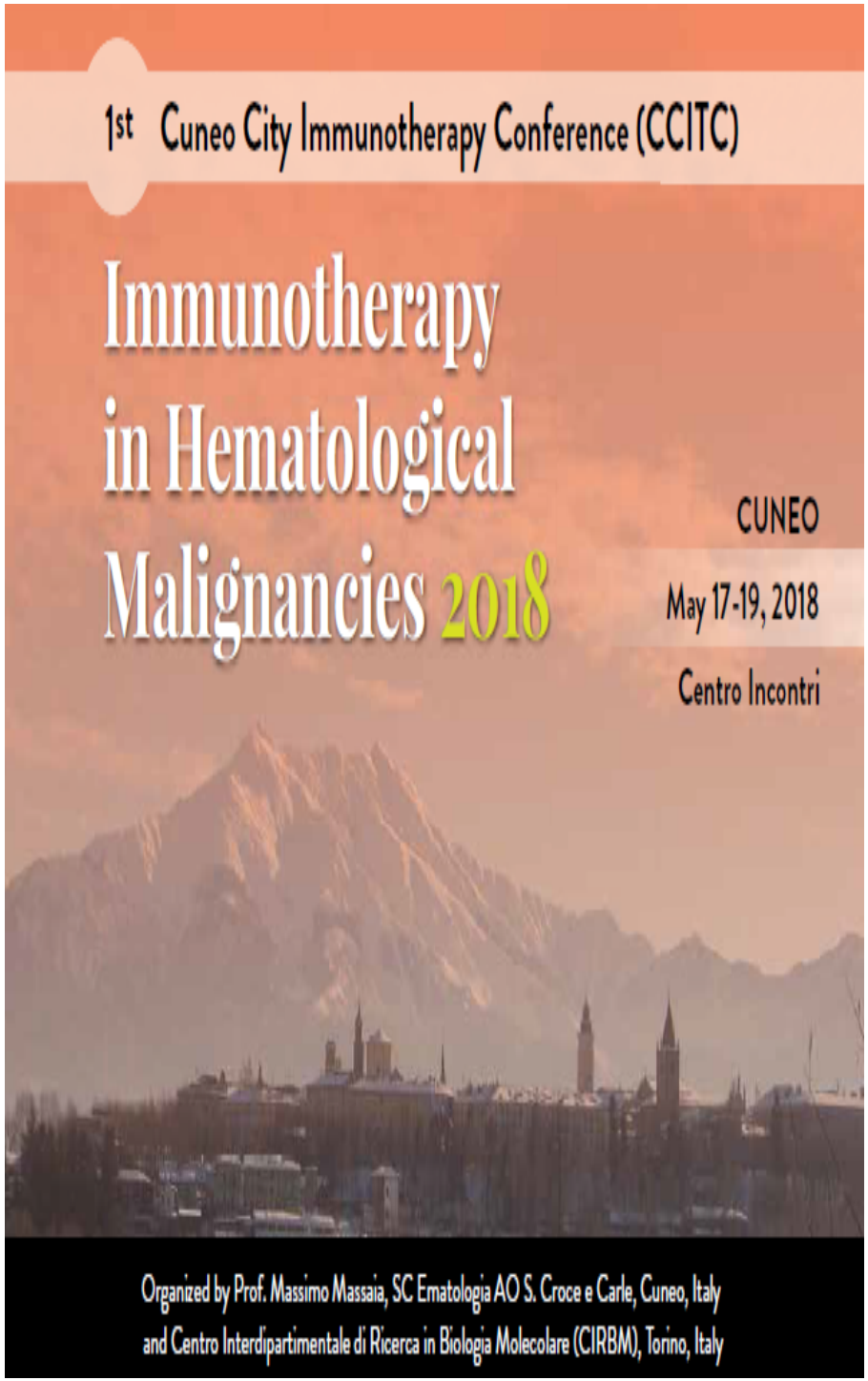

Passive immunotherapy: antibody drug conjugates

Anti CD-79b: Polatuzumab

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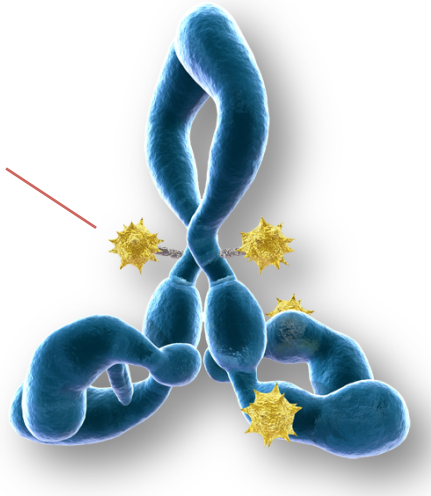
Dip. Biotecnologie Cellulari ed Ematologia
Sapienza Università di Roma

Polatuzumab vedotin: CD79b target

Molecular Information

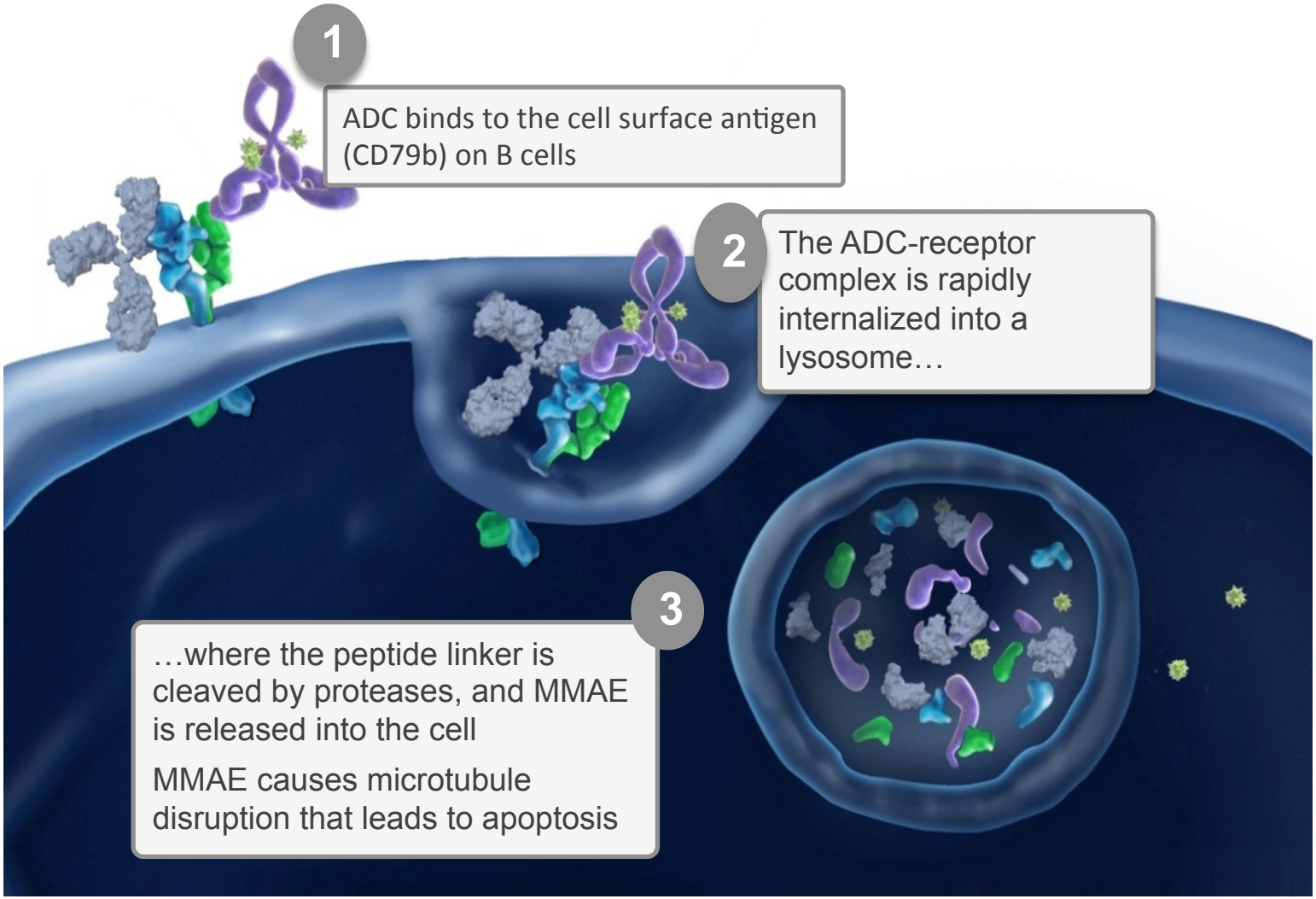


Binds CD79b and ADC-receptor complex internalized

CD79b

- Forms a portion of the B-cell receptor (BCR)
- Is expressed on most cells of the B-cell lineage but not on stem cells
- Specificity for B cells makes CD79b an ideal target for B-cell–specific ADCs1,2 in cancers such as NHL and CLL

Polatuzumab vedotin: proposed mechanism of action



Polatuzumab Vedotin: outline of discussion

- Relapsed or refractory Non Hodgkin’s lymphoma
- Previously untreated Diffuse Large B-Cell Lymphoma (DLBCL)

Polatuzumab Vedotin: outline of discussion

- Relapsed or refractory Non Hodgkin's lymphoma
- Previously untreated Diffuse Large B-Cell Lymphoma (DLBCL)

Safety and activity of the anti-CD79B antibody–drug conjugate polatuzumab vedotin in relapsed or refractory B-cell non-Hodgkin lymphoma and chronic lymphocytic leukaemia: a phase 1 study

***Lancet Oncology* June 2015**

Maria Corinna A Palanca-Wessels, Myron Czuczman, Gilles Salles, Sarit Assouline, Laurie H Sehn, Ian Flinn, Manish R Patel, Randeep Sangha, Anton Hagenbeek, Ranjana Advani, Herve Tilly, Olivier Casasnovas, Oliver W Press, Sreeni Yalamanchili, Robert Kahn, Randall C Dere, Dan Lu, Surai Jones, Cheryl Jones, Yu-Waye Chu, Franck Morschhauser

	Diffuse large B-cell lymphoma (n=40)	Indolent NHL (n=30)	Mantle-cell lymphoma (n=7)	Chronic lymphocytic leukaemia (n=18)*
Age (years)	67 (20–81)	67 (41–86)	71 (60–85)	69 (54–74)
Sex				
Men	25 (63%)	22 (73%)	7 (100%)	13 (72%)
Women	15 (38%)	8 (27%)	0	5 (28%)
ECOG performance status				
0	11 (28%)	13 (43%)	2 (29%)	7 (39%)
1	19 (48%)	15 (50%)	4 (57%)	10 (56%)
2	10 (25%)	2 (7%)	1 (14%)	1 (6%)
Number of previous systemic therapies				
1	2 (5%)	2 (7%)	0	1 (6%)
2	3 (8%)	7 (23%)	4 (57%)	0
≥3	35 (88%)	21 (70%)	3 (43%)	17 (94%)
Previous stem-cell transplantation	13 (33%)	3 (10%)	2 (29%)	0
Refractory to last therapy †	31 (78%)	16 (53%)	4 (57%)	9 (50%)
Previous radiotherapy	21 (53%)	7 (23%)	1 (14%)	1 (6%)
Previous rituximab therapy (at any timepoint)	39 (98%)	28 (93%)	7 (100%)	17 (94%)

Safety and activity of the anti-CD79B antibody–drug conjugate polatuzumab vedotin in relapsed or refractory B-cell non-Hodgkin lymphoma and chronic lymphocytic leukaemia: a phase 1 study

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Lancet Oncology June 2015

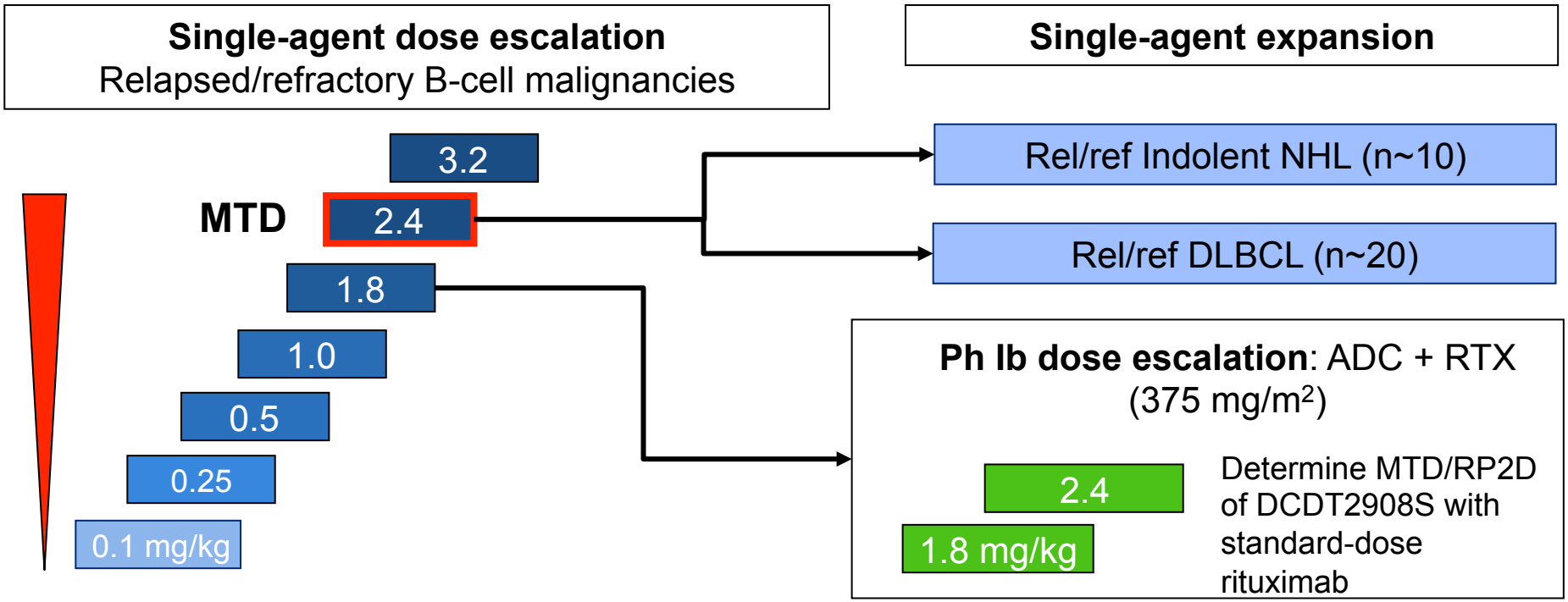
Response

	Indolent B-cell lymphoma*		Diffuse large B-cell lymphoma			Mantle-cell lymphoma	
	<1·8 mg/kg (n=9)	2·4 mg/kg (n=16)	<1·8 mg/kg (n=8)	1·8 mg/kg (n=4)	2·4 mg/kg (n=27)	1·8 mg/kg (n=2)	2·4 mg/kg (n=2)
Complete response	0	3	0	0	4	0	0
Partial response	0	4	1	2	10	2	2
Stable disease	3	5	0	1	4	0	0
Progressive disease	5	3	7	1	7	0	0
Unable to evaluate†	0	0	0	0	1	0	0
Missing‡	1	1	0	0	1	0	0

Conclusions

- After the dose escalation the recommended MTD phase 2 study is 2,4mg/kg as single agent and in combination with rituximab in NHL
- The MTD in CLL was 1.0 mg / Kg as result of dose- limiting toxic effects
- The combination with Rituximab improve the overall response compared to single agent (ORR 54 % vs 77%)
- No objective responses were observed in patients with CLL

Phase I Study of the anti-CD22 Antibody-Drug Conjugate (Pinatuzumab) in Relapsed or Refractory B-NHL



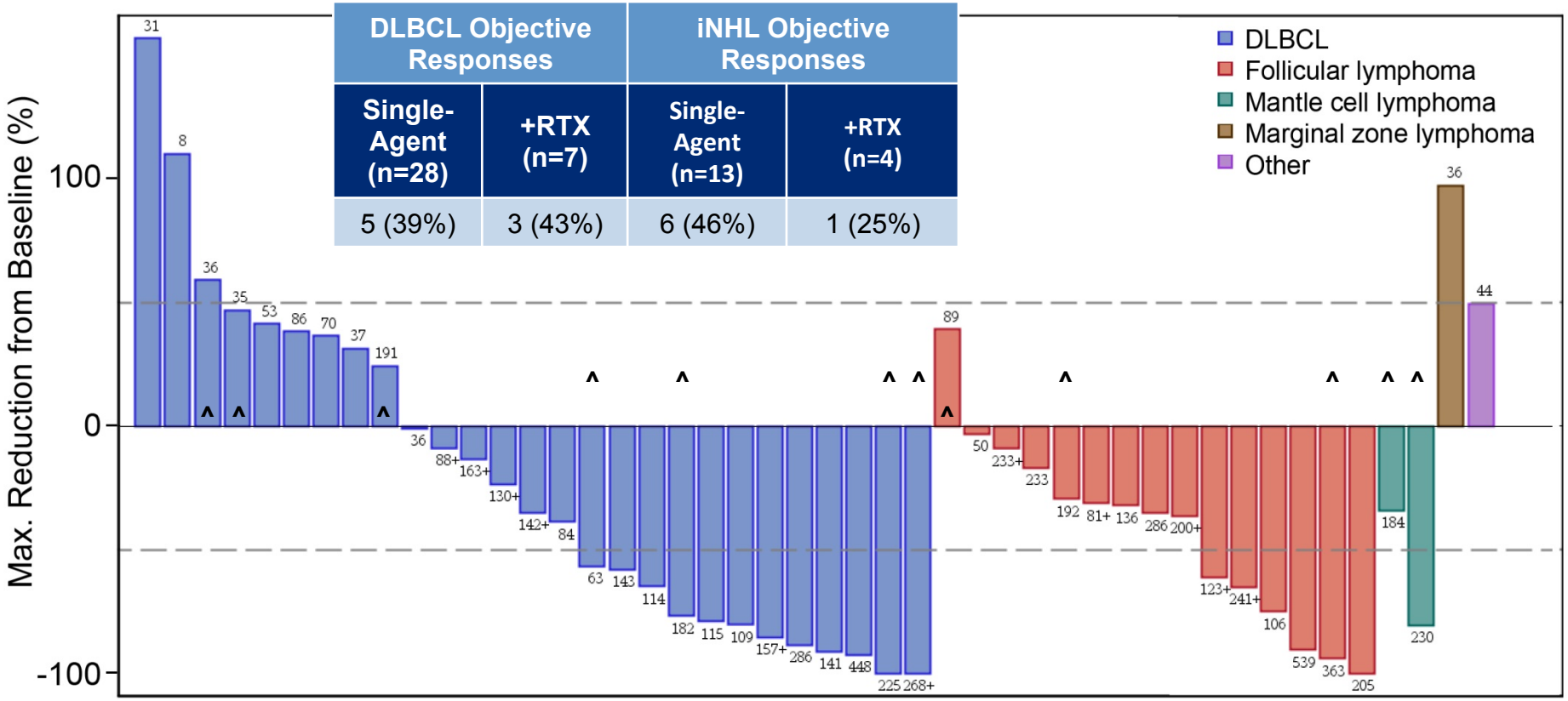
- Single-agent MTD 2.4 mg/kg administered every 21 days
- Enrollment into NHL dose expansion and Phase Ib cohorts completed
- Data cut-off date of 22 February 2013

RH Advani, ICML 2013

Anti-Tumor Responses By Lymphoma Subtypes

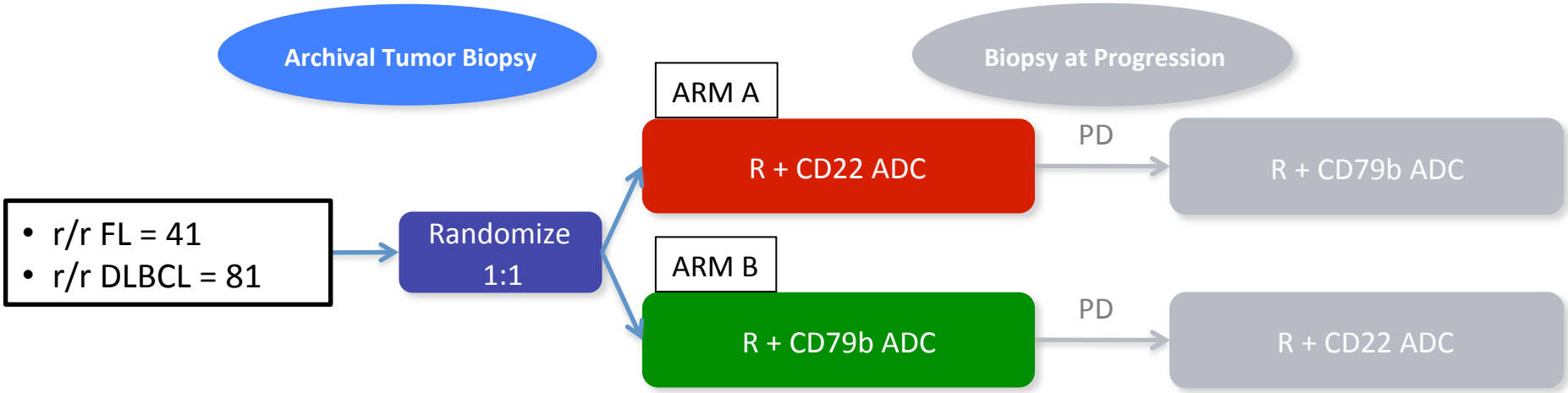
Pinatuzumab (anti CD22) ≥ 1.8 mg/kg

DLBCL Objective Responses		iNHL Objective Responses	
Single-Agent (n=28)	+RTX (n=7)	Single-Agent (n=13)	+RTX (n=4)
5 (39%)	3 (43%)	6 (46%)	1 (25%)



- Numbers below each bar represent days on study
- + indicates patient still on study
- ^ indicates treatment with Pinatuzumab (anti CD22) plus rituximab

ROMULUS Study Design



Rituximab (R) (375 mg/m^2) + ADC (2.4 mg/kg) administered in every-21-day cycles up to one year

Clinical Evaluations

- Treatment-emergent adverse events graded per NCI CTCAE v4.0
- Anti-tumor activity was evaluated per revised IWG criteria (Cheson et al. 2007) every three months; PET scans were performed at the discretion of the investigator

Pharmacokinetic and Pharmacodynamic Evaluations

- Total antibody, conjugate (antibody-conjugated cytotoxic agent MMAE [acMMAE]), unconjugated MMAE

Data as of 21 February 2014; median time of follow up was 9.9 months (Range 0.23-14.9 months)

- Data from crossover patients not included in this presentation

Morschhauser F et al, The ASH Annual Meeting, 2015,

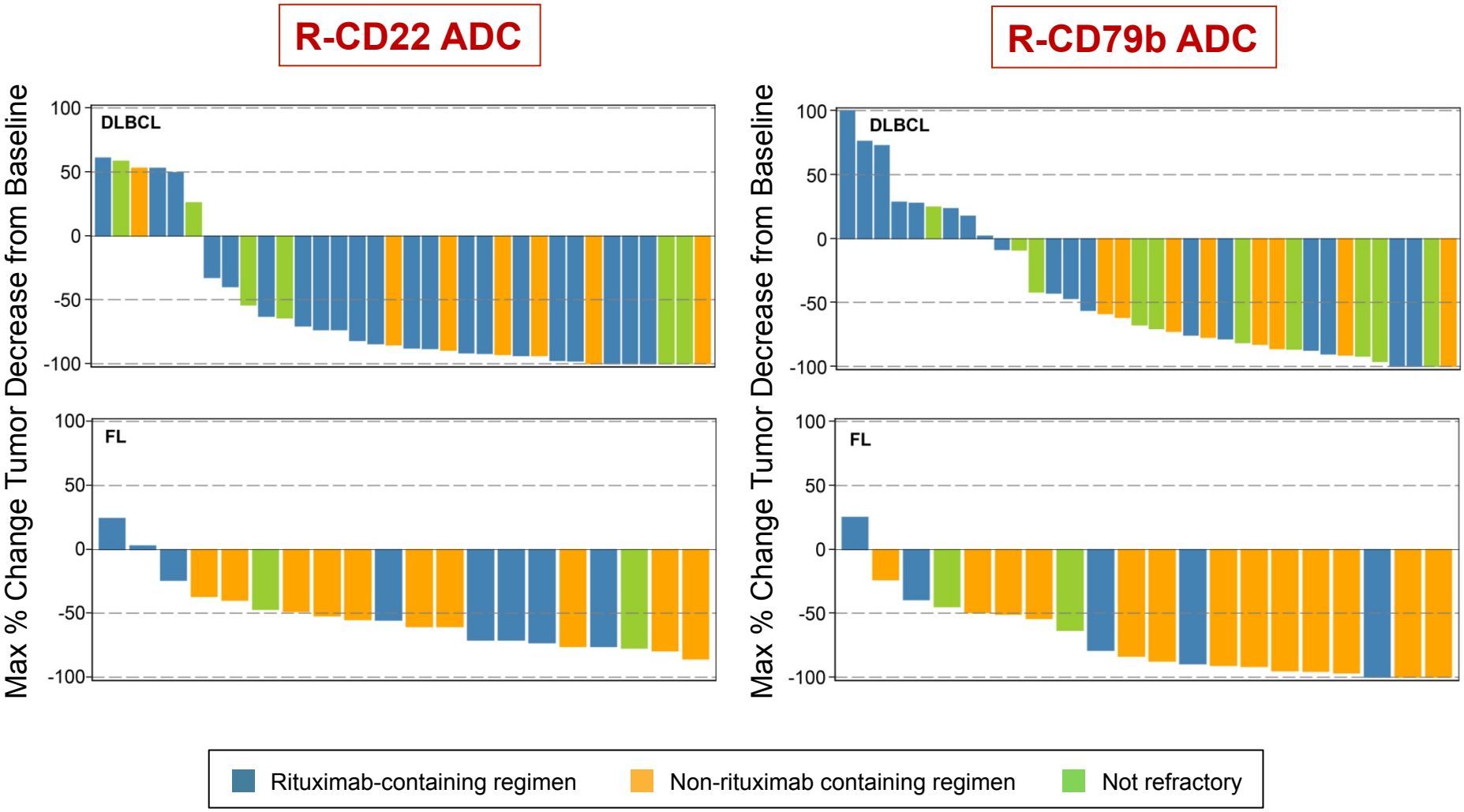
Romulus study : investigator-assessed best responses in Treated Patients

	DLBCL		FL	
	R+CD22 ADC (N=42)	R+CD79b ADC (N=39)	R+CD22 ADC (N=21)	R+CD79b ADC (N=20)
Objective response, n (%)	**24 (57%)**	**22 (56%)**	**13 (62%)**	**14 (70%)**
Complete Response	10 (24%)	6 (15%)	**2 (10%)**	**8 (40%)**
95% CI	[12%-39%]	[6%-31%]	[11%-30%]	[19%-64%]
Partial Response	14 (33%)	16 (41%)	11 (52%)	6 (30%)
95% CI	[20%-50%]	[26%-58%]	[30%-74%]	[12%-54%]
Stable disease, n (%)	3 (7%)	4 (10%)	6 (29%)	6 (30%)
Progressive disease, n (%)	7 (21%)	11 (30%)	1 (5%)	0
Unable to evaluate, n (%)	8 (19%)	2 (5%)	1 (5%)	0
Median Duration of Response, mo. (95% CI)	6.0 (2.9-12.2)	NR (2.6-NR)	5.8 (2.6-10.1)	***NR (5.7-NR)***

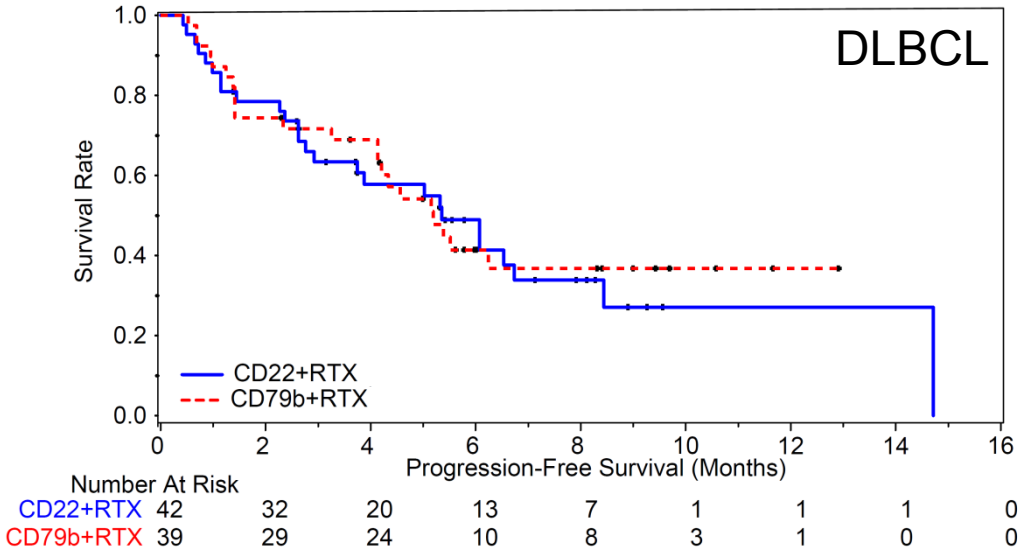
[a] Patients who received ≥ 1 dose of study treatment; patients unable to evaluate did not have a post-baseline tumor assessment

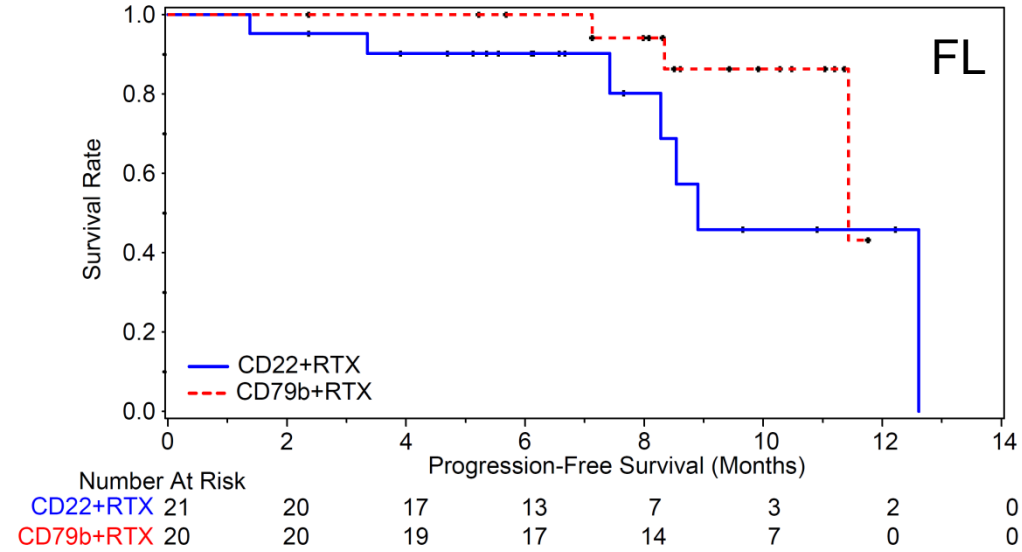
NR = Not reached

Anti-Tumor Responses Observed By Lymphoma Subtypes and Refractoriness to Last Prior Therapy



ROMULUS : progression free survival





Median PFS, mo. (95% CI)	
R+CD22 ADC (N=42)	R+CD79b ADC (N=39)
5.4 mo. (2.8-8.4)	5.2 mo. (4.1-NR)

NR = Not reached

Poster: 284

Polatuzumab Vedotin plus Bendamustine and Rituximab or Obinutuzumab in Relapsed/Refractory Follicular Lymphoma or Diffuse Large B-Cell Lymphoma: Updated Results of a Phase IB/II Study

Matthew Matasar,[1] Alex F. Herrera, [2*] Manali Kamdar,[3*] Amitkumar Mehta,[4] Sarit Assouline,[5] Isabelle Fleury,[6] Tae Min Kim,[7] Won Seog Kim,[8] Francesc Bosch,[9] John Radford,[10] Christopher R. Flowers,[11] Lilian Bu,[12] Wan-Jen Hong,[13] Laurie H. Sehn[14]

*[1]Memorial Sloan Kettering Cancer Center, New York, NY, US; [2]City of Hope, Duarte, CA, US; [3]University of Colorado, Denver, Department of Medicine, Denver, CO, US; [4]University of Birmingham, Birmingham, AL, US; [5]Jewish General Hospital, Montreal, Canada; [6]Department of Hematology, Maisonneuve-Rosemont Hospital and University of Montreal, Montreal, Canada; [7]Seoul National University Hospital, Seoul, South Korea; [8]Samsung Medical Center, Seoul, South Korea; [9]Hospital Universitari Vall d'Hebron, Barcelona, Spain; [10]University of Manchester and the Christie NHS Foundation Trust, Manchester Academic Health Science Centre, Manchester, UK; [11]Winship Cancer Institute of Emory University, Atlanta, GA, US; [12]Roche, Shanghai, China; [13]Genentech, Inc., South San Francisco, CA, US; [14]BC Cancer Agency, Vancouver, Canada; *Presenting author*

OBJECTIVES

Primary

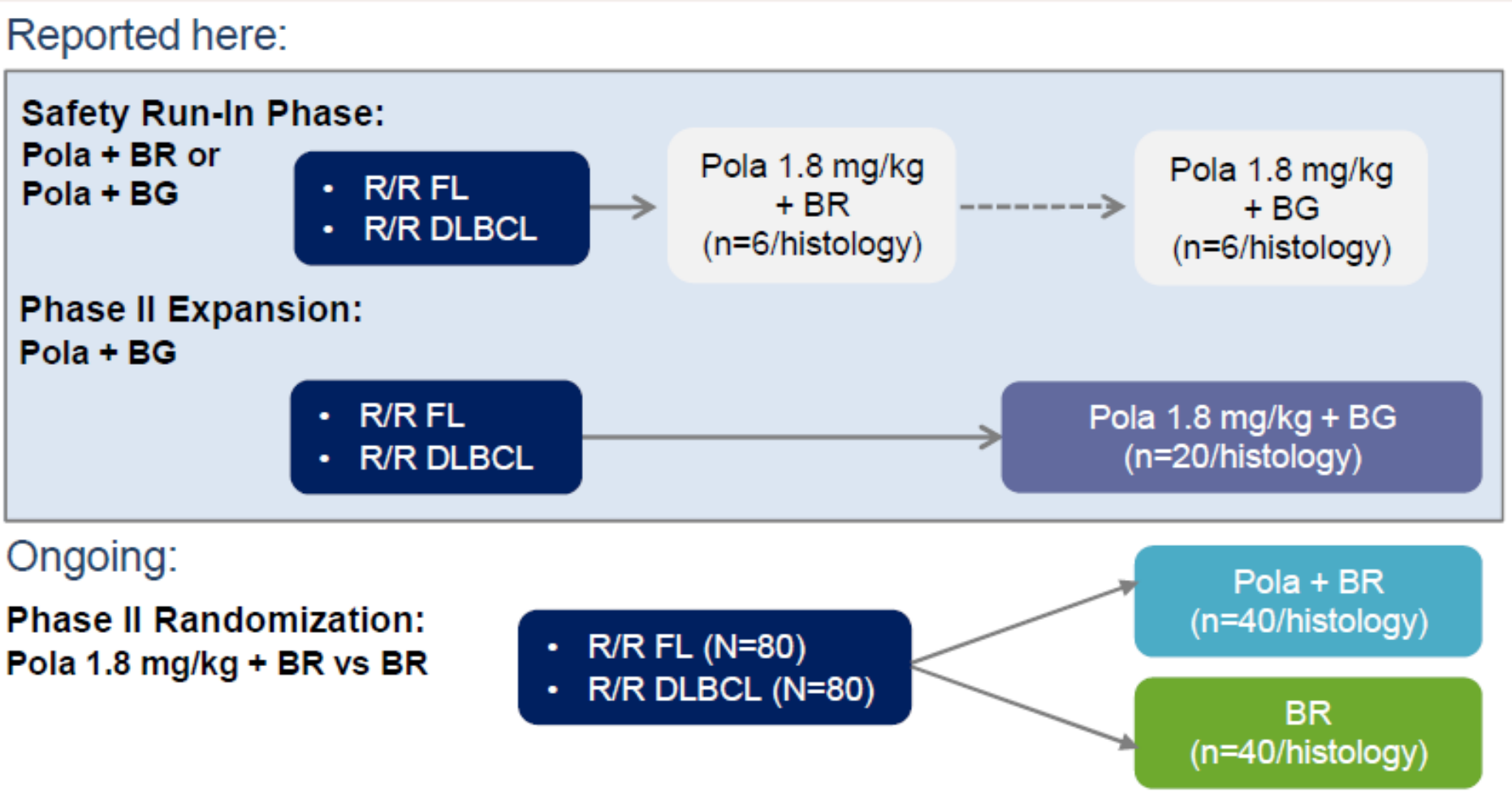
- Phase Ib
  - Safety and tolerability of Pola + BR or BG
  - Identify the recommended Phase II dose (RP2D) of Pola when given in combination with BR or BG

Key Secondary

- To evaluate the efficacy of the combination of Pola + BG as measured by:
  - Best objective response, objective response at end of treatment (tx), and complete response (CR) at end of tx by investigator or independent review committee (IRC) (IRC data not yet available)

M. Matasar et al, EHA 2017 oral presentation

Figure 2: Study Design



Tx: Pola 1.8 mg/kg IV with BR or BG every 28 days for FL pts and every 21 days for DLBCL pts for a total of 6 cycles. Response assessed after 3 cycles, end of tx, and every 6 months during follow-up

M. Matasar et al, EHA 2017 oral presentation

Results

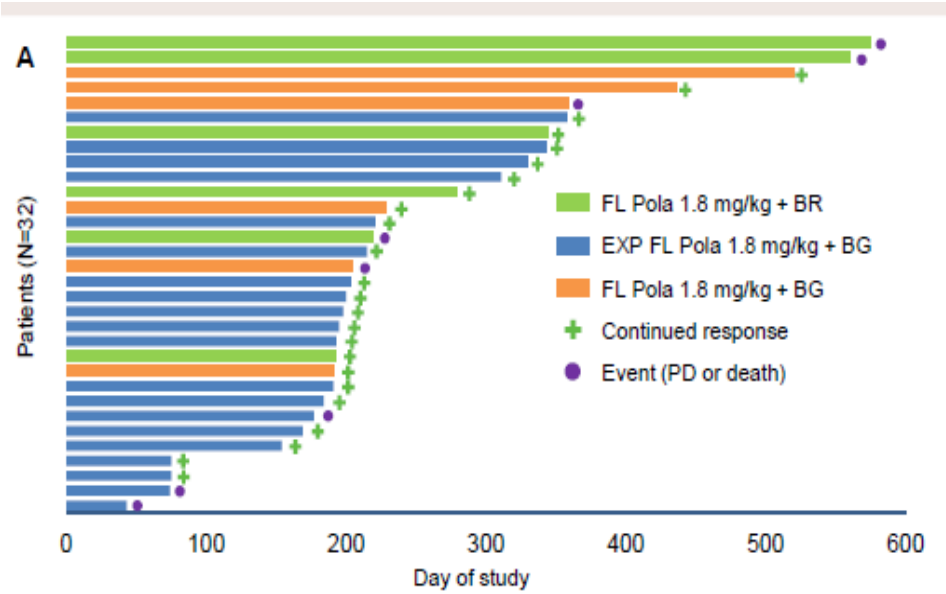
Table 5: Investigator-Assessed Response by PET/CT[a]

	FL		DLBCL	
	Pola + BR (n=6)	Pola + BG (n=26)	Pola + BR (n=6)	Pola + BG (n=27)
Best Objective Response				
ORR, n (%)	6 (100)	23 (89)	3 (50)	16 (60)
CR	4 (67)	17 (65)	2 (33)	11 (41)
PR	2 (33)	6 (23)	1 (17)	5 (19)
SD	0	0	0	2 (7)
PD	0	1 (4)	2(33)	6 (22)
UE	0	2 (8)	1 (17)	3 (11)
Objective Response at End of Tx				
ORR, n (%)	5 (83)	21 (81)	3 (50)	10 (37)
CR	4 (67)	17 (65)	2 (33)	9 (33)
PR	1 (17)	4 (15)	1 (17)	1 (4)
Median duration of response, mo (range)[b]	16.1 (3.8–16.3)	NR (15.2–20.6)	NR (0.03–14.5)	NR (0.03–15.7)
Median PFS, mo (range)[b]	18.4 (7.2–18.9)	NR (1.4–17.1)	NR (1.5–22.7)	5.4 (0.03–17.6)

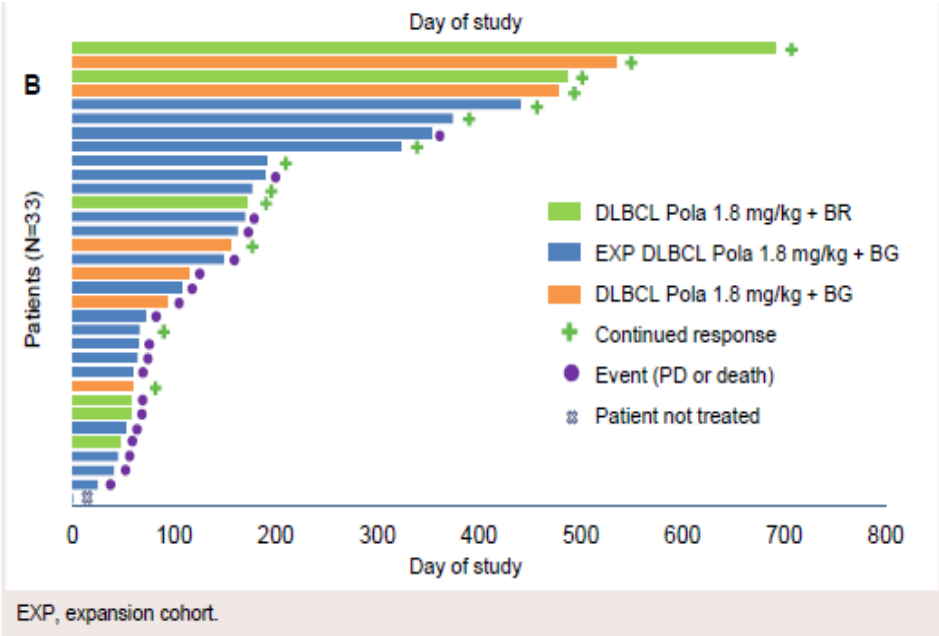
[a]Modified Lugano 2014 response criteria: for CR, repeat bone marrow biopsy required to confirm clearance of bone marrow if involved at screening. [b]Kaplan-Meier method; range data are at clinical data cut-off. NR, not reached; ORR, objective response rate; PD, progressive disease; PFS, progression-free survival; PR, partial response; SD, stable disease; UE, unable to evaluate.

Results

Time to PFS in FL



Time to PFS in DLBCL

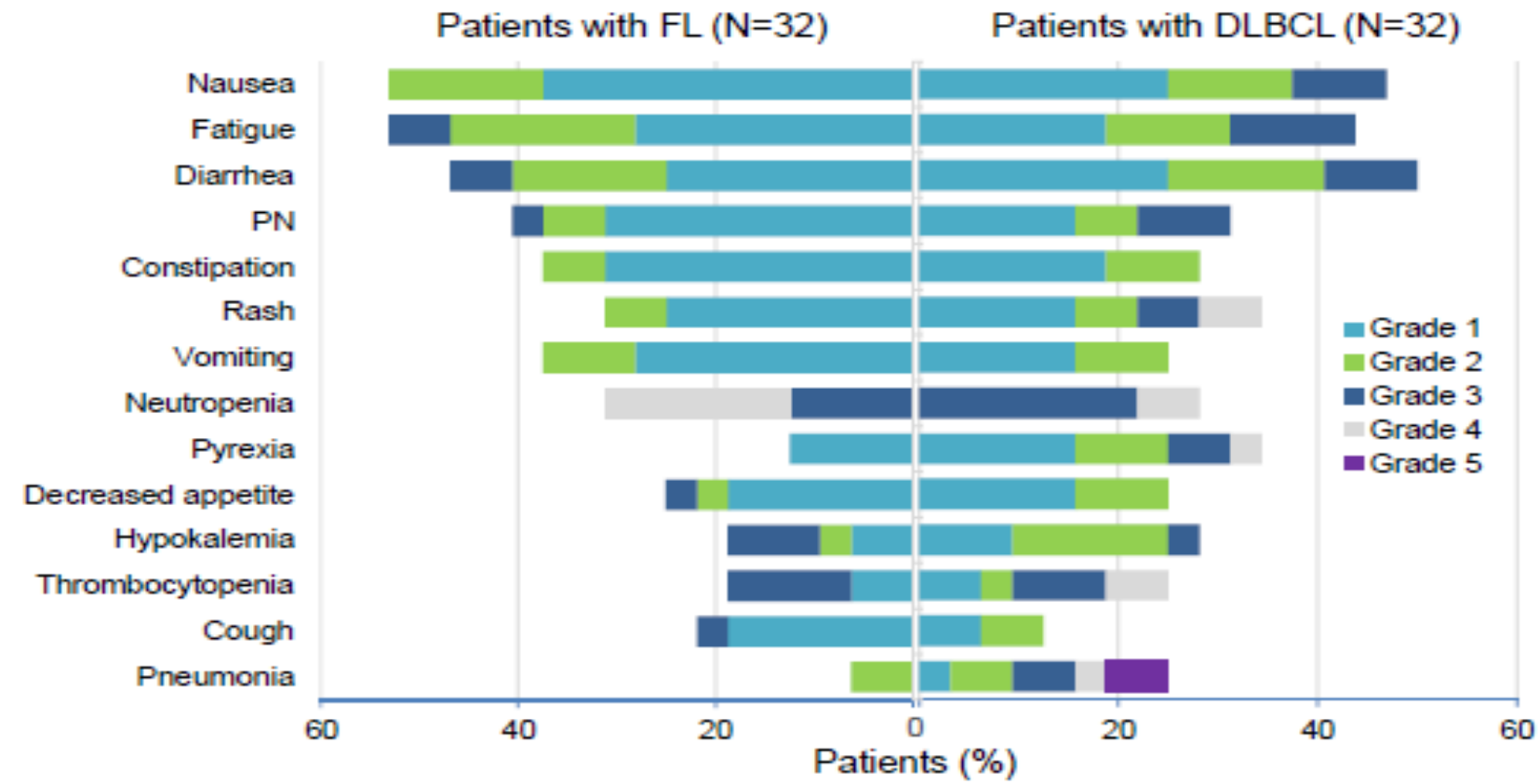


EXP, expansion cohort.

M. Matasar et al, EHA 2017 oral presentation

Results

Figure 3: Adverse Events (>20% patients)



Data are for BR and BG groups combined

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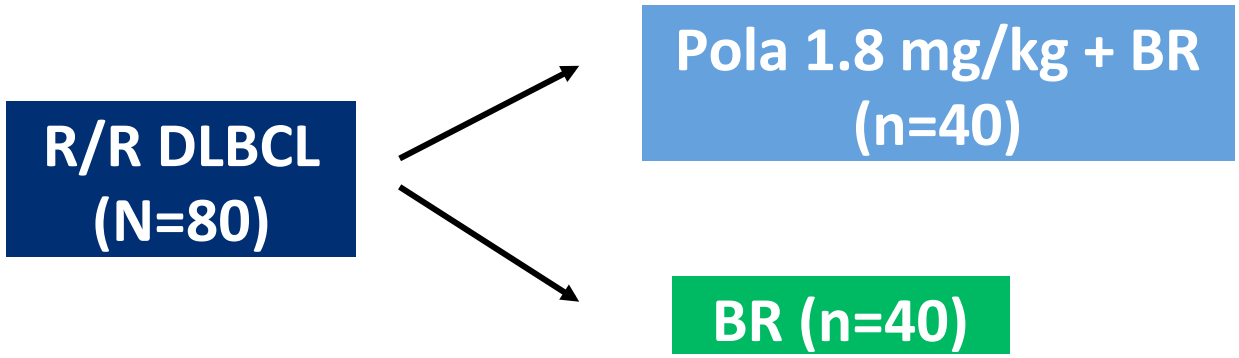
Addition of Polatuzumab Vedotin to Bendamustine and Rituximab (BR) Improves Outcomes in Transplant-Ineligible Patients with Relapsed/Refractory Diffuse Large B-Cell Lymphoma Versus BR Alone: Results from a Randomized Phase 2 Study

Laurie H. Sehn,[1] Alex F. Herrera,[2] Matthew Matasar,[3] Manali Kamdar,[4] Andrew McMillan,[5] Tae Min Kim,[6] Won Seog Kim,[7] Mark Hertzberg,[8] Muhit Ozcan,[9] Elicia Penuel,[10] Ji Cheng,[11] Jamie Hirata,[10] Grace Ku,[10] Christopher R. Flowers[12]

Sehn et al; 59th ASH, Dec 2017, Abstract No.: 2821

Study design

Study design schema: R/R DLBCL Phase 2 randomization



Stratification factor:
Duration of response ≤12 months vs >12 months

Treatment administered every 21 days x 6 cycles

- Pola: 1.8 mg/kg, D1 of each cycle
- R: 375 mg/m^2, D1 of each cycle
- B: 90 mg/m^2, D2 and D3 in Cycle 1, then D1 and D2 in each subsequent cycle

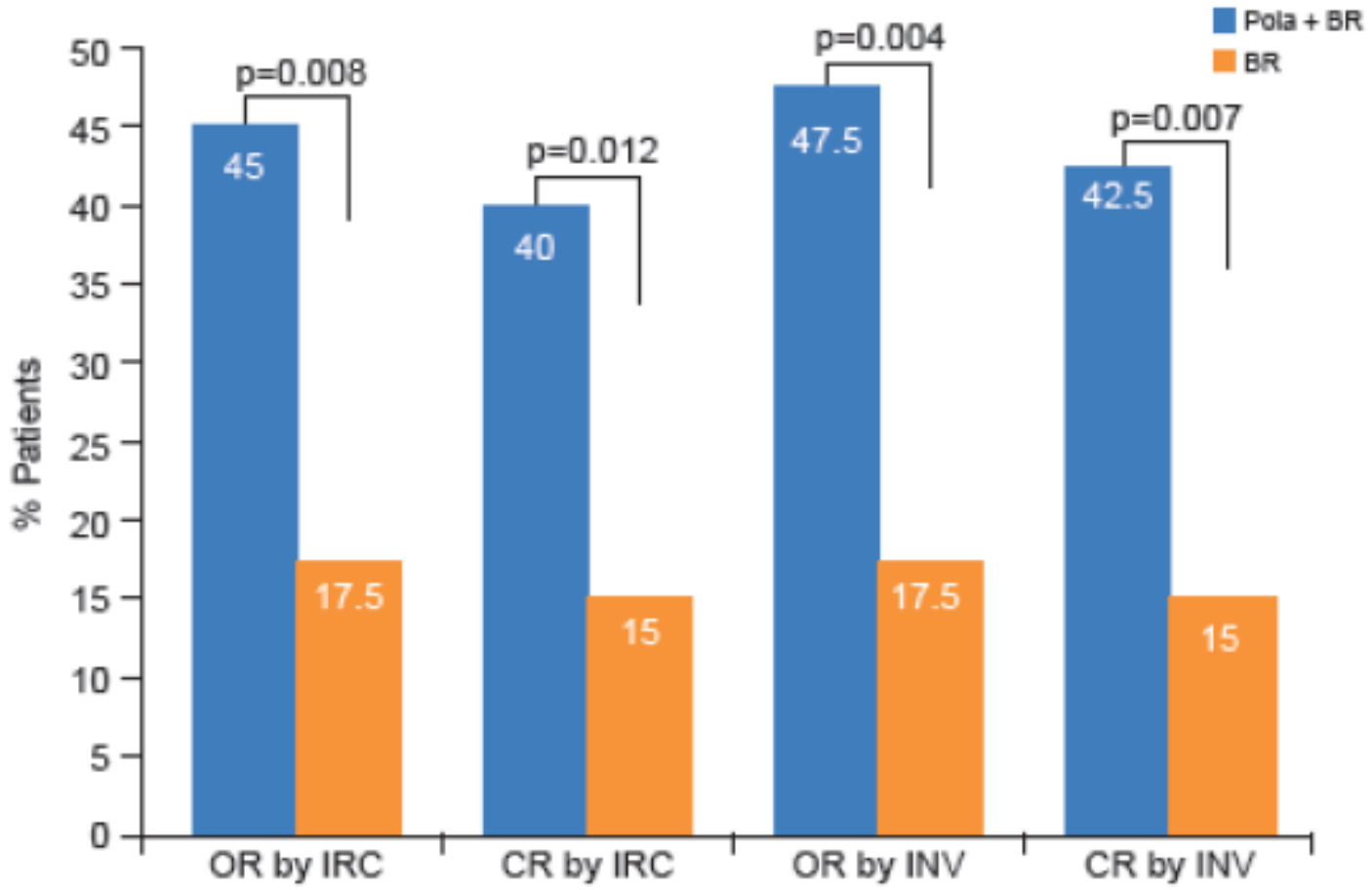
Sehn et al; 59th ASH, Dec 2017, Abstract No.: 2821

Baseline characteristics

	Pola + BR (n=39)	BR (n=39)
Median age, years (range)	67 (33–86)	71 (30–84)
Male sex, n (%)	27 (69.2)	25 (64.1)
ECOG 2, n (%)	6 (15.4)	8 (20.5)
Bulky disease ≥7.5 cm, n (%)	9 (23.1)	15 (38.5)
Ann Arbor Stage III/IV, n (%)	33 (84.6)	35 (89.7)
Extranodal involvement, n (%)	26 (66.7)	29 (74.4)
IPI grade 3–5 at enrollment, n (%)	21 (53.8)	28 (71.8)
Median # of prior therapies (range) 1 line 2 lines ≥3 lines	2 (1–7) 11 (28.2) 14 (35.9) 14 (35.9)	2 (1–5) 13 (33.3) 9 (23.1) 17 (43.6)
Refractory to last treatment, n (%)	29 (74.4)	32 (82.1)
Duration of response to last treatment ≤ 12 months, n (%)	31 (79.5)	33 (84.4)
Received anti-CD20 agents	38 (97.4)	39 (100)

Sehn et al; 59th ASH, Dec 2017, Abstract No.: 2821

Objective response and complete response (IRC and INV) by PET-CT

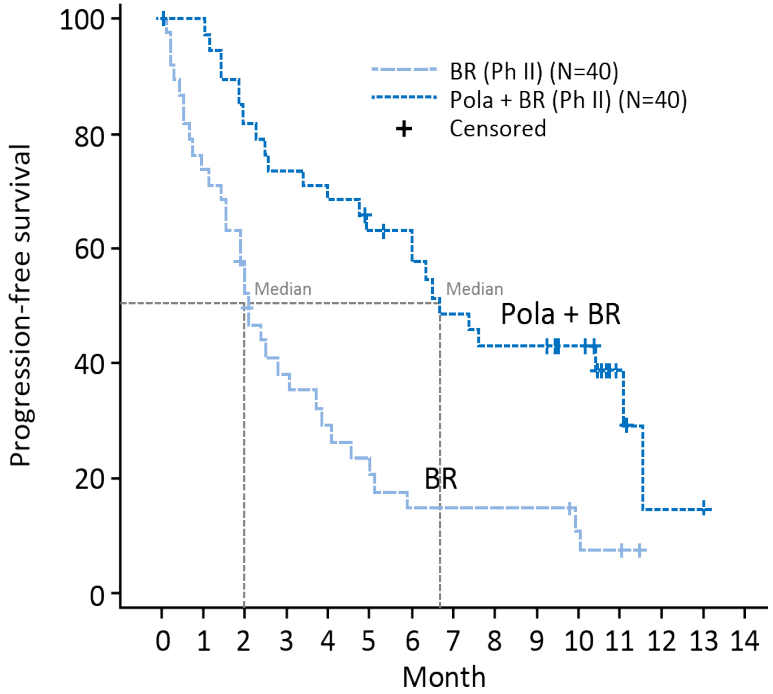


- **Primary endpoint**: IRC assessed PET-CR at time of PRA, 6-8 weeks after Cycle 6 Day 1 or last dose of therapy.

Sehn et al; 59th ASH, Dec 2017, Abstract No.: 2821

Survival

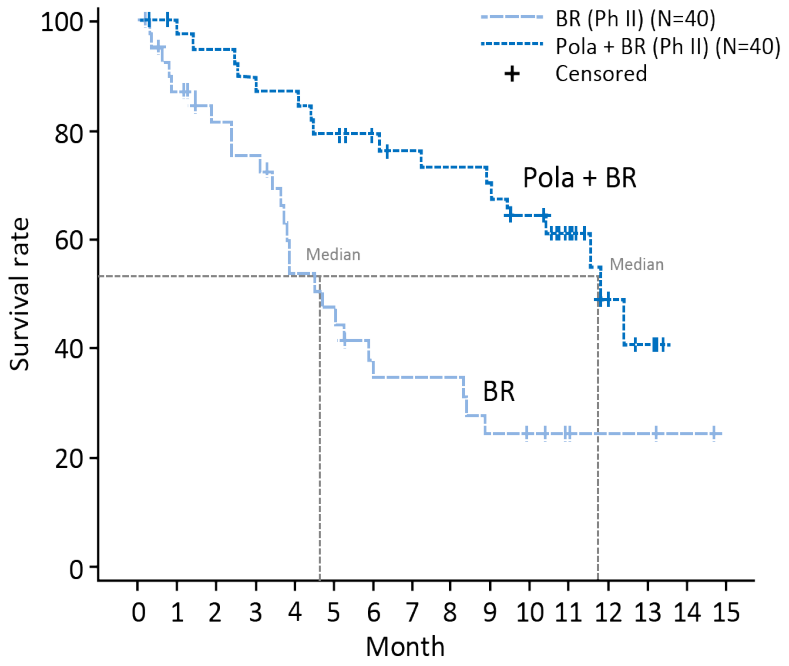
PFS



No. of patients at risk

BR (Ph II)	40	28	19	13	10	8	5	5	5	5	3	2		
Pola + BR (Ph II)	40	38	31	28	26	23	21	17	15	15	12	4	1	1

OS



No. of patients at risk

BR (Ph II)	40	33	27	25	17	15	11	10	10	7	8	3	2	2	1
Pola + BR (Ph II)	40	38	36	34	33	30	27	25	24	23	20	14	6	4	

Sehn et al; 59th ASH, Dec 2017, Abstract No.: 2821

Results - safety

	Pola + BR (n=39)	BR (n=39)
Total number of patients with ≥1 AE	39 (100)	38 (97.4)
Grade 5 AE*, n (%)	6 (15.4)	7 (17.9)
SAE, n (%)	20 (51.3)	20 (51.3)
SAE occurring in ≥3 patients		
Infections, n (%)	8 (20.5)	10 (25.6)
Pneumonia, n (%)	3 (7.7)	3 (7.7)
Febrile neutropenia, n (%)	4 (10.3)	2 (5.1)
Neutropenia, n (%)	0	3(7.7)
Pyrexia, n (%)	4 (10.3)	1 (2.6)
Grade 3–4 AE, n (%)	33 (84.6)	26 (66.7)
Grade 3–4 AE occurring in ≥10% patients		
Neutropenia	18 (46.2)	14 (35.9)
Febrile neutropenia	4 (10.3)	2 (5.1)
Thrombocytopenia	13 (33.3)	8 (20.5)
Anemia	10 (25.6)	5 (12.8)
Infections	7 (17.9)	7 (17.9)

Sehn et al; 59th ASH, Dec 2017, Abstract No.: 2821

Polatuzumab Vedotin: outline of discussion

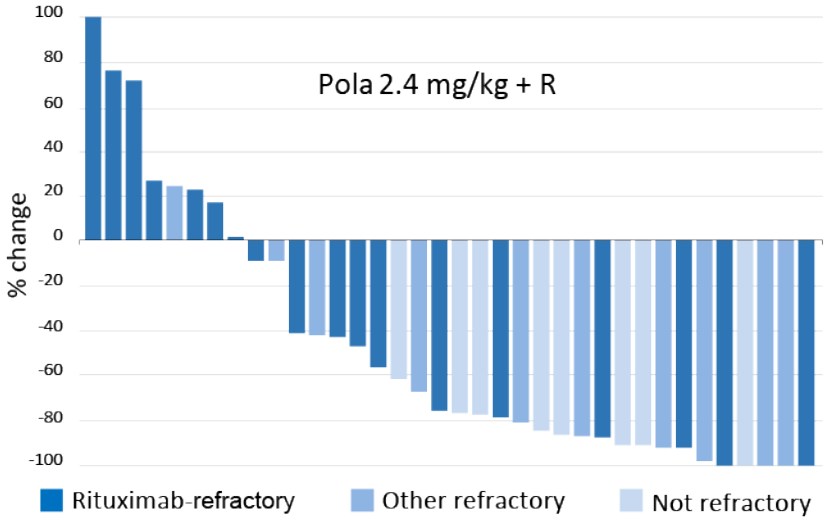
- Relapsed or refractory Non Hodgkin's lymphoma
- Previously untreated Diffuse Large B-Cell Lymphoma (DLBCL)

Polatuzumab Vedotin in R/R DLBCL

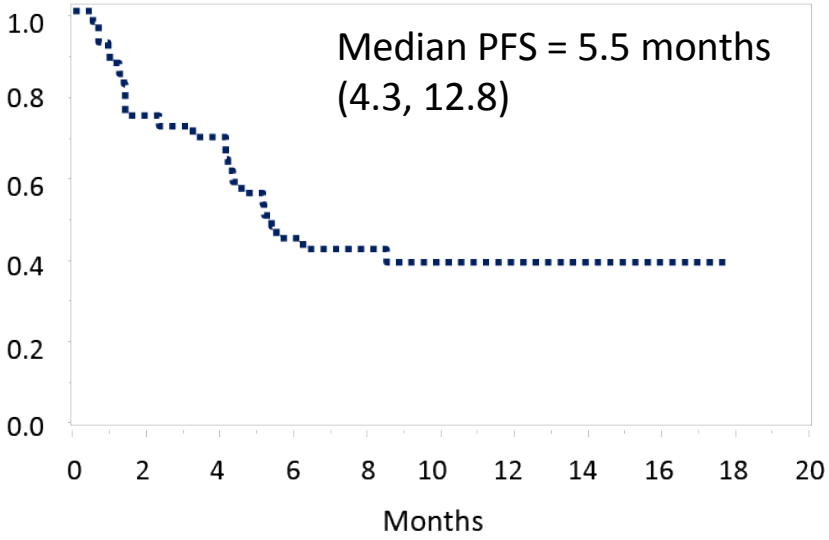
Disease	Treatment Regimen	Best Overall Response
R/R DLBCL	Pola 1.8–2.4 mg/kg	51%[1]
	Pola 1.8–2.4 mg/kg + rituximab	56%[2]

R/R DLBCL from the ROMULUS trial: pola + rituximab

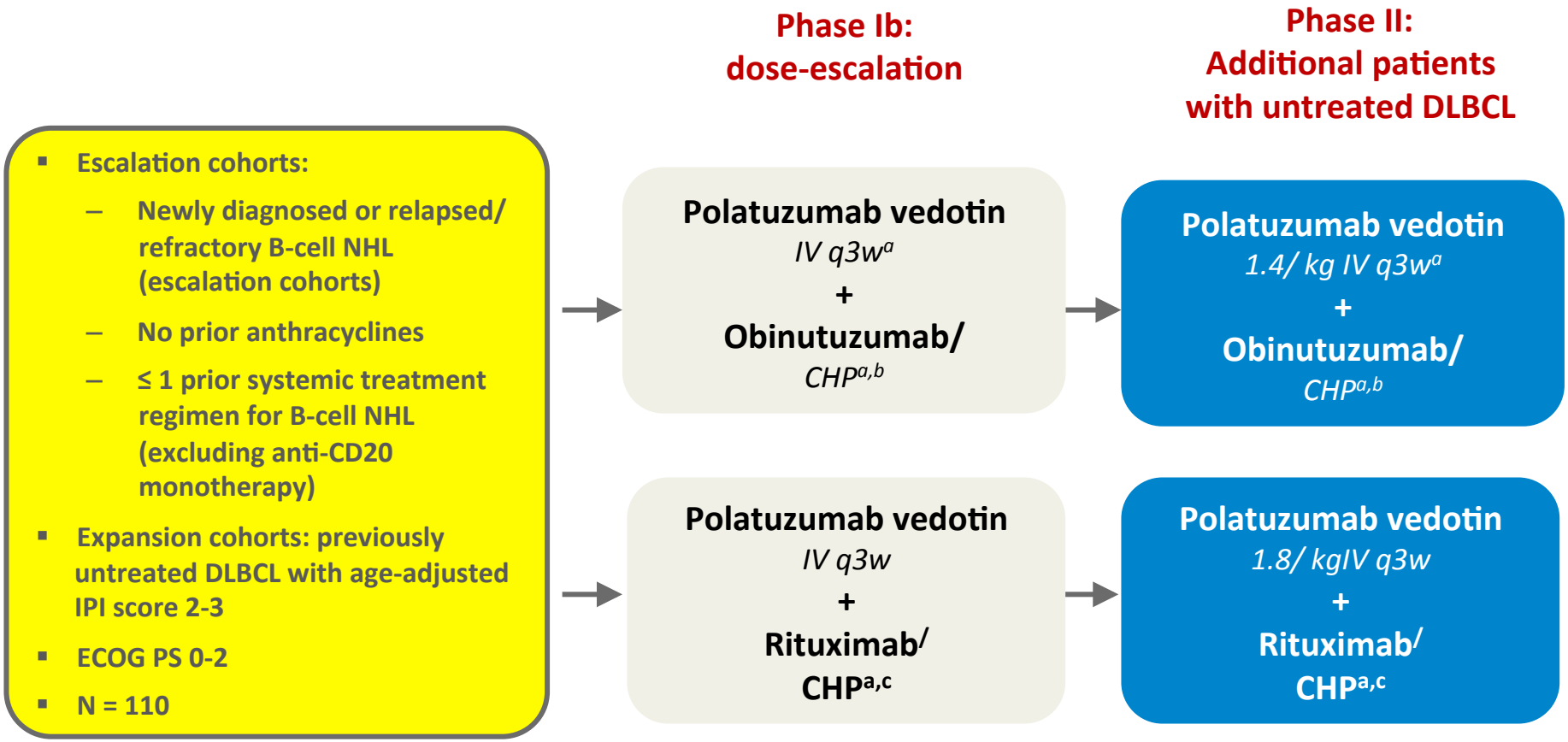
Best SPD Change from Baseline



Progression-Free Survival



Polatuzumab vedotin: DLBCL phase Ib/II study GO29044

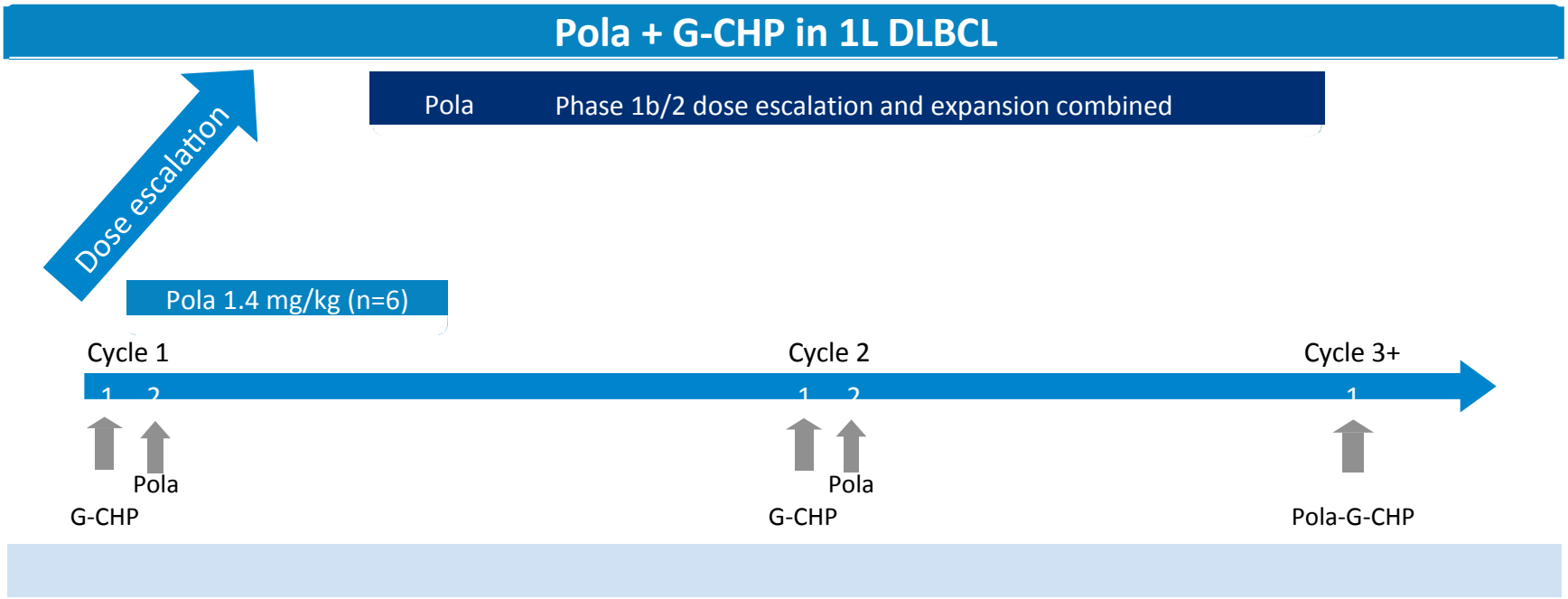


Polatuzumab vedotin combined with obinutuzumab, cyclophosphamide, doxorubicin, and prednisone (G-CHP) for patients with previously untreated DLBCL: Updated results of a phase 1b/2 study

Andres Forero-Torres,[1] Kathryn S. Kolibaba,[2,7] Hervé Tilly,[3] Gilles Salles,[4] Lijia Wang,[5] Calvin Lee,[5] Jeff Sharman[6,7]

Andres Forero-Torres et al; 59th ASH, Dec 2017, Abstract No.: 4120

Study design – pola-G-CHP cohort



G= obinutuzumab 1000 mg IV on day 1, 8, 15 of Cycle 1; on day 1 of subsequent cycles
C= cyclophosphamide 750 mg/m^2 IV on day 1
H= doxorubicin 50 mg/m^2 IV on day 1
P= prednisone 100 mg/day po on days 1–5
Pola administered on day 2 of cycles 1 and 2 (for pharmacokinetics); on day 1 of subsequent cycles

Treatment was administered every 21 days for total of 6 or 8 cycles; granulocyte-colony stimulating factor (G-CSF) was allowed as primary prophylaxis

1L, first line; DLBCL, diffuse large B-cell lymphoma

Andres Forero-Torres et al; 59th ASH, Dec 2017, Abstract No.: 4120

Baseline characteristics

	N=21
Median Age, years (range)	67 (28–76)
Male, n (%)	12 (57)
ECOG, n (%) 0–1 2	 17 (81) 4 (19)
Stage, n (%) I/II III/IV	 3 (14) 18 (86)
IPI, n (%) 0–1 2 3 4–5	 3 (15) 10 (48) 4 (19) 4 (19)
Available Cell of Origin (GEP)* ABC GCB Unclassified	**(N=13)** 3 (23) 10 (77) 0

Results – efficacy

- End-of-treatment responses by PET/CT (Cheson 2007 criteria)
  - ***Complete response in 17 (81%) patients***
  - ***Partial response in 2 (10%) patients***
  - Two patients unevaluable (discontinued study as a result of adverse events [septic shock, thrombocytopenia] prior to response assessment).

- At data cut-off date 21 July 2017, median study duration was 12.6 months; two patients had experienced an OS event.

Andres Forero-Torres et al; 59th ASH, Dec 2017, Abstract No.: 4120

Results - safety

Adverse event profile, pola-G-CHP (N=21)	
	n (%)
Any adverse event (AE)	21 (100)
Grade 3/4 AE	15 (71)
Serious AE	9 (43)
AE leading to treatment discontinuation*	4 (19)
AE leading to pola dose reduction	0
Peripheral neuropathy, all grades grade ≥2	8 (38) 2 (10)
Deaths†	1 (5)

Andres Forero-Torres et al; 59th ASH, Dec 2017, Abstract No.: 4120

Pola-R-CHP: Polatuzumab Vedotin Combined with Rituximab, Doxorubicin, Cyclophosphamide, Prednisone for Patients with Previously Untreated DLBCL

Hervé Tilly[1], Jeff Sharman[2,11], Nancy Bartlett[3], Franck Morschhauser[4], Corinne Haioun[5], Javier Munoz[6], Andy Chen[7], Thierry Lamy[8], Lijia Wang[9], Elicia Penuel[9], Jamie Hirata[9], Calvin Lee[9], Gilles Salles[10]

Tilly et al Presented at ICML 2017

Pola-R-CHP administration

Drug	Route	Dose	Days
Rituximab	IV	375 mg/m^2	1
Cyclophosphamide	IV	750 mg/m^2	1
Doxorubicin	IV	50 mg/m^2	1
Vincristine	-	-	-
Prednisone	PO	100 mg/day	1–5
Polatuzumab vedotin	**IV**	**1.8 mg/kg**	**2** (cycle 1 and cycle 2) **1** (subsequent cycles)

6–8 cycles at 21-day interval
Response evaluation (CT and PET) after 4 cycles and end of treatment

Objectives
To assess safety, tolerability and efficacy of Pola-R-CHP

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Patient Baseline Characteristics

Characteristics	N = 45
Median age, yr (range)	**69** (45–80)
Sex	
Male, n (%)	22 (49)
Female, n (%)	23 (51)
ECOG PS, n (%)	
0–1	30 (67)
2	15 (33)
Stage III/IV disease, n (%)	**37 (82)**
International Prognosis Index (IPI), n (%)	
0–1	1 (2)
2	9 (20)
3	**18 (40)**
4–5	**17 (38)**
Available cell of origin, n = 34	
Activated B-cell, n (%)	12 (35)
Germinal center B-cell, n (%)	17 (50)
Unclassified, n (%)	5 (15)

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PET Response at End of Treatment

	Pola-R-CHP (N =45)	90% CI
Overall response rate	41 (91)	[81, 97]
Complete response	35 (78)	[65, 87]
Partial response	6 (13)	[6, 25]
Progressive disease	3 (7)	[2, 16]
Unevaluable/missing	1 (2)	[0, 10]

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PET Response at End of Treatment by Biomarker Subgroups

	Cell of origin available n = 34 (%)		
	ABC n = 12	GCB n = 17	Unclassified n = 5
Overall response rate	**12 (100)**	**17 (100)**	3 (60)
Complete response	**11 (92)**	**15 (88)**	2 (40)
Partial response	**1 (8)**	**2 (12)**	1 (20)

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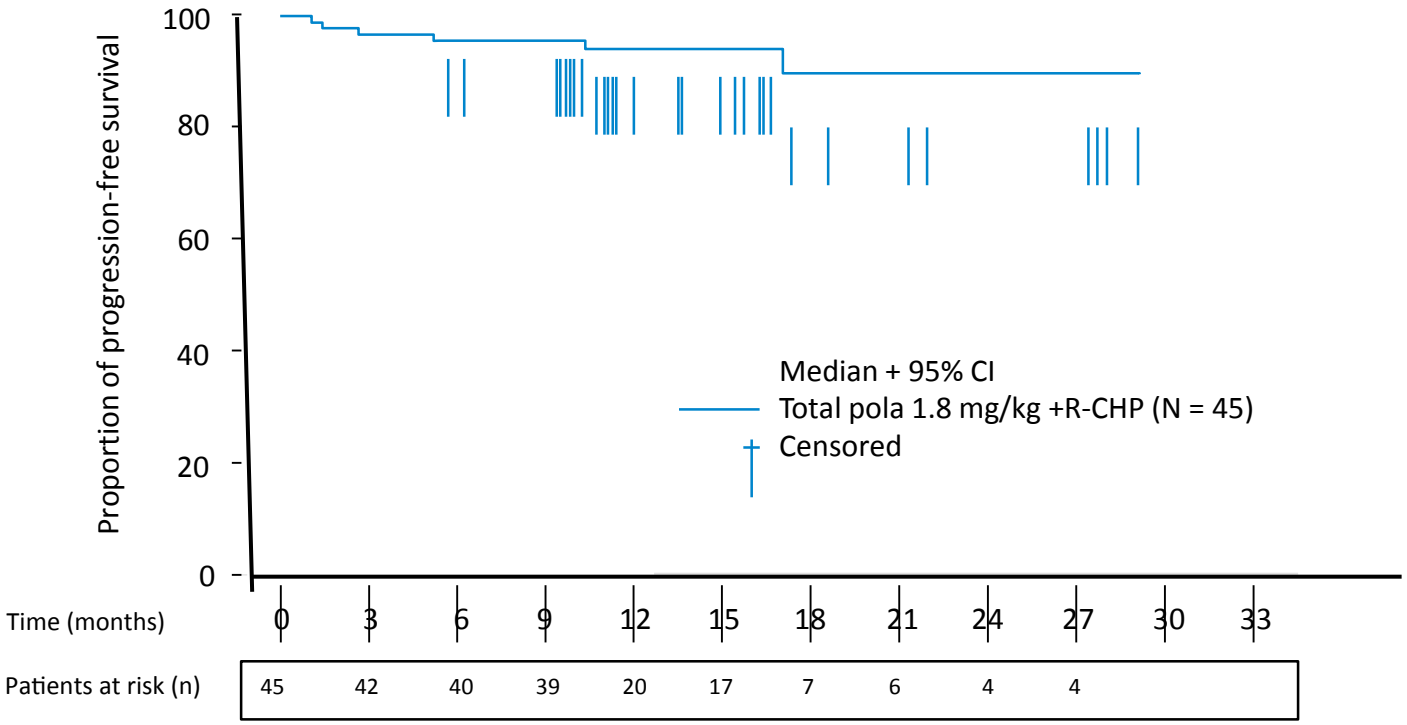
Progression-Free Survival

- Median study duration = 14.9 months



Adverse Events

	Pola-R-CHP N = 45 n (%)	BO21005/GOYA[1] R-CHOP-21 N = 703 (%)
Grade 3–5 adverse events	**26 (58)**	**(65)**
Neutropenia	12 (27)	(38)
Febrile neutropenia	5 (11)	(15)
Infections and infestations	5 (11)	(15)
Thrombocytopenia	2 (4)	(1)
Grade 5 adverse events	**1 (2)***	**(4)**
Serious adverse events	**17 (38)**	**(38)**
Infections and infestations	5 (11)	NA
Febrile neutropenia	3 (7)	NA
Pulmonary embolism	2 (4)	NA

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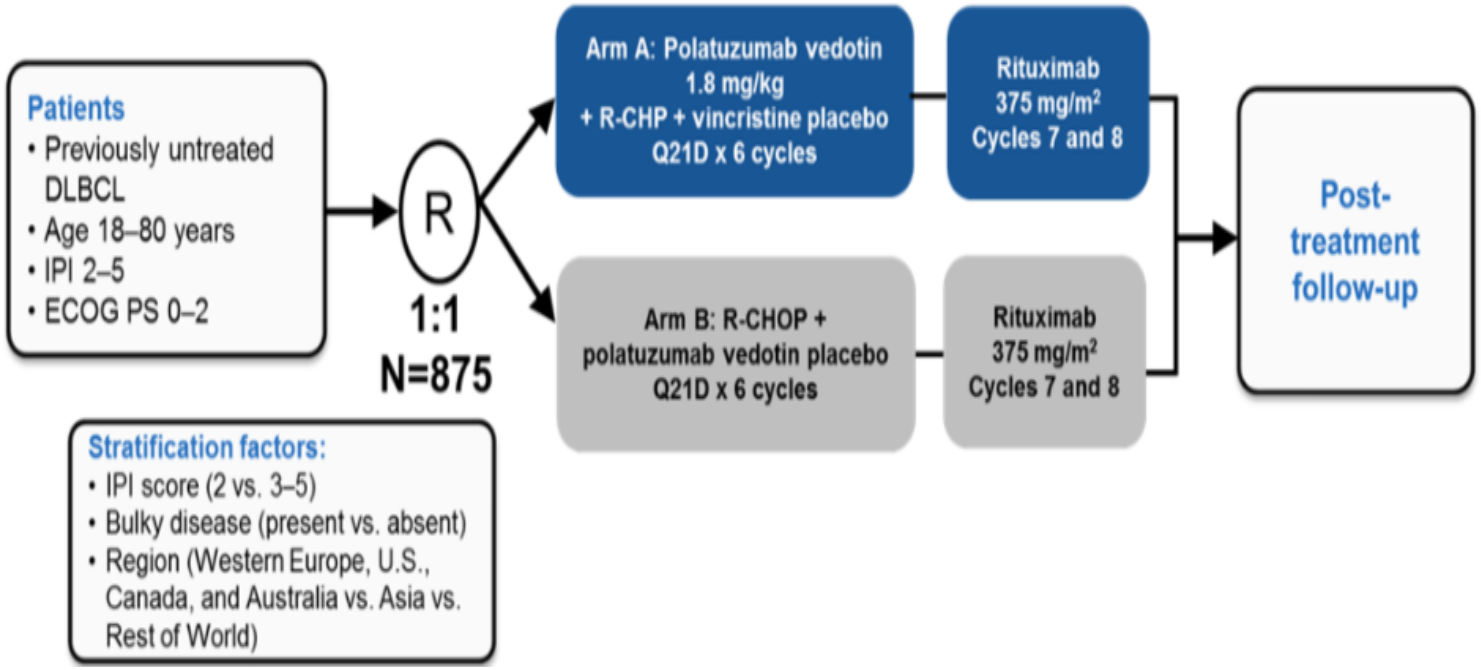
PHASE III TRIAL COMPARING EFFICACY AND SAFETY OF POLATUZUMAB R-CHP VS R-CHOP IN DLBCL

POLARIX

Figure 1 Study Schema



Clinical trials in Progress

- A phase1b/2 study (NCT02611323) is evaluating ***Polatuzumab*** vedotin combined with ***obinutuzumab or Rituximab and venetoclax*** in patients with ***R/R FL and DLBCL***

- A phase1b/2 study (NCT02600897) is evaluating ***Polatuzumab*** vedotin combined with ***obinutuzumab and Lenalidomide*** in patients with ***R/R FL*** and ***Polatuzumab*** vedotin combined with ***Rituximab and Lenalidomide in R/R DLBCL***

- A phase1b/2 study (NCT02729896) is evaluating ***Polatuzumab*** vedotin combined with ***obinutuzumab and Atezolizumab*** in patients with ***R/R FL*** and ***Polatuzumab*** vedotin combined with ***Rituximab and Atezolizumab in R/R DLBCL***

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