Polatuzumab Vedotin

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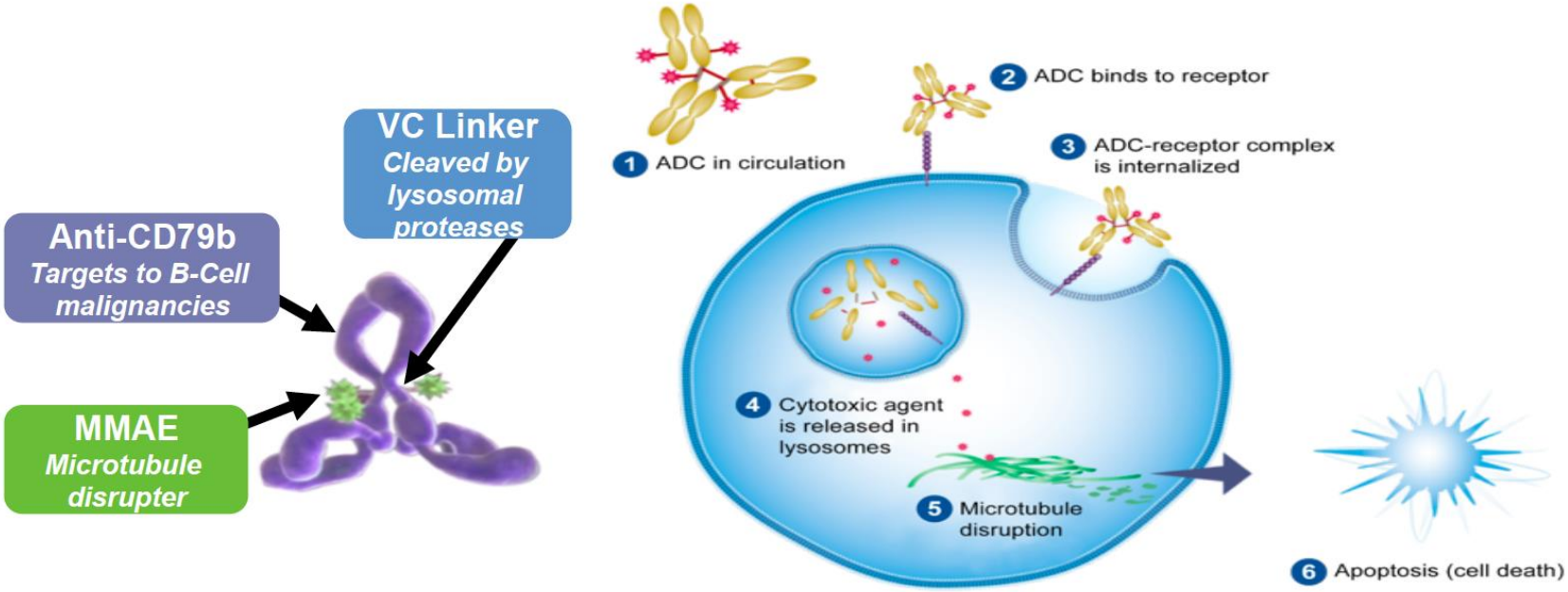
Disclosures

- Consulting/Honoraria: Abbvie, AstraZeneca, BMS/Celgene, Kite/Gilead, Incyte, Janssen, Merck, Roche/Genentech, Sandoz, Seagen, Teva, Takeda, TG Therapeutics

- Research funding: Teva, Roche/Genentech

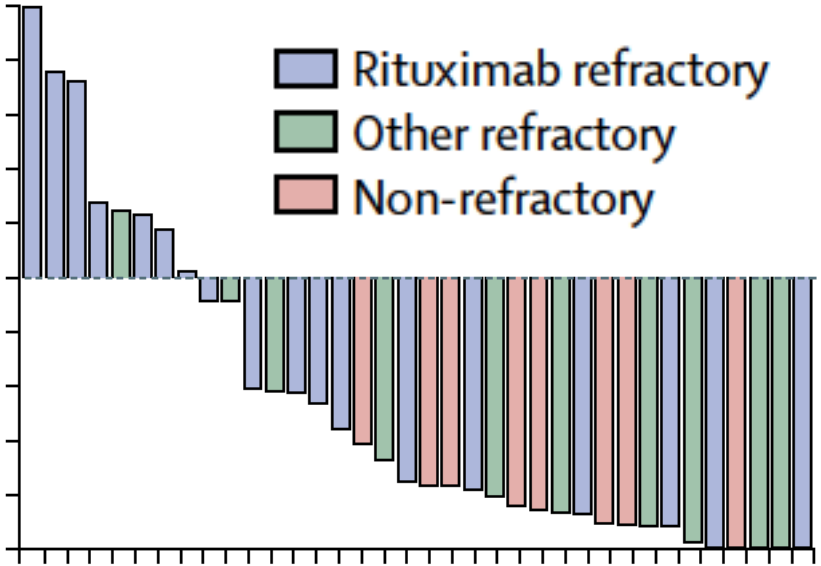
Polatuzumab Vedotin: Anti-CD79b Drug Conjugate

- Microtubule inhibitor MMAE conjugated to CD79b monoclonal antibody via a protease-cleavable peptide linker



Polatuzumab Vedotin: Early Studies

- Efficacy seen in a variety of B-cell NHL subtypes
- Response rates improved with rituximab
- In rel/refr DLBCL: Pola-R induced ORRs up to 54% (CR ~21%)

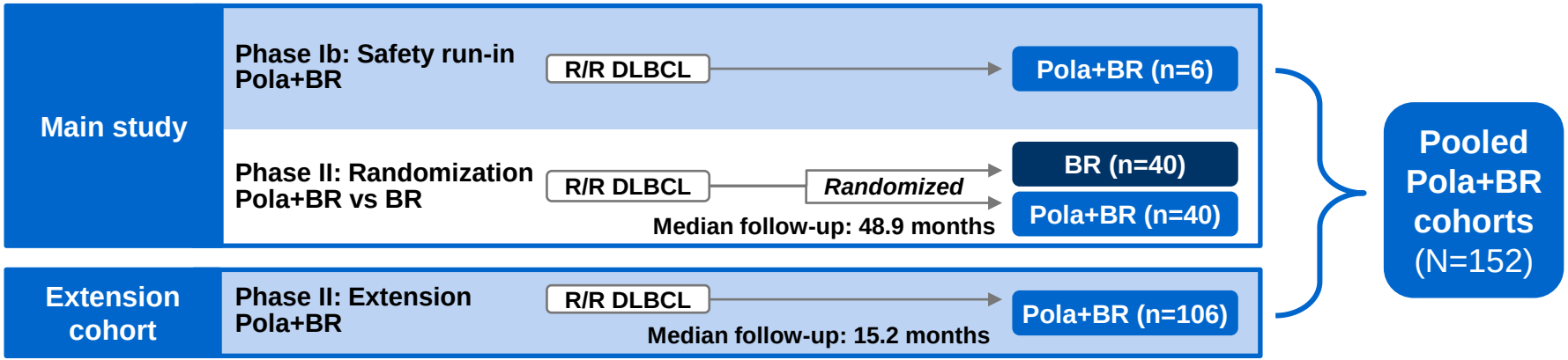


Morchhauser et al, Lancet Hematol 2019

GO29365 Phase 1b/2 Study: Pola-BR in ASCT-Ineligible DLBCL

Inclusion: transplant-ineligible DLBCL, ≥1 line of therapy

Exclusion: prior allo-SCT; history of transformation; current grade >1 PN



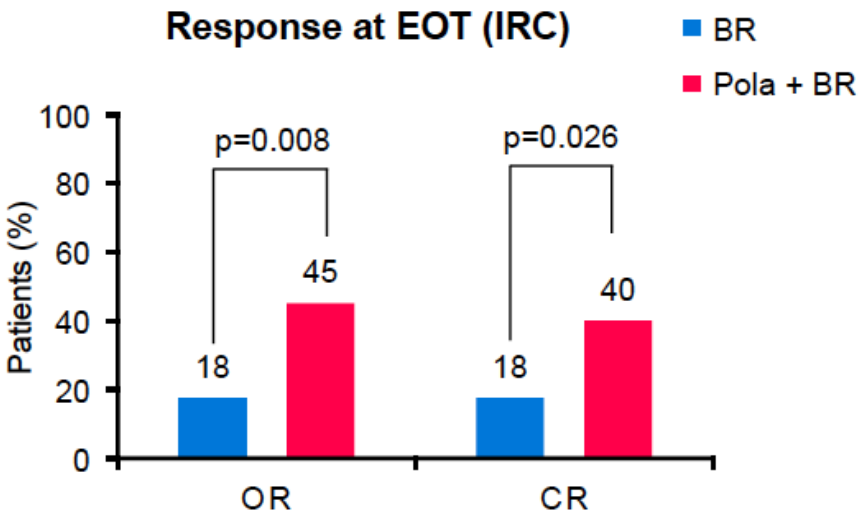
*Pola 1.8 mg/kg on D1 of each cycle of BR; up to 6 cycles at 3-weekly interval

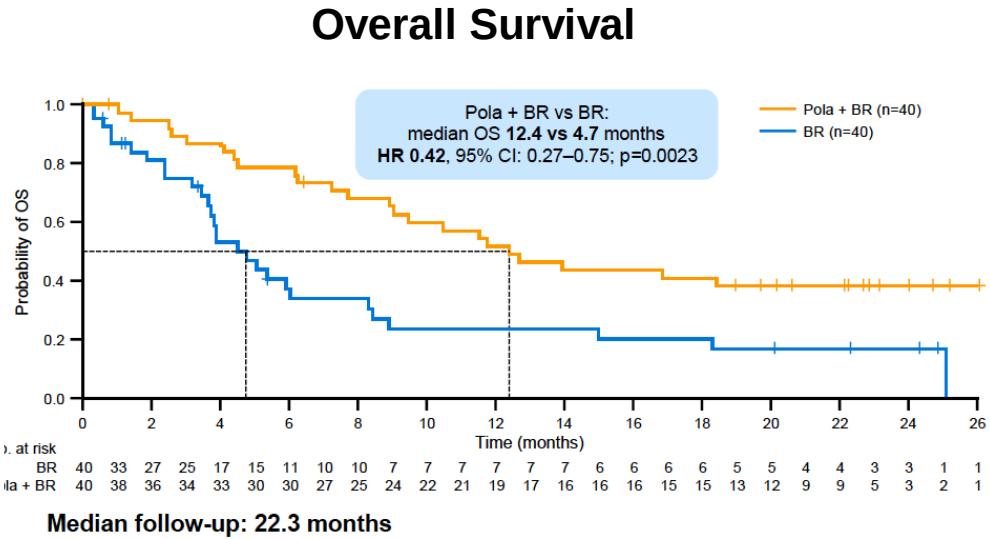
Patient Characteristics: Randomized and Extension Cohorts

	Randomized		Extension cohort	Pooled Pola+BR*
	BR (N=40)	Pola+BR (N=40)	Pola+BR (N=106)	Pola+BR (N=152)
Median age, years (range)	71 (30–84)	67 (33–86)	70 (24–94)	69 (24–94)
Male, n (%)	25 (62.5)	28 (70.0)	52 (49.1)	84 (55.3)
ECOG PS score, n (%)				
0–1	31 (77.5)	33 (82.5)	92 (86.8)	131 (86.2)
2	8 (20.0)	6 (15.0)	14 (13.2)	20 (13.2)
Ann Arbor Stage III/IV at study entry, n (%)	36 (90.0)	34 (85.0)	84 (79.0)	122 (80.0)
IPI score 3–5 at enrollment, n (%)	29 (72.5)	22 (55)	70 (66.0)	94 (61.8)
Median no. of prior therapies (range)	2 (1–5)	2 (1–7)	2 (1–7)	2 (1–7)
1 line	12 (30.0)	11 (27.5)	37 (34.9)	50 (32.9)
2 lines	9 (22.5)	11 (27.5)	27 (25.5)	42 (27.6)
3 lines	10 (25.0)	12 (30.0)	19 (17.9)	31 (20.4)
≥4 lines	9 (22.5)	6 (15.0)	23 (21.7)	29 (19.1)
Prior stem cell transplant, n (%)	6 (15.0)	10 (25.0)	17 (16.0)	27 (17.8)
Primary refractory, n (%)	28 (70.0)	21 (52.5)	73 (68.9)	97 (63.8)
Refractory to last prior therapy, n (%)	33 (82.5)	30 (75.0)	81 (76.4)	116 (76.3)

Sehn et al, Blood Advances 2021

Randomized Phase II: Pola-BR vs BR

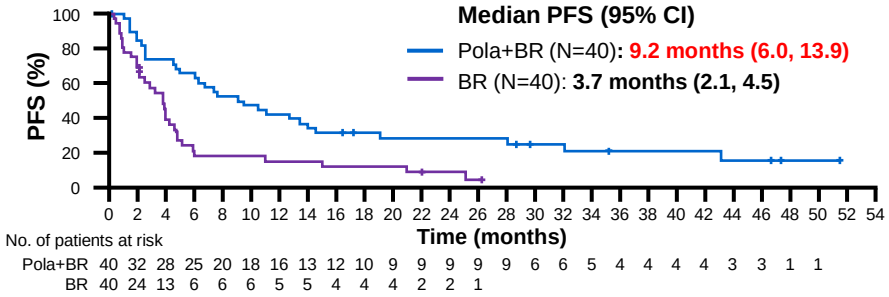


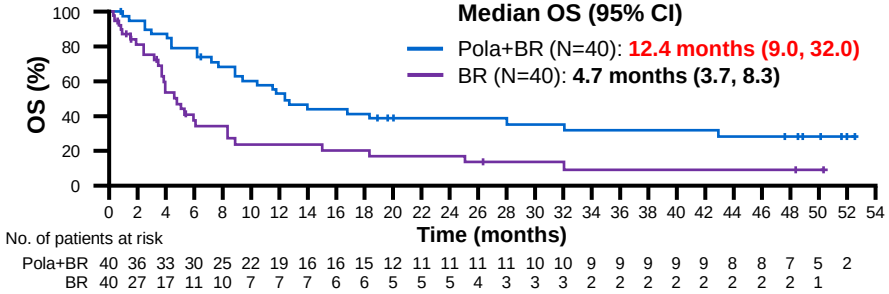


Sehn et al, JCO 2020

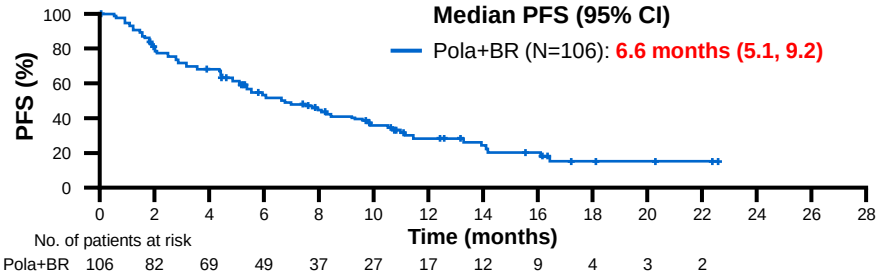
PFS and OS in Randomized and Extension Cohorts

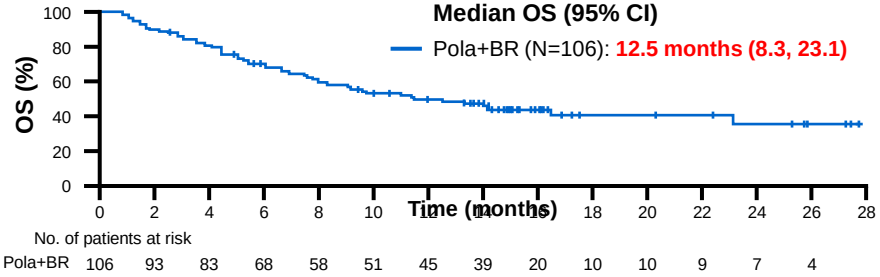
Randomized





Extension cohort





<u>Randomized cohort</u>:

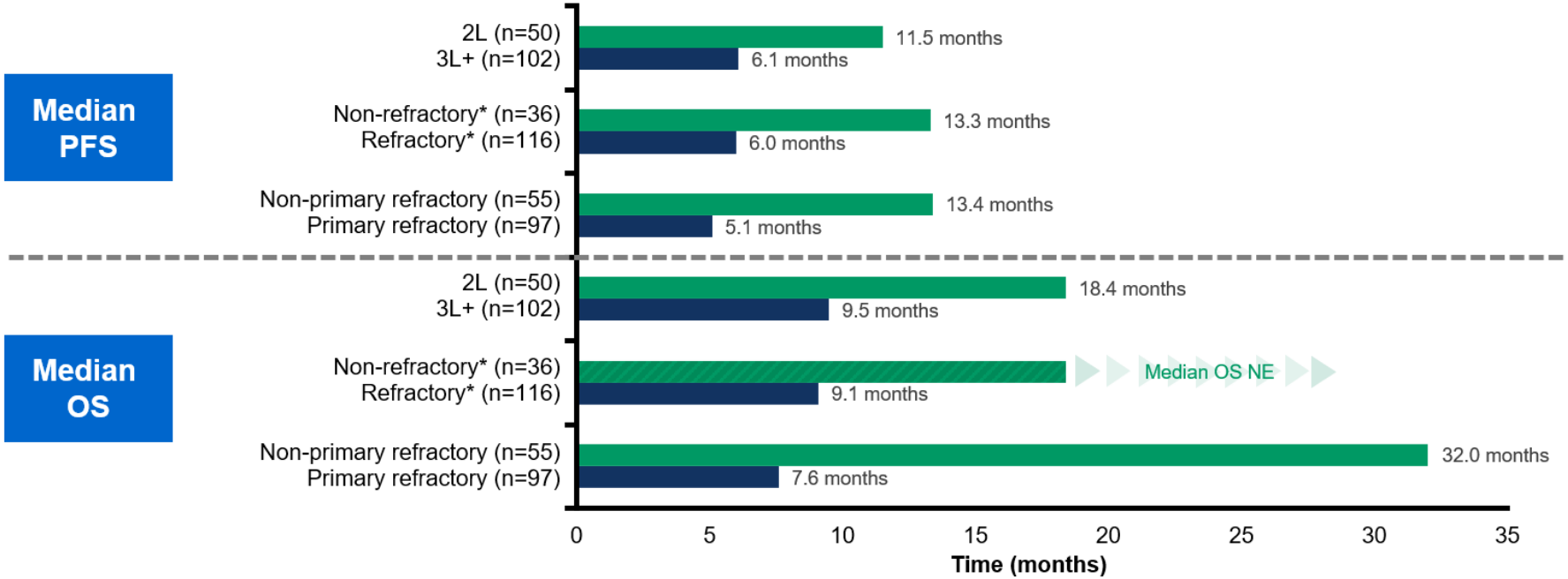
- Survival benefit persists with longer follow-up
- 2-y PFS: 28.4%, 2-y OS was 38.2%

<u>Pooled cohort</u>:

- Non-primary refractory patients:
  Median PFS: 13.4 m, median OS: 32 m

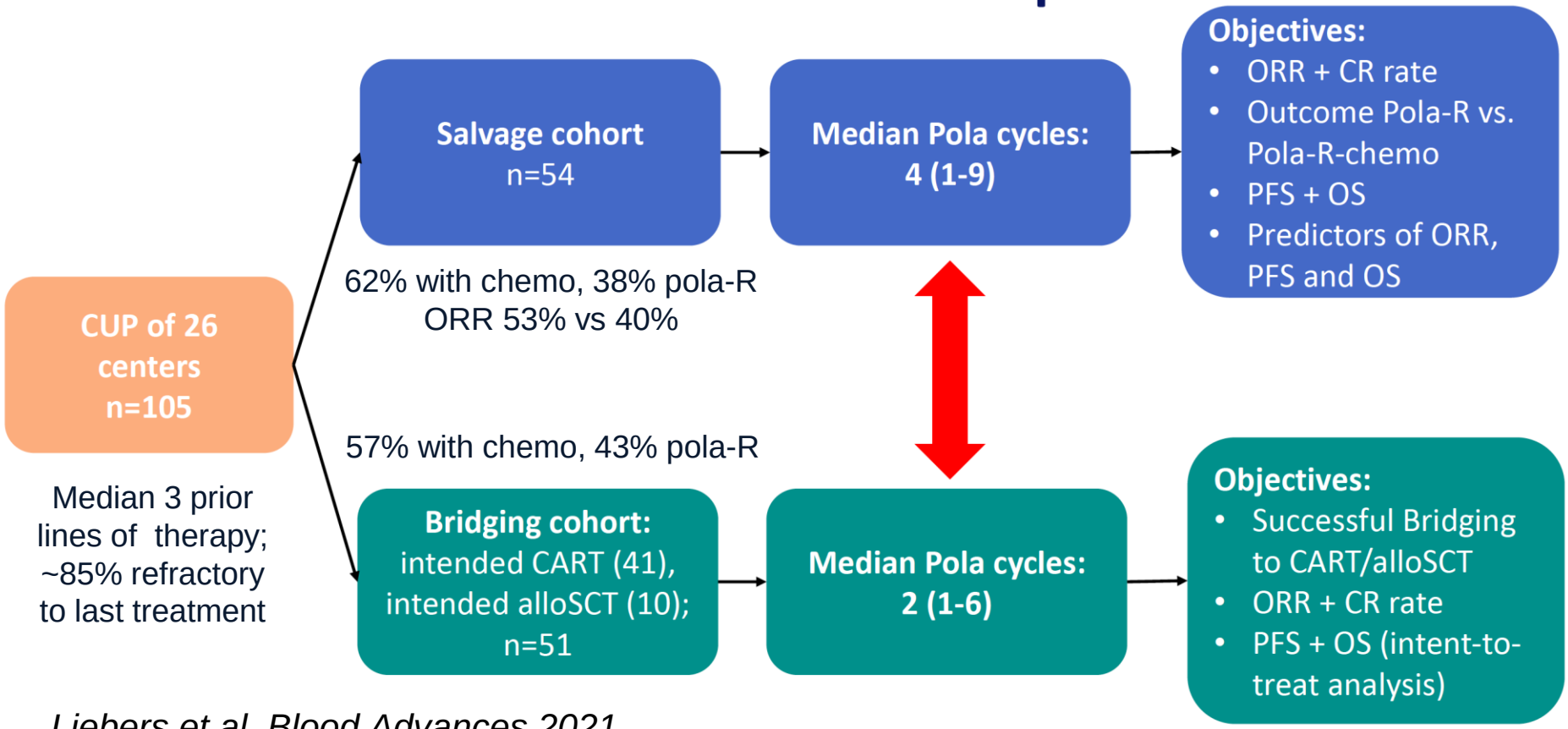
Sehn et al, Blood Advances 2021

Median PFS and OS in the Pooled Pola+BR cohort according to line of therapy and refractory status



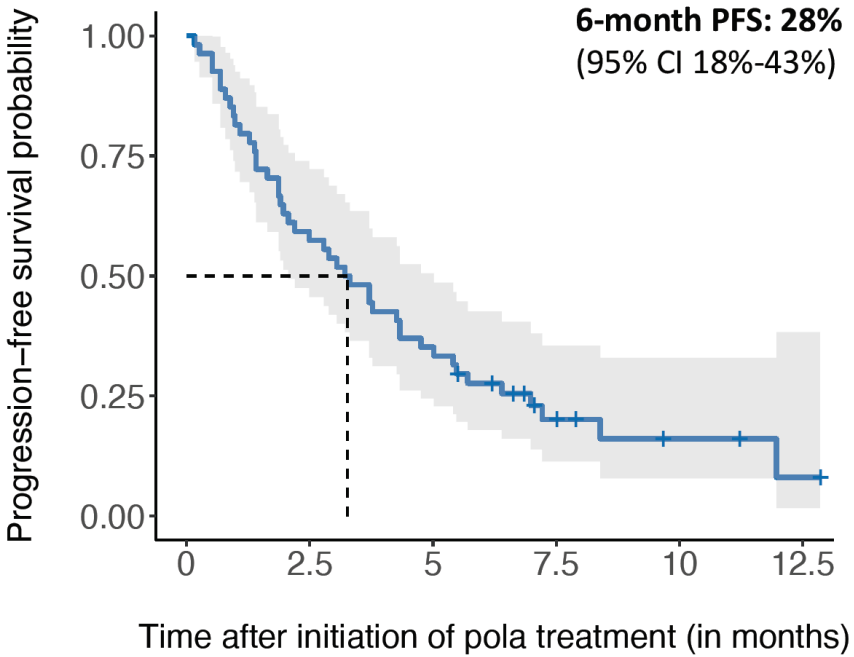
Sehn L et al. Blood Advances 2022

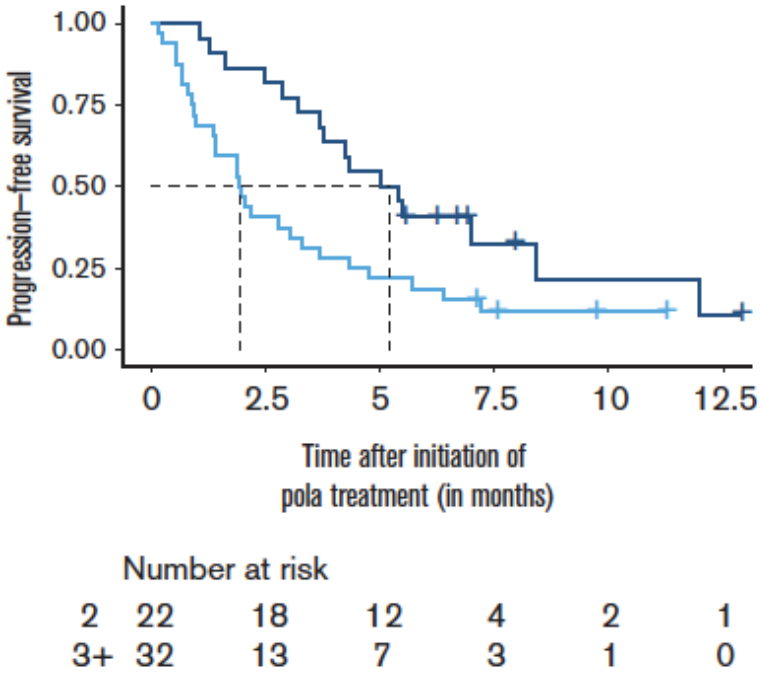
Pola as salvage treatment and as bridging treatment to cellular immunotherapies



Liebers et al, Blood Advances 2021

Outcome of Salvage Cohort



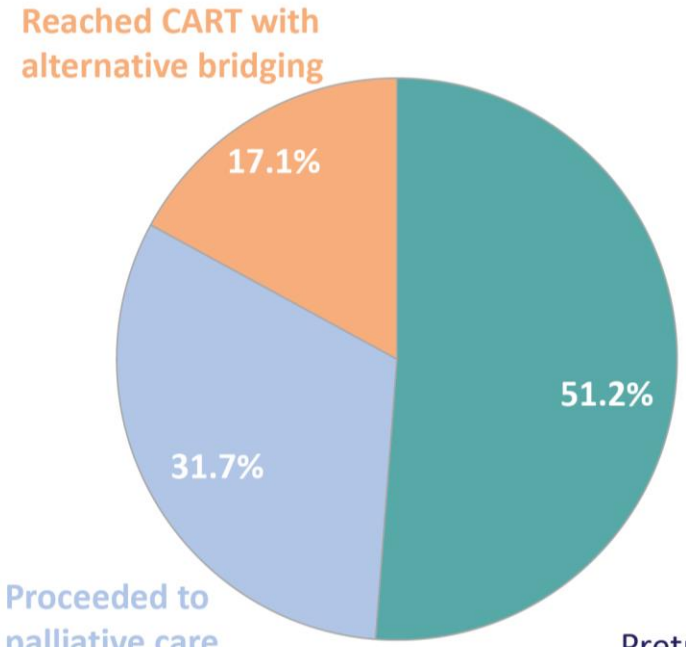


n=54; median follow-up 7.5 m

ORR 48%, CR 15%

Liebers et al, Blood Advances 2021

Bridging Cohort to Intended CAR-T

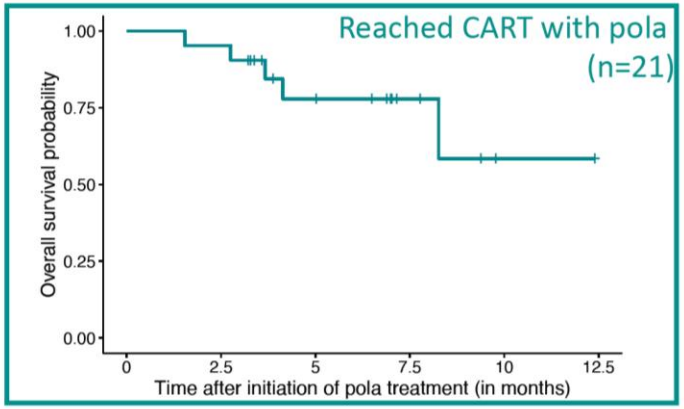


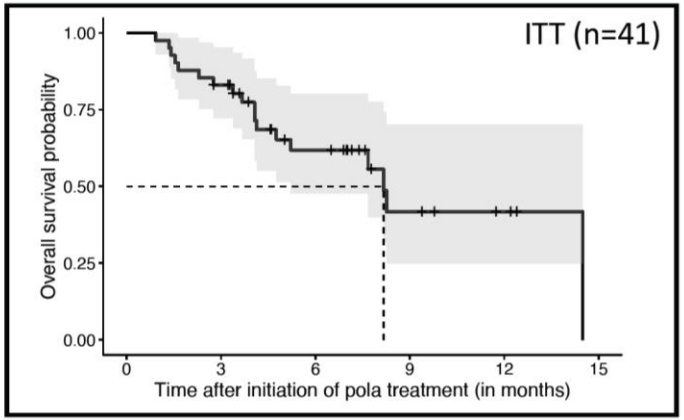
Reached CART with Pola-bridging

2/10 Pola-BR patients needed 2 leukaphereses, 1 failed

Pretreatment

5/41 patients had previous alloHCT





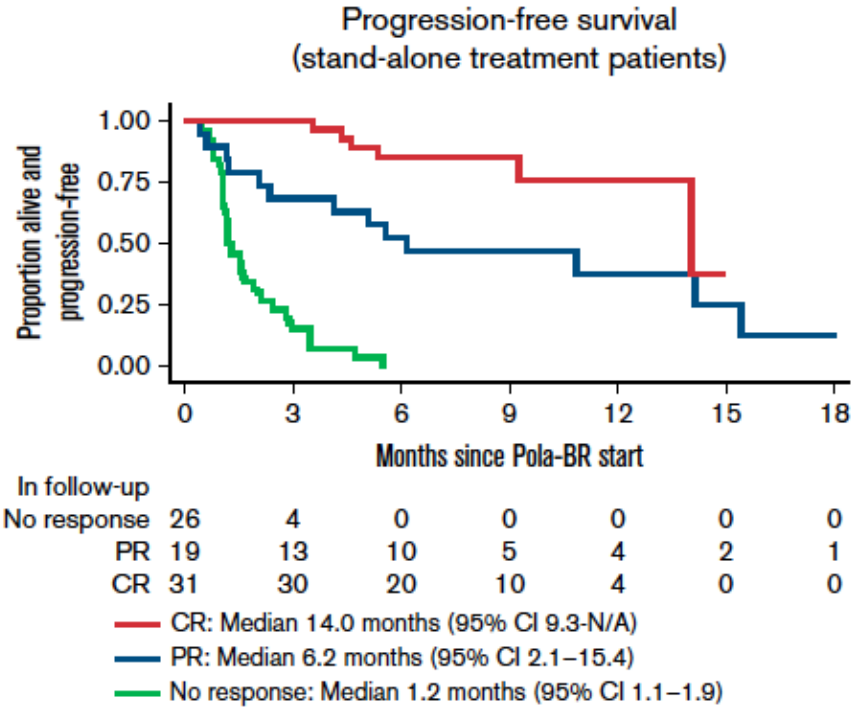
Liebers et al, Blood Advances 2021

Real-World Assessment of Pola-BR in R/R DLBCL

- Retrospective UK cohort, access program
- Median follow-up 7.7 m
- >85% received bendamustine

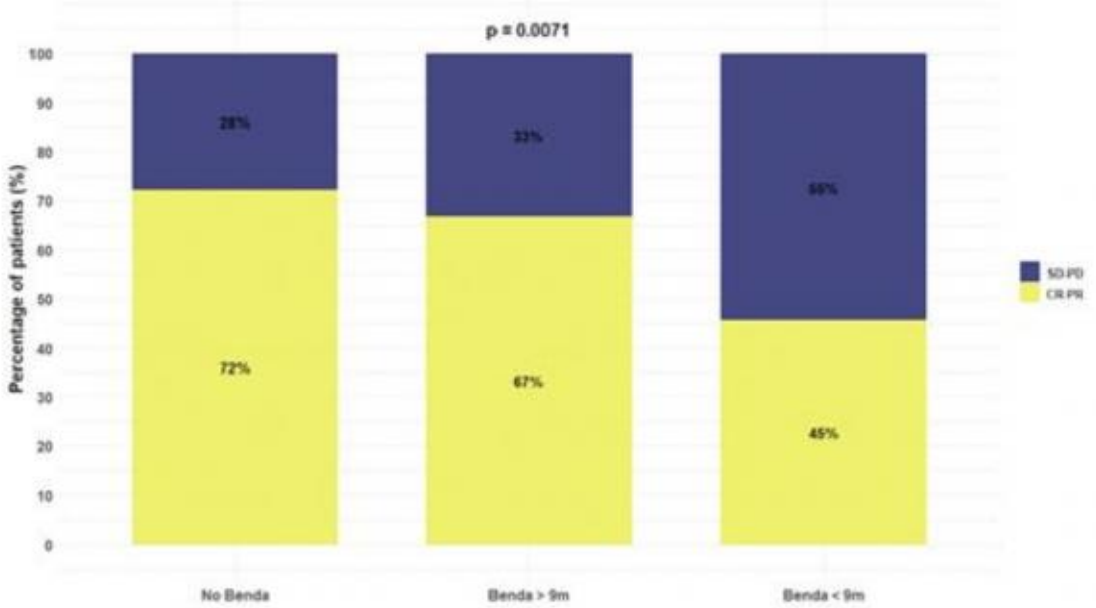
- Stand-alone therapy n=78
  - median age 75 y, median prior lines 1
  - Median cycles: 4
  - ORR 65.8% (39.7%CR, 24.4% PR)
  - Median PFS: 5.4 m (95%CI 3.0-10.8)

- Bridge to CAR T-cell therapy n=40
  - median age 67 y, median prior lines 2
  - Median cycles: 1
  - ORR 42.1% (17.5%CR, 22.5% PR)
  - 77.5% received CAR T-cell therapy



Northend M et al. Blood Advances 2022

Prior Bendamustine Negatively Impacts CAR T-cell Outcomes in DLBCL



Altered T-cell composition and T-cell peak expansion

Iacoboni G et al. ASH 2022

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

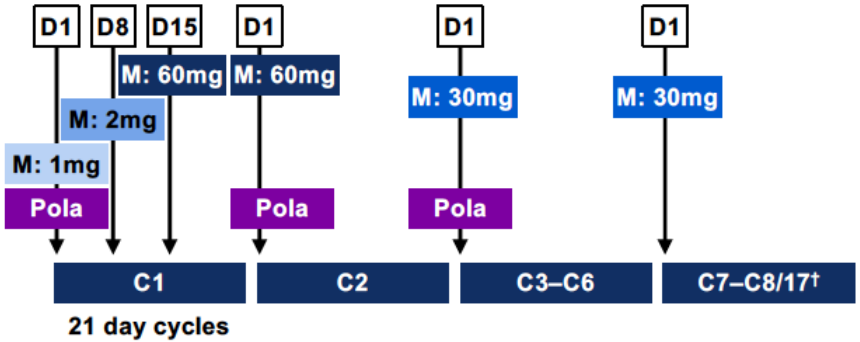
M-Pola administration in Phase II expansion*

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

Baseline patient and disease characteristics

N (%) unless stated	All patients N=63	DLBCL patients N=60
Median age, years (range)	68 (20–83)	68 (20–83)
Male	39 (61.9)	37 (61.7)
ECOG PS at entry		
0–1	59 (93.7)	56 (93.3)
2	4 (6.3)	4 (6.7)
Histology		
DLBCL	60 (95.2)	60 (100)
de novo DLBCL	44 (69.8)*	44 (73.3)
transformed FL	12 (19.0)†	12 (20.0)
Grade 3b FL	4 (6.3)	4 (6.7)
FL Grade 1–3a	3 (4.8)	0
Bulky disease (≥10 cm)	6 (9.5)	6 (10.0)

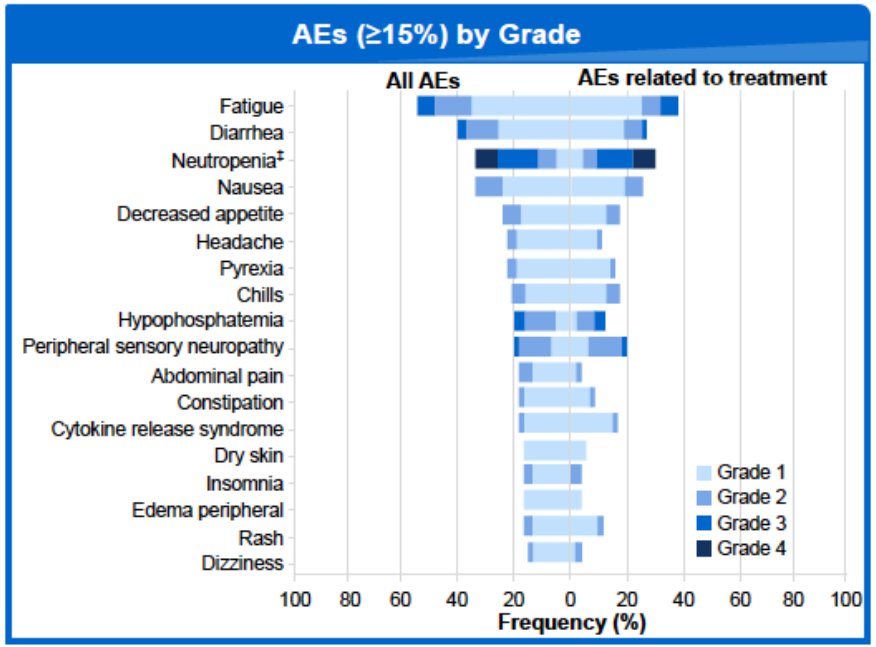
N (%) unless stated	All patients N=63	DLBCL patients N=60
Ann Arbor stage at entry		
I–II	13 (20.6)	12 (20.0)
III–IV	50 (79.4)	48 (80.0)
Number of prior lines of therapy		
1–2	24 (38.1)	24 (40.0)
3+	39 (61.9)	36 (60.0)
Median prior lines of therapy, range	3 (1–10)	3 (1–8)
Prior CAR-T therapy	25 (39.7)	24 (40.0)
Refractory to last prior therapy	48 (76.2)	46 (76.7)

Budde E et al, ASH 2021

Adverse event overview: manageable safety profile

- Median time on study: 5.7 months (range: 0.7–27.5)

N (%)	N=63
AE M-Pola related	62 (98.4) 55 (87.3)
Grade 3–4 AE M-Pola related	33 (52.4) 23 (36.5)
Serious AE M related / Pola related	24 (38.1) 13 (20.6) / 8 (12.7)
Grade 5 (fatal) AE* M-Pola related	3 (4.8)† 1 (1.6)
AE leading to M discontinuation M related	5 (7.9) 3 (4.8)
AE leading to Pola discontinuation Pola related	8 (12.7) 6 (9.5)



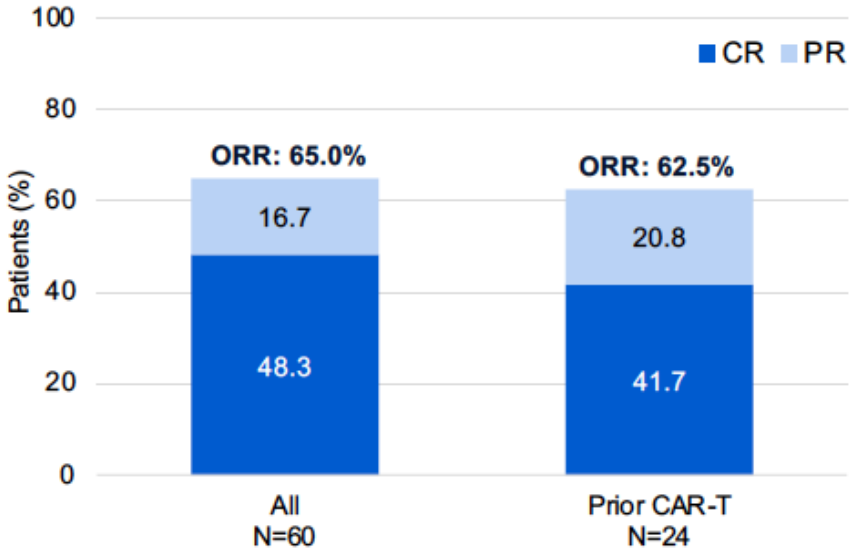
- **The majority of AEs were low Grade**

CRS 15.9% grade 1; 1.6% grade 2

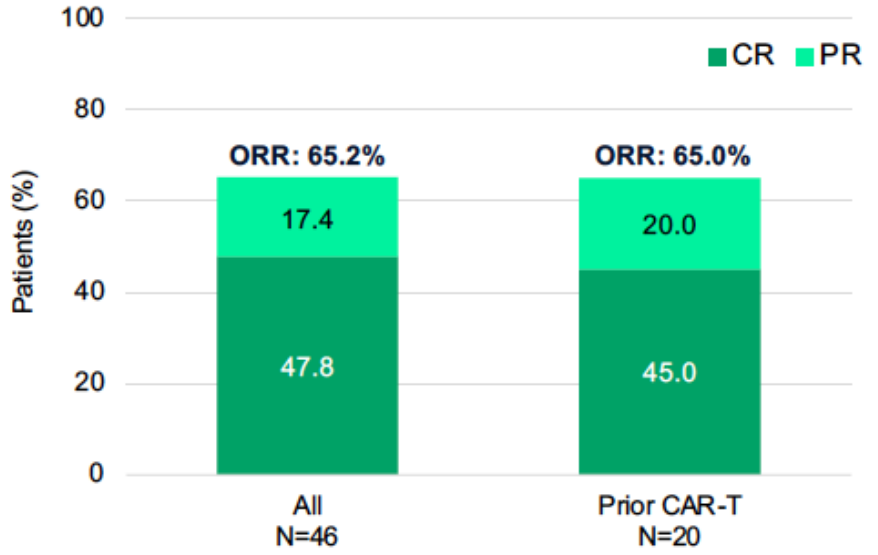
Response in DLBCL patients*

- Median duration of response in all DLBCL patients: NR (95% CI: 6.3, NE)

Response in all DLBCL patients receiving mosunetuzumab at 1/2/9mg to 1/2/60/30mg (N=60)



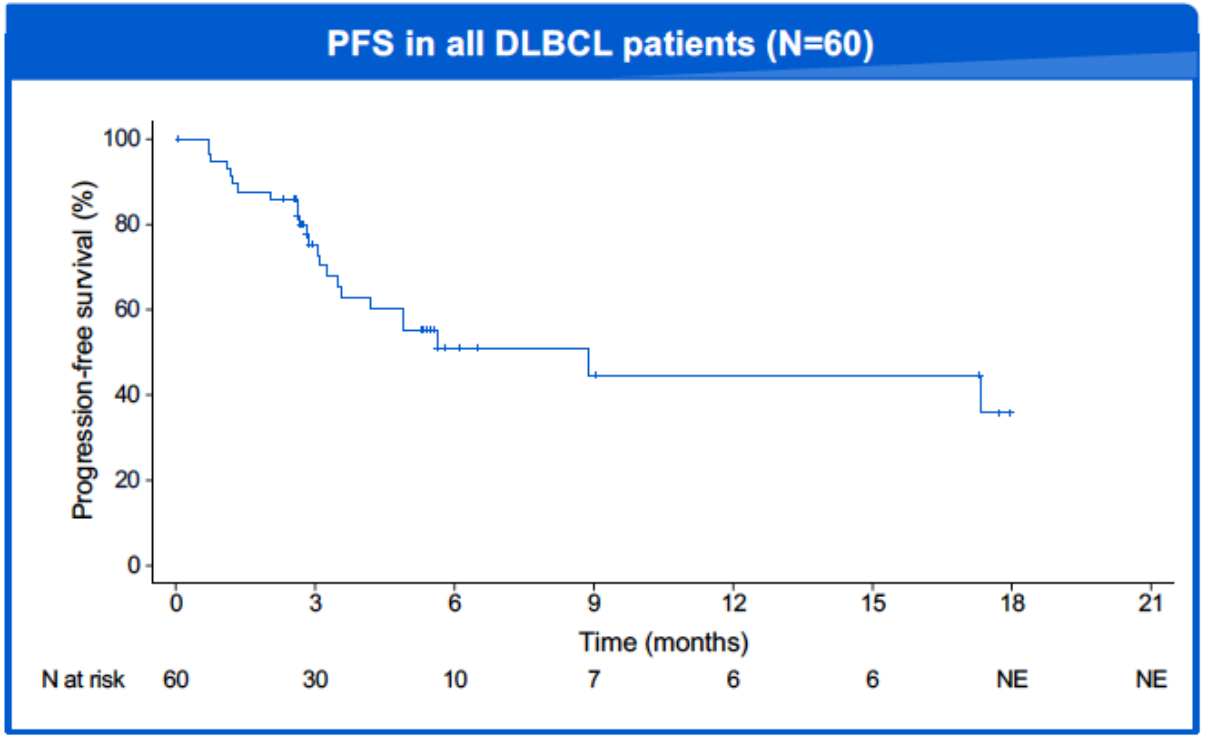
Response in all DLBCL patients receiving mosunetuzumab at the RP2D (1/2/60/30mg) (N=46)



Mosun alone (median prior tx 3): ORR 42%; CR 24%, Bartlett et al Blood Adv 2023

Budde E et al, ASH 2021

Progression-free survival



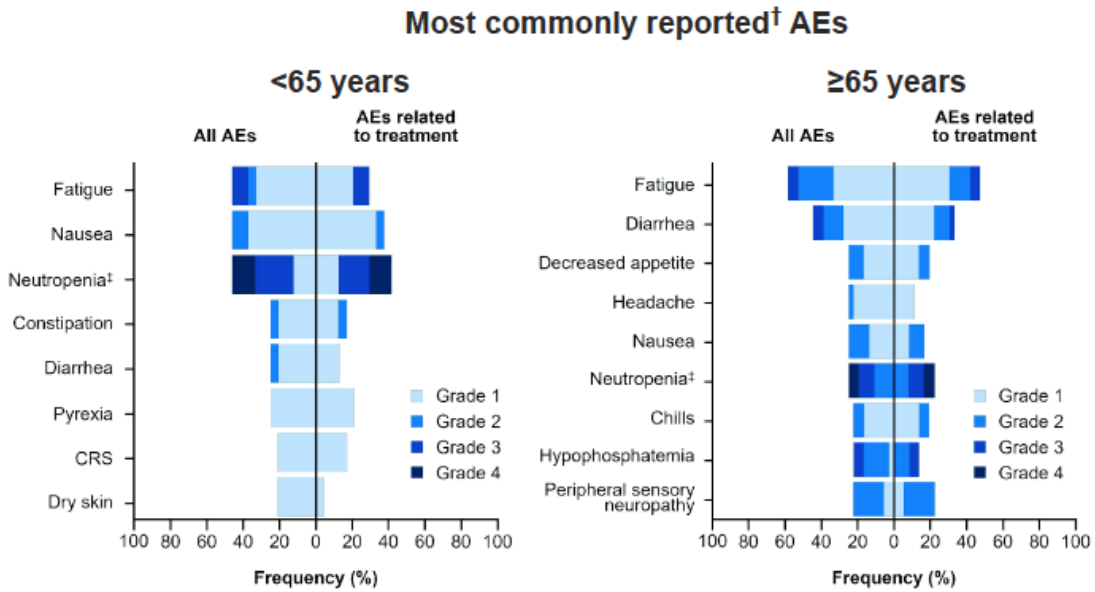
- Median PFS: 8.9 months (95% CI: 3.5, NE)
- PFS data are immature

- Of 29 patients who achieved CR, 28 (96.6%) remained in CR and 1 (3.4%) had PD
  - the patient with PD subsequently received retreatment and achieved a CR

Budde E et al, ASH 2021

M-Pola had a manageable safety profile in younger and older patients

n (%)	<65 years n=24	≥65 years n=36
AE	23 (96)	36 (100)
M-Pola related	20 (83)	33 (92)
Grade 3/4 AE	14 (58)	14 (39)
M-Pola related	9 (38)	12 (33)
Serious AE	8 (33)	14 (39)
M-Pola related	4 (17)	8 (22)
Grade 5 (fatal AE)*	0	3 (8)
M-Pola related	0	1 (3)
AE leading to M discontinuation	0	4 (11)
M related	0	2 (6)
AE leading to Pola discontinuation	1 (4)	6 (17)
Pola related	1 (4)	4 (11)



*Fatal AEs not including progressive disease: pneumonia (M-Pola related), respiratory failure, sudden cardiac death (all n=1). †≥20% of patients.
‡Grouped term including preferred term 'neutropenia' and 'neutrophil count decreased'. AE, adverse event.

Olszewski, A ASH 2022

Glofitamab Plus Polatuzumab Vedotin in R/R DLBCL

Key inclusion criteria (DLBCL arm)

- Age ≥18 years
- R/R DLBCL (including trFL and HGBCL)
- ECOG performance status 0–2

Objectives

Primary:

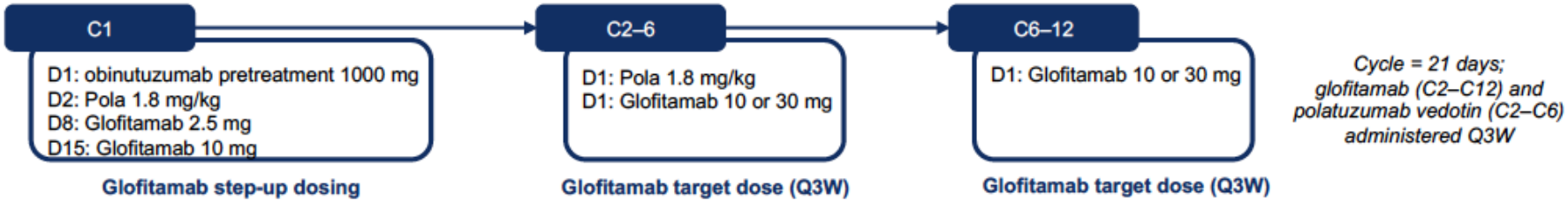
- DLTs
- Determine MTD and/or RP2D for Glofit + Pola (including obinutuzumab pretreatment)

Secondary:

- Safety and tolerability
- Efficacy (CR rate and BORR per Lugano 2014[1])

Glofit + Pola administration in R/R DLBCL

- Target enrollment ~90 patients
- CRS mitigation: obinutuzumab IV 1000 mg 7 days prior to glofitamab administration (step-up dosing)
- Efficacy assessments with PET-CT C3D1, C6D1 C8D15, EOT and Q3M



Hutchings M et al, ASH 2021

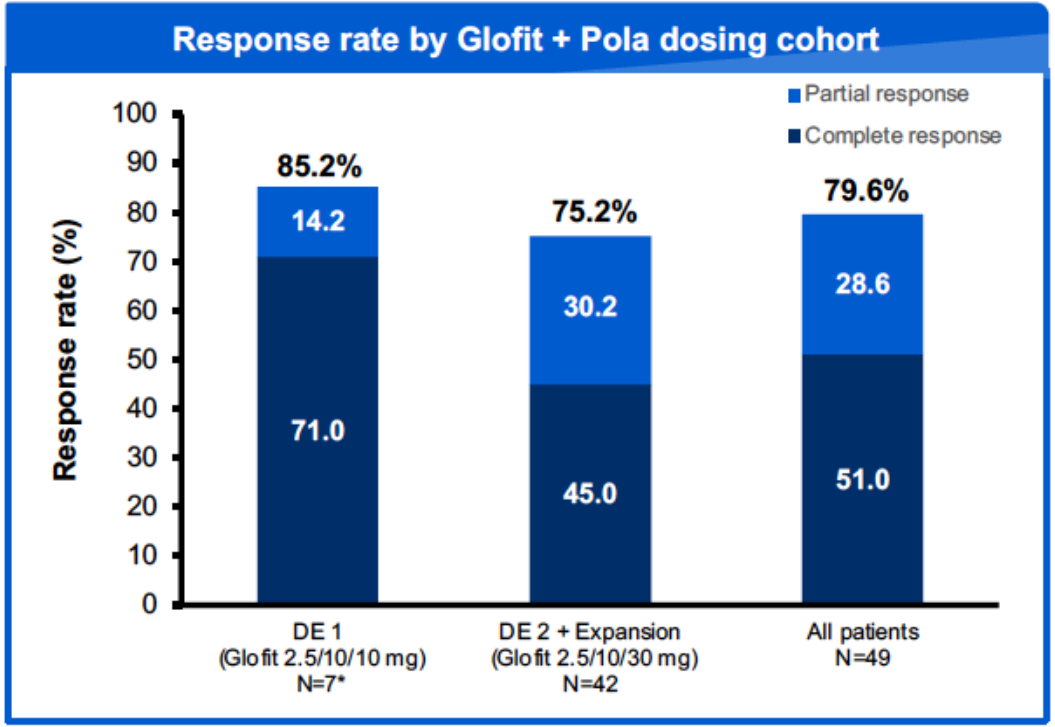
Baseline characteristics

N (%) of patients unless stated		DE 1 (2.5/10/10 mg) N=6	DE 2/Expansion (2.5/10/30 mg) N=53	All patients N=59
Median age, years (range)		65.5 (55–76)	63.8 (29–82)	59.0 (29–82)
Male gender		3 (50.0)	33 (62.2)	36 (61.0)
ECOG PS 0–1		6 (100.0)	49 (92.4)	55 (94.9)
Ann Arbor Stage III–IV at study entry		4 (66.7)	42 (79.2)	46(78.0)
NHL histology	DLBCL	5 (83.3)	31 (58.4)	36 (61.0)
	HGBCL	0	9 (16.9)	9 (15.3)
	trFL	1 (16.7)	13 (24.5)	14 (23.7)
Median prior lines of therapy, n (range)		3 (1–4)	2 (1–5)	2 (1–5)
Refractory status	Any prior therapy	3 (50.0)	45 (84.9)	48 (81.0)
	Most recent therapy line	3 (50.0)	38 (71.6)	41 (69.5)
	Any prior anti-CD20	3 (50.0)	42 (79.2)	45 (76.3)

- **Most patients were high risk and/or refractory to their last prior therapy**

Hutchings M et al, ASH 2021

Response rates



- **49/59 patients were evaluable for interim response**
- **7/49 (14.3%) patients had PD as best response and discontinued study treatment**
- **Encouraging ORR and CR rates in patients with:**
  - trFL: ORR, 8/11 and CR, 7/11
  - HGBCL: ORR, 5/8 and CR, 4/8

Median follow-up <4m, durable responses observed

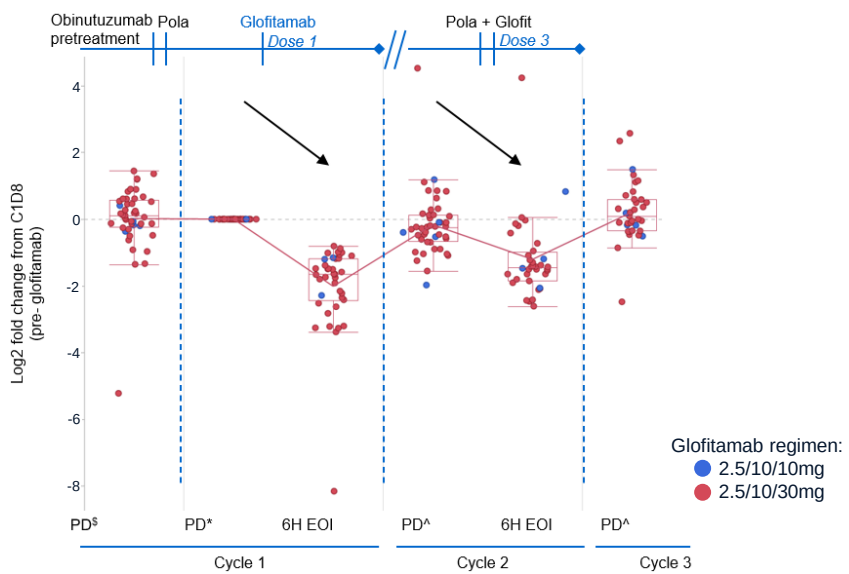
- **Glofit + Pola combination resulted in high response rates**

Glofit alone (median prior tx: 3) : ORR 52%; CR 39%, Dickinson et al NEJM 2022

Hutchings M et al, ASH 2021

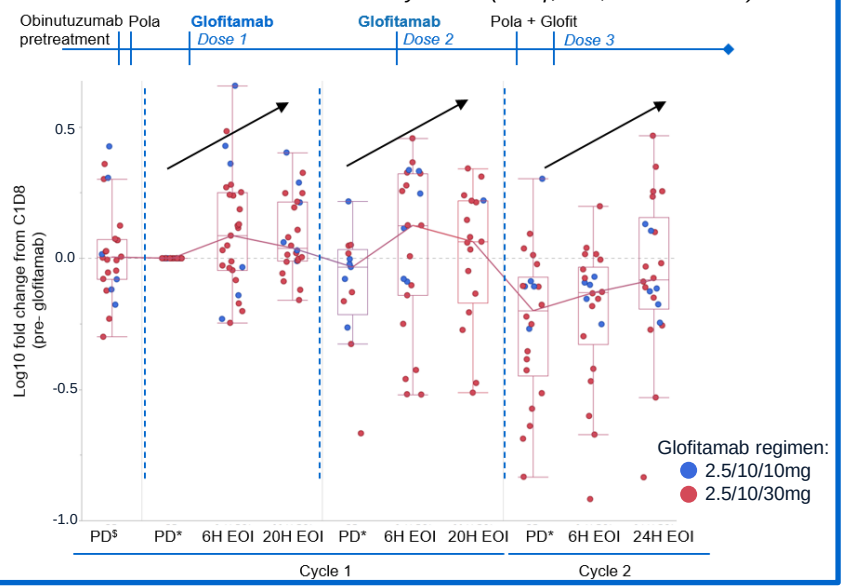
Biomarker analysis shows immunomodulatory effect of Glofit + Pola during step-up dosing

Transient margination of T cells (CD3+) after glofitamab infusion



Transient increase of cytokines, like TNF-α, after glofitamab infusion

- *Similar kinetics are observed for other cytokines (IFN-γ, IL-6, IL-8 and IL-10)*

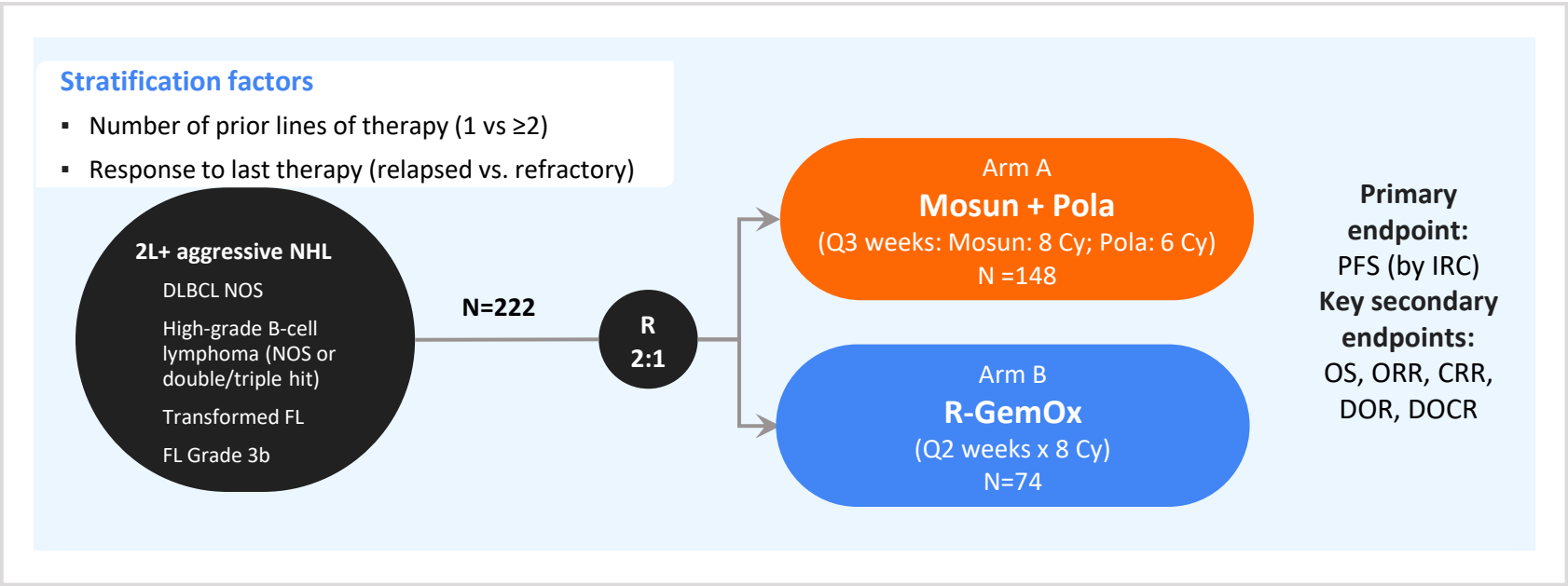


- **Glofitamab driven immune-cell activation is also observed in combination with polatuzumab vedotin**

PD, predose; PD$, predose obinutuzumab; PD*, predose glofitamab; PD^, predose polatuzumab vedotin; EOI, end of infusion glofitamab

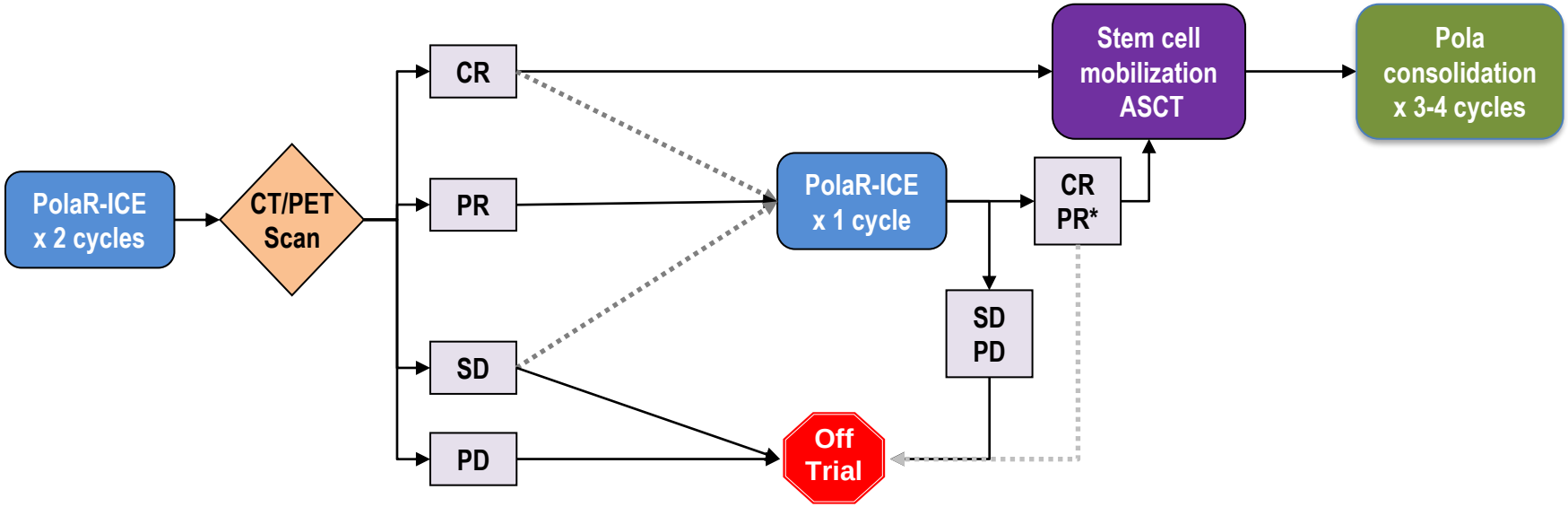
SUNMO (GO43643)

A Phase III Randomized, Open-Label, Multicenter Study Evaluating Efficacy and Safety of Mosunetuzumab in combination with Polatuzumab Vedotin in Comparison with Rituximab in Combination with Gemcitabine Plus Oxaliplatin in Patients with Relapsed or Refractory Aggressive B-Cell Non-Hodgkin's Lymphoma



***2L**,second–line; **CRR**, complete response rate; **Cy**, cycles; **DLBCL**, diffuse large B-cell lymphoma; **FL**, follicular lymphoma; **IRC**, independent review committee; **Mosun**, mosunetuzumab; **NOS**, not otherwise specified; **ORR**, overall response rate; **OS**, overall survival; **Pola**, polatuzumab vedotin; **PFS**, progression-free survival; **Q2**, every 2 weeks; **Q3**, every 3 weeks; **R-GemOx**, rituximab plus gemcitabine and oxaliplatin; **R/R**, relapsed or refractory*

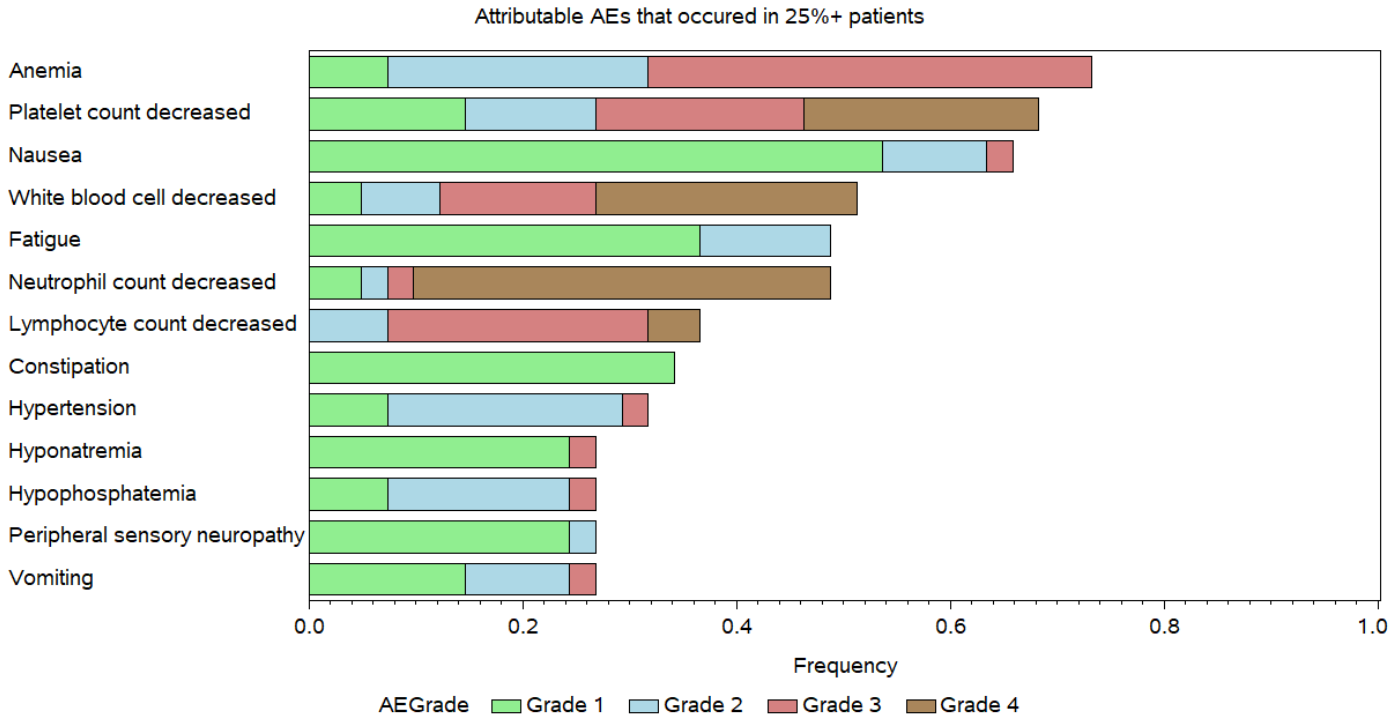
Pola-RICE as Second-line Therapy in R/R DLBCL



Primary Endpoints: Safety (lead-in), CR after PolaR-ICE x 2 (Ph 2)

Herrera, A et al, ASH 2022

Most Common Treatment Related AEs



Herrera, A et al, ASH 2022

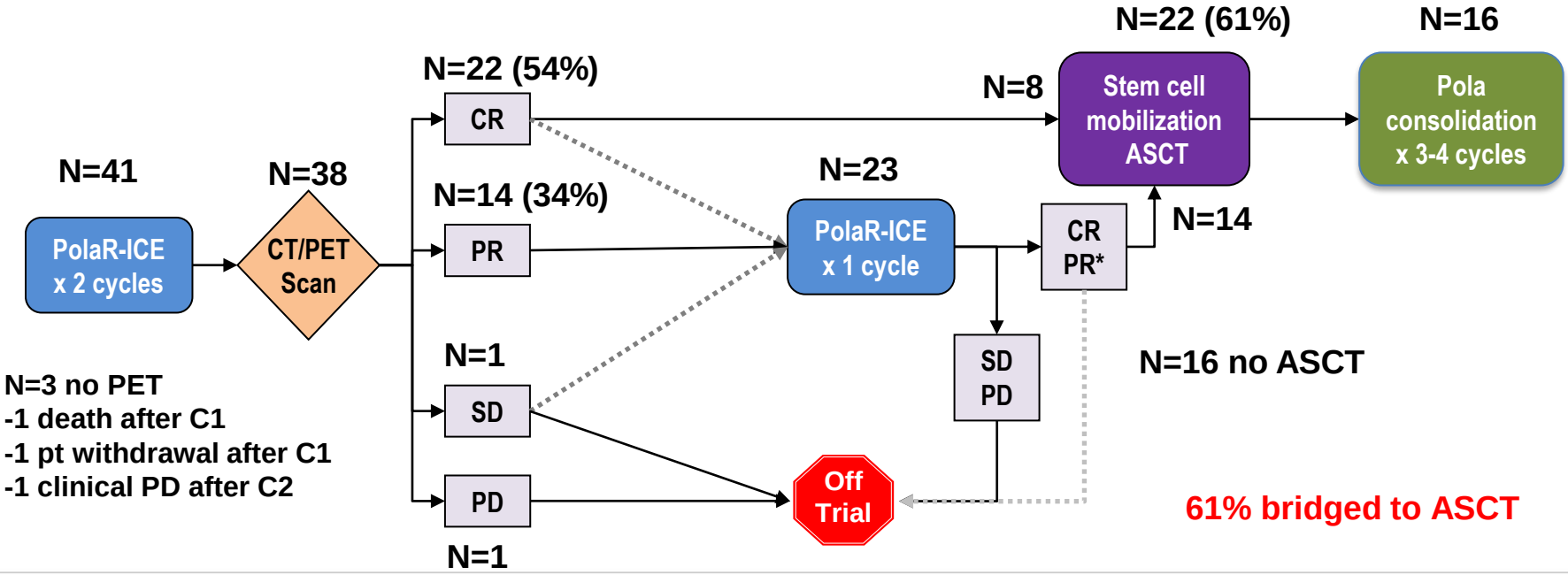
Response to PolaR-ICE

Response after 2 cycles (all-treated)

- **ORR 88%, CR 54%**

Response at end of salvage (all-treated)

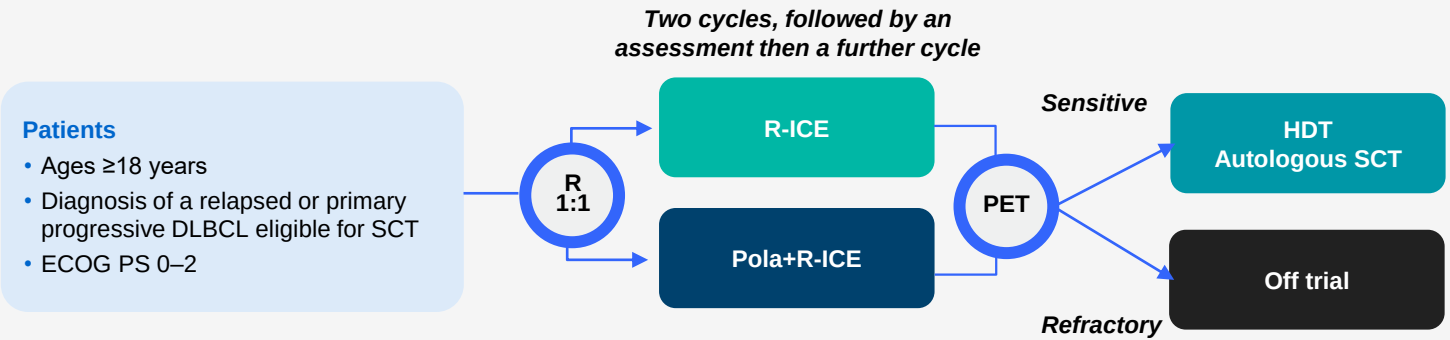
- **ORR 80%, CR 56%**



Herrera, A et al, ASH 2022

POLARICE (MO40599)

Study design



Sponsor: **GWT-TUD GmbHn Pr** (PI: Bertram Glass, Helios Klinikum Berlin-Buch, Germany)
Endpoints

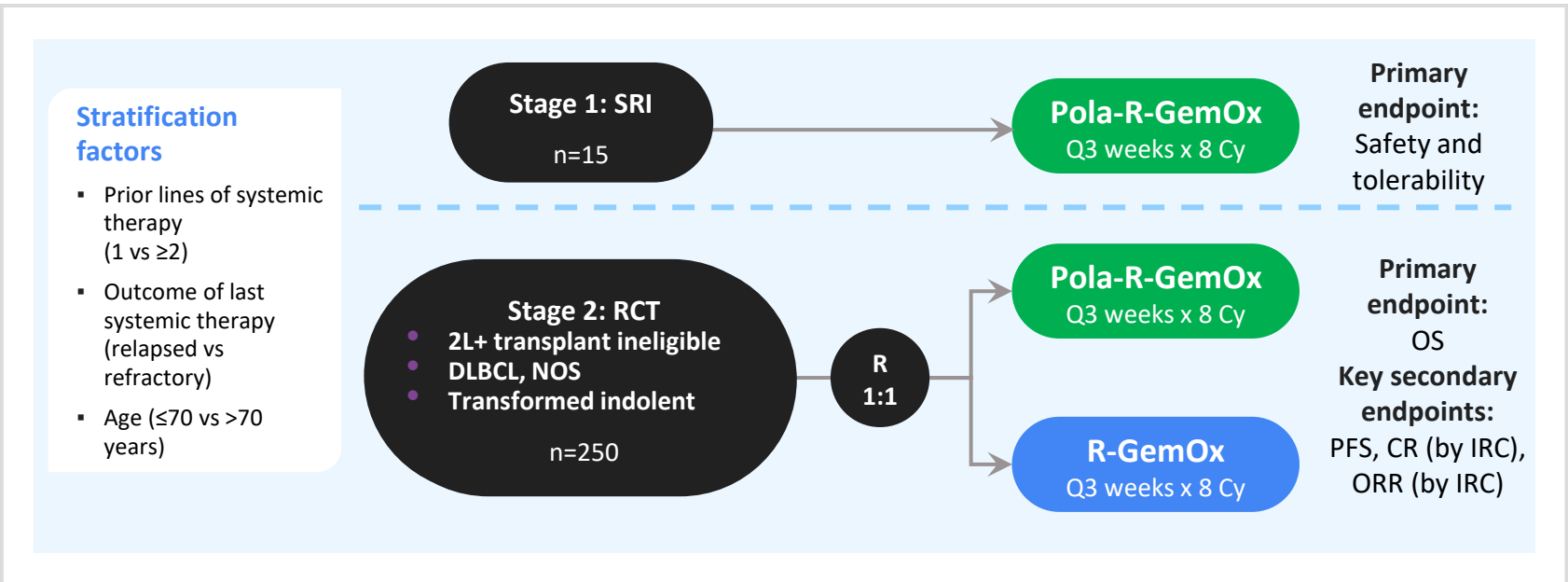
Primary: 2-year PFS rate

Secondary: other efficacy and safety

Status : **Recruitment ongoing, no result available**
Participating countries: Germany, Austria, UK and Spain

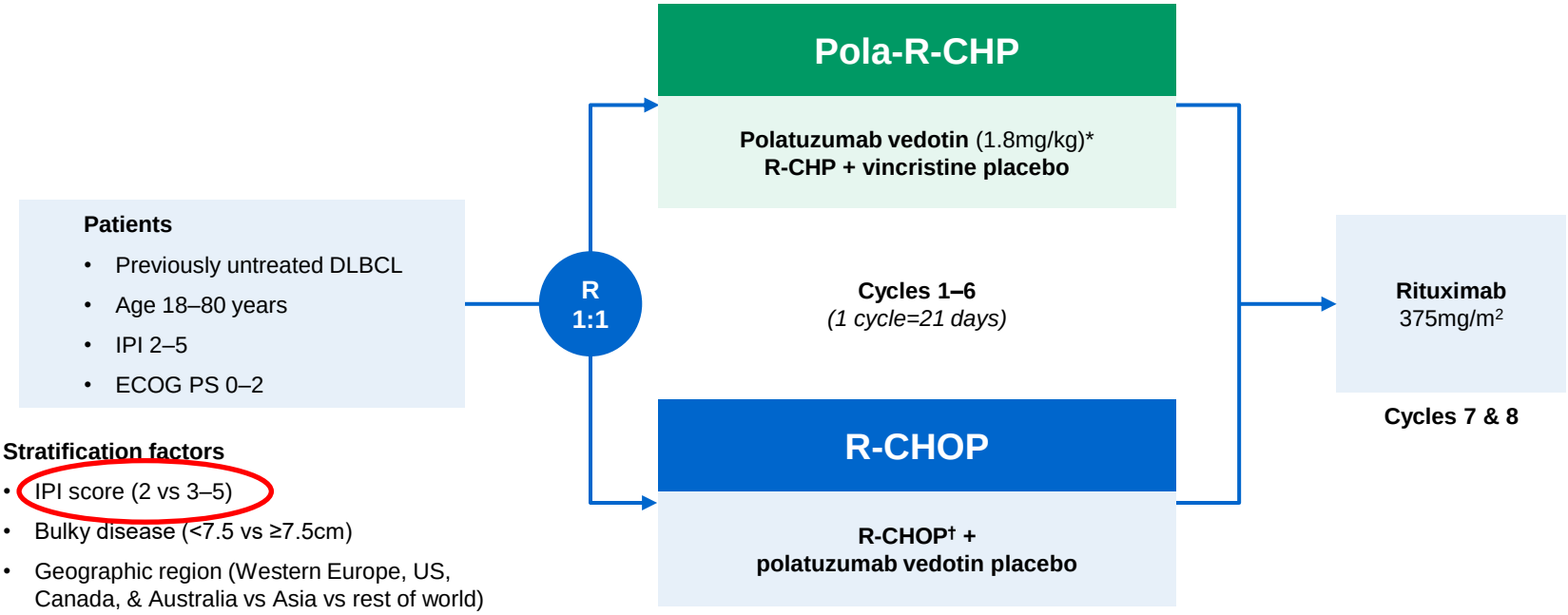
POLARGO (MO40598)

A Phase III Open-Label, Multicenter Randomized Study Evaluating the Safety and Efficacy of Polatuzumab Vedotin in Combination with Rituximab Plus Gemcitabine Plus Oxaliplatin (R-Gemox) Versus R-Gemox Alone in Patients with Relapsed/Refractory DLBCL



***2L**,second–line; **CR**, complete response rate; **Cy**, cycles; **DLBCL**, diffuse large B-cell lymphoma; **IRC**, independent review committee **ORR**, overall response rate; **OS**, overall survival; ; **Pola**, polatuzumab vedotin; **Q2**, every 2 weeks; **Q3**, every 3 weeks; **R-GemOx**, rituximab plus gemcitabine and oxaliplatin; **PFS**, progression-free survival; **RCT**, randomized controlled trial; **SRI**, safety run-in*

POLARIX: A randomized double-blinded study

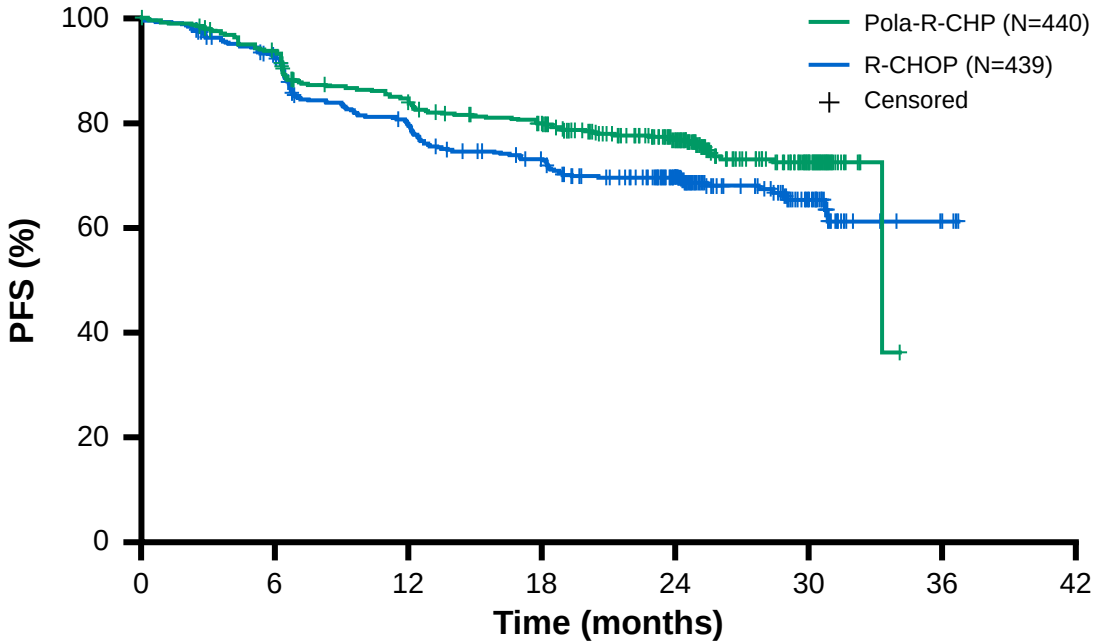


*IV on Day 1; †R-CHOP: IV rituximab 375mg/m², cyclophosphamide 750mg/m², doxorubicin 50mg/m², and vincristine 1.4mg/m² (max. 2mg) on Day 1, plus oral prednisone 100mg once daily on Days 1–5.
IPI, International prognostic index; ECOG PS, Eastern Cooperative Oncology Group performance status; R, randomized.

Tilly H et al. NEJM 2021

Primary endpoint: Progression-free survival

Pola-R-CHP significantly improved PFS versus 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

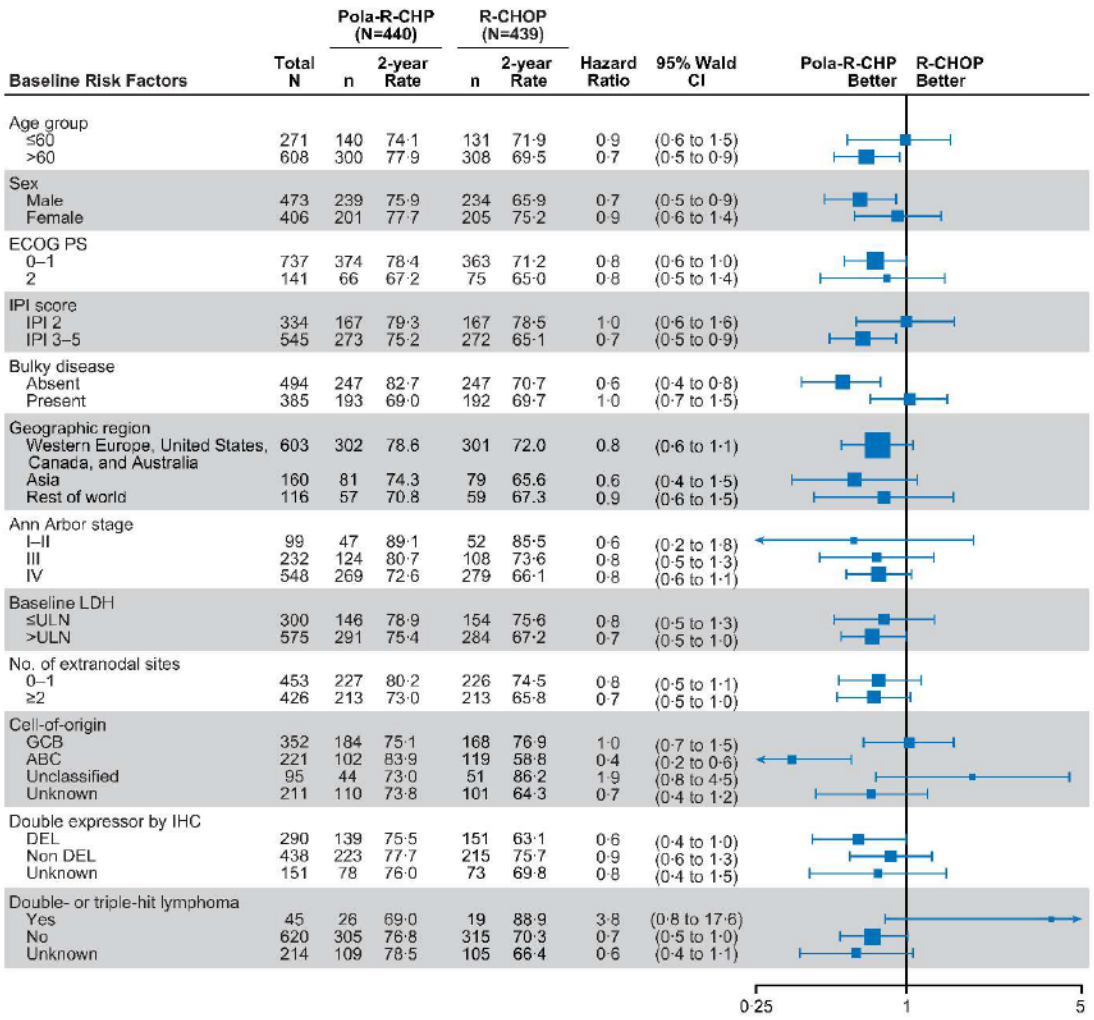
HR 0.73 **(P<0.02)**

95% CI: 0.57, 0.95

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

ITT population. Data cut-off: June 28, 2021; median 28.2 months' follow-up.
NE, not evaluable.

Tilly H et al. NEJM 2021



? Benefit

Younger ≤ 60y

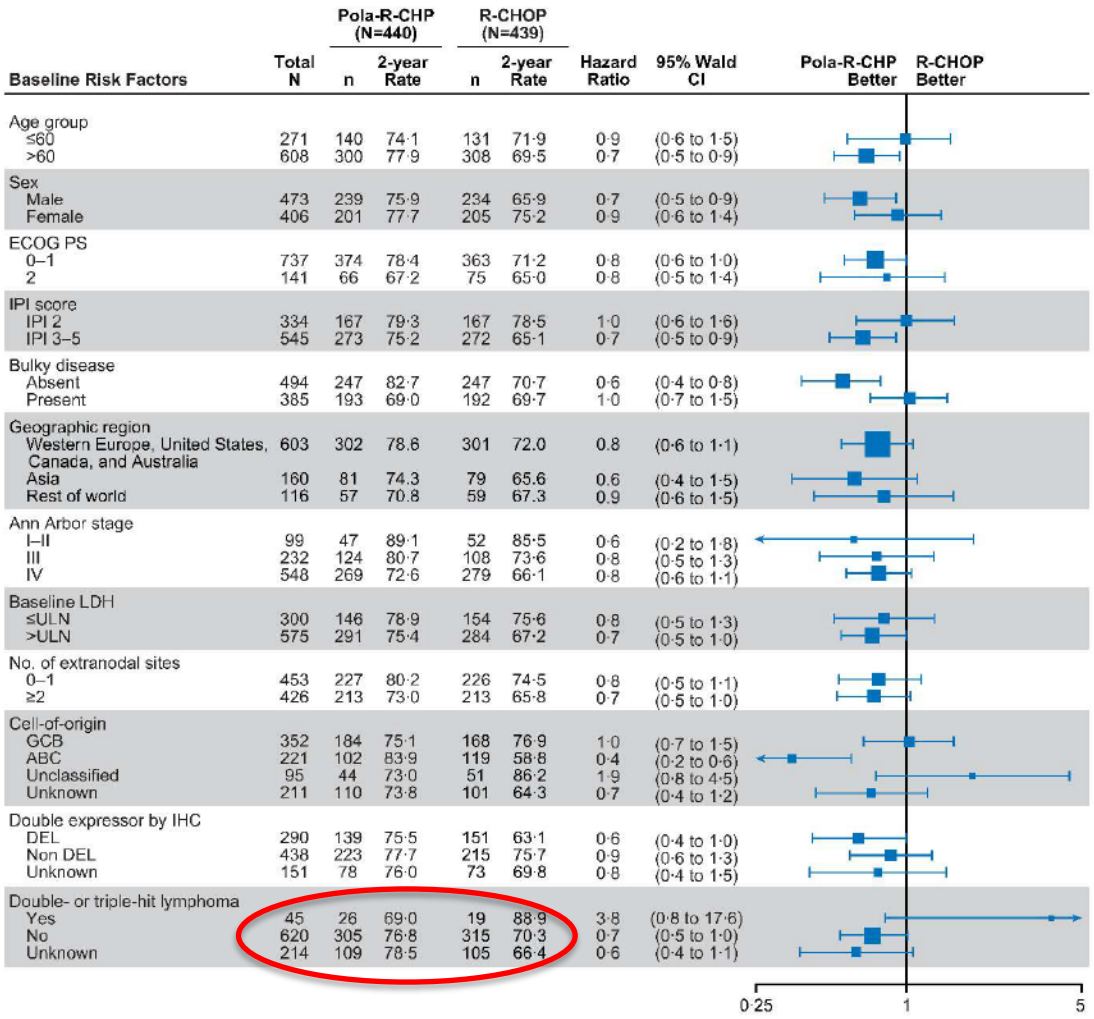
Females

IPI = 2

Bulk ≥ 7.5 cm

GCB Subtype

DH/TH lymphoma



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)

? Benefit

Younger ≤ 60y

Females

IPI = 2

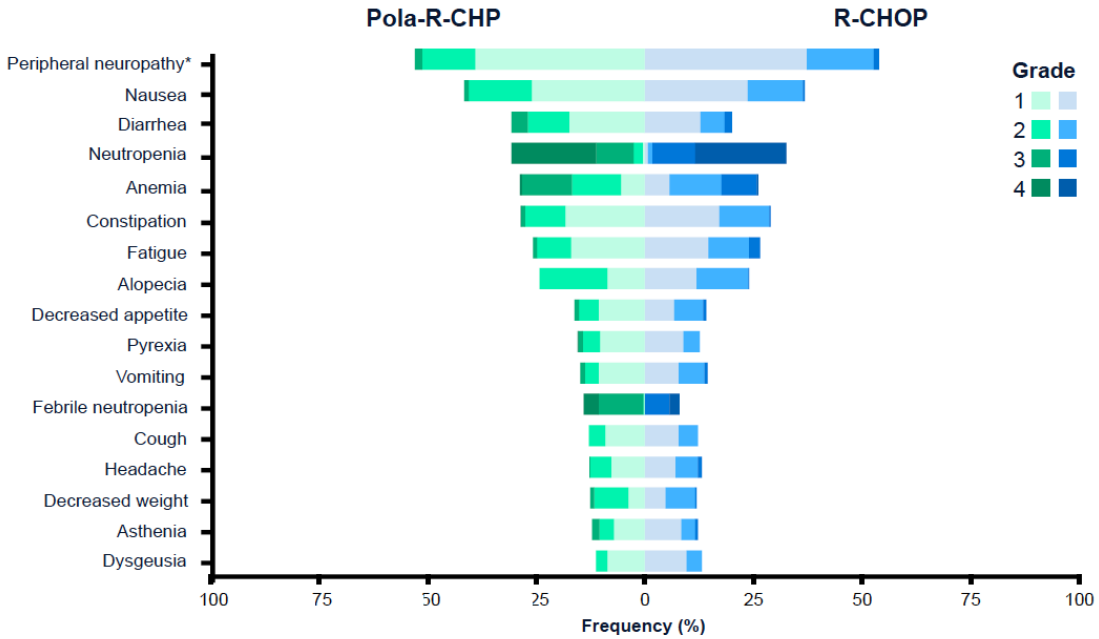
Bulk ≥ 7.5 cm

GCB Subtype

DH/TH lymphoma

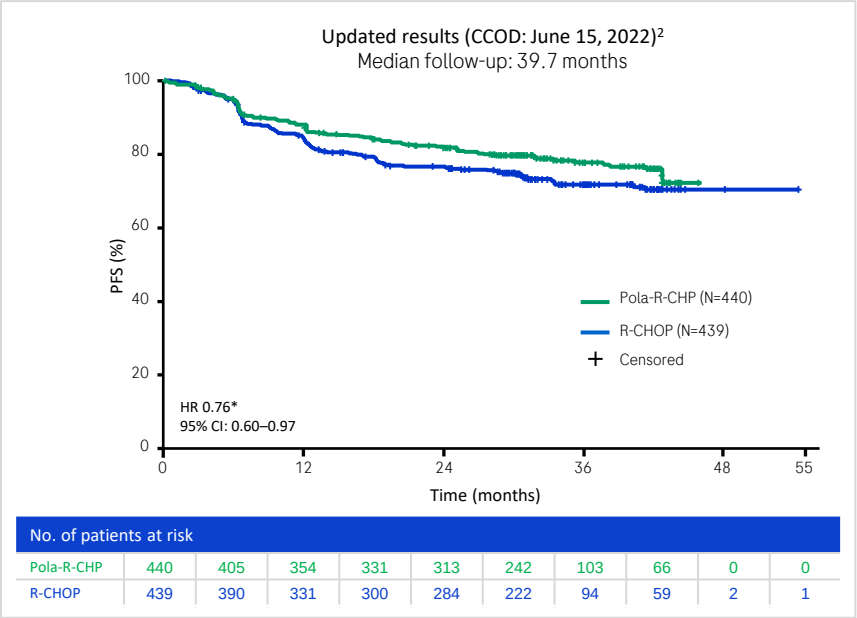
Safety and Adverse Events

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)

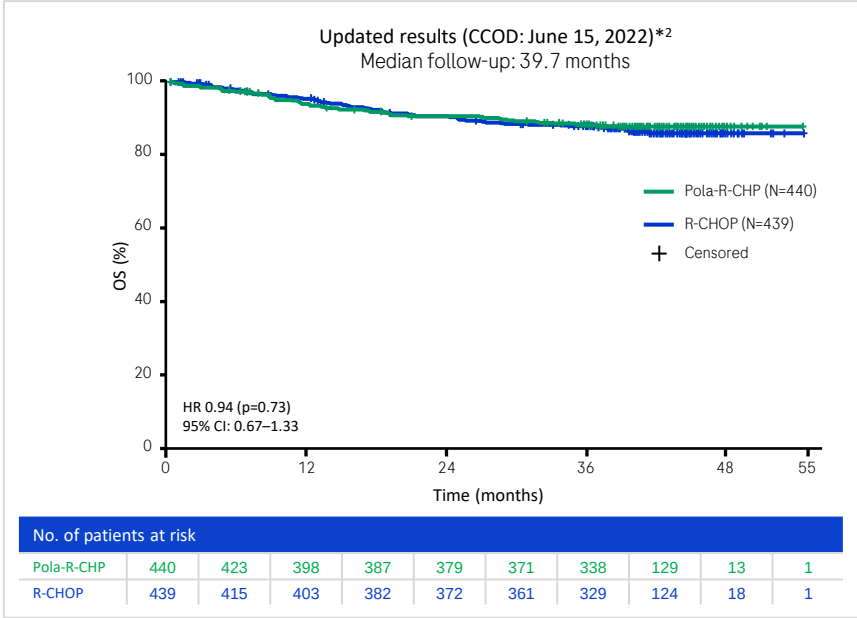


Tilly H et al. NEJM 2021

Three-year Update POLARIX: PFS and OS



No. of patients at risk										
Pola-R-CHP	440	405	354	331	313	242	103	66	0	0
R-CHOP	439	390	331	300	284	222	94	59	2	1



No. of patients at risk										
Pola-R-CHP	440	423	398	387	379	371	338	129	13	1
R-CHOP	439	415	403	382	372	361	329	124	18	1

PFS benefit with Pola-R-CHP vs R-CHOP was maintained with longer follow-up
(HR 0.76, 95% CI: 0.60–0.97)

Herrera A et al. ASH 2022

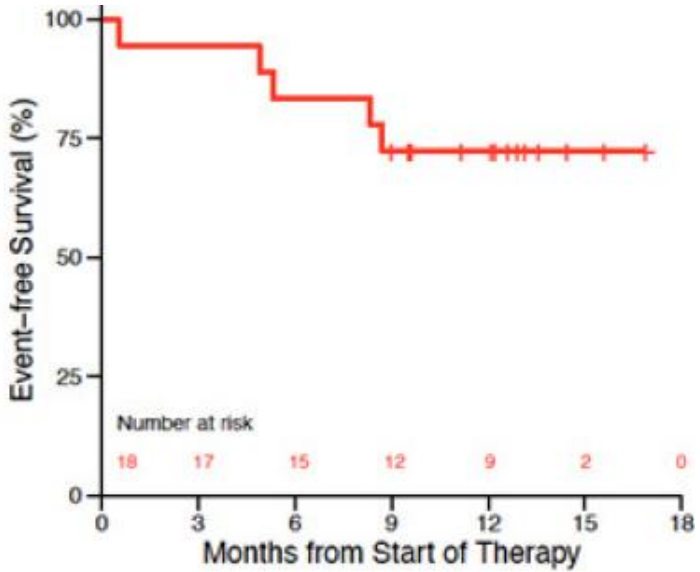
Three-year Update POLARIX: Subsequent Therapy

	Pola-R-CHP (N=440)	R-CHOP (N=439)
Total number of patients with ≥1 subsequent anti-lymphoma treatment, n (%)*	107 (24.3)	144 (32.8)
Total number of subsequent anti-lymphoma treatments (radiotherapy and systemic), n*	196	315
Total number of radiotherapy treatments, n	45	77
Patients with at least one radiotherapy treatment, n (%)	42 (9.5)	61 (13.9)
Patients with pre-planned treatment, n (%)	11 (2.5)	18 (4.1)
Patients with unplanned treatment, n (%)	31 (7.0)	43 (9.8)
Total number of systemic therapy regimens, n (%)†	151	238
Patients who received at least one systemic therapy	83 (18.9)	114 (26.0)
Patients who received stem cell transplant	19 (4.3)	34 (7.7)
Patients who received CAR-T	9 (2.0)	16 (3.6)

Data cut-off June 2022

Polatuzumab with Infusional Therapy in Untreated Aggressive B-Cell Lymphoma (Pola-DA-EPCH-R)

Histology, Age/Gender	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6
HGBCL, 48F	1	2	3	4	5	5
PMBCL, 45F	1	2	3	4	4	5
DLBCL, 52M	1	2	3	4	4	4
DLBCL, 58F	1	2	3	4	4	4
HGBCL, 64M	1	2	3	4	4	3
DLBCL, 68M	1	1	2	3	3	3
DLBCL, 64M	1	1	2	3	2	3
DLBCL, 74M	1	1	2	3	3	3
DLBCL, 69M	1	1	2	3	3	2
HGBCL, 73F	1	2	2	2	2	2
HGBCL, 55M	1	2	2	2	2	2
HGBCL, 66M	1	1	2	2	2	2
DLBCL, 61F	1	2	2	2	2	2
PMBCL, 64M	1	2	2	2	2	2
PMBCL, 41M	1	1	2	2	2	2
PMBCL, 48F**	1	2	2	2	1	1
HGBCL, 71F*	1	1	1	-1	-1	-1
DLBCL, 64F***	1					

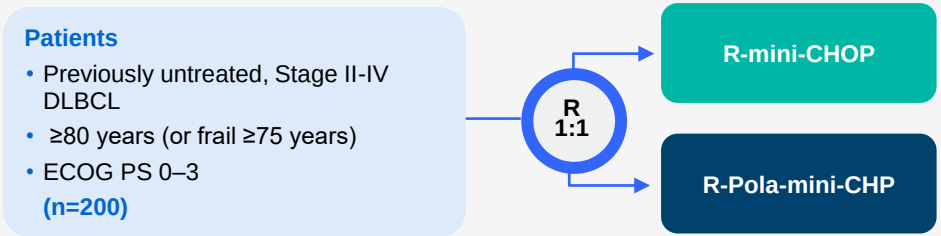


N=18

Lynch, R et al. Blood Advances 2022

POLARBEAR

A Phase III Randomized, Multicenter Trial Comparing Treatment with R-Mini-Chop with R-Mini-CHP + Polatuzumab Vedotin in Patients with Elderly Patients with Untreated Diffuse Large B-Cell Lymphoma



Sponsor
Nordic Lymphoma Group

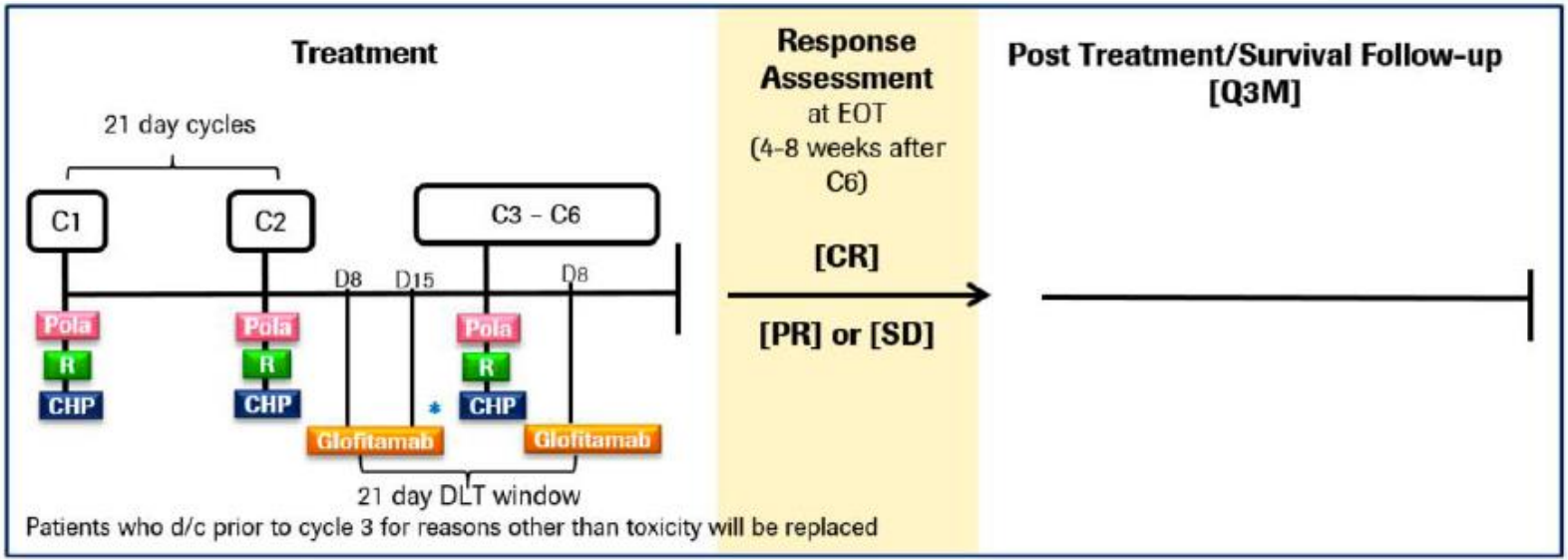
Participating Countries
Sweden, Norway, Finland, Denmark, and Italy

Endpoints
Primary: PFS
Secondary: CR, ORR, HRQOL (QLQ-C30), lymphoma specific survival (LSS), OS, safety

Glofitamab + Pola-R-CHP (NP40126) in Untreated DLBCL: Phase Ib

Inclusion Criteria

- Histologically-confirmed previously-untreated DLBCL (IPI 2-5) that is expected to express CD20



C cycle; CHOP cyclophosphamide (C), doxorubicin (H), vincristine (O), and prednisone (P); CHP cyclophosphamide (C), doxorubicin (H), and prednisone (P); CR complete response; d/c discontinued; D day; DLT dose-limiting toxicity; EOInd end of induction; EOT end of treatment; G obinutuzumab; IMC Internal Monitoring Committee; IV intravenously; M month; Pola polatuzumab vedotin; PR partial response; Q2M every 2 months; Q3M every 3 months; R rituximab; SD stable disease.

Dickinson M et al, ASCO 2023

Planned Phase 3 Trial in Untreated DLBCL: Glofit-Pola-R-CHP vs Pola-R-CHP

Summary

- Pola-BR is effective in transplant-ineligible DLBCL
- Pola-R-CHP results in improved PFS in frontline setting with similar toxicity profile to R-CHOP
- Ongoing trials are evaluating Pola in combination with chemotherapy as salvage and in alternative front-line regimens, as well as in combination with chemotherapy-free novel agents