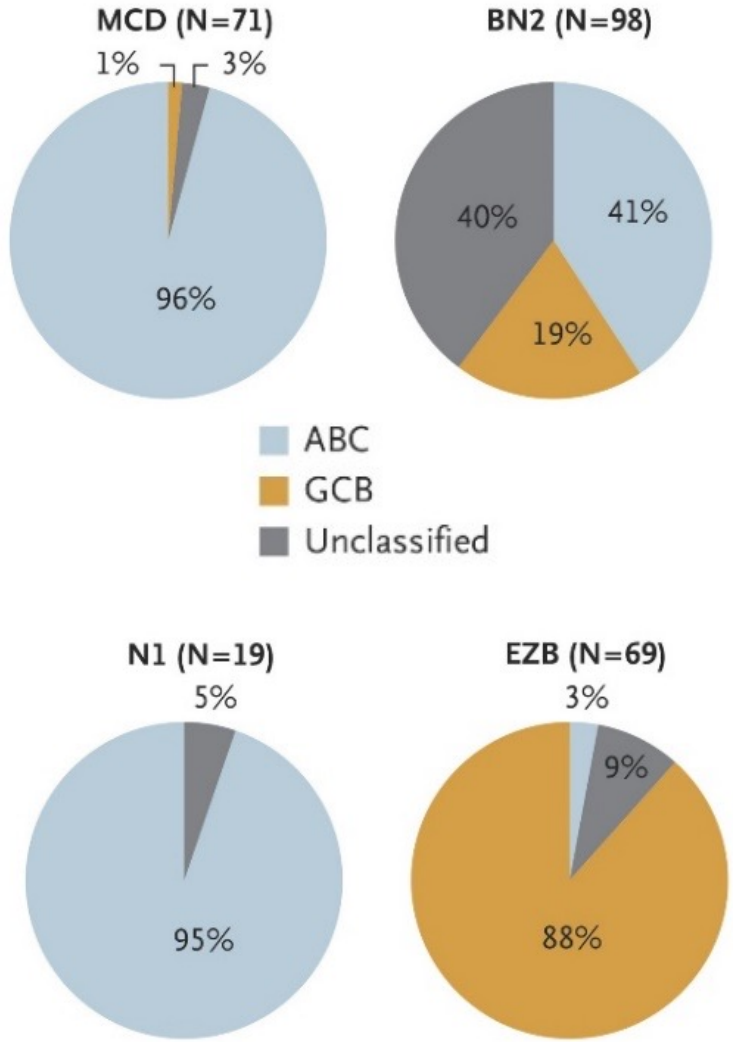


DLBCL Genomic Subtype

DLBCL Gene Expression Subgroup



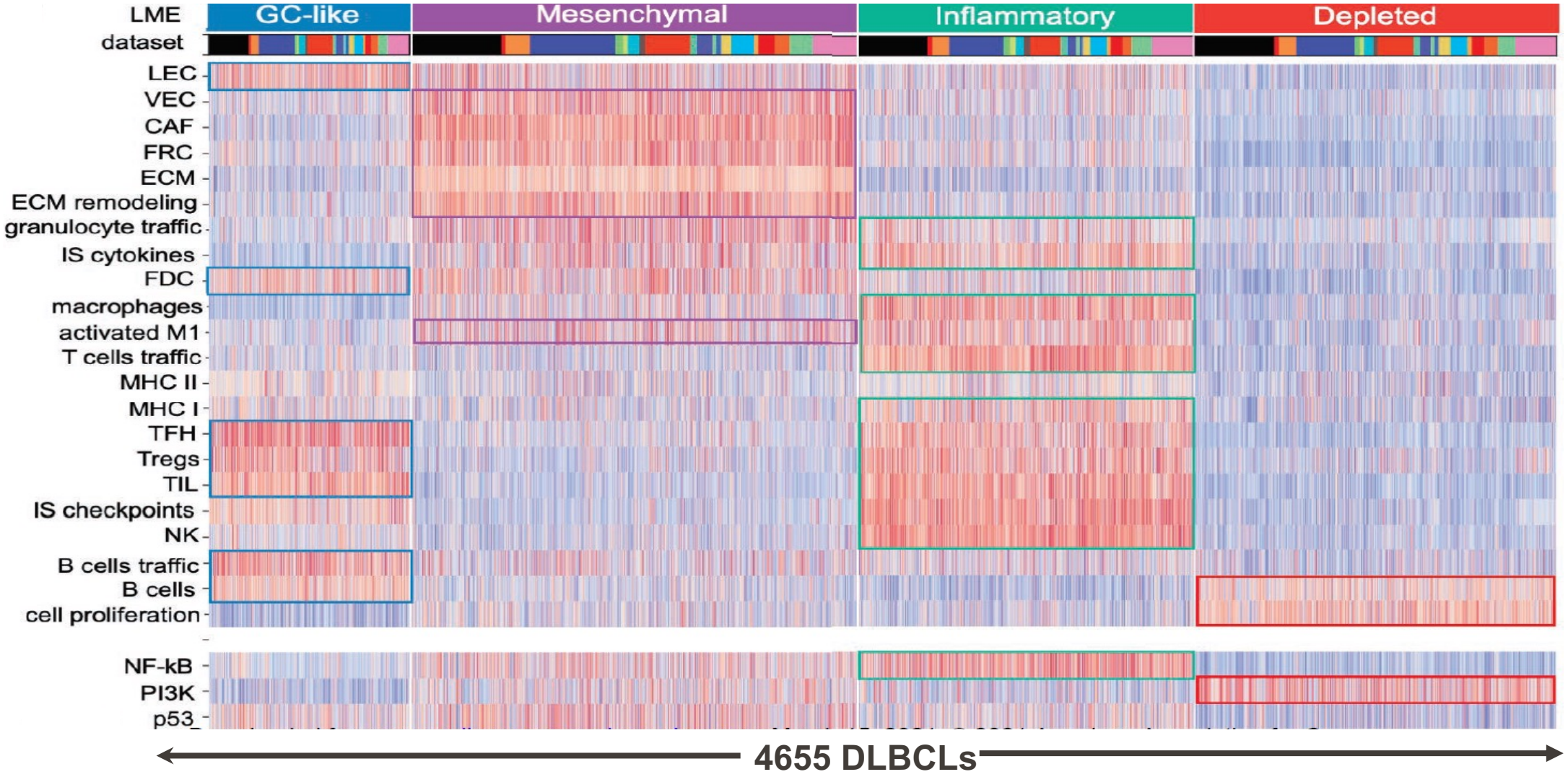
Prevalence	5-yr overall survival
8.7%	40% (All) 37% (ABC)
1.7%	27% (All) 22% (ABC)
5.8%	63% (All) 33% (ABC) 100% (GCB)
13.3%	67% (All) 76% (ABC) 100% (GCB) 38% (UC)
6.4%	84% (All) 81% (GCB)
5.9% (MYC^+) 17.6% (MYC^-)	48% (MYC^+) 82% (MYC^-)
40.6%	**Unclassified**



Wright *Cancer Cell* 2020

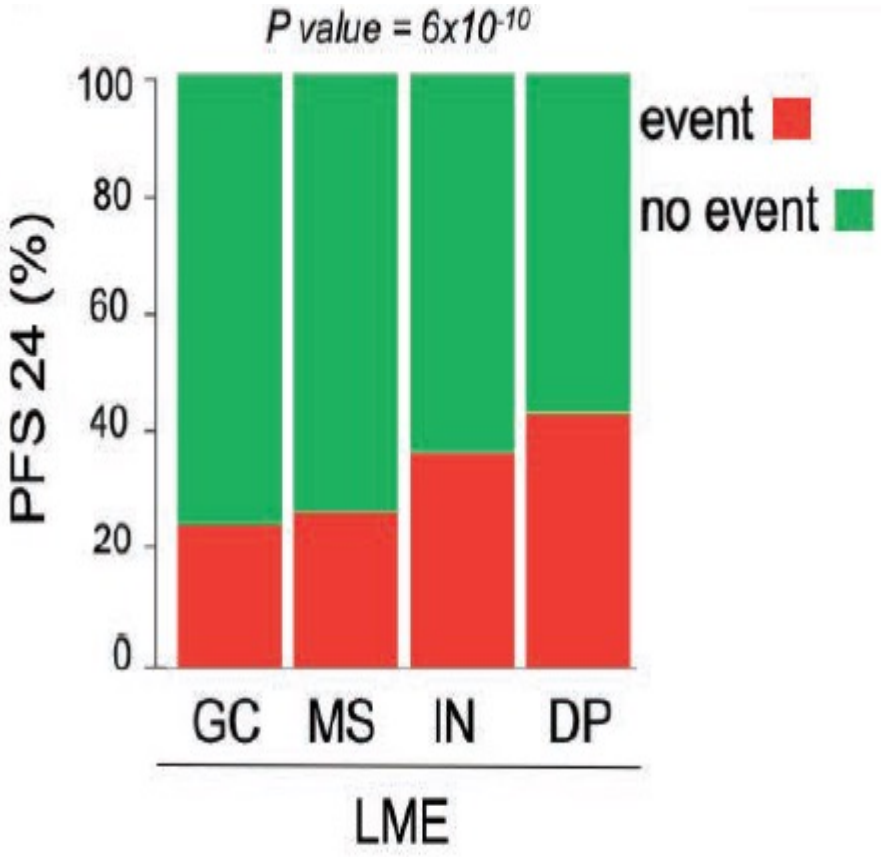
Schmitz NEJM 2018

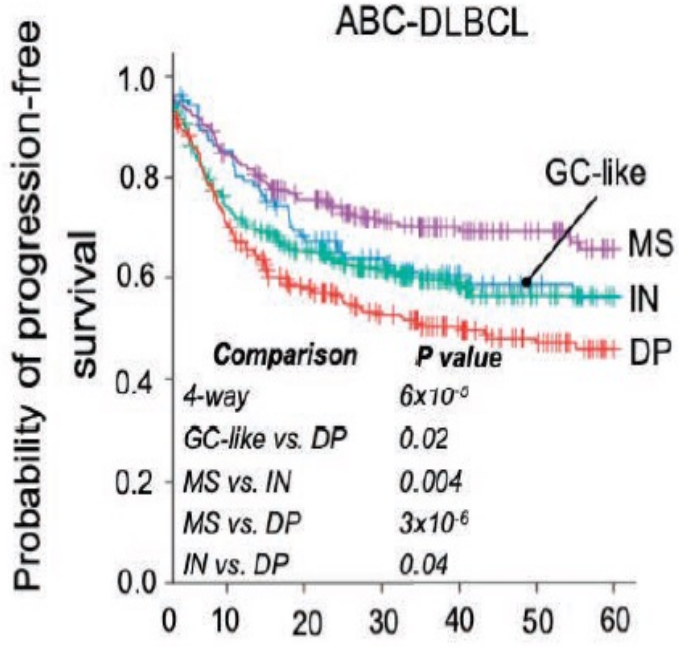
Heat map of the activity scores of 25 FGES (x-axis) denoting four major LME clusters termed as GC-like, mesenchymal, inflammatory and depleted



Kotlov N e al. *Cancer Discov*. 2021

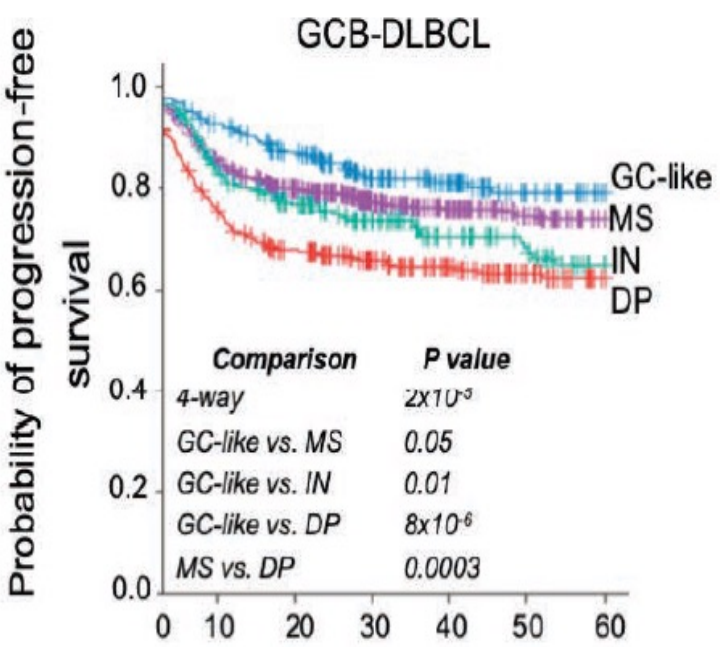
PFS at 24 months (PFS24) in DLBCL patients according to the LME category
Kaplan-Meier models of PFS according to LME category in ABC- and GCB DLBCL





No. at risk

GC-like	105	88	66	51	35	26	21
MS	224	178	148	108	87	69	50
IN	326	234	186	142	98	71	57
DP	258	176	126	93	69	50	31



No. at risk

GC-like	224	218	214	207	203	203	200
MS	558	525	489	473	464	457	451
IN	206	193	176	172	165	154	146
DP	300	259	227	214	211	205	199

Kotlov N e al. *Cancer Discov*. 2021

Feasibility of Genomics/Transcriptomics for Patients With Lymphoma

Protocol: 2022-0396; ClinicalTrials.gov Identifier: NCT05464823

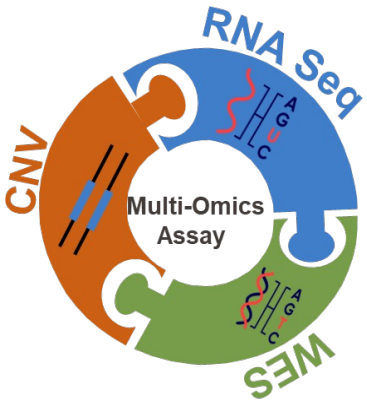
Study Design:

DLBCL

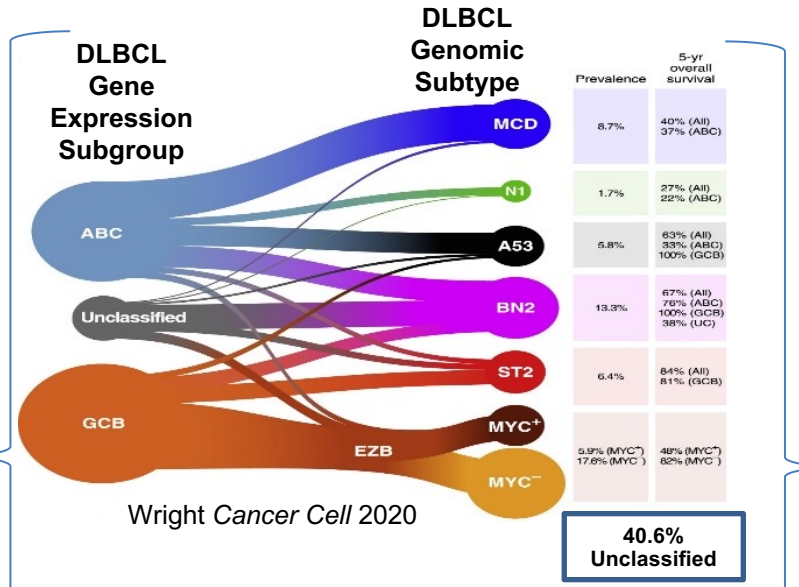
- **Initial Diagnosis (n=40)**
- **Relapsed / Refractory (n=40)**

FFPE

Tissue Biopsy

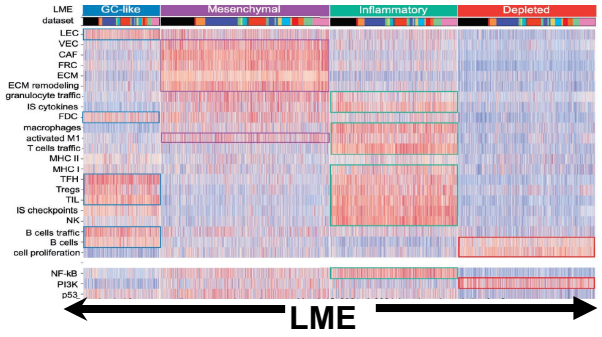


LymphGen and LME Classification



Wright *Cancer Cell* 2020

40.6% Unclassified

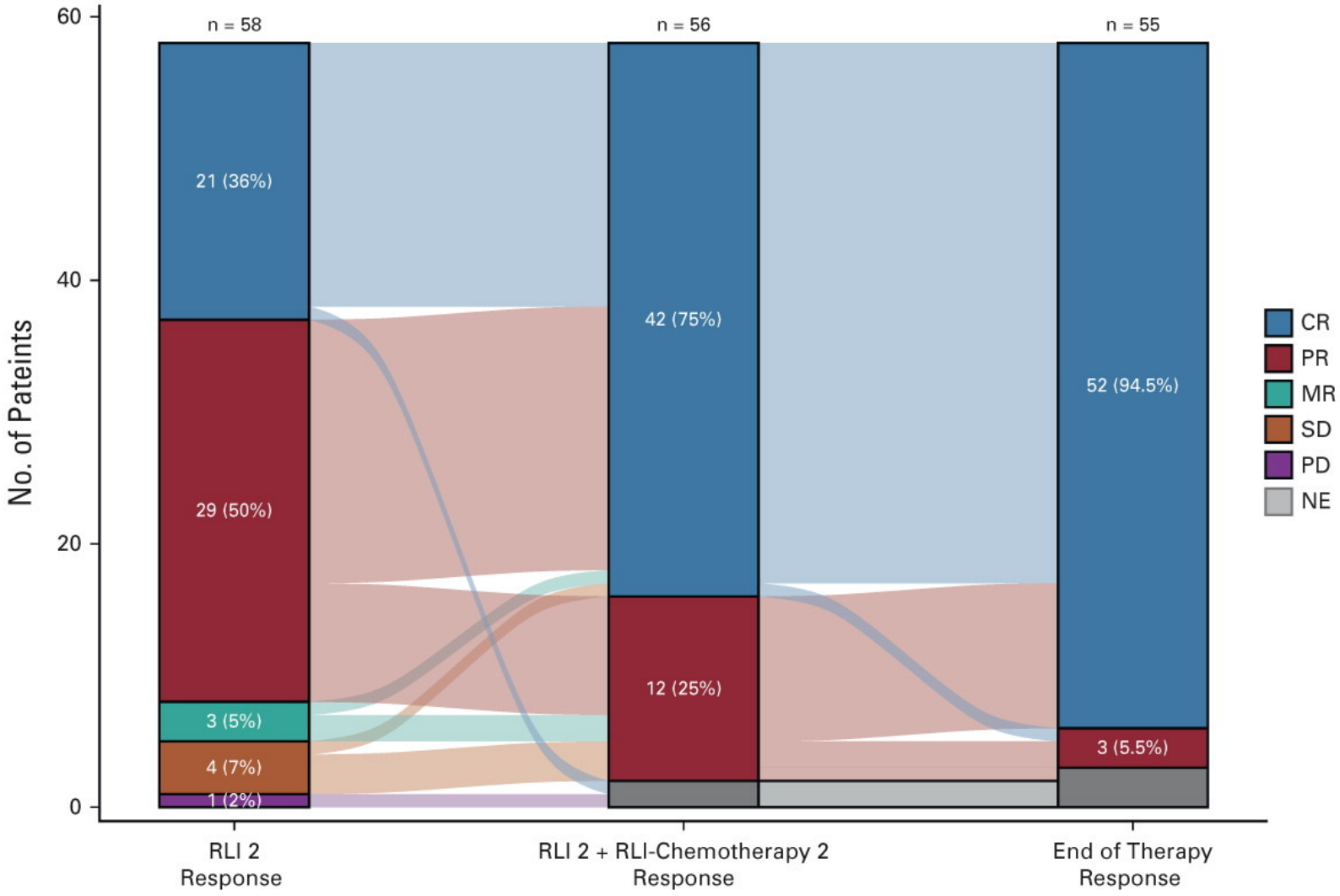


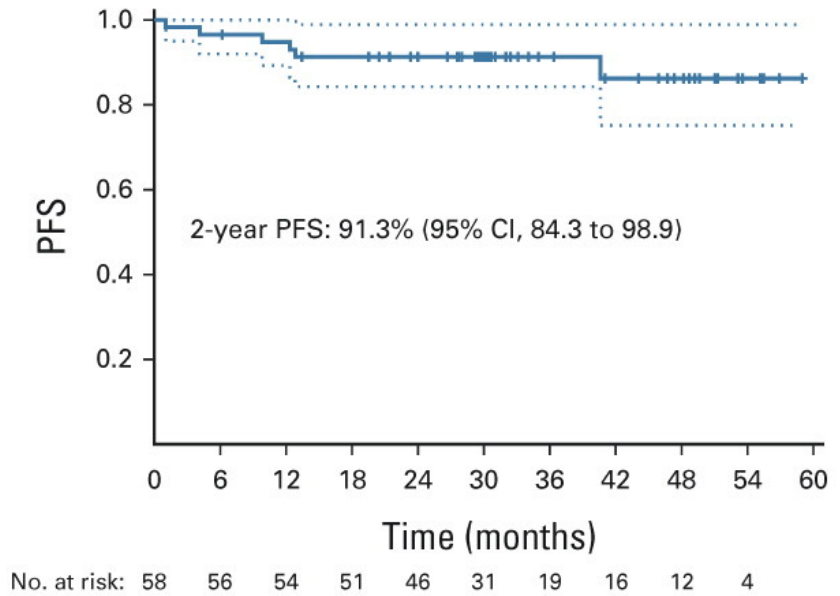
Kotlov N e al. *Cancer Discov*. 2021

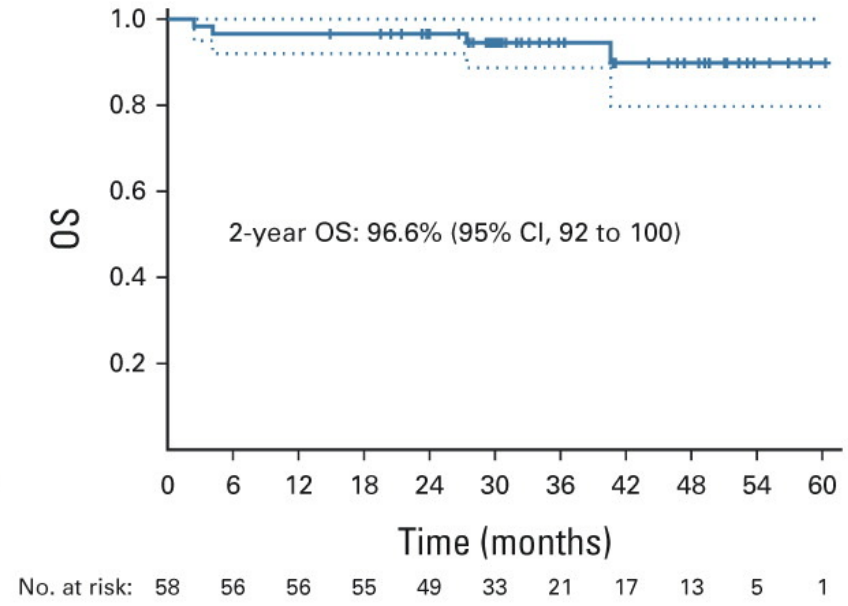
Results available (≤7 days) from submission?

- **Yes**
  - **Target: >65% results**
  - **Evaluate:**
    - **DTI Prevalence & Response by:**
    - **NCI Clusters**
    - **LME subgroups**
- **No**

Smart Start: Results

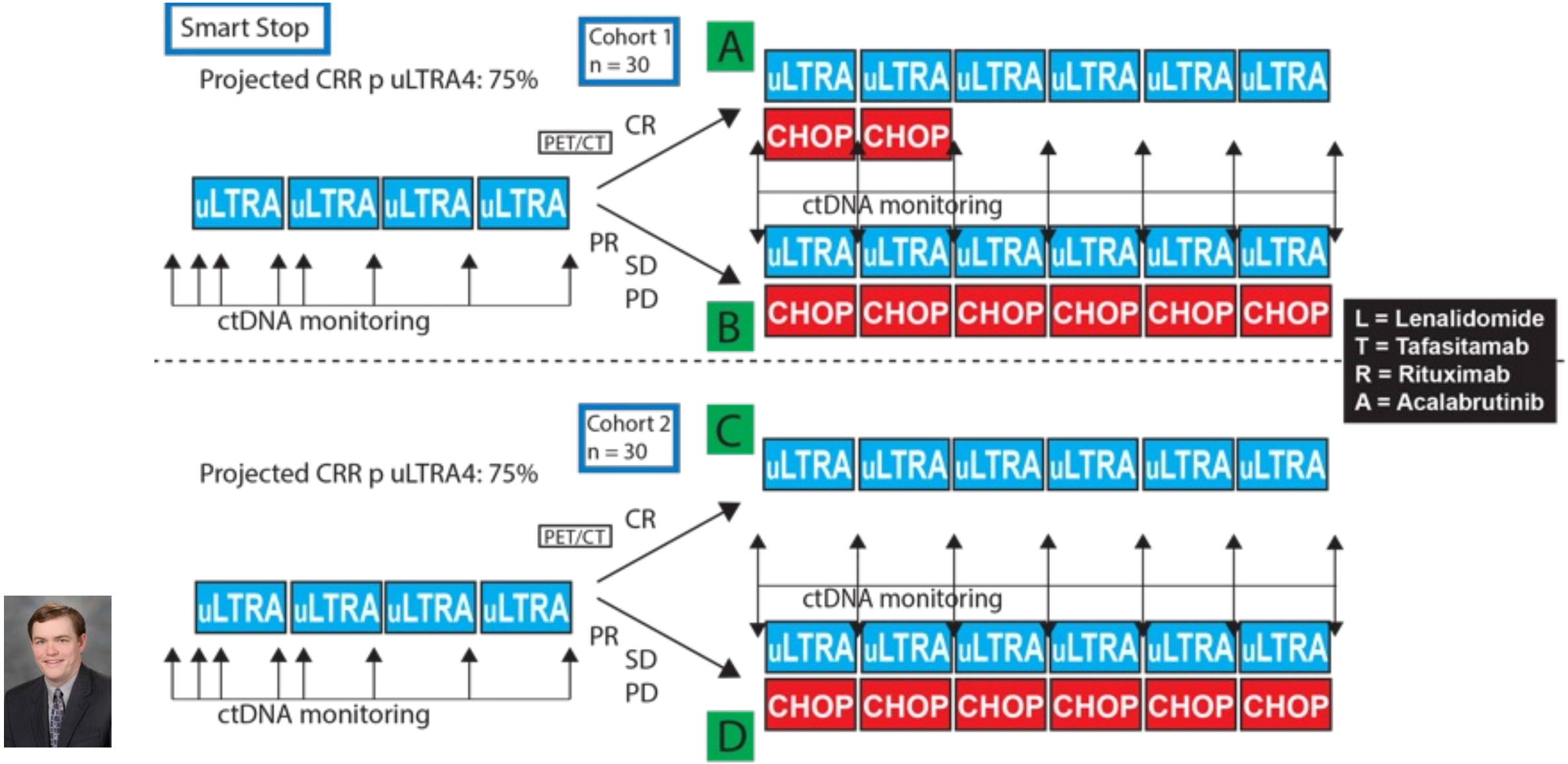






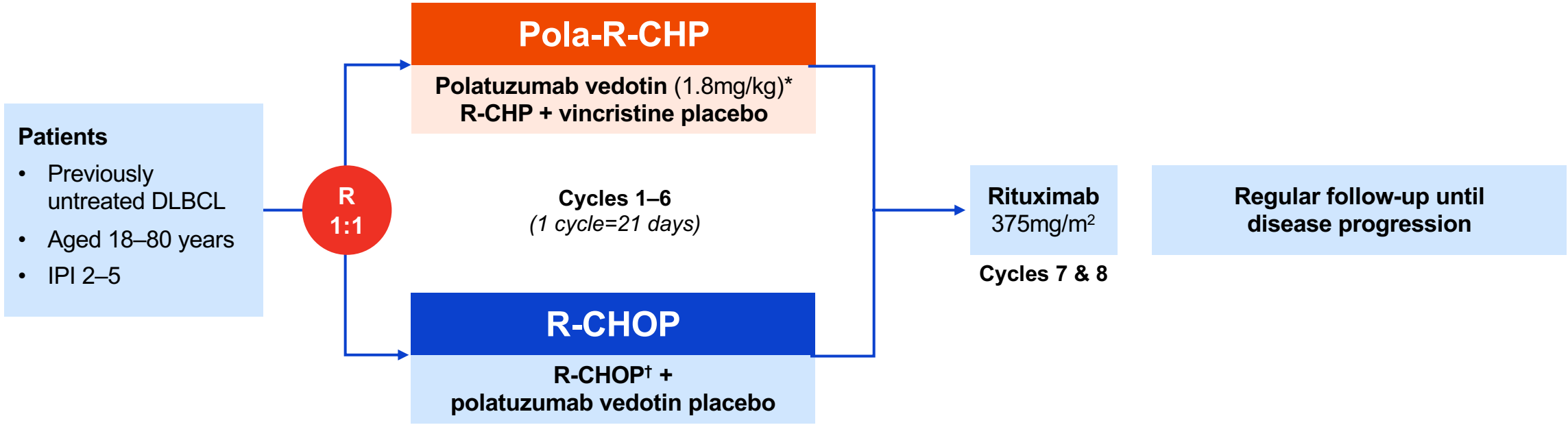
Westin et al. J Clin Oncol. 2022

A Phase II trial of Rituximab, Lenalidomide, Acalabrutinib, Tafasitamab prior to and with standard chemotherapy for patients with newly diagnosed DLBCL



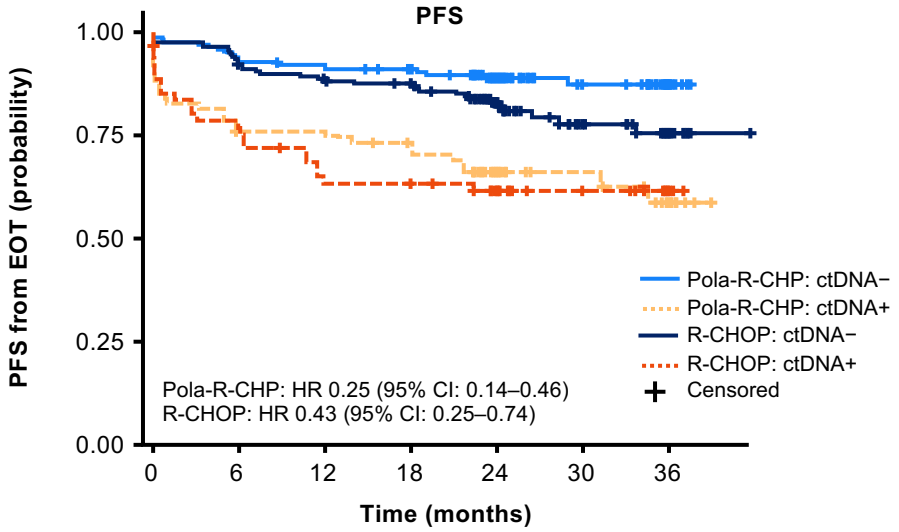
Jason Westin, MD MS FACP

POLARIX: A randomized double-blind study

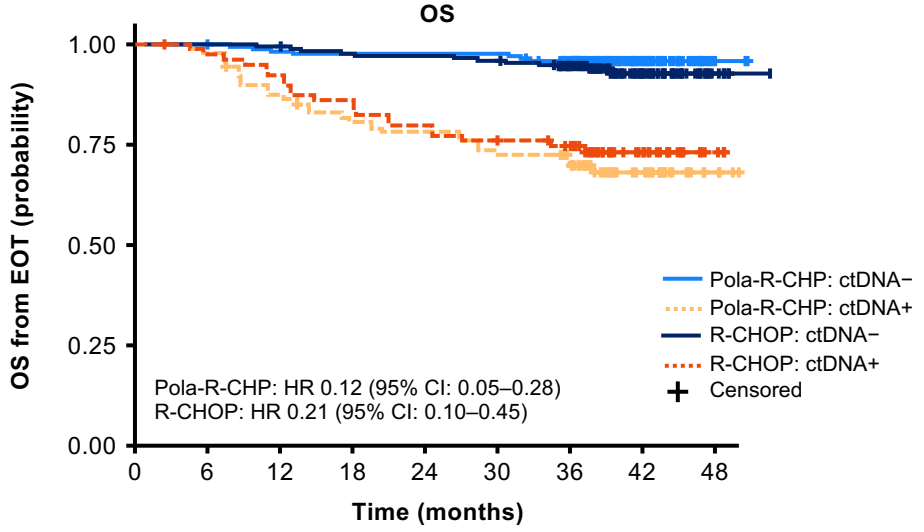


Tilly H, et al. N Engl J Med 2022;386:351–63

EOT ctDNA prognostic for R-CHOP & Pola-R-CHP



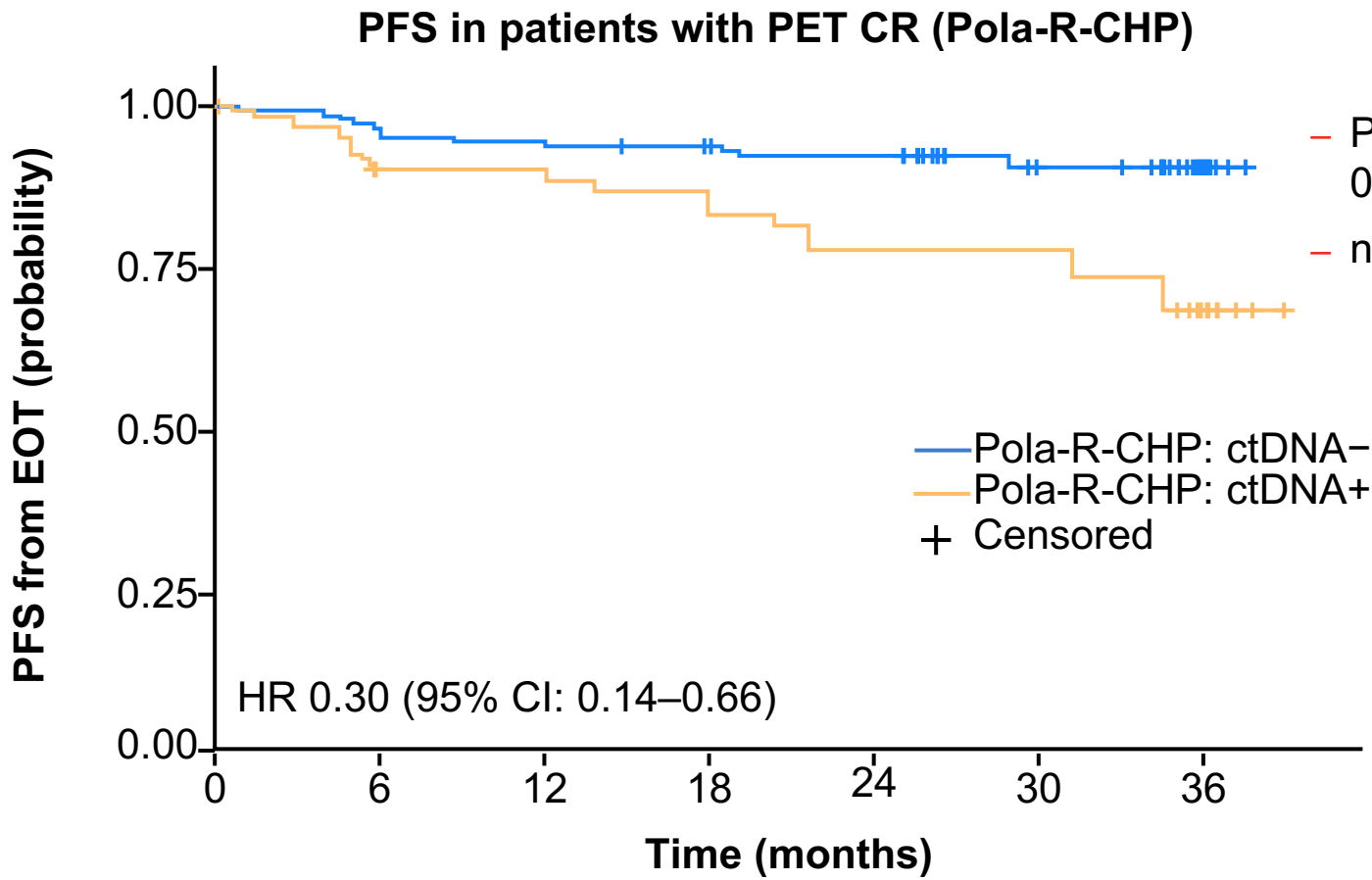
Number at risk							
Pola-R-CHP: ctDNA–	169	156	152	147	94	48	18
Pola-R-CHP: ctDNA+	75	55	55	40	30	19	8
R-CHOP: ctDNA–	169	155	148	144	90	41	16
R-CHOP: ctDNA+	62	46	37	37	27	15	6



Number at risk									
Pola-R-CHP: ctDNA–	172	172	168	167	167	167	150	54	3
Pola-R-CHP: ctDNA+	88	86	75	69	67	62	58	25	4
R-CHOP: ctDNA–	171	171	170	166	165	163	146	55	8
R-CHOP: ctDNA+	80	77	73	68	63	60	56	25	3

Longer PFS was observed in patients with ctDNA– treated with Pola-R-CHP versus R-CHOP; HR 0.56 (95% CI: 0.32–0.98)

Combined use of ctDNA levels and PET CR may improve risk stratification with Pola-R-CHP



- Pola-R-CHP OS HR: 0.20 (95% CI: 0.07–0.60)
- not observed with R-CHOP:
  - PFS HR 0.74 (95% CI: 0.34–1.63)
  - OS HR 1.11 (95% CI: 0.30–4.16).

Number at risk

Pola-R-CHP: ctDNA–	147	140	137	133	86	46	16
Pola-R-CHP: ctDNA+	61	53	53	48	29	18	8

Take Home Points & Future Directions

- Pola-R-CHP provides a novel 1L therapy with ↑ PFS
  - Testable hypothesis on ABC specificity
  - Additional subtype data (e.g. LymphGen/LME) needed and coming
- Molecularly targeted therapy for DLBCL?
  - Novel testing approaches
  - Novel trial designs
- ctDNA predicts outcomes
  - Strategies to tailor therapy?

Agenda

Module 1 – Up-Front Management of Diffuse Large B-Cell Lymphoma (DLBCL) — Dr Flowers

Module 2 – Selection and Sequencing of Therapy for Relapsed/Refractory (R/R) DLBCL — Dr Lunning

Module 3 – Role of CD20 x CD3 Bispecific Antibodies in the Management of DLBCL — Dr Sehn

Shaachi Gupta, MD, MPH
Lake Worth, Florida

Neil Morganstein, MD
Summit, New Jersey

RTP
RESEARCH
TO PRACTICE

68-year-old man:
s/p R-CHOP, now with recurrent DLBCL, ischemic heart disease

Shaachi Gupta, MD, MPH

70-year-old man:
CHF, renal dysfunction;
s/p R-GCVP

Neil Morganstein, MD

Questions for the Faculty

Use of CAR T-cell therapy and/or bispecific antibodies in patients with cardiovascular disease?

Sequence of therapies in patients who are and are not candidates for CAR T-cell therapy or bispecific antibodies?

How do you approach the sequencing of loncastuximab tesirine, tafasitamab/lenalidomide, polatuzumab vedotin/BR?

Bispecifics in the community setting?

RTP
RESEARCH TO PRACTICE

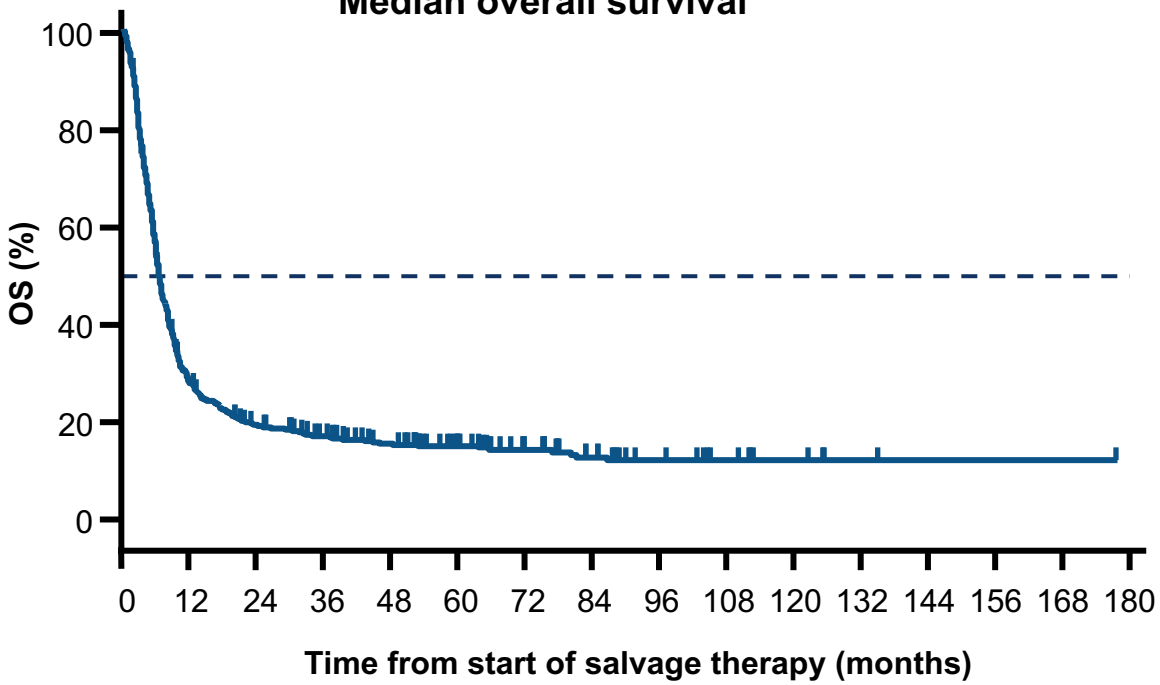
How Do We Trap Deep Blue: Shifting Strategies in Relapsed/Refractory DLBCL

Matthew Lunning, DO, FACP
Associate Professor
University of Nebraska Medicine

SCHOLAR-1: Needing A New Strategy

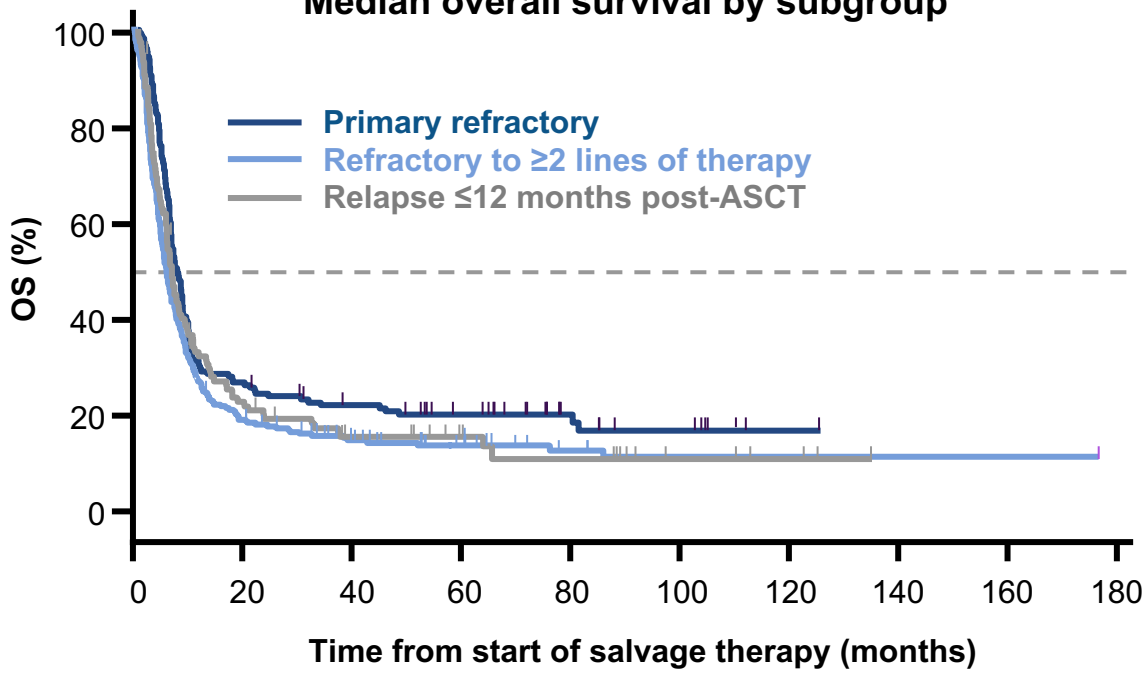
SCHOLAR-1: Retrospective analysis of outcomes in patients with R/R DLBCL (N = 636)

Median overall survival



	Median OS (months)	2-yr survival
All	6.3	20%

Median overall survival by subgroup

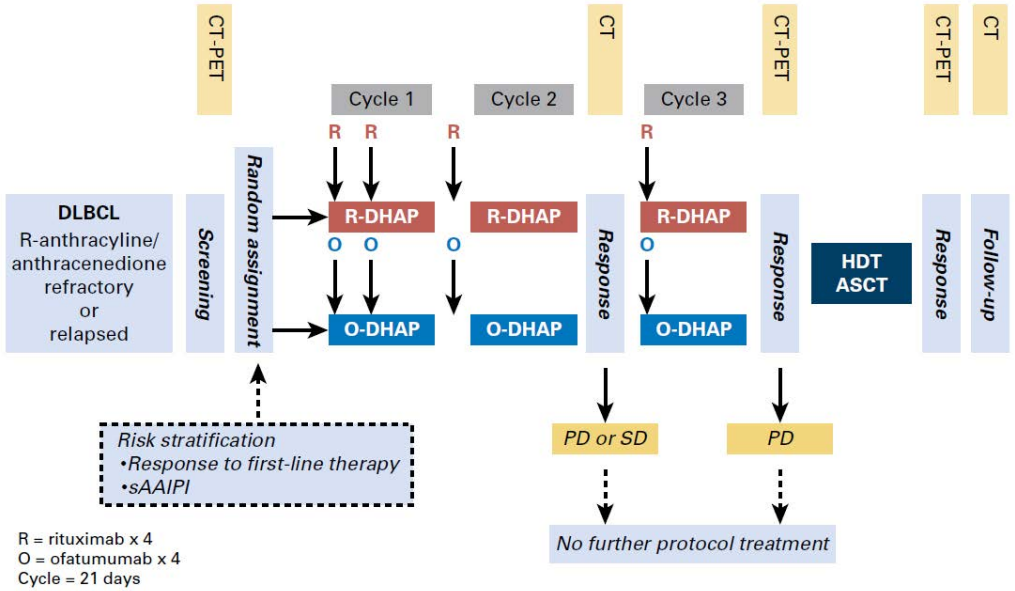


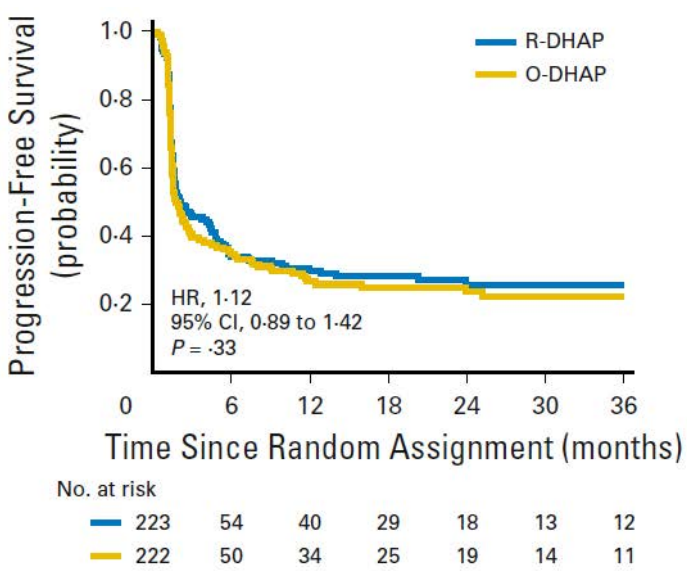
	Median OS (months)	2-yr survival
Primary refractory	7.1	24%
Refractory to ≥2 lines of therapy	6.1	17%
Relapse ≤12 months post-ASCT	6.2	19%

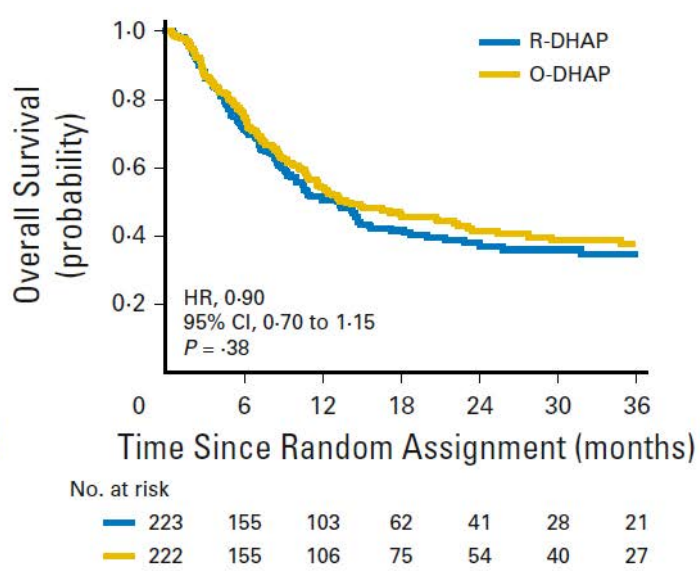
Crump et al. Blood 2017.

UNMC

R/R DLBCL: 2010 Traps







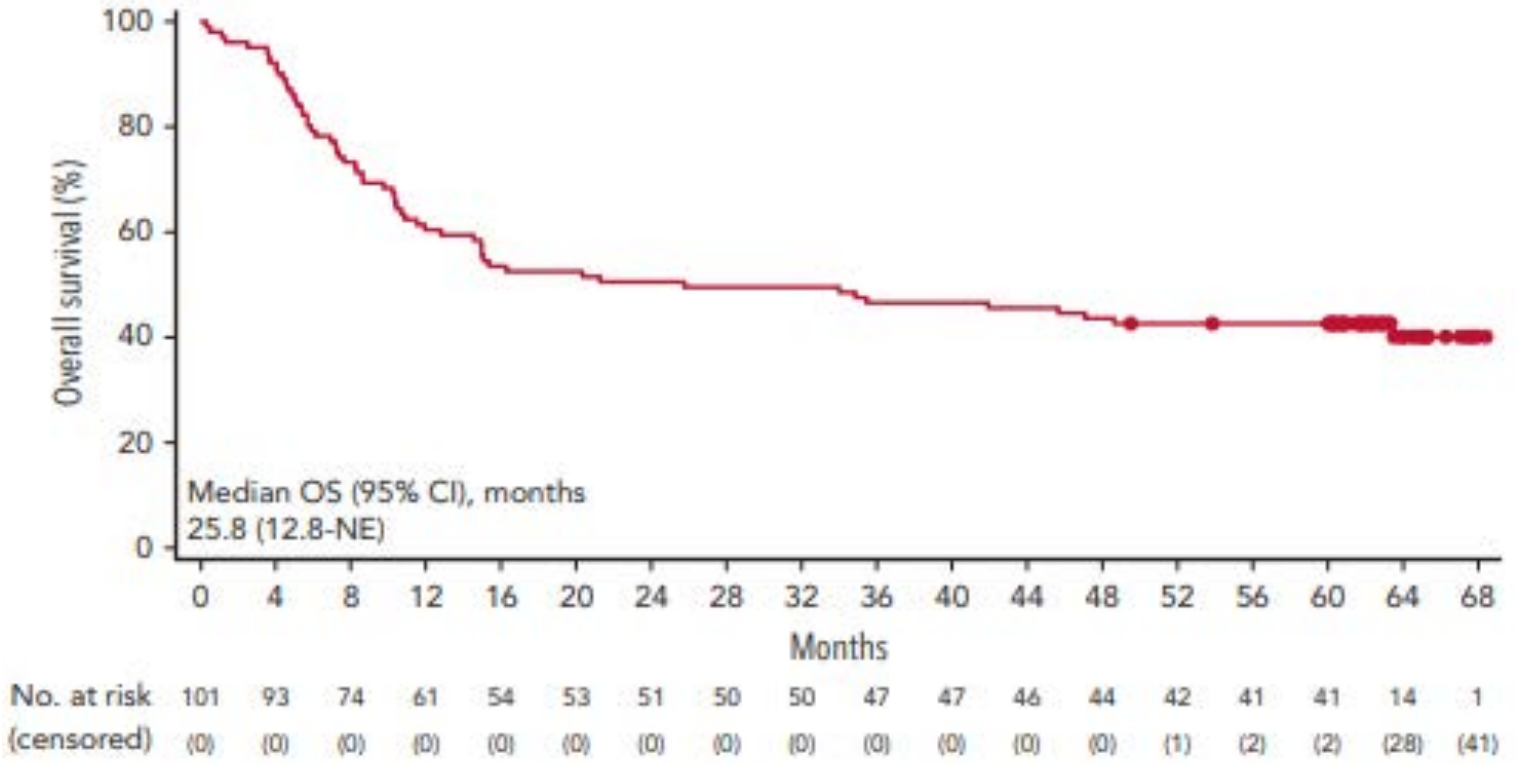
van Imhoff et al. JCO 2017

R/R DLBCL: 2017 The Danish Gambit

Are they CAR-T eligible for third line and beyond?

R/R DLBCL: 2017 The Danish Gambit

ZUMA-1: 5-year Outcomes with Axi-Cel



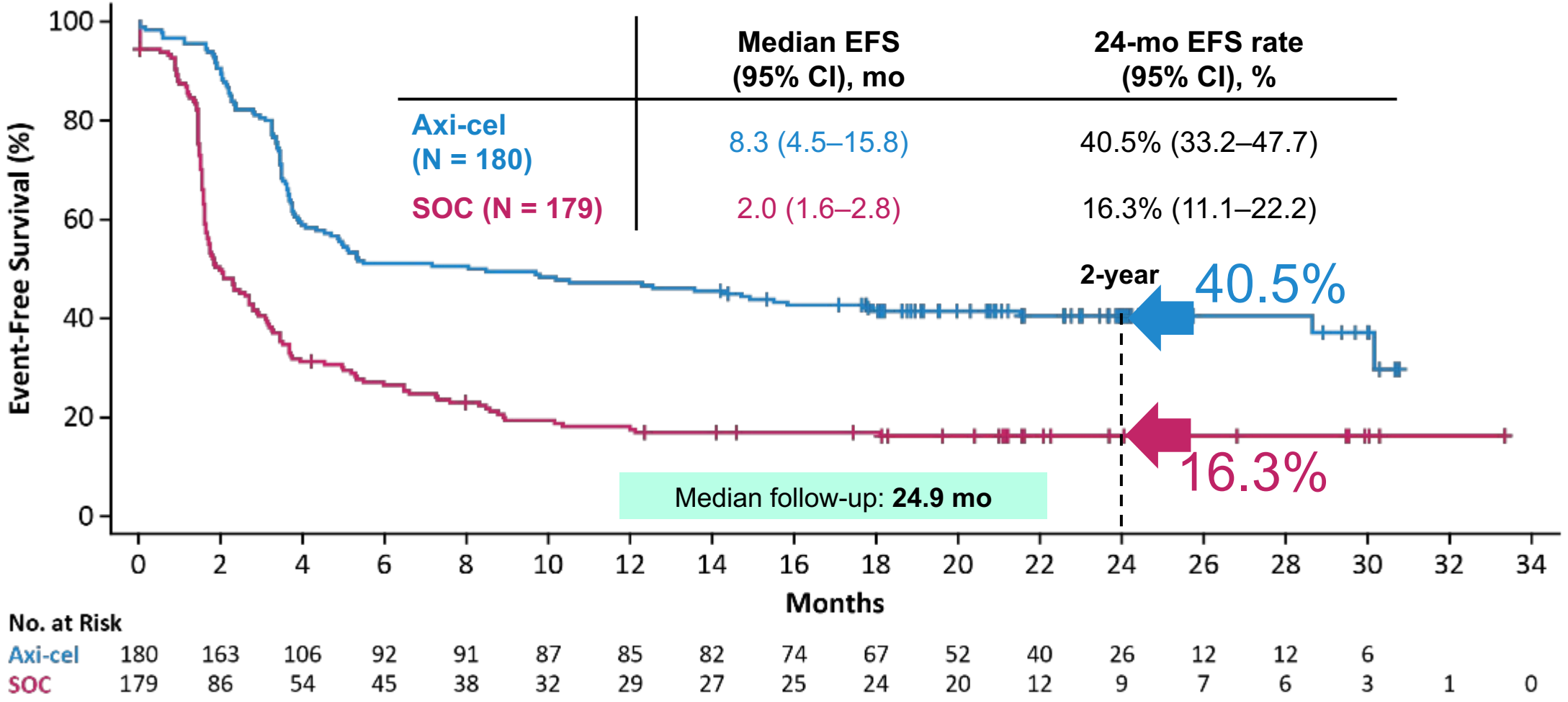
Neelapu et al. Blood 2023

R/R DLBCL: The Queens Gambit

Are they CAR-T eligible for second line?

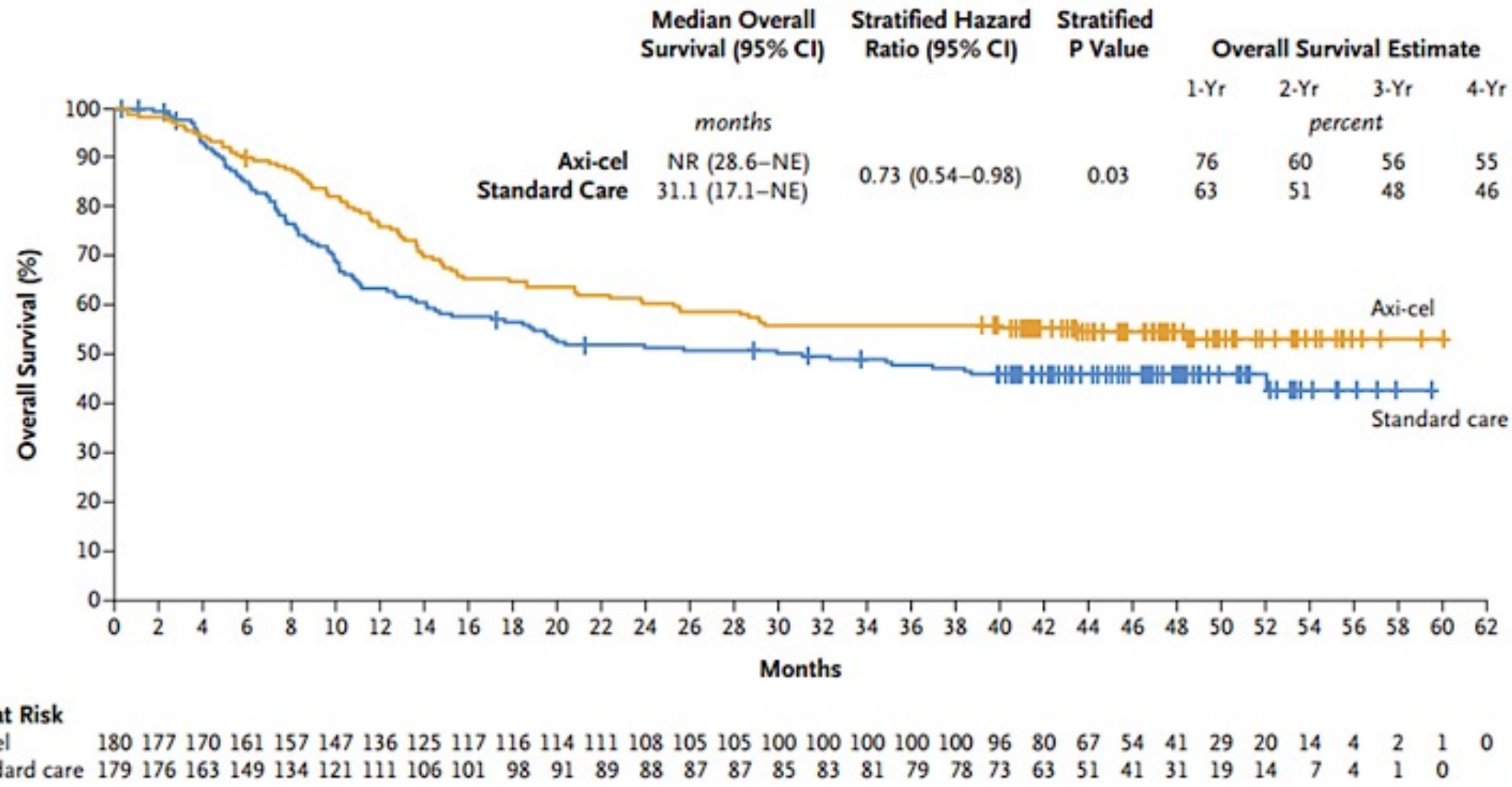
ZUMA-7 (Axi-cel)

HR 0.398 (95% CI: 0.308–0.514); *P* <.0001



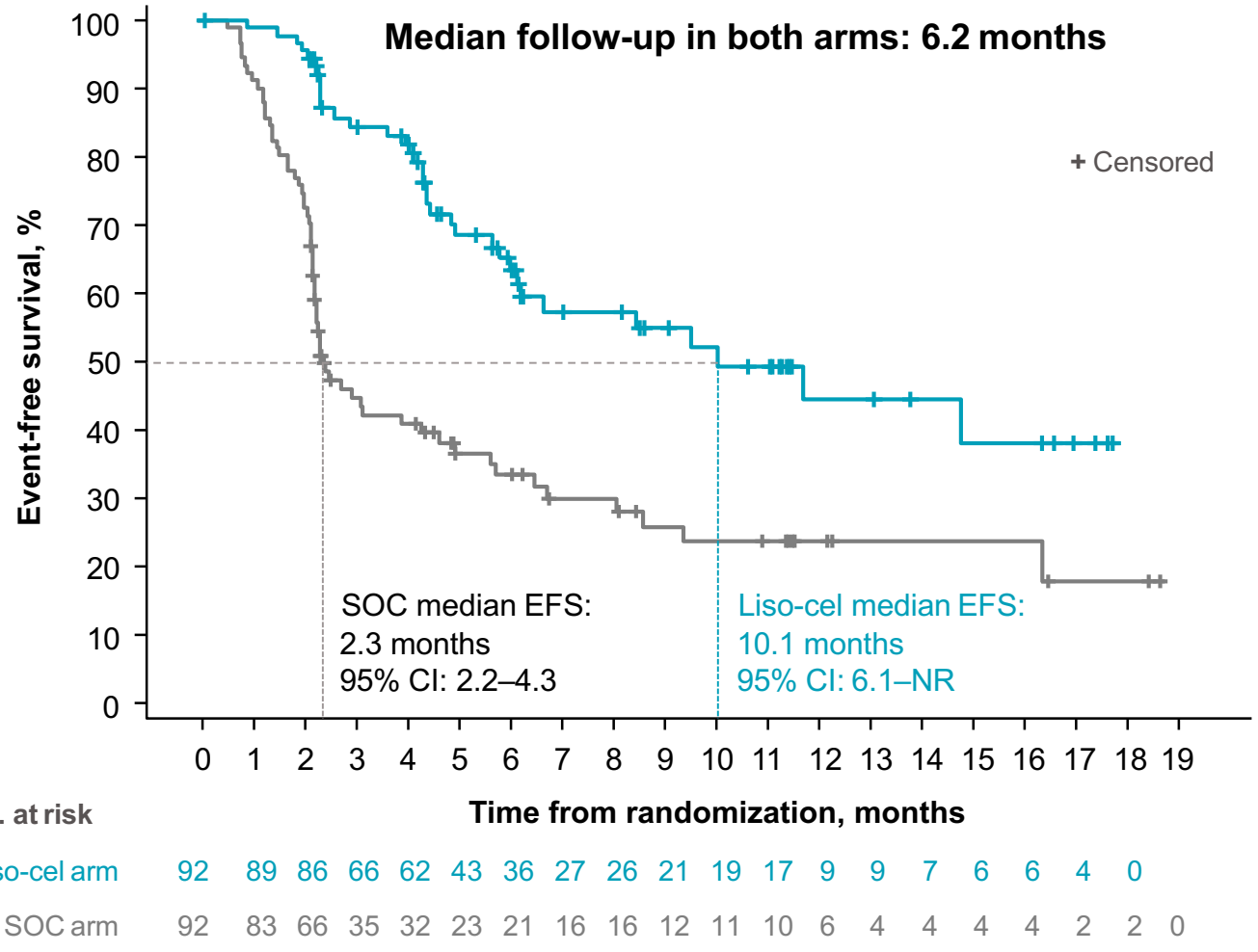
Locke et al. NEJM 2022

ZUMA-7 (Axi-cel)



Wèstin et al. NEJM 2023.

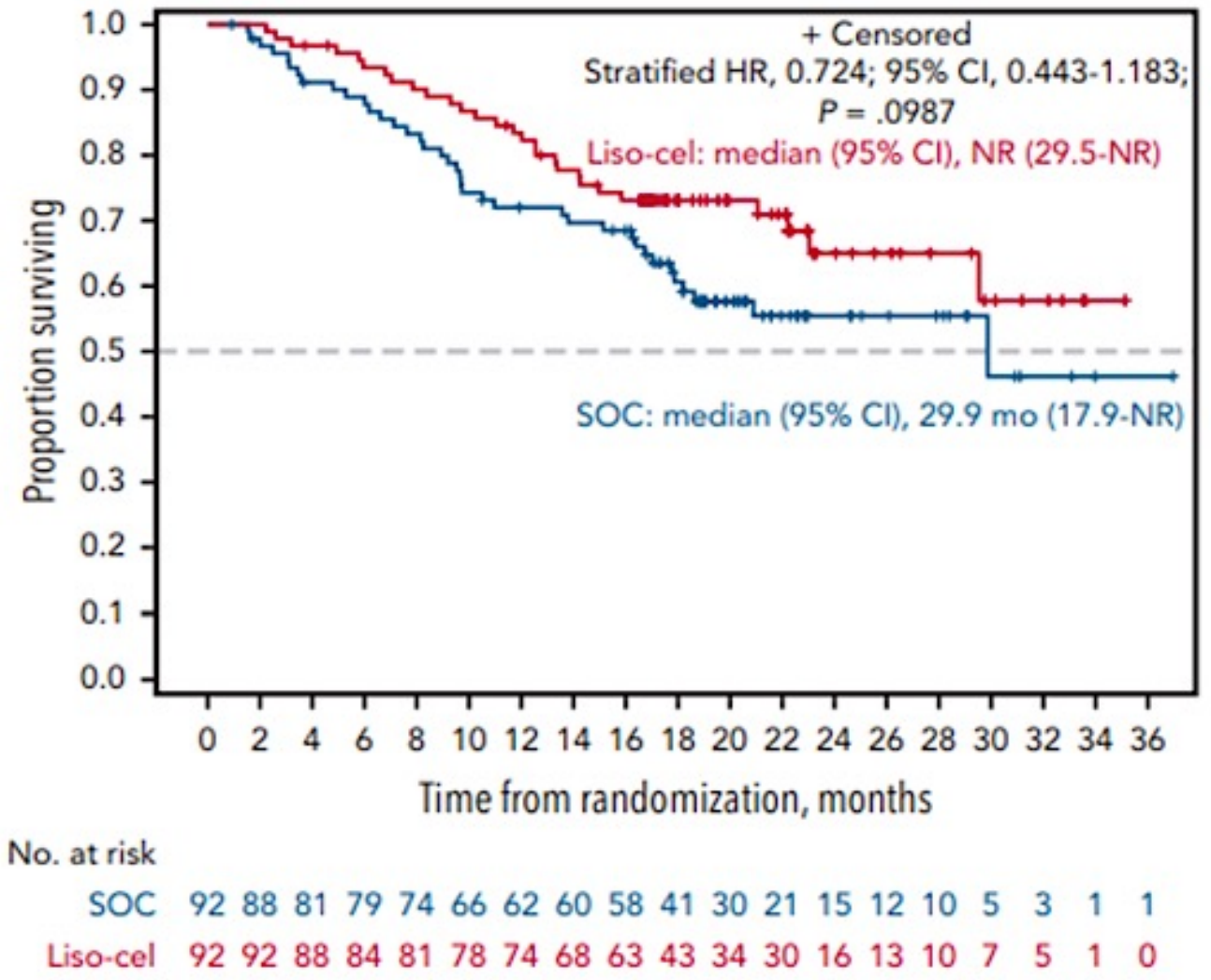
TRANSFORM (Liso-cel)



	Liso-Cel Arm (n = 92)	SOC Arm (n = 92)
Patients with events, n	35	63
Stratified HR (95% CI)	**0.349** (0.229–0.530) *P* <.0001	
6-month EFS rate, % (SE) 2-sided 95% CI	63.3 (5.77) 52.0–74.7	33.4 (5.30) 23.0–43.8
12-month EFS rate, % (SE) 2-sided 95% CI	44.5 (7.72) 29.4–59.6	23.7 (5.28) 13.4–34.1

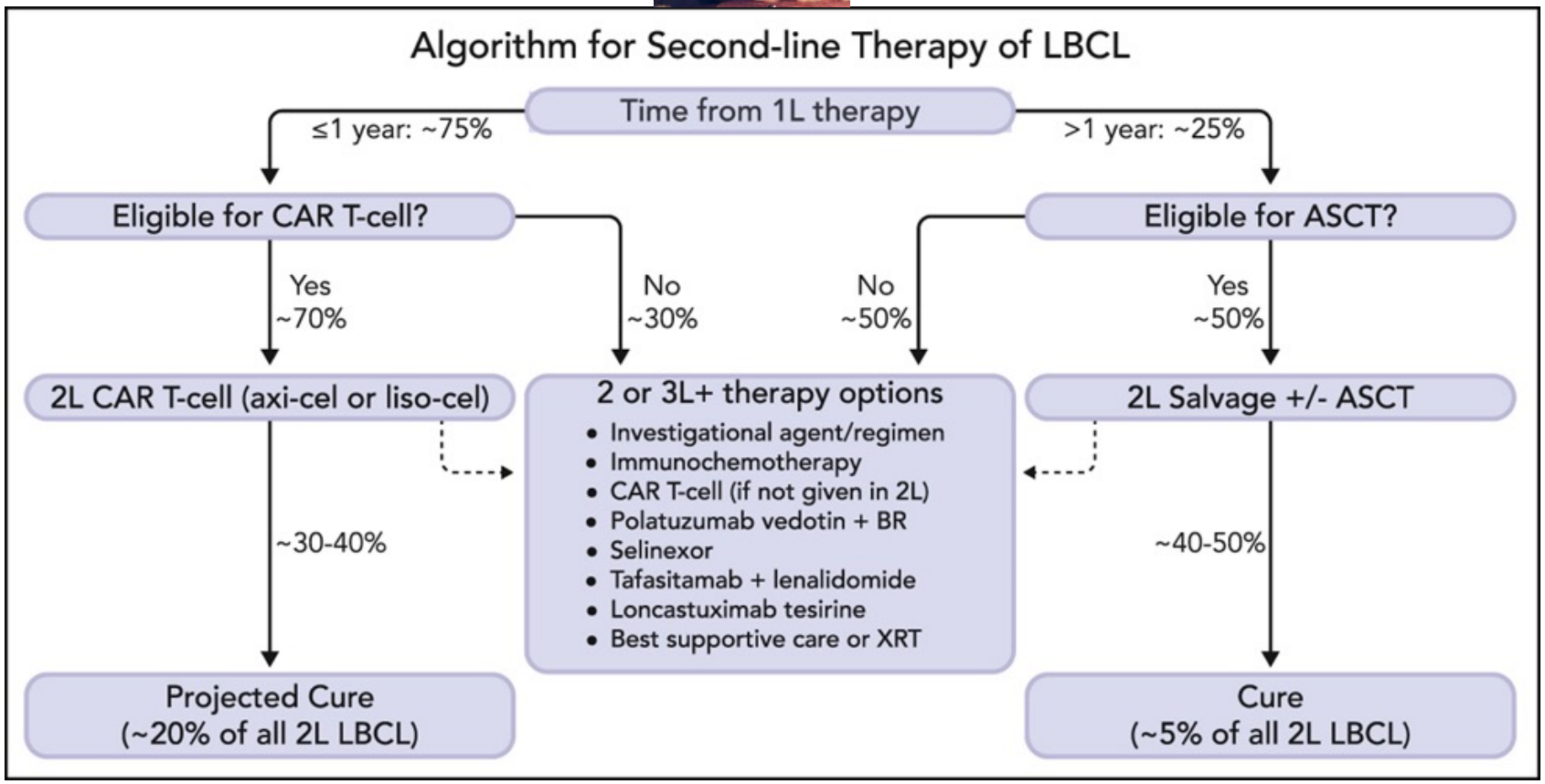
Kamdar et al. ASH 2021 Abs 91; Kamdar et al. Lancet 2022.

TRANSFORM (Liso-cel)



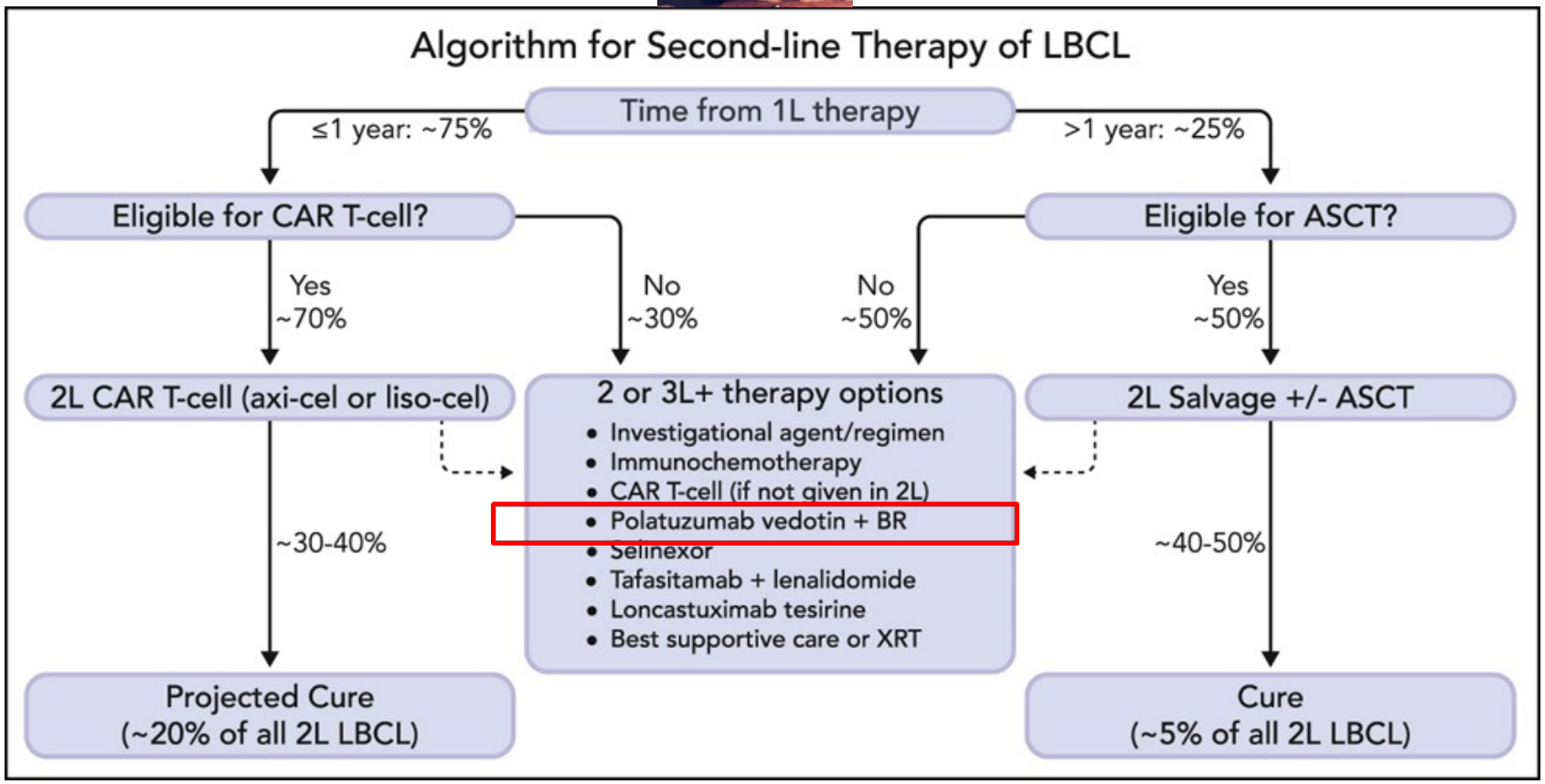
Abramson et al. Blood 2023.

Rel/Ref DLBCL 2022: Resetting the Board



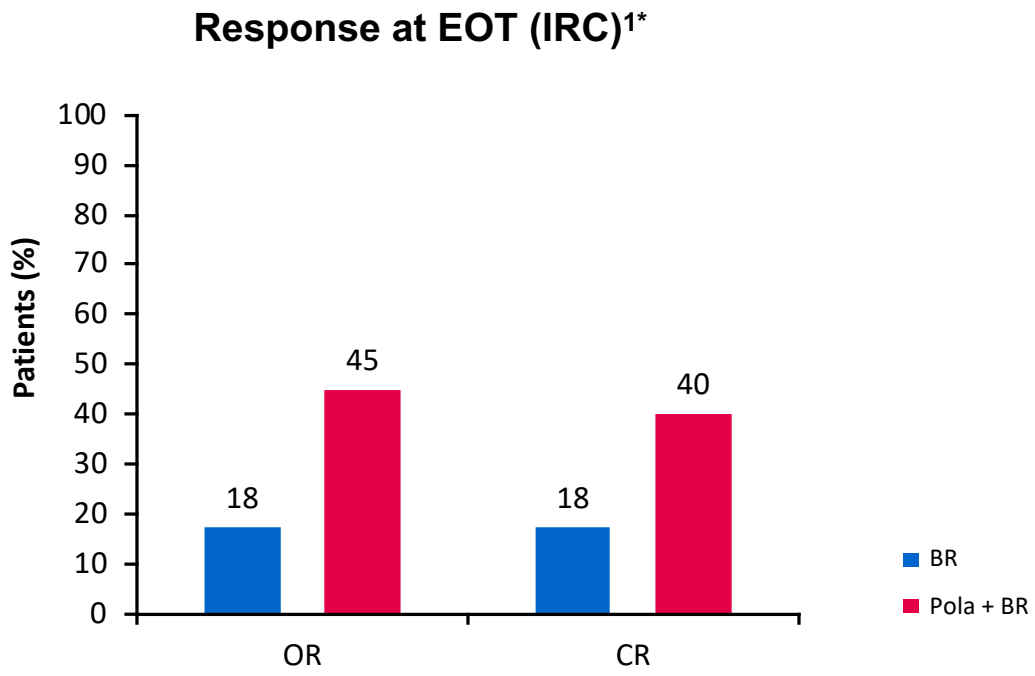
Westin et al. *Blood* 2022.

2022: Resetting the Board

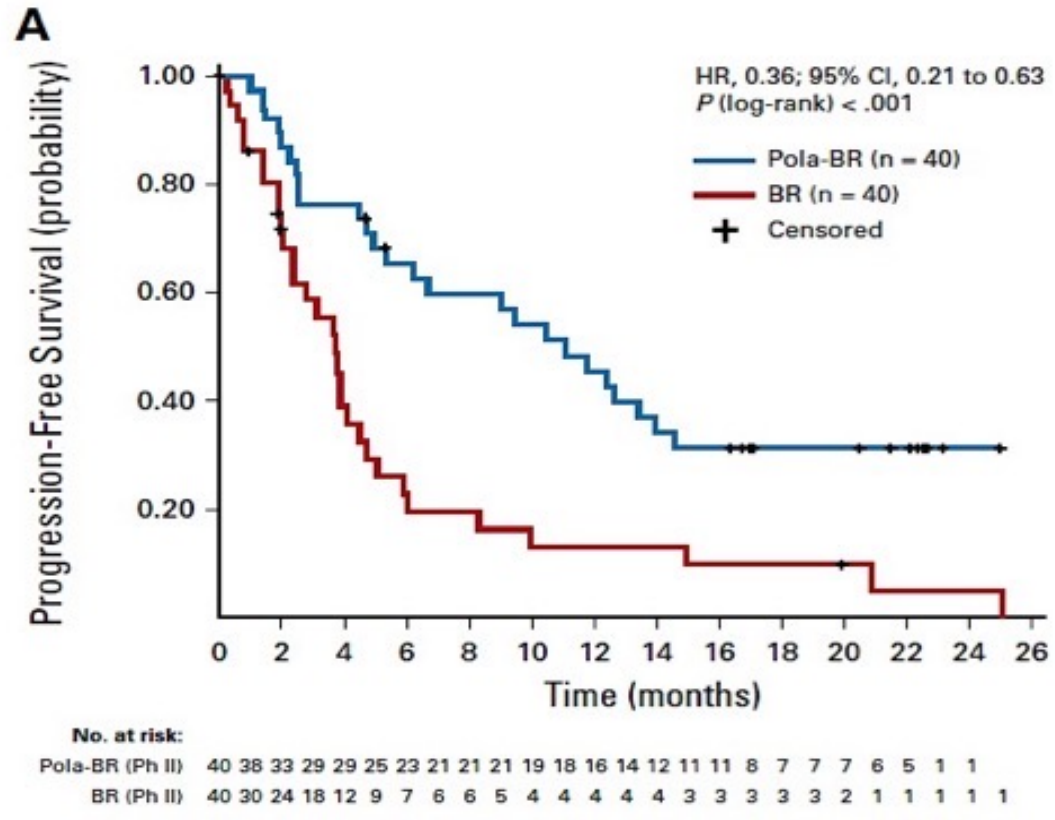


Westin et al. *Blood* 2022.

Knights: Polatuzumab +/- B +/- R



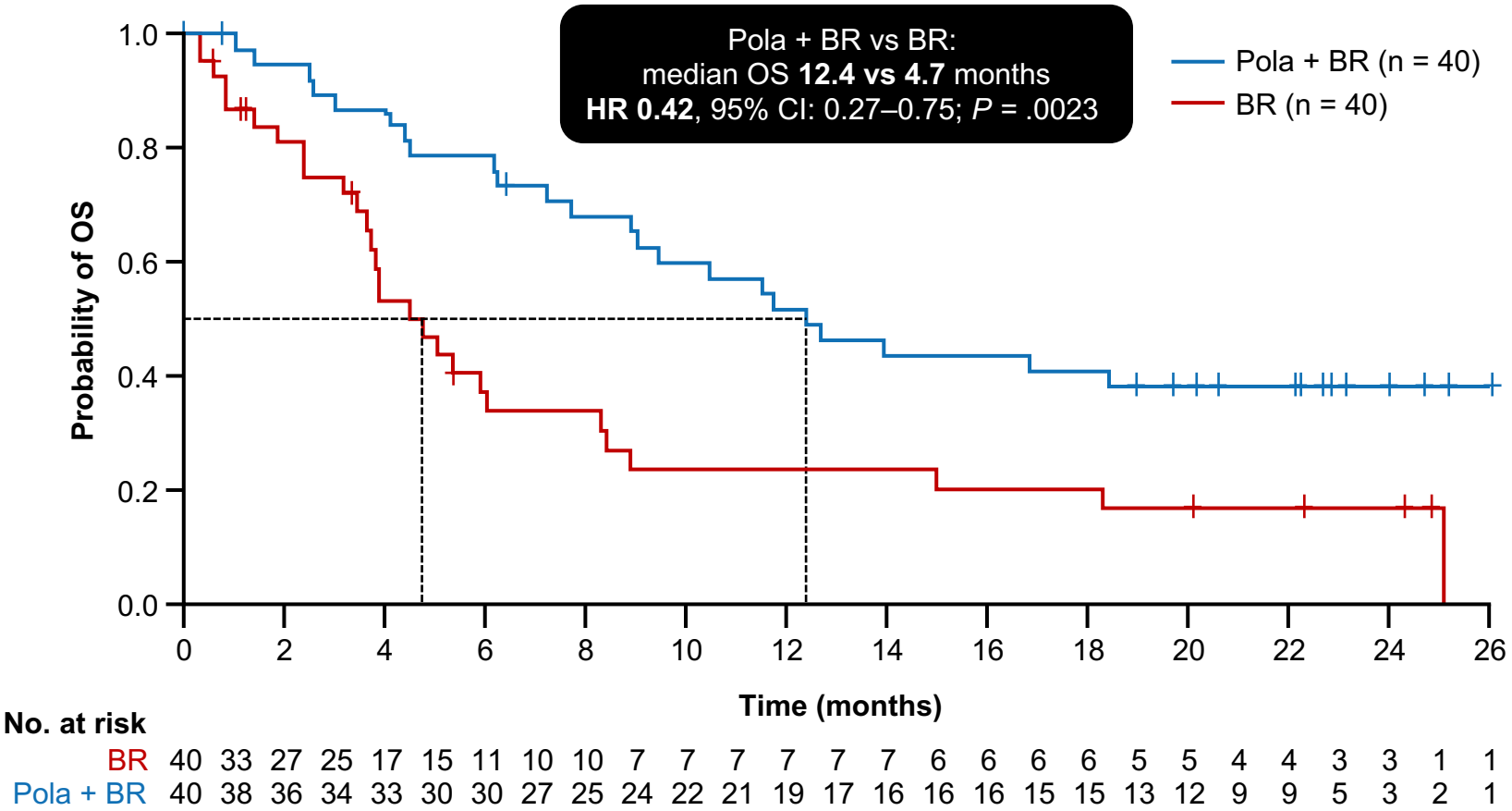
Seven patients have ongoing response durations of ≥20 months at data cut-off



Toxicities: hematologic, infectious, neurologic

Sehn et al. JCO 2020.

Knights: Polatuzumab +/- B +/- R

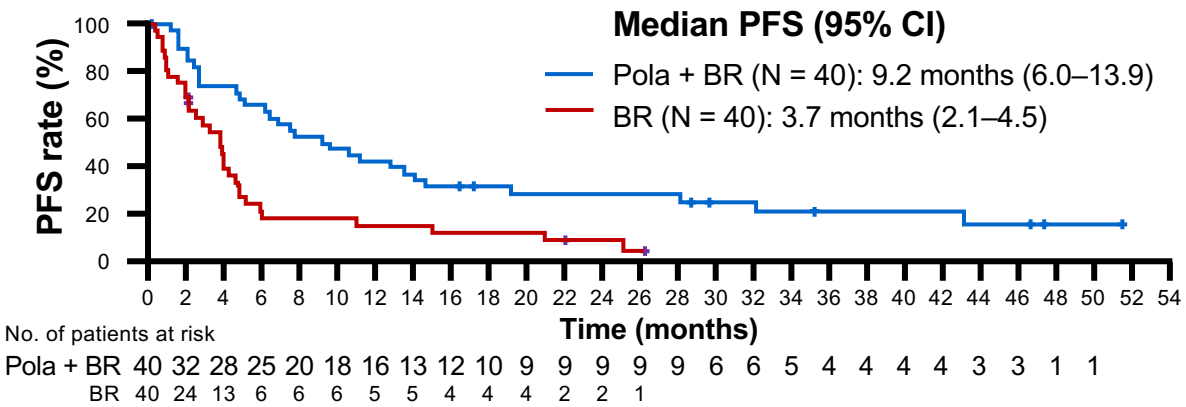


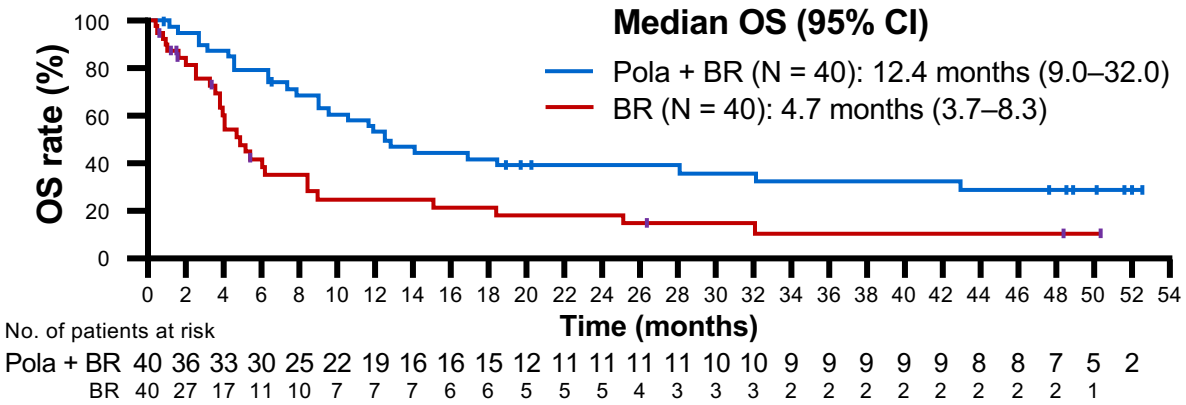
Median follow-up: 22.3 months

Sehn et al. JCO 2020.

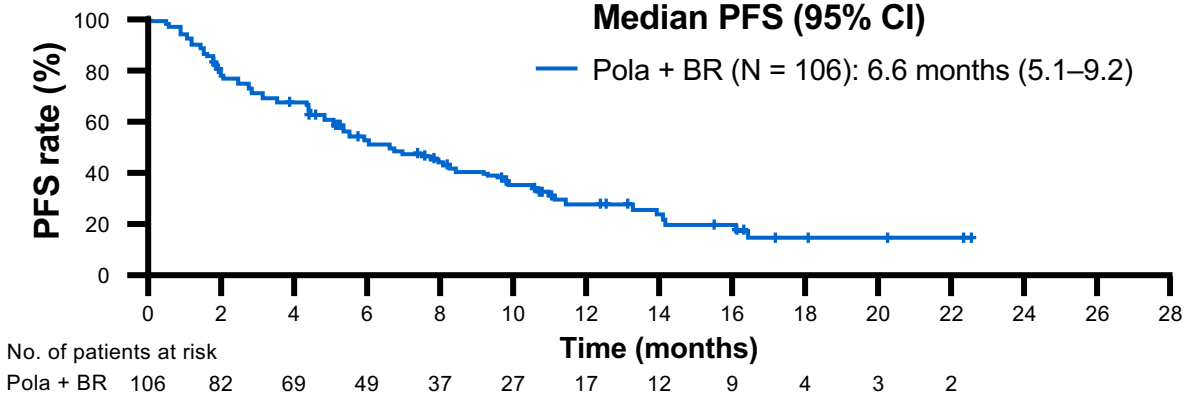
Knights: Polatuzumab +/- B +/- R

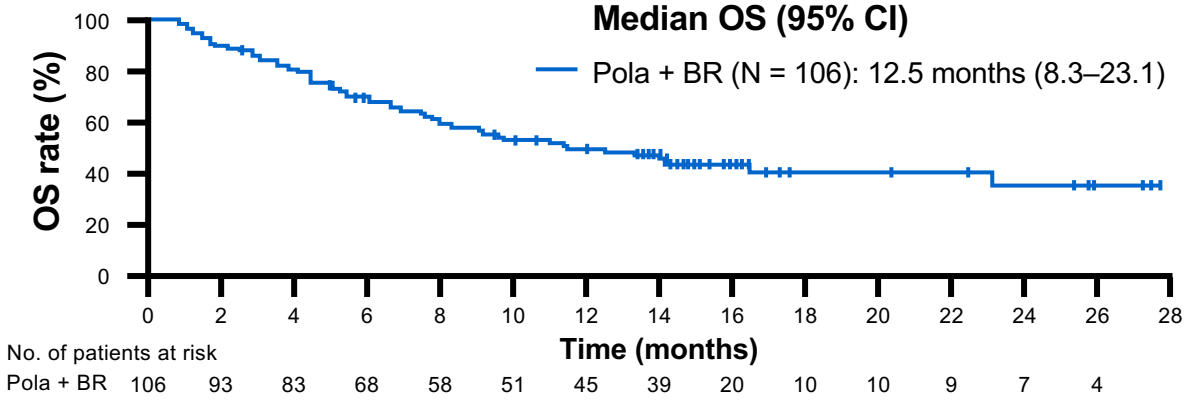
Randomized





Extension cohort

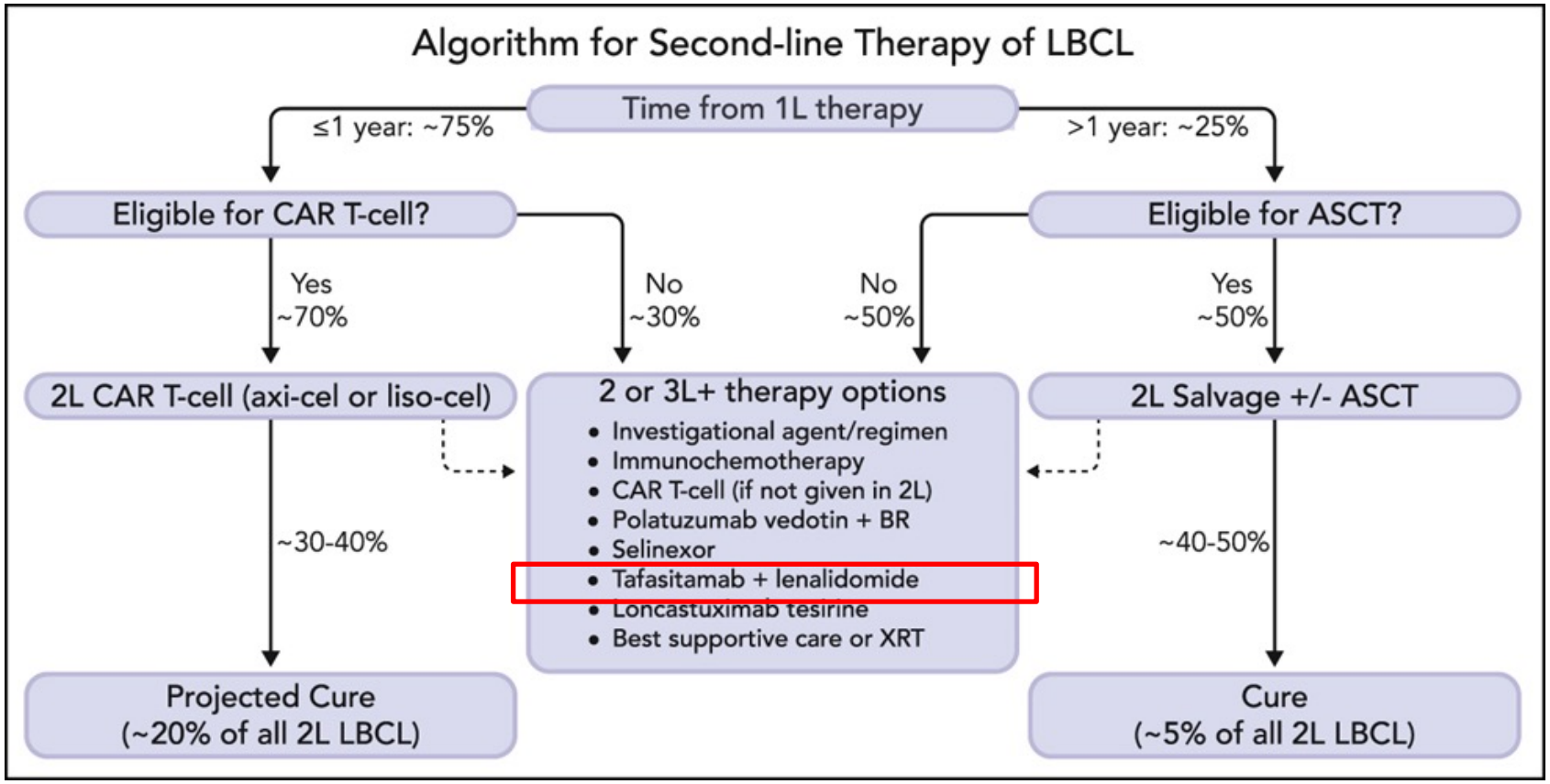




- The significant survival benefit with Pola + BR persists with longer follow-up
- 11 patients (28%) from the randomized Pola + BR cohort are long-term survivors with OS >24 months (range: 28.0–52.5 months)

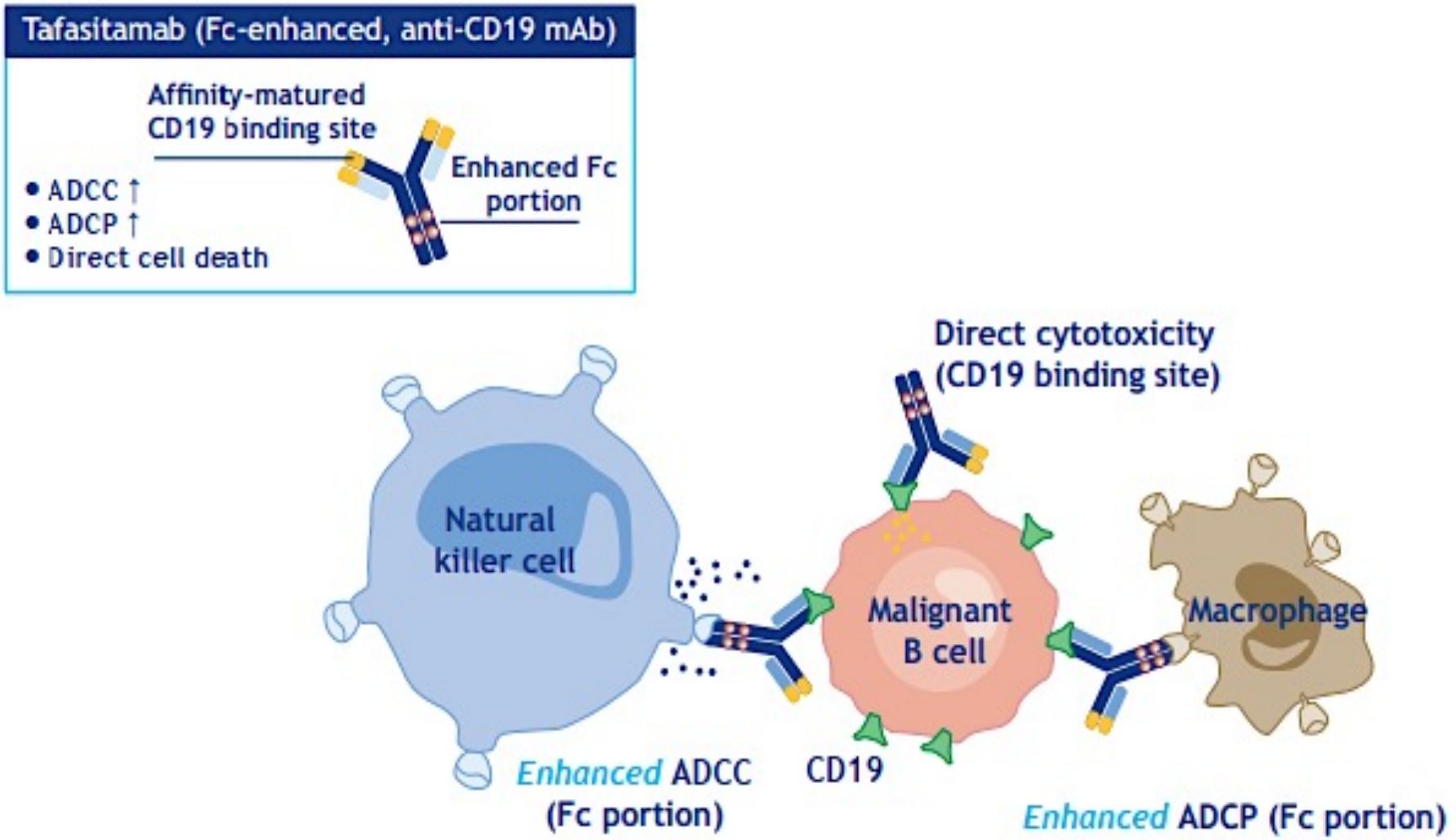
Sehn et al. ASH 2020. Abs 3020. Sehn et al. Blood Adv 2022.

2022: Resetting the Board



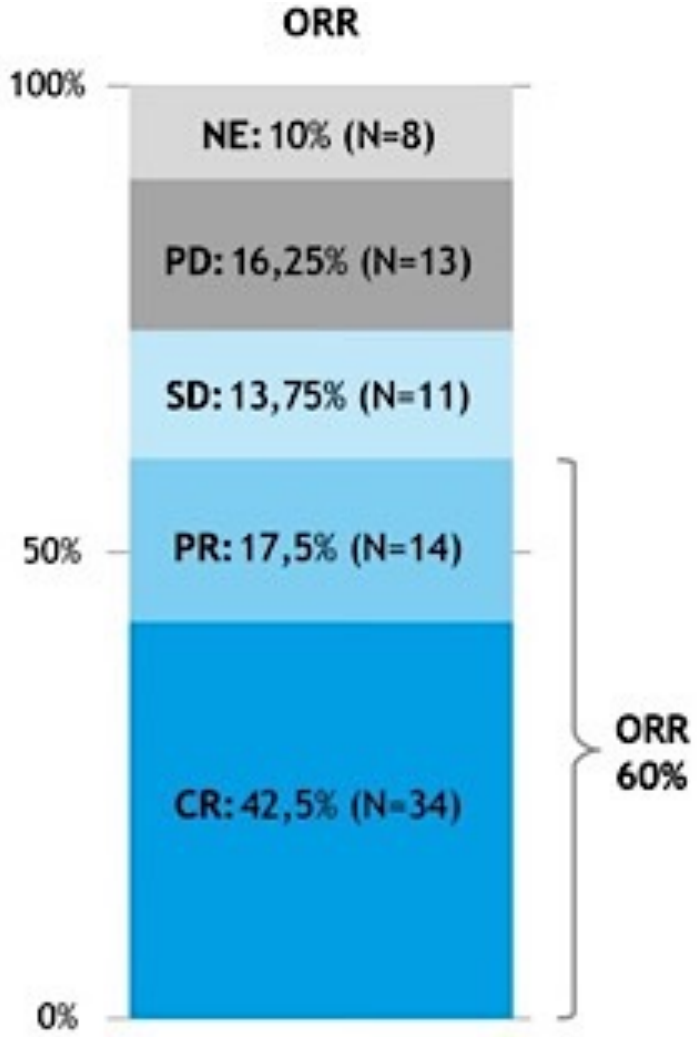
Westin et al. *Blood* 2022.

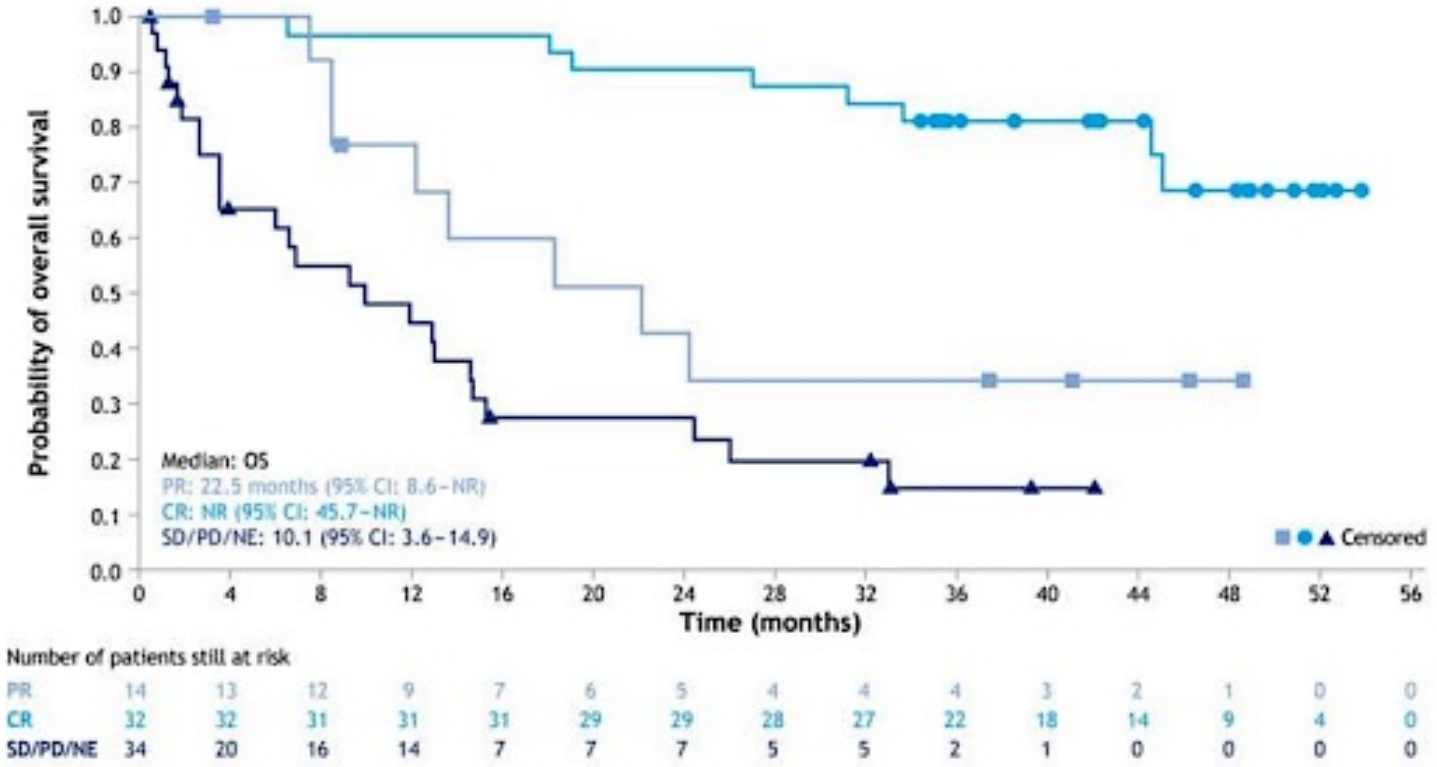
Rooks: Tafasitamab + Lenalidomide



Duell et al. Haematologica 2021.

Rooks: Tafasitamab + Lenalidomide





Salles et al. Lancet 2020; Duell et al. Haematologica 2021

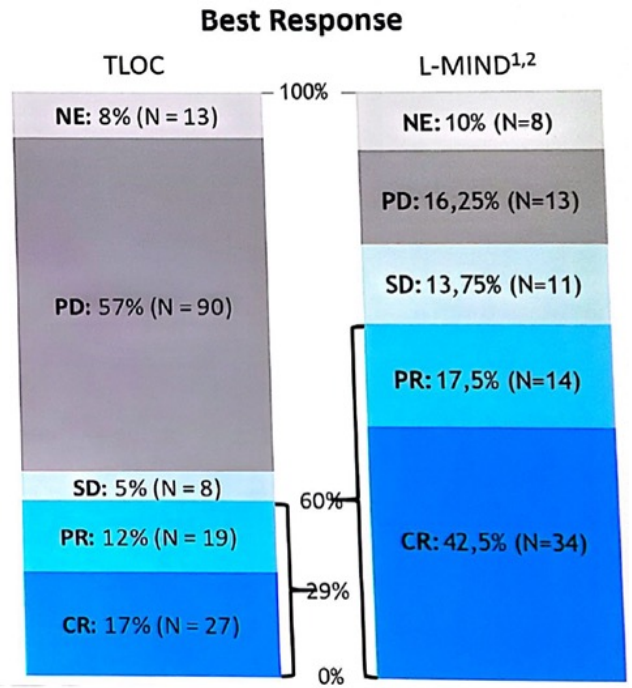
Rooks: Tafasitamab + Lenalidomide

N = 157

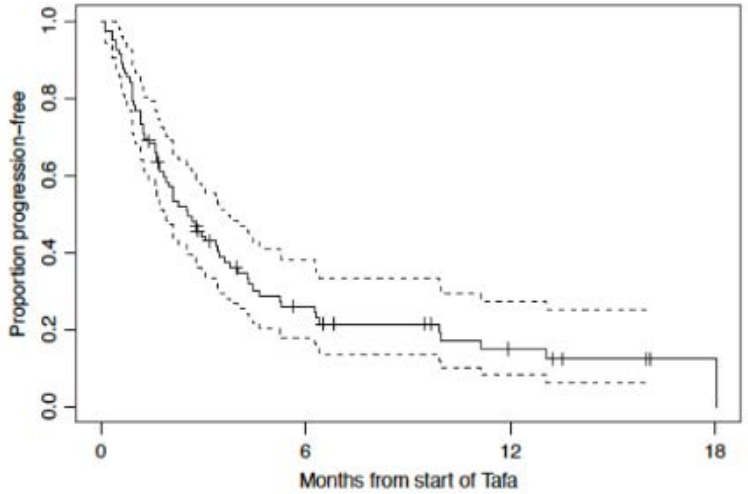
L-MIND Eligible: 11%

Reasons for L-MIND ineligibility:

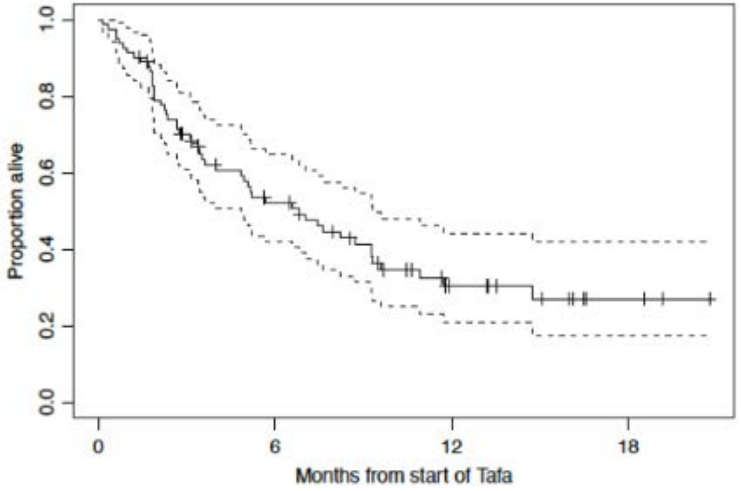
• EGFR < 60 ml/min	33%
• Prior anti-CD19 therapy	28%
• >3 prior lines of therapy	23%
• ECOG PS 3-4	18%
• High-grade B cell lymphoma	15%



Median PFS was 2.1 mo

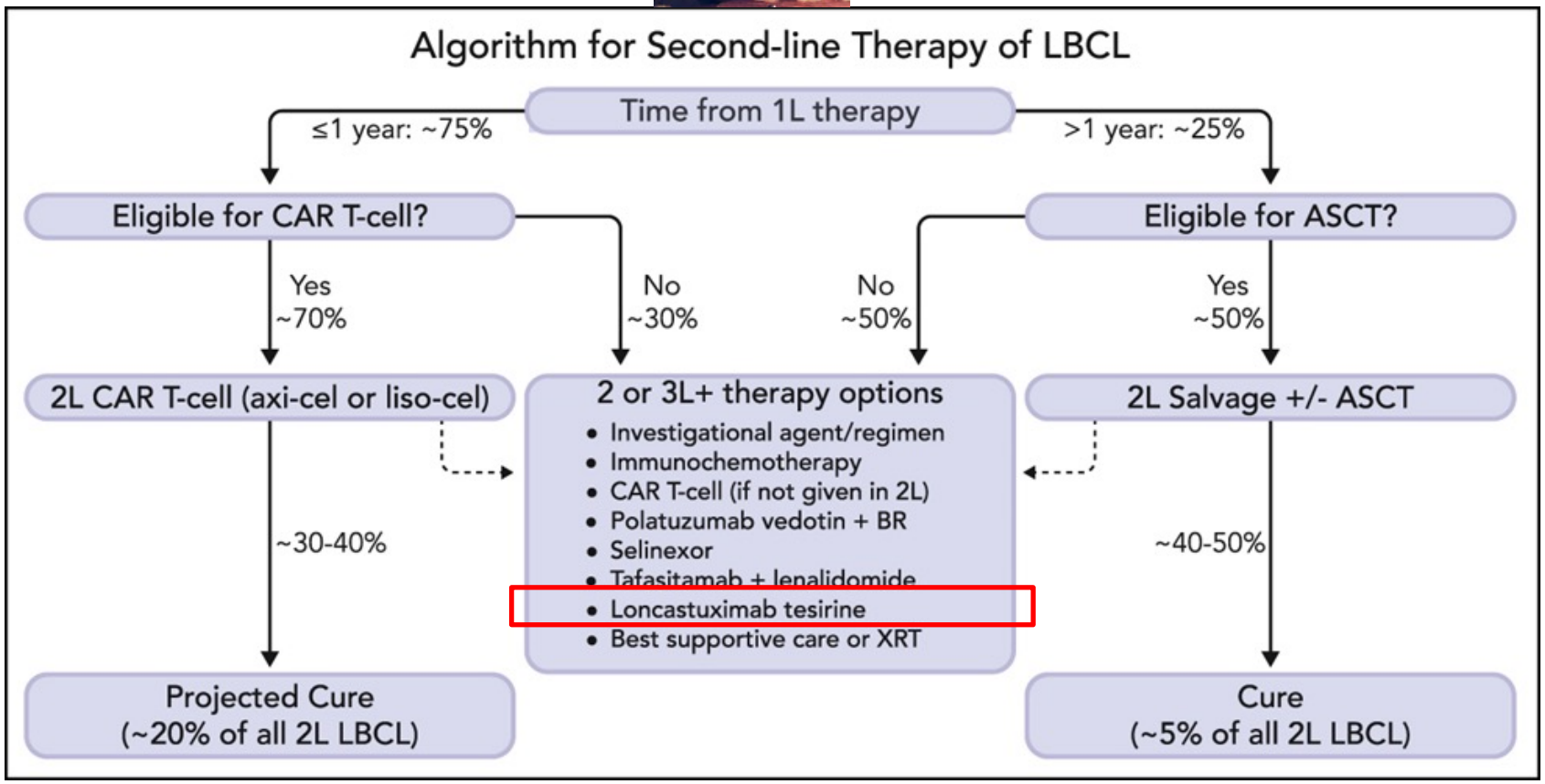


Median OS was 7.3 mo



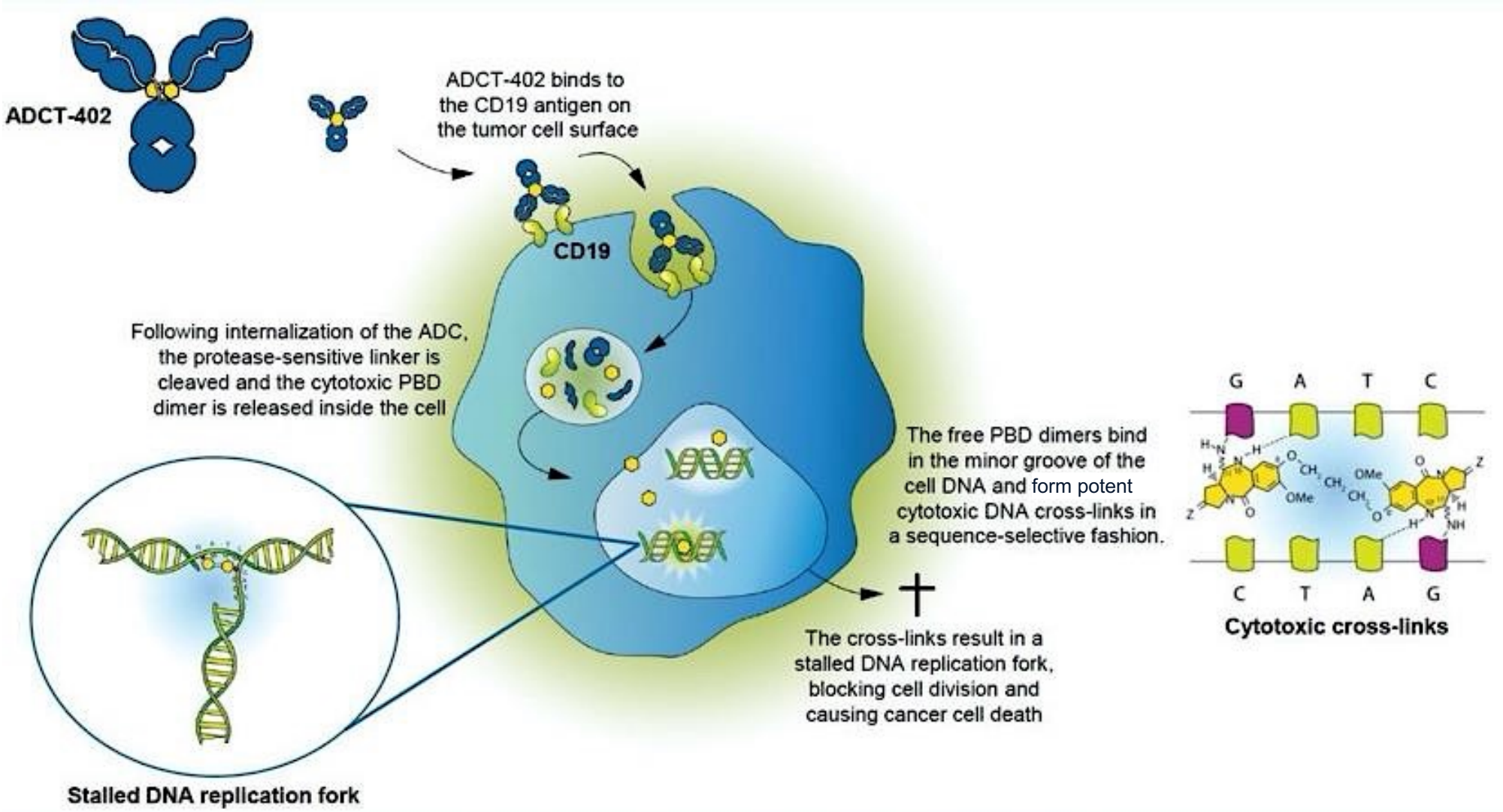
Qualls D ASH 2022. Abs # 323

Rel/Ref DLBCL 2022: Resetting the Board



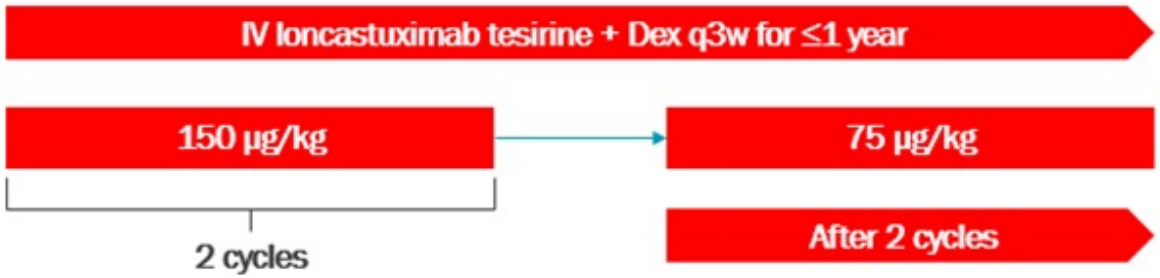
Westin et al. *Blood* 2022.

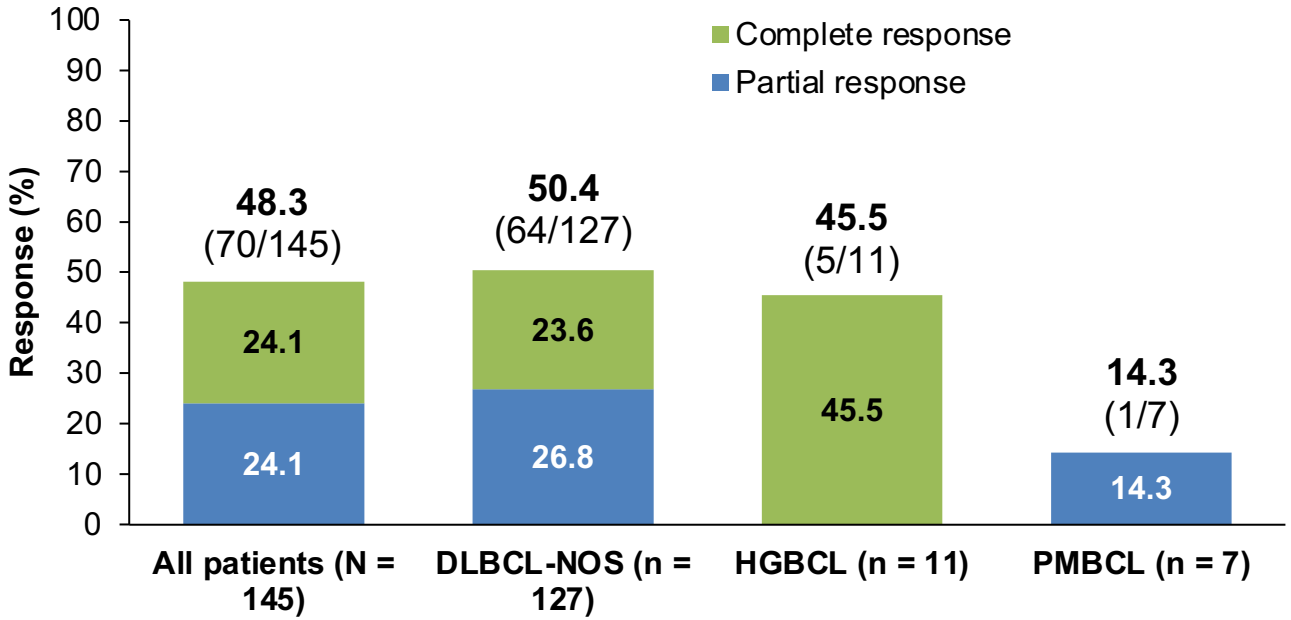
Bishops: Loncastuximab Tesirine (Lonca-T) + Dex



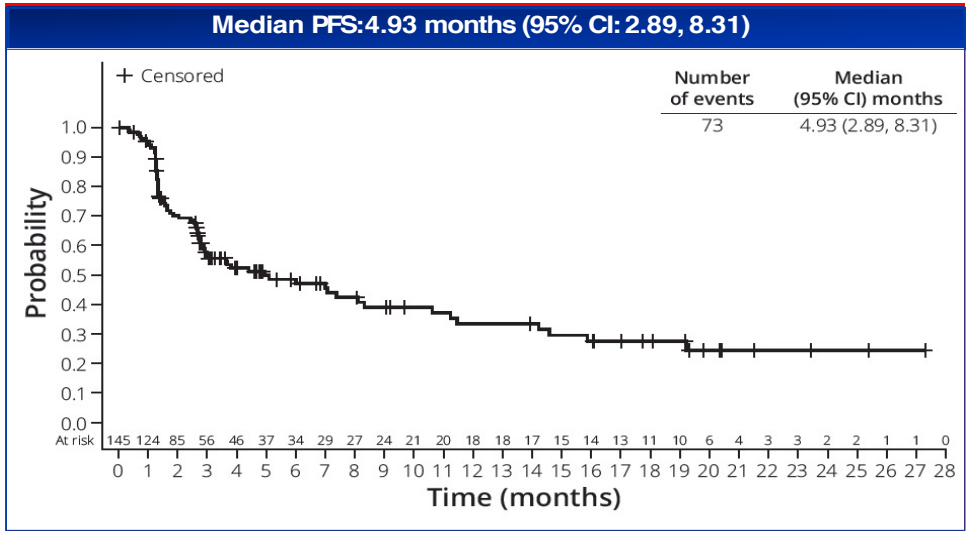
1. Hartley JA. The development of pyrrolobenzodiazepines as antitumour agents. *Expert Opin Investig Drugs* 2011;20(6):733-744.

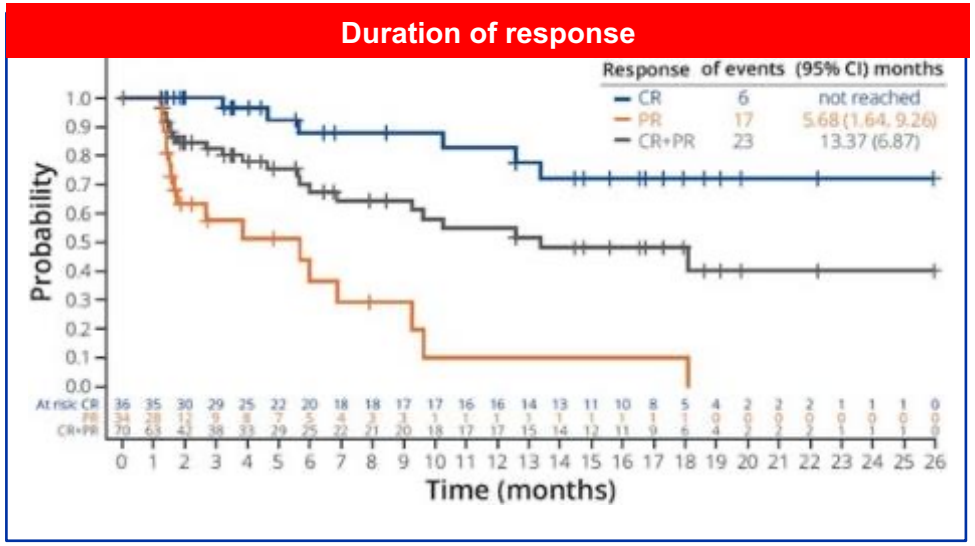
Bishops: Lonca-T + Dex





Median DOR: 10.25 months (95% CI: 5.98–NR)





Caimi et al. Lancet Oncol 2021; Caimi et al. EHA 2023 Abs #P1132.

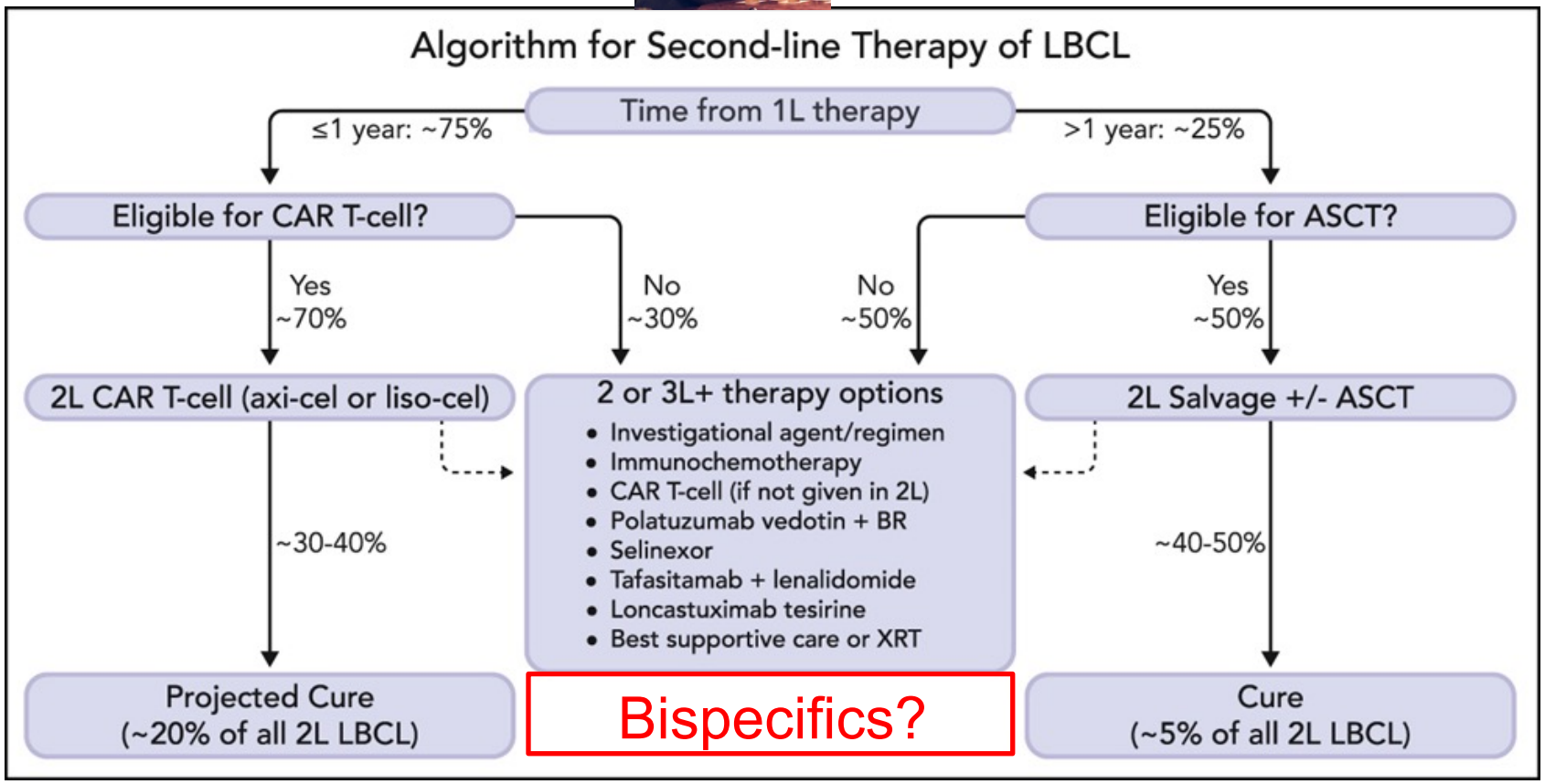
UNMC

Bishops: Lonca-T + Dex

		n=13
Lonca-T after CAR T-cell therapy, n (%)	CR	2 (15)
	PR	4 (31)
	SD	1 (8)
	PD	2 (15)
		n=14
CAR T-cell after Lonca-T, n (%)	CR	6 (43)
	PR	1 (7)
	Refractory	7 (50)

Caimi et al. Clin Lymphoma Myeloma Leuk 2022; Thapa et al. Blood Adv 2020.

2023: The Next Piece and Play



Westin et al. Blood 2022.

Agenda

Module 1 – Up-Front Management of Diffuse Large B-Cell Lymphoma (DLBCL) — Dr Flowers

Module 2 – Selection and Sequencing of Therapy for Relapsed/Refractory (R/R) DLBCL — Dr Lunning

Module 3 – Role of CD20 x CD3 Bispecific Antibodies in the Management of DLBCL — Dr Sehn

Priya Rudolph, MD
Athens, Georgia

Warren S Brenner, MD
Boca Raton, Florida

RTP
RESEARCH
TO PRACTICE

Priya Rudolph, MD

73-year-old woman: Recurrent DLBCL, NASH, portal hypertension, thrombocytopenia

Warren S Brenner, MD

81-year-old man: Recurrent non-GCB DLBCL with ECOG PS 2 primarily from tumor

Questions for the Faculty

Choice of systemic therapy for DLBCL in patients with liver disease, portal hypertension and thrombocytopenia?

What is your approach for elderly, frail patients with recurrent DLBCL and poor PS (eg, ECOG 2)?

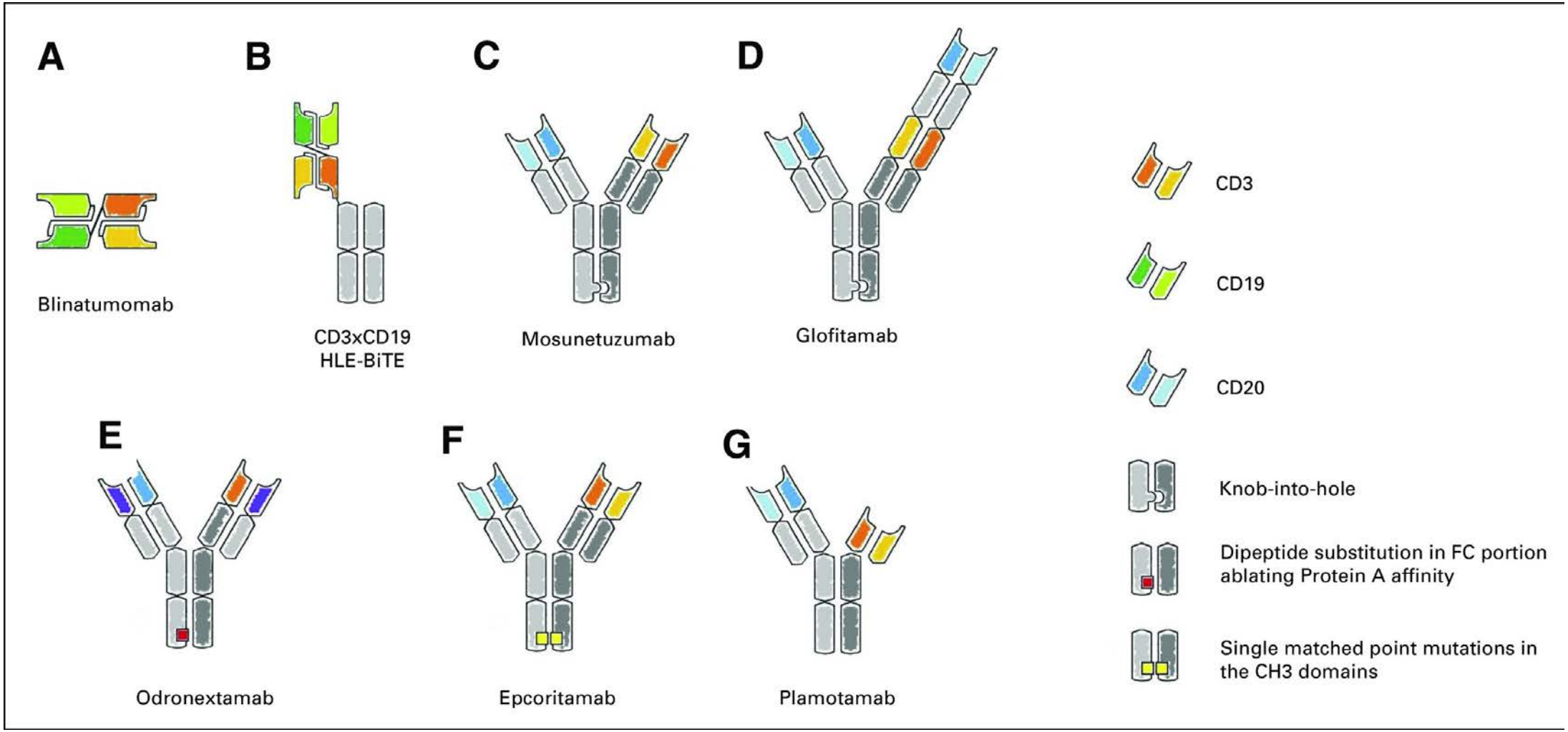
Role of CD20 x CD3 Bispecific Antibodies in the Management of DLBCL

Laurie H. Sehn, MD, MPH

Chair, Lymphoma Tumour Group

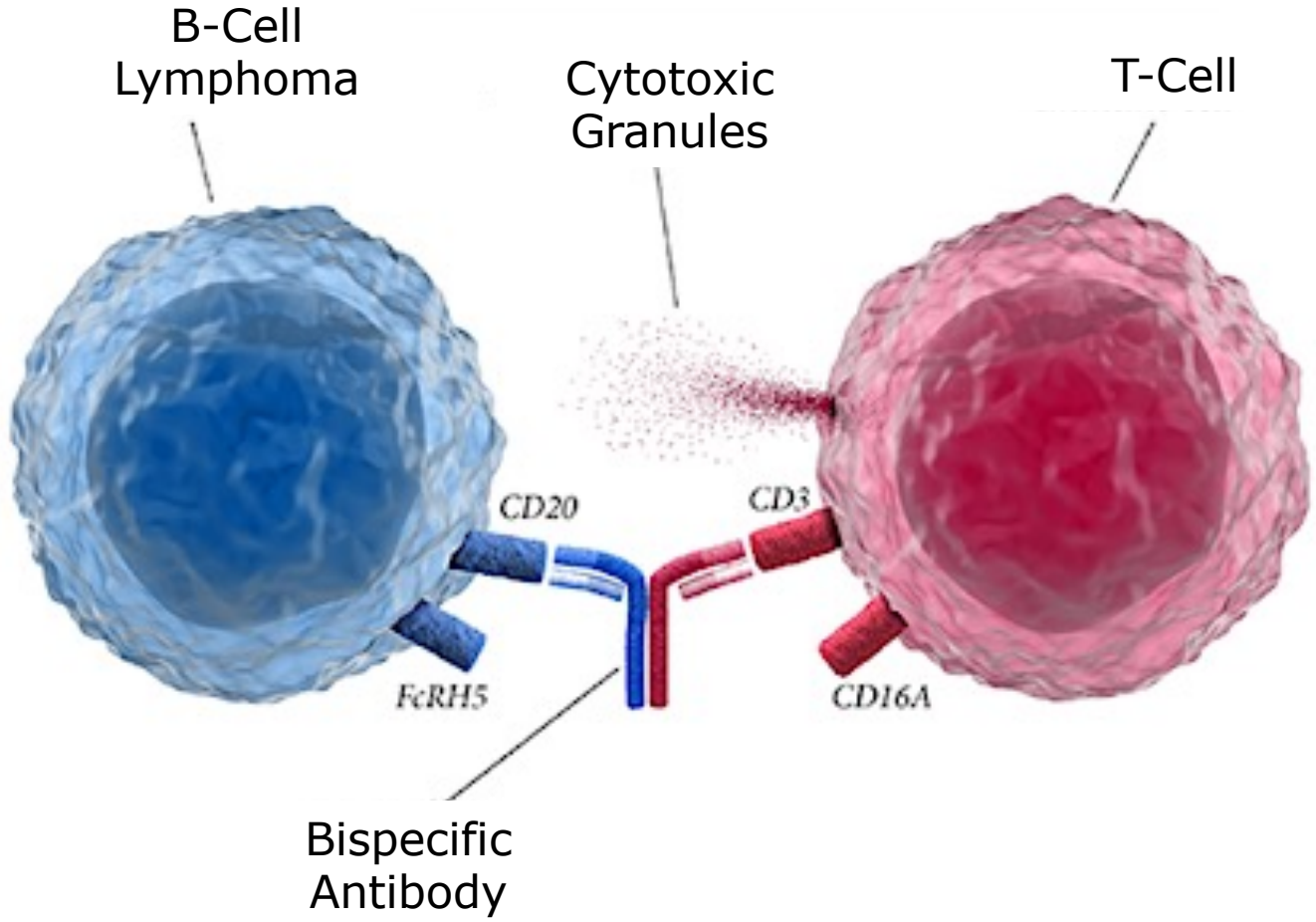
BC Cancer Centre for Lymphoid Cancer
Vancouver, Canada

Bispecific Antibodies in B-NHL



Lussana F, Gritti G; Rambaldi A. J Clin Oncol 2021

Mechanism of Action and Administration



- Redirect native T-cells to eliminate malignant B-cells

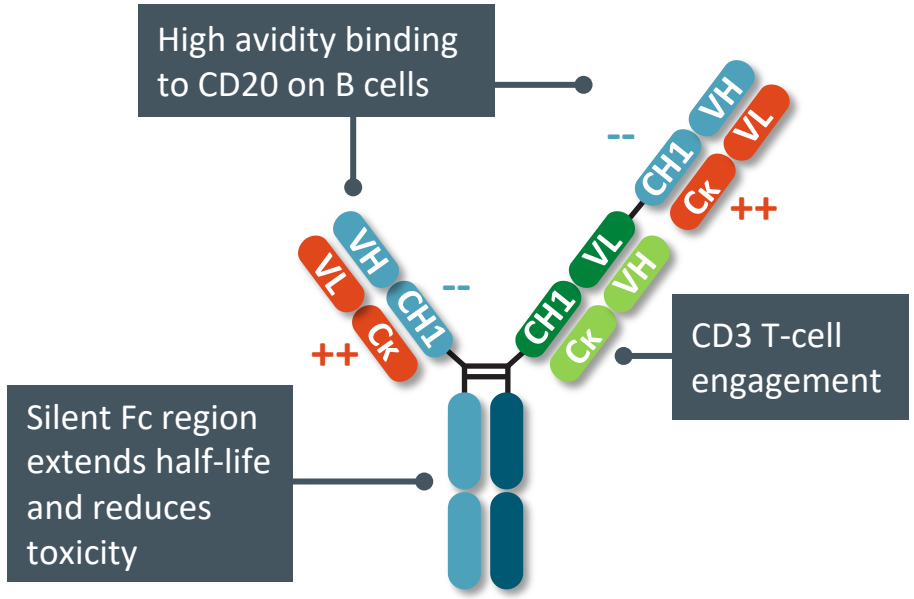
- Various delivery schedules under evaluation
  - Step-up dosing cycle 1
  - Weekly to every 4 weeks
  - IV or SC formulations
  - Finite therapy (9 months) to indefinite (to progression)

Phase 1 Studies of CD3xCD20 Bispecific Antibodies in B-NHL

Bispecific antibody	Aggressive B-NHL			Indolent B-NHL		
	No	ORR	CRR	No	ORR	CRR
Mosunetuzumab	129	35%	19%	68	66%	49%
Glofitamab	69	61%	49%	29	69%	59%
Odronextamab	45	40%	36%	32	91%	72%
Epcoritamab	22	68%	45%	10	90%	50%

Budde E, et al. J Clin Oncol 2022;
Hutchings M, et al. J Clin Oncol. 2021
Bannerji R, et al. Lancet Haematol 2022
Hutchings M, et al. Lancet 2021

Glofitamab: Pivotal Phase II Study in Aggressive B-Cell Lymphoma



Pivotal phase II expansion in patients with R/R DLBCL and ≥2 prior therapies (NP30179)

Key inclusion criteria

- DLBCL NOS, HGBCL, transformed FL or PMBCL
- ECOG PS 0-1
- ≥ 2 prior therapies, including:
  - Anti-CD20 Ab
  - Anthracycline

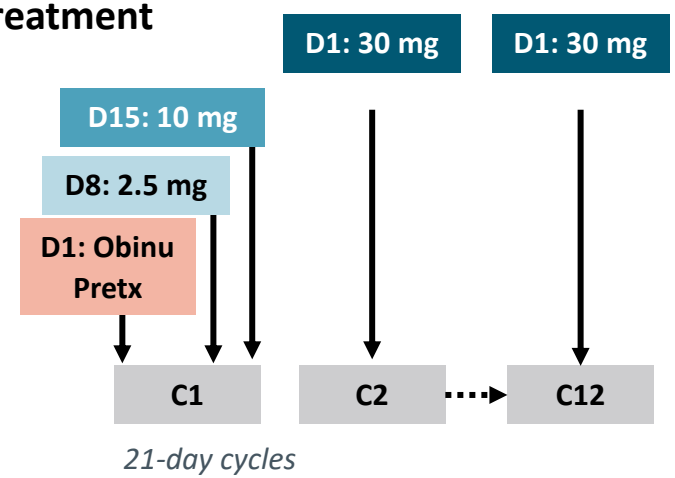
Glofitamab IV administration

Fixed-duration treatment

- max. 12 cycles

CRS mitigation

- Obinutuzumab pretreatment (1 x 1000 mg)
- C1 step-up dosing
- Monitoring after first dose (2.5 mg)



Endpoints

- **Primary: CR (best response) rate by IRC**
- **Key secondary:** ORR rate, DoR, DoCR, PFS, and OS

Dickinson M et al. NEJM 2022

Glofitamab Phase II Study: Baseline Characteristics

Characteristic	Glofitamab (N = 154)
Median age, yr (range)	66.0 (21-90)
Male, n (%)	100 (64.9)
Ann Arbor stage, n (%)	
▪ I	10 (6.5)
▪ II	25 (16.2)
▪ III	31 (20.1)
▪ IV	85 (55.2)
NHL subtype	
▪ DLBCL	110 (71.4)
▪ Transformed from FL	27 (17.5)
▪ HGBCL	11 (7.1)
▪ PMBCL	6 (3.9)
Bulky disease, n (%)	
▪ >6 cm	64 (41.6)
▪ >10 cm	18 (11.7)

Characteristic	Glofitamab (N = 154)
Prior lines of therapy, median (range)	3 (2-7)
▪ 2 prior lines, n (%)	62 (40.3)
▪ ≥3 prior lines, n (%)	92 (59.7)
Prior therapy received, n (%)	
▪ Anti-CD20 antibody	154 (100)
▪ Anthracycline	149 (96.8)
▪ CAR T-cell therapy	51 (33.1)
▪ ASCT	28 (18.2)
Refractory disease, n (%)	
▪ To any prior therapy	139 (90.3)
▪ To last prior therapy	132 (85.7)
▪ Primary refractory	90 (58.4)
▪ To prior CAR T-cell therapy	46 (29.9)
▪ To any prior anti-CD20 antibody	128 (83.1)

Dickinson M et al. NEJM 2022

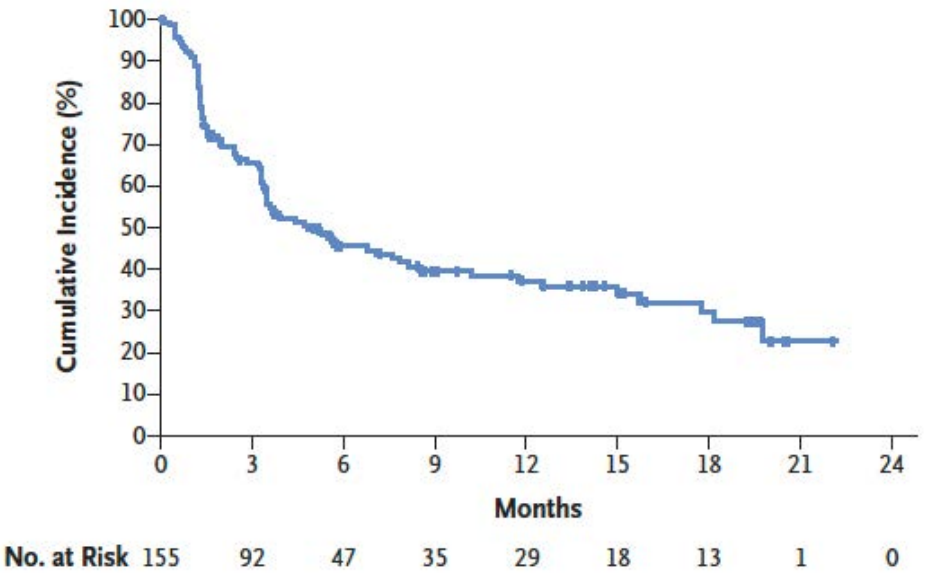
Glofitamab Phase II Study: Efficacy

Median follow-up: 12.6 mo

Response, %	N = 155
Best response	
▪ ORR	51.6
▪ CR	39.4
Subgroup CR rate	
▪ Post CAR T-cell therapy	35
▪ Relapsed	70
▪ Refractory	34

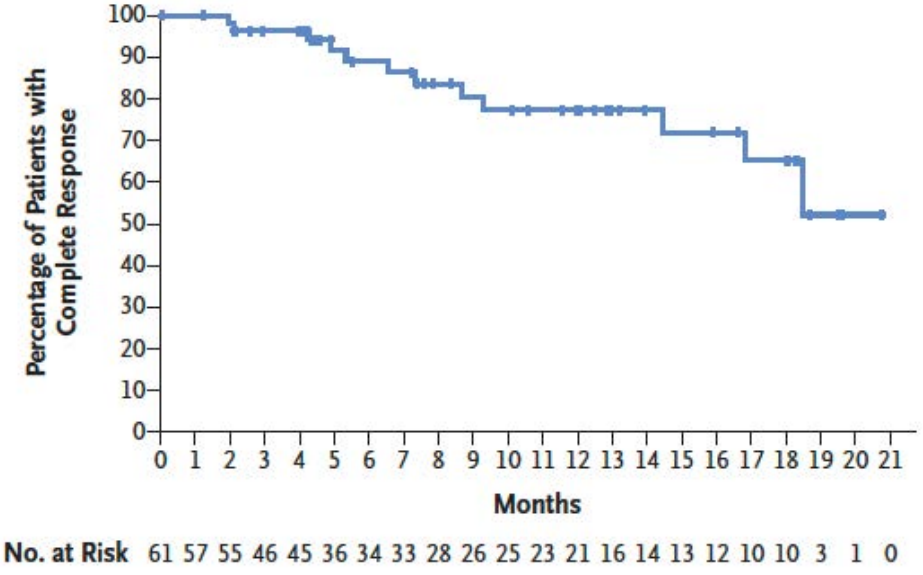
Survival, Mo	N = 155
Median PFS	4.9
Median OS	11.5

Progression-free Survival



12-month PFS: 37%

Duration of Complete Response



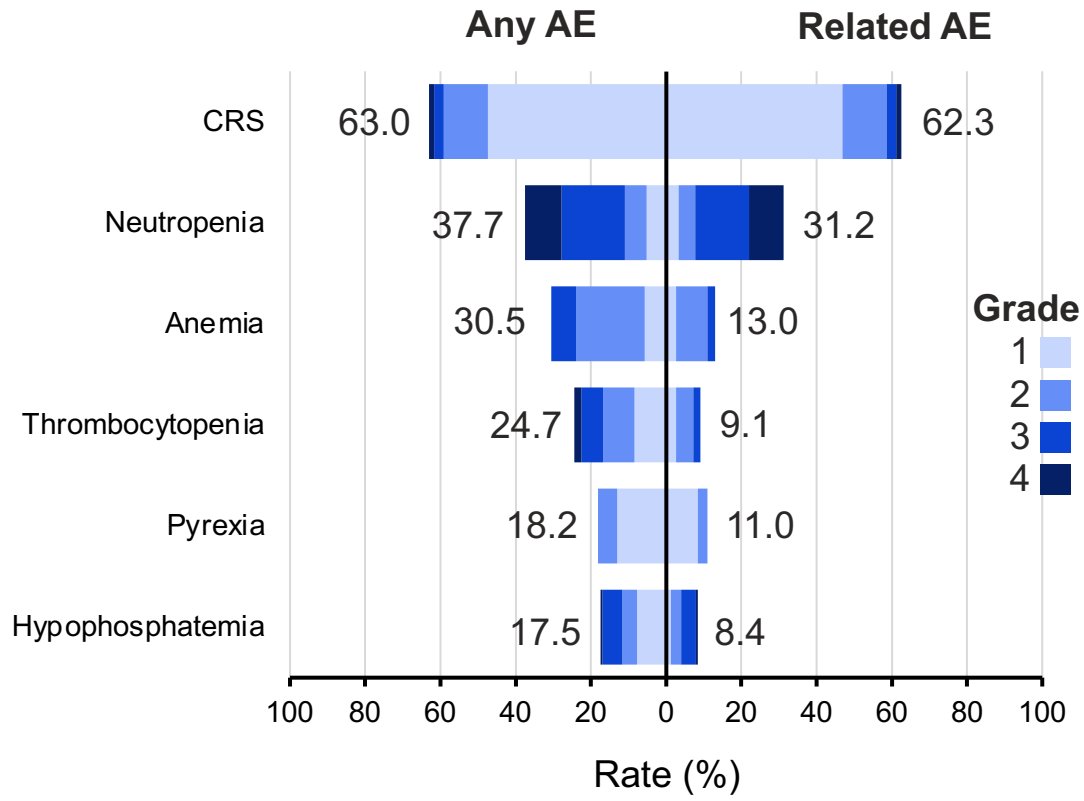
12-month DOR: 78%

Dickinson M et al. NEJM 2022

Glofitamab Phase II Study: Safety Profile

n (%)	N=154
Median no. of cycles received (range)	5 (1–13)
Median relative dose intensity, % (range)	100 (94–100)
AE	152 (98.7)
Related AE	140 (90.9)
Grade 3–4 AE	87 (56.5)
Related AE	64 (41.6)
Serious AE	73 (47.4)
Related AE	46 (29.9)
Grade 5 (fatal AE)	8 (5.2)
Related AE	0
AE leading to treatment discontinuation	14 (9.1)
Related AE	5 (3.2)

AEs (≥15%) by grade and relationship with glofitamab

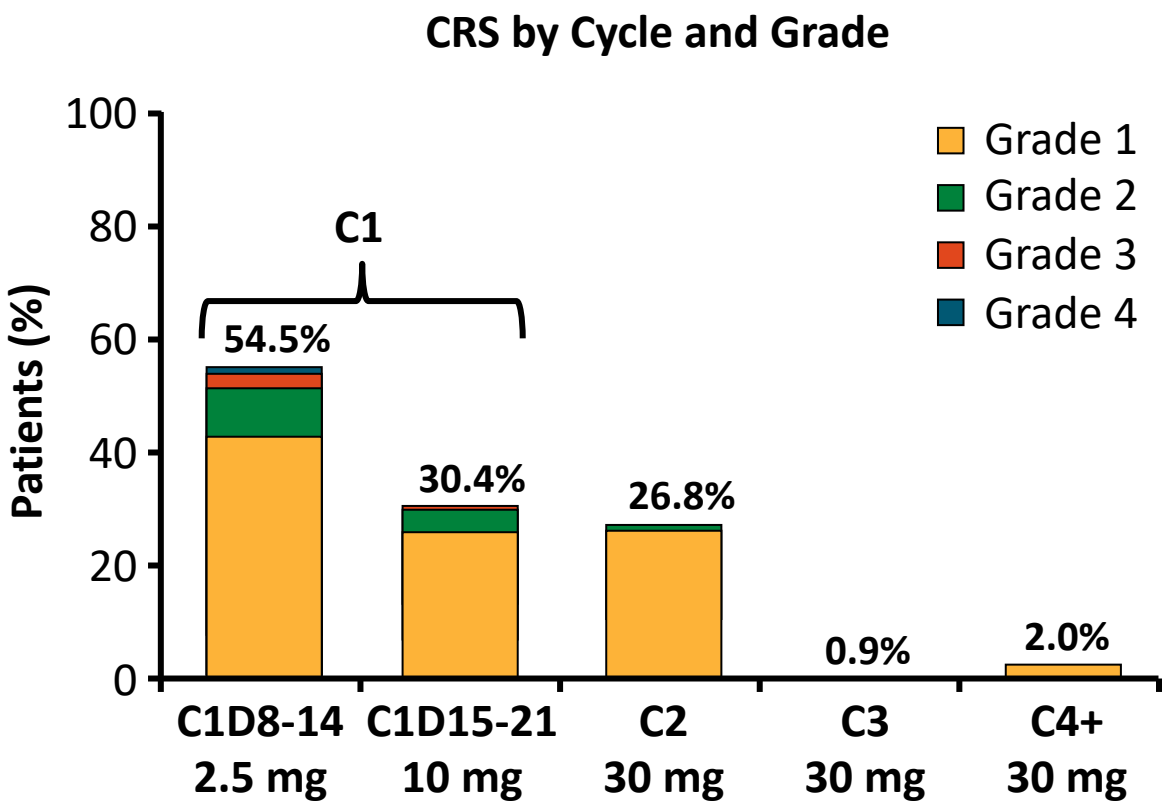


Grade ≥3 CRS: 4%; Grade ≥3 Neuro events: 3%

Dickinson M et al. NEJM 2022

Glofitamab Phase II Study: CRS

CRS Parameter	Glofitamab (N = 154)
Any-grade CRS, n (%)	97 (63.0)
▪ Grade 1	73 (47.4)
▪ Grade 2	18 (11.7)
▪ Grade 3	4 (2.6)
▪ Grade 4	2 (1.3)
Median time to CRS onset from cycle 1 Day 8 dose, hr (range)	13.6 (6.2-51.8)
Corticosteroids given, n/N (%)	27/97 (27.8)
Tocilizumab given, n/N (%)	31/97 (32.0)
Any ICANS	12 (7.8)
▪ Grade ≥3	4 (2.6)



Dickinson M et al. NEJM 2022

Pivotal Phase 2 Trial: Subcutaneous Epcoritamab in R/R LBCL

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

Thieblemont et al, EHA 2022; Thieblemont et al, J Clin Oncol 2022

Epcoritamab in R/R LBCL: Patients

Demographics	LBCL, N=157
Median age (range), y	64 (20–83)
<65 y, n (%)	80 (51)
65 to <75 y, n (%)	48 (31)
≥75 y, n (%)	29 (18)
ECOG PS, n (%)	
0	74 (47)
1	78 (50)
2	5 (3)
Disease Characteristics[a]	**LBCL, N=157**
Disease type, n (%)	
DLBCL	139 (89)
De novo	97/139 (70)
Transformed	40/139 (29)
Unknown	2/139 (1)
HGBCL	9 (6)
PMBCL	4 (3)
FL Gr3B	5 (3)

Prior Treatments	LBCL, N=157
Median time from initial diagnosis to first dose, y	1.6
Median time from end of last therapy to first dose, mo	2.4
Median prior lines of therapy (range)	3 (2–11)
≥3 Lines of therapy, n (%)	111 (71)
Primary refractory[b] disease, n (%)	96 (61)
Refractory[b] to last systemic therapy, n (%)	130 (83)
Refractory[b] to ≥2 consecutive lines of therapy, n (%)	119 (76)
Prior ASCT, n (%)	31 (20)
Prior CAR T therapy, n (%)	61 (39)
Progressed within 6 mo of CAR T therapy	46/61 (75)

Median follow-up: 10.7 m

Thieblemont et al, EHA 2022; Thieblemont et al, J Clin Oncol 2022

Epcoritamab in R/R LBCL: Efficacy

Best Response Rates

- ORR: 63.0%
- CR: 39.0%

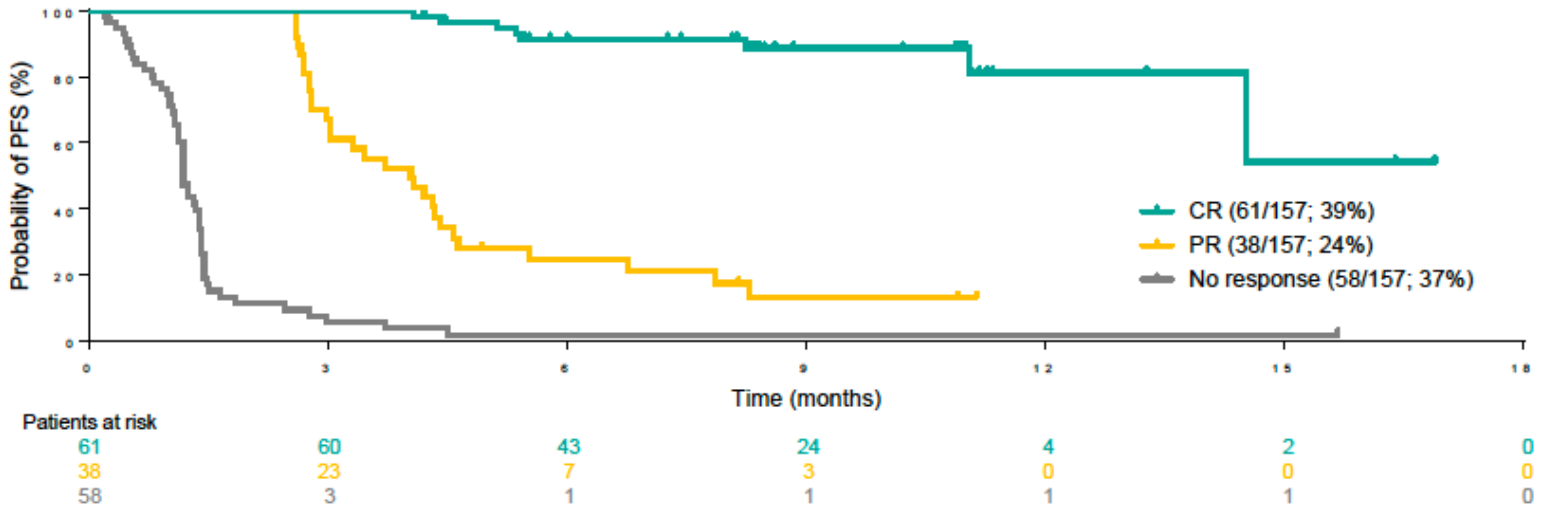
Subgroup CR rate

- Post CAR T-cell: 34%
- Refractory 30%

Survival

- PFS: 4.4 mo
- OS: 57% at 12 mo

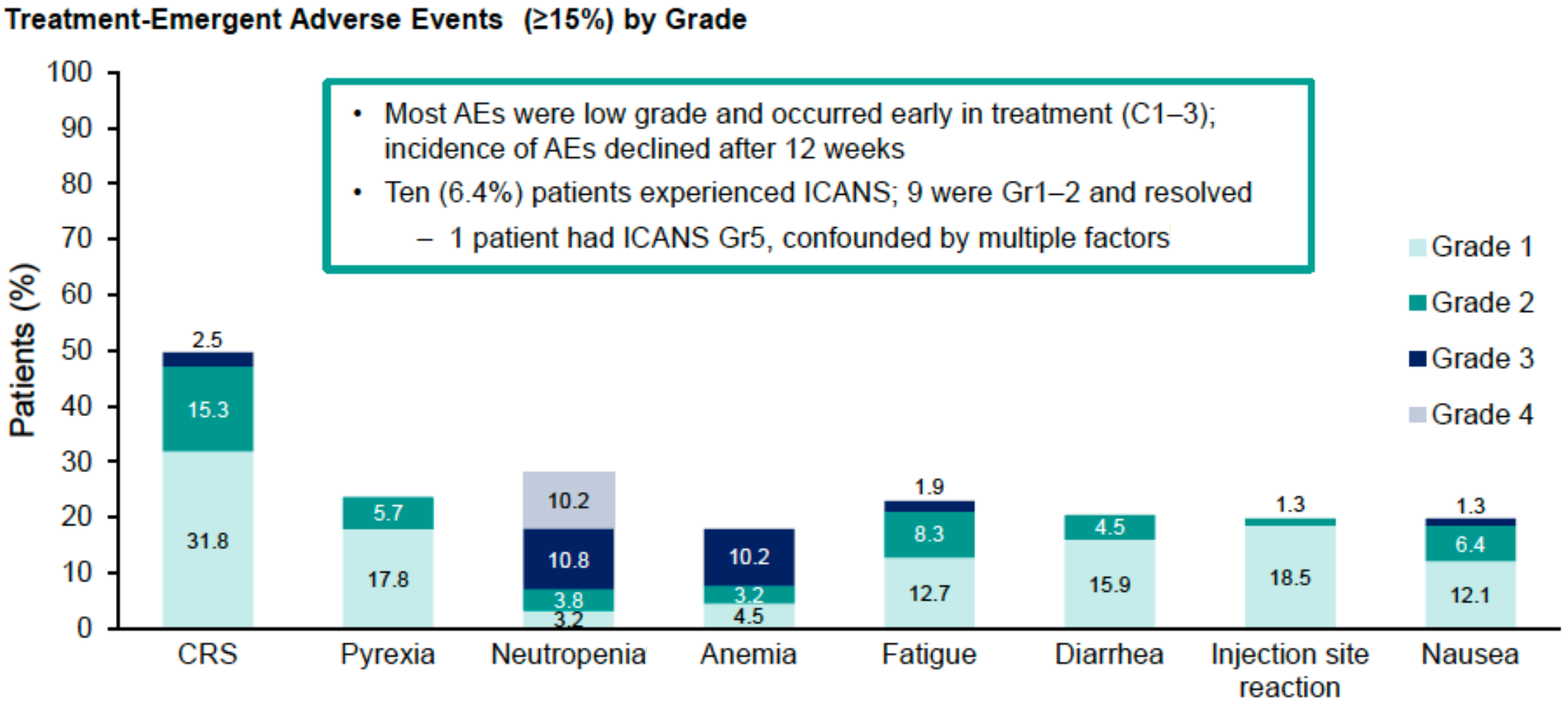
PFS by Best Response per IRC



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)

Thieblemont et al, EHA 2022; Thieblemont et al, J Clin Oncol 2022

Epcoritamab in R/R LBCL: Safety

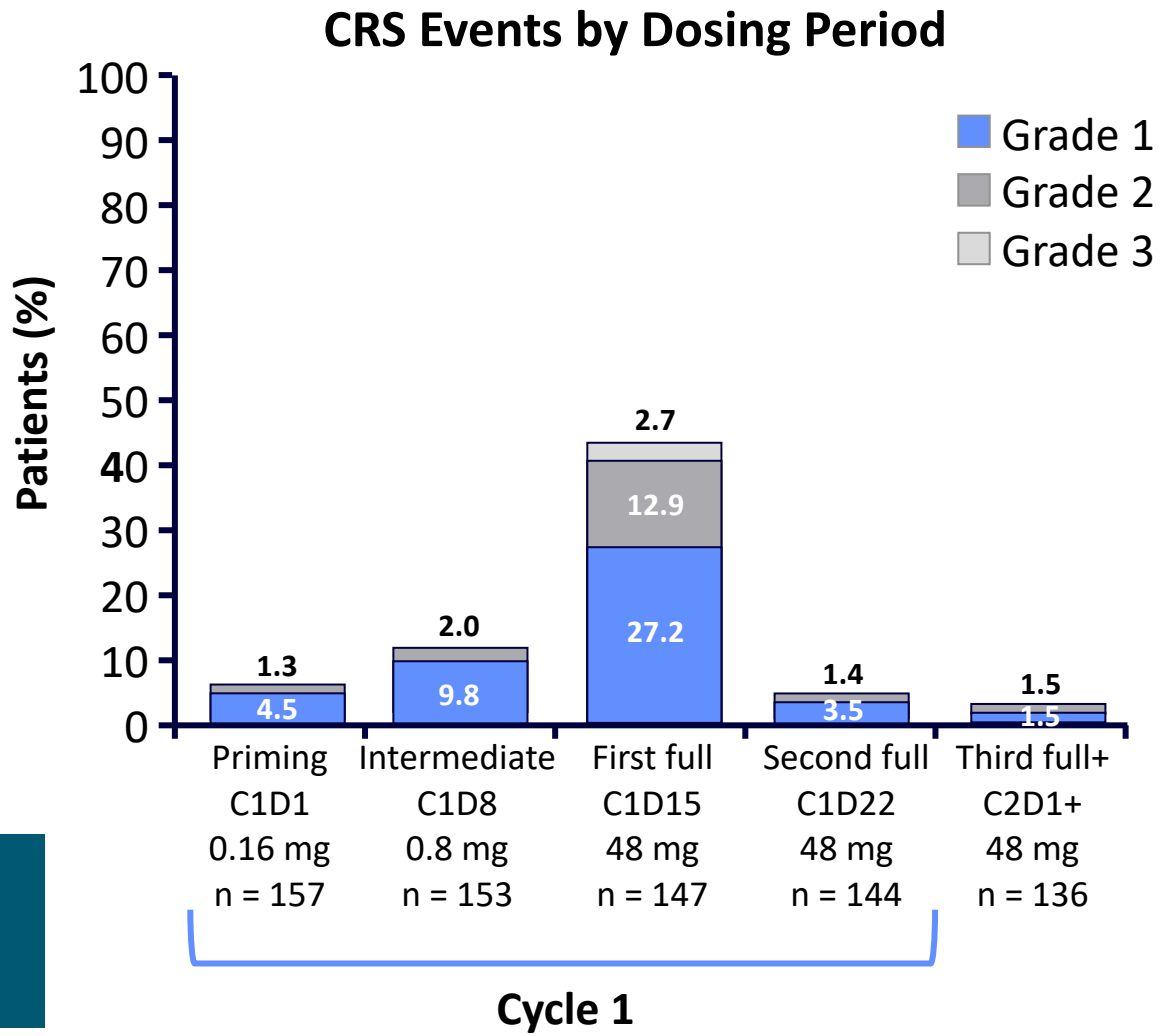


Thieblemont et al, EHA 2022; Thieblemont et al, J Clin Oncol 2022

Epcoritamab in R/R LBCL: CRS

CRS	LBCL (N = 157)
CRS events,* n (%) ▪ Grade 1 ▪ Grade 2 ▪ Grade 3	78 (49.7) 50 (31.8) 24 (15.3) 4 (2.5)
CRS resolution, n (%)	77 (98.7)
Median time to CRS onset from first full dose, days	0.8
Median time to CRS resolution from first full dose, days	2
CRS treatment ▪ Tocilizumab ▪ Corticosteroids	 22 (14.0) 16 (10.2)
CRS leading to treatment discontinuation, n (%)	1 (0.6)

- ICANS: 6.4%
  - All grade 1/2 except 1 case of grade 5 (with multiple confounders)



Thieblemont et al, EHA 2022; Thieblemont et al, J Clin Oncol 2022

Odronextamab ELM-2 Study: R/R DLBCL Cohort

- Relapsed/Refractory DLBCL after ≥2 prior lines of therapy
- Median follow-up: 21.3 months

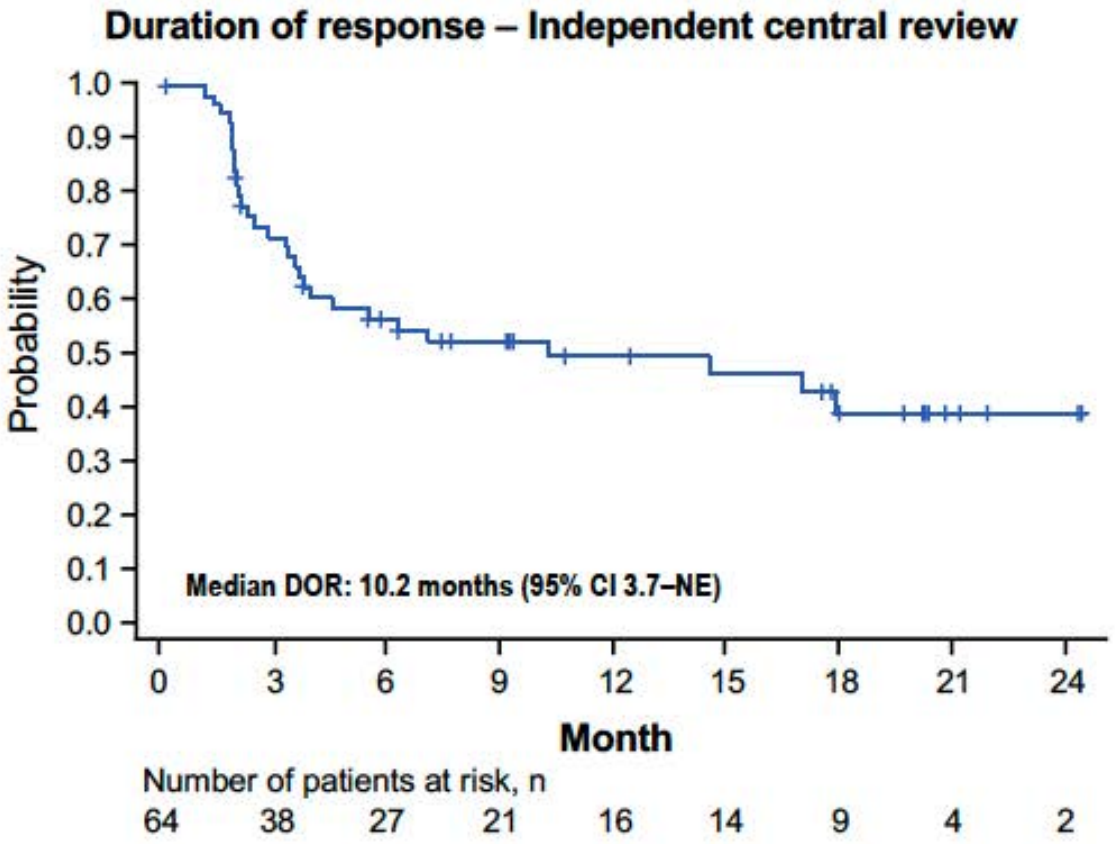
Odronextamab administration:

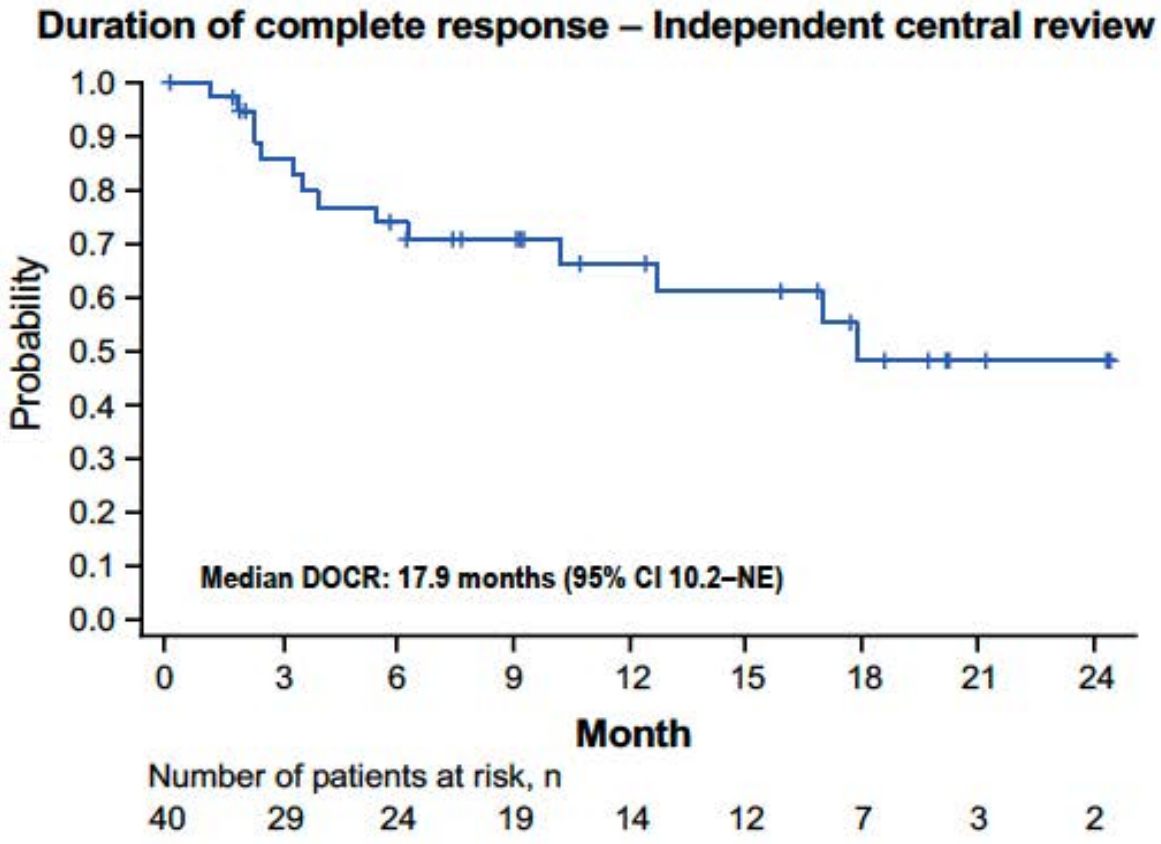
- IV, 21-day cycles
- Cycle 1 Step-up
- Cycles 2-4 160mg Days 1, 8,15
- Cycle 5 onwards 320mg Q2W
- Treatment until disease progression

Best Overall Response	IRC N=130	Investigator N=130
Objective response rate (ORR)†	**49.2%** [95% CI 40.4%–58.1%]	**50.0%** [95% CI 41.1%–58.9%]
Complete response	**30.8%**	**36.2%**
Partial response	18.5%	13.8%
Stable disease	3.8%	3.1%
Progressive disease	22.3%	21.5%

Kim WS et al. ASH 2022

Odronextamab ELM-2 Study: Duration of Response





Kim WS et al. ASH 2022

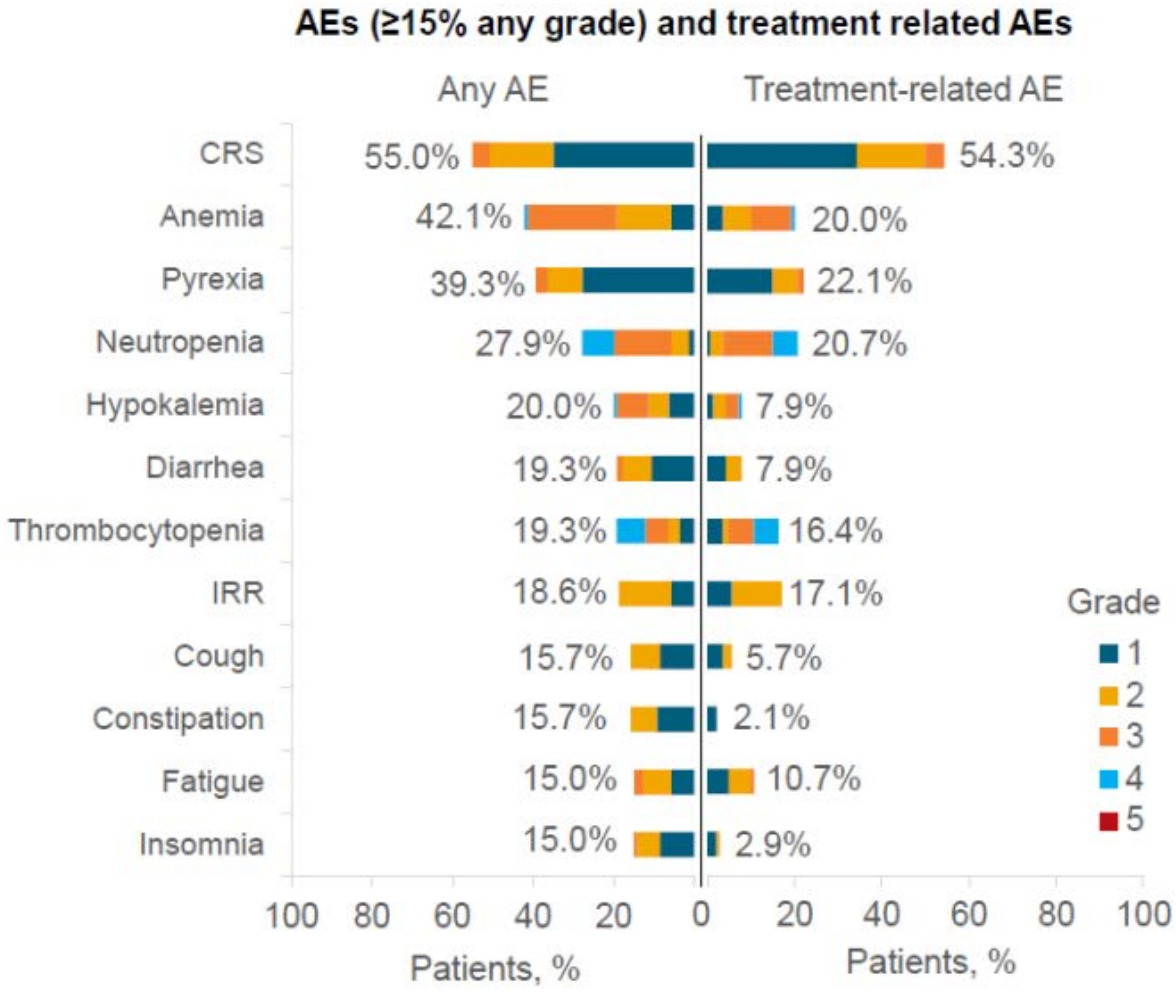
Odronextamab phase 2 DLBCL expansion cohort – adverse events

Treatment-emergent adverse events, n (%)	Patients N=140 Any event	Treatment-related
Any TEAE	139 (99.3%)	123 (87.9%)
Grade ≥3 TEAE	110 (78.6%)	74 (52.9%)
Serious AE	85 (60.7%)	64 (45.7%)
Grade 5 TEAE Related to COVID-19 Other grade 5 events	20 (14.3%) 5 (3.6%) 15 (10.7%)	5 (3.6%) 1 (0.7%) 4 (2.9%)
TEAE leading to treatment discontinuation	14 (10.0%)	11 (7.9%)

Kim WS, et al. ASH annual meeting 2022, abstract #444.

Odronextamab phase 2 DLBCL expansion cohort – CRS

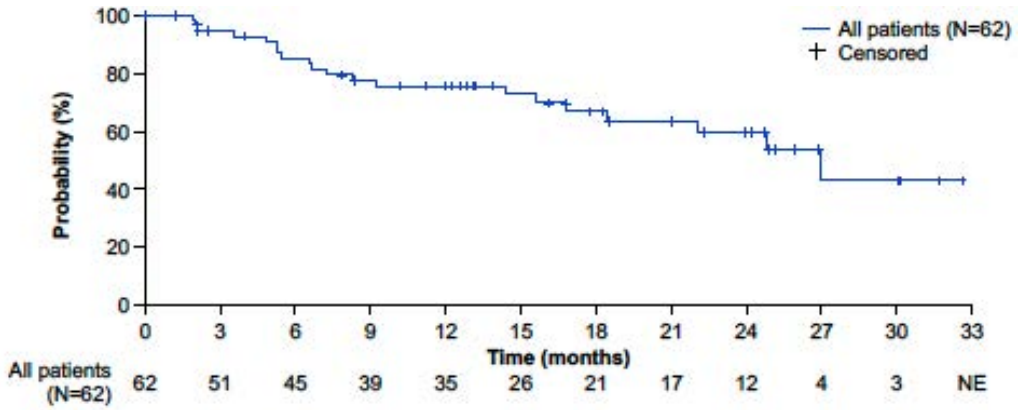
n, (%)	1/20 regimen N=67	0.7/4/20 regimen N=73
CRS any Grade	38 (56.7%)	39 (53.4%)
Grade 1	21 (31.3%)	28 (38.4%)
Grade 2	12 (17.9%)	10 (13.7%)
Grade 3	5 (7.5%)	1 (1.4%)
Grade 4	0	0
Grade 5	0	0
Received corticosteroids	13 (19.4%)	15 (20.5%)
Received tocilizumab	10 (14.9%)	19 (26.0%)
Received vasopressors	5 (7.5%)	1 (1.4%)



Kim WS, et al. ASH annual meeting 2022, abstract #444.

Duration of CR for Bispecifics with Longer Follow-up

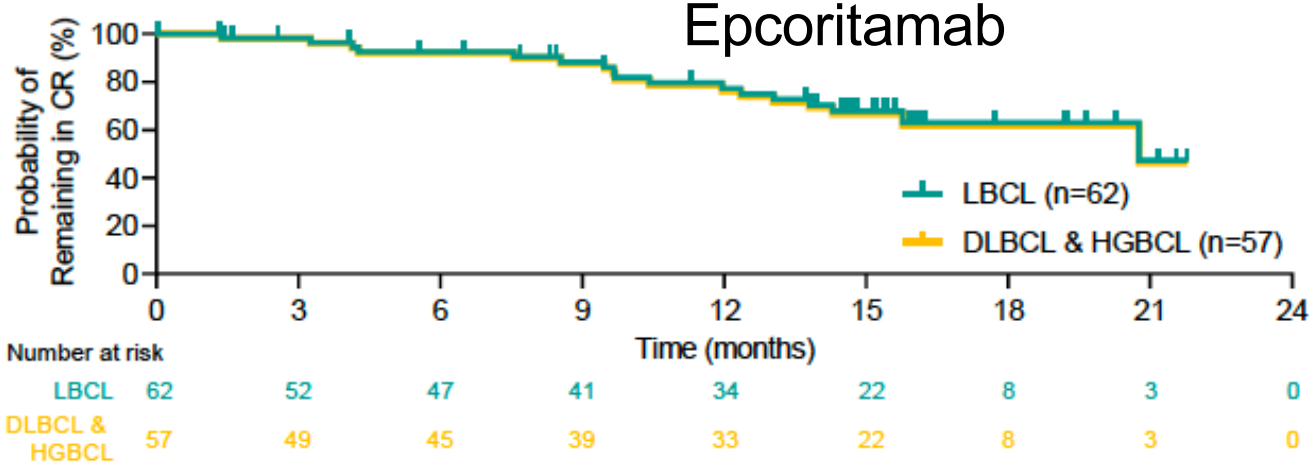
Glofitamab



Median time on study 21.2 m

Falchi et al, ASCO 2023

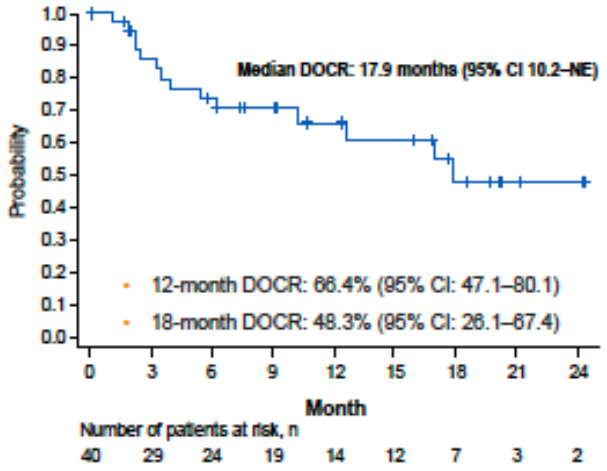
Epcoritamab



Median follow-up 20.0 m

Karimi et al, ASCO 2023

Odronextamab

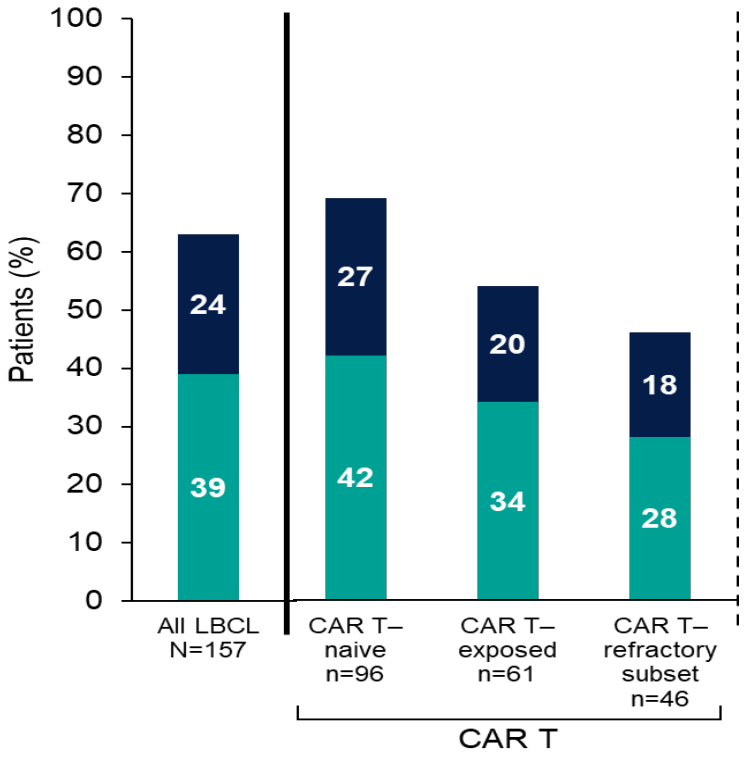


Median follow-up 21.3 m

Walewski EHA 2023

Benefit Comparable in Post CAR T-cell Patients

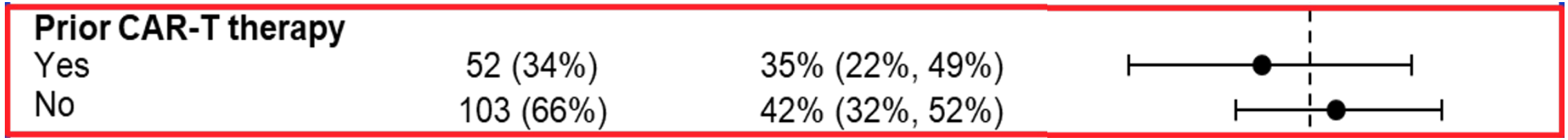
Epcoritamab



Odronextamab

Best overall response	All Independent central review N=130*	Prior CAR- T Independent central review N=31
Objective response rate (ORR)†	**49.2%** [95% CI 40.4%–58.1%]	**48.4%** [95% CI 30.2%–66.9%]
Complete response	**30.8%**	**32.3%**
Partial response	18.5%	16.1%
Stable disease	3.8%	6.5%
Progressive disease	22.3%	9.7%

Glofitamab – Complete Response



Thieblemont C et al. EHA 2022;Abstract LB2364. Kim WS et al. ASH 2022;Abstract 444. Dickinson MJ et al. *N Engl J Med* 2022;387:2220-31.

Mosunetuzumab Plus Polatuzumab Vedotin in R/R B-cell NHL

- Phase Ib/II dose-escalation and dose-expansion study in patients with R/R B-NHL

Key inclusion criteria

- DLBCL (*de novo* DLBCL, transformed FL, or Grade 3b FL): Phase Ib AND Phase II
- FL Grade 1–3a: Phase Ib only

Primary objectives

- Efficacy of M-Pola in patients with R/R B-NHL
- Safety and tolerability of M-Pola in patients with R/R B-NHL

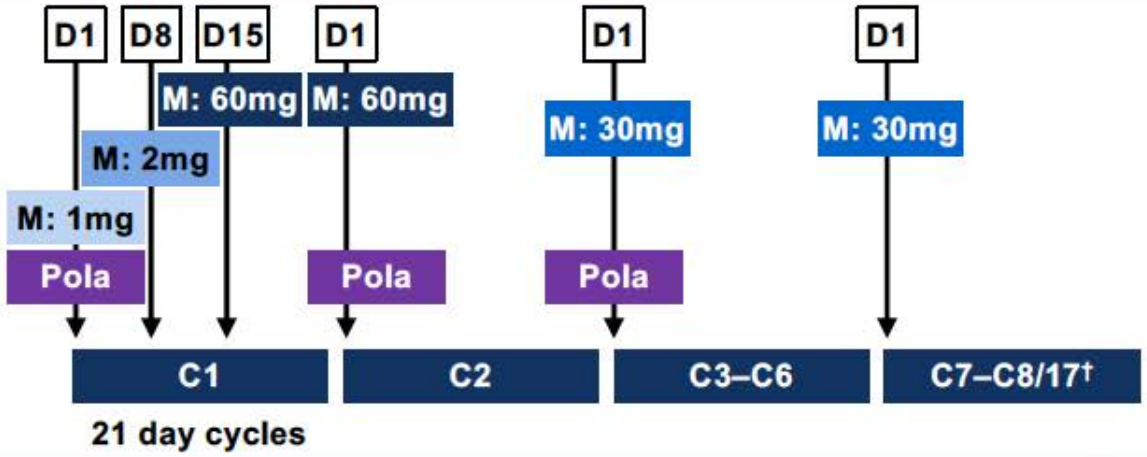
M-Pola administration in Phase II expansion*

Mosunetuzumab

- Q3W intravenous infusions at RP2D (C1–8/17)†
- C1 step-up dosing for CRS mitigation
- **No mandatory hospitalization**

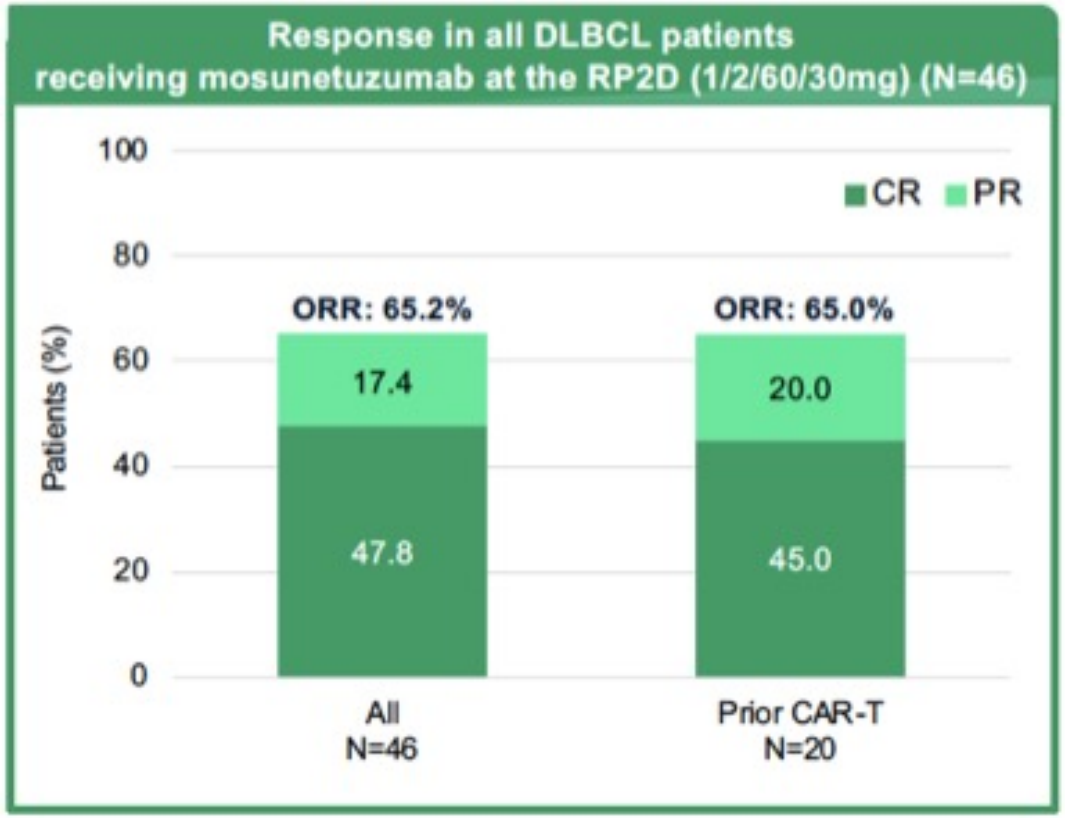
Polatuzumab vedotin

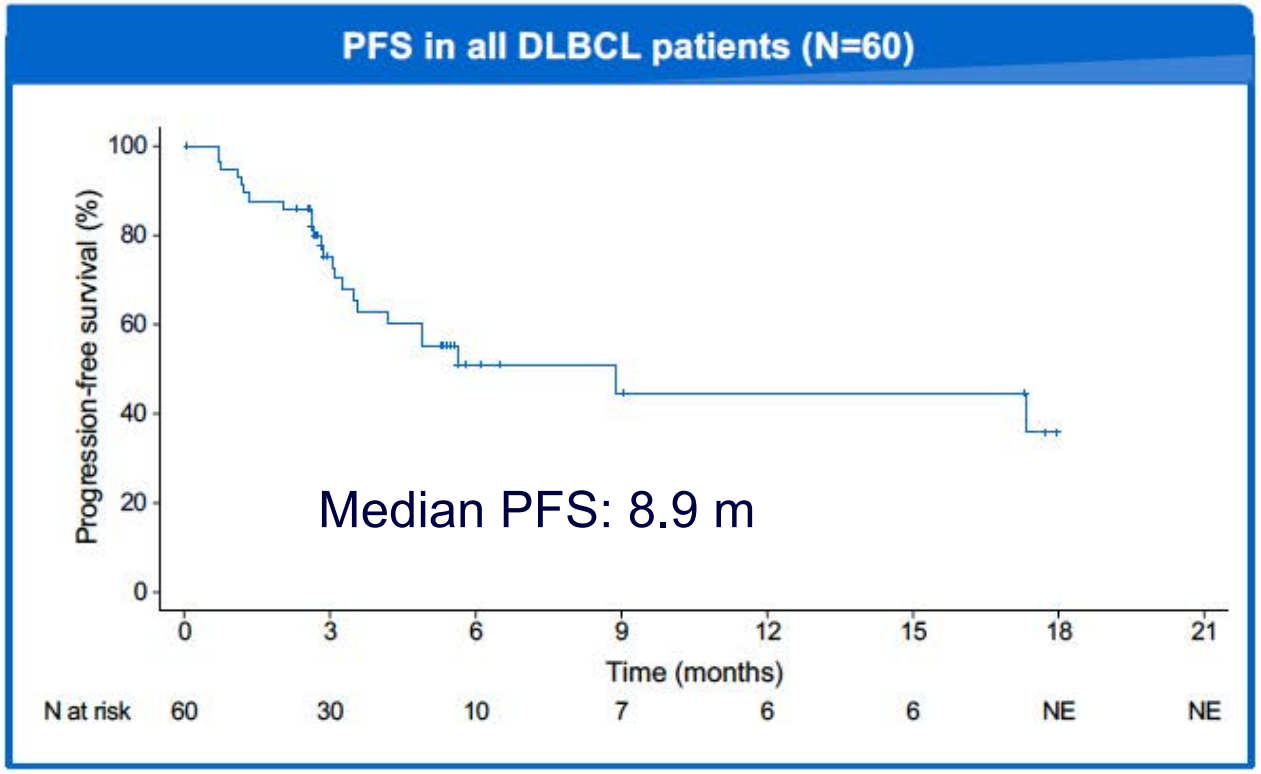
- Q3W intravenous infusions (1.8mg/kg) (D1 C1–6)



Budde E et al, ASH 2021

Mosunetuzumab Plus Polatuzumab Vedotin: Efficacy in DLBCL

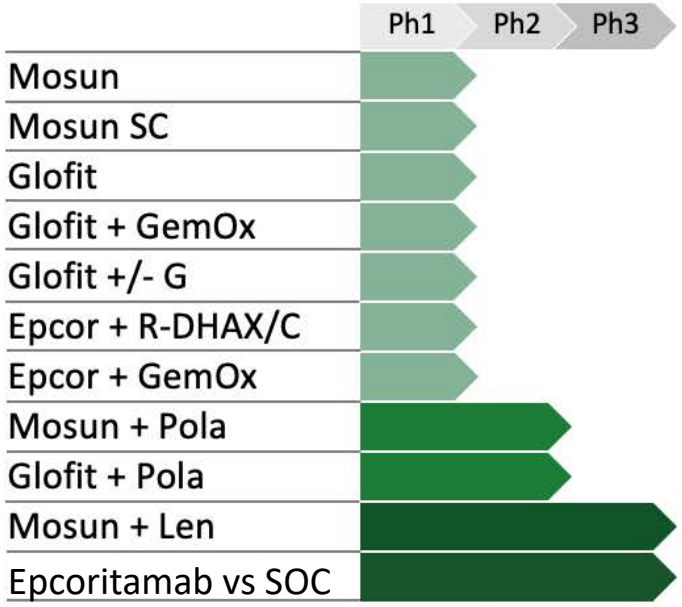




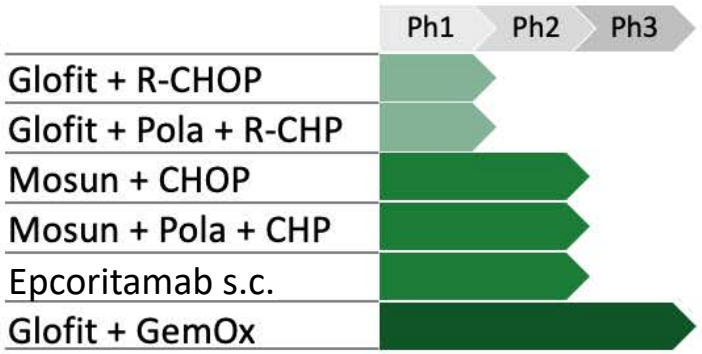
Budde E et al, ASH 2021

Ongoing Combination Studies with CD3xCD20 Bispecific Antibodies in DLBCL

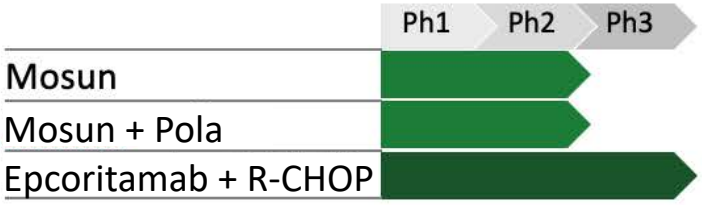
R/R DLBCL



1st Line DLBCL



Elderly/Unfit DLBCL



EPCORE™ NHL-2 Arm 1: Epcoritamab + R-CHOP

A phase 1b/2, open-label trial evaluating the safety and antitumor activity of epcoritamab + R-CHOP in adults with previously untreated DLBCL[a]

Key inclusion criteria

- Newly diagnosed CD20+ DLBCL[b]
  - DLBCL, NOS
  - T-cell/histiocyte-rich DLBCL
  - Double-hit or triple-hit DLBCL[c]
  - FL grade 3B
- IPI score ≥3
- ECOG PS 0–2
- Measurable disease by CT or MRI
- Adequate organ function

Data cutoff: January 31, 2023
Median follow-up: 14.2 mo
ClinicalTrials.gov: NCT04663347

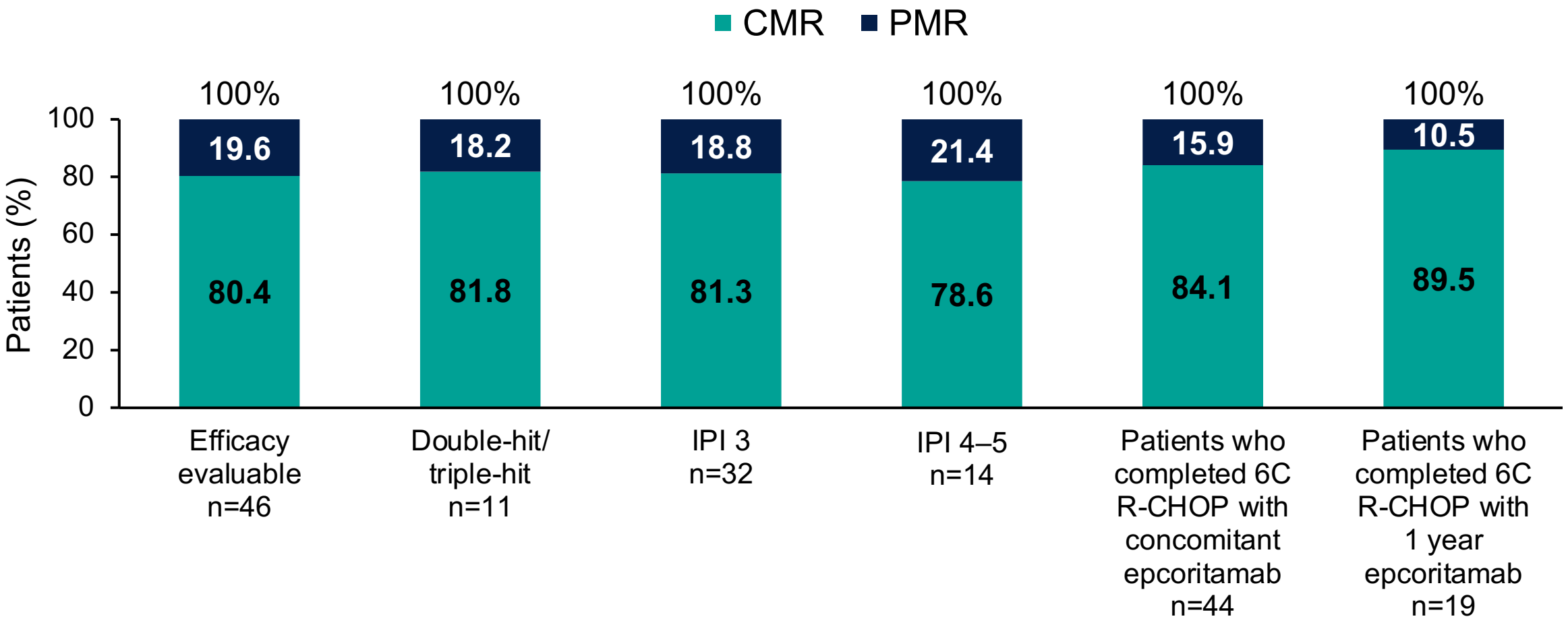
Treatment regimen: Concomitant epcoritamab SC 48 mg + R-CHOP

	Agent	C1–C4	C5–C6	C7+
	Epcoritamab SC 48 mg	QW	Q3W	Q4W Up to 1 year
R-CHOP	Rituximab IV 375 mg/m^2	Q3W		
R-CHOP	Cyclophosphamide IV 750 mg/m^2			
R-CHOP	Doxorubicin IV 50 mg/m^2			
R-CHOP	Vincristine[d] IV 1.4 mg/m^2			
R-CHOP	Prednisone IV or oral 100 mg/d	D1–5 of each cycle		

Primary objective: Antitumor activity[e]

[a]Patients received SC epcoritamab with 2 step-up doses (SUD) before the first full dose and corticosteroid prophylaxis to mitigate CRS. R-CHOP was given in 21-d cycles. Subsequent cycles of epcoritamab were 28 d. [b]De novo or histologically transformed from FL or nodal marginal zone lymphoma. [c]Classified as HGBCL, with *MYC* and *BCL2* and/or *BCL6* translocations. [d]Recommended maximum 2 mg. [e]Tumor response was evaluated by PET-CT obtained at 6, 12, 18, 24, 36, and 48 wk, and every 24 wk thereafter, until disease progression.

High Rates of Complete Response Across Subgroups



Data cutoff: January 31, 2023. Best response was based on modified response-evaluable population, defined as patients with ≥1 target lesion at baseline and ≥1 postbaseline response evaluation and patients who died within 60 d of first trial treatment prior to first assessment. One patient was not considered response evaluable because this patient withdrew consent from the trial without receiving a response evaluation.

Cases from the Community: Investigators Discuss the Application of Available Research in the Care of Patients with Diffuse Large B-Cell Lymphoma

A CME Satellite Symposium During the Society of Hematologic Oncology 2023 Annual Meeting

Friday, September 8, 2023
11:37 AM – 12:37 PM CT

Faculty

Matthew Lunning, DO
Laurie H Sehn, MD, MPH

Moderator

Christopher R Flowers, MD, MS

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Spencer Henick Bachow, MD
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Shams Bufalino, MD
Advocate Aurora Health
Park Ridge, Illinois

Shaachi Gupta, MD, MPH
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Kimberly Ku, MD
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Neil Morganstein, MD
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Priya Rudolph, MD
Georgia Cancer Specialists
Athens, Georgia

Erik Rupard, MD
Drexel University College of Medicine
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