Nuove strategie terapeutiche anti-CD19 nel paziente ricaduto/refrattario DLBCL

Le alternative terapeutiche attuali

MONDO
LINFOMI:
UN'INCREDIBILE DINAMICITÀ

7 NOVEMBRE 2023
Mercure Villa Romanazzi Carducci

Bari

Disclosures of Giacomo Loseto

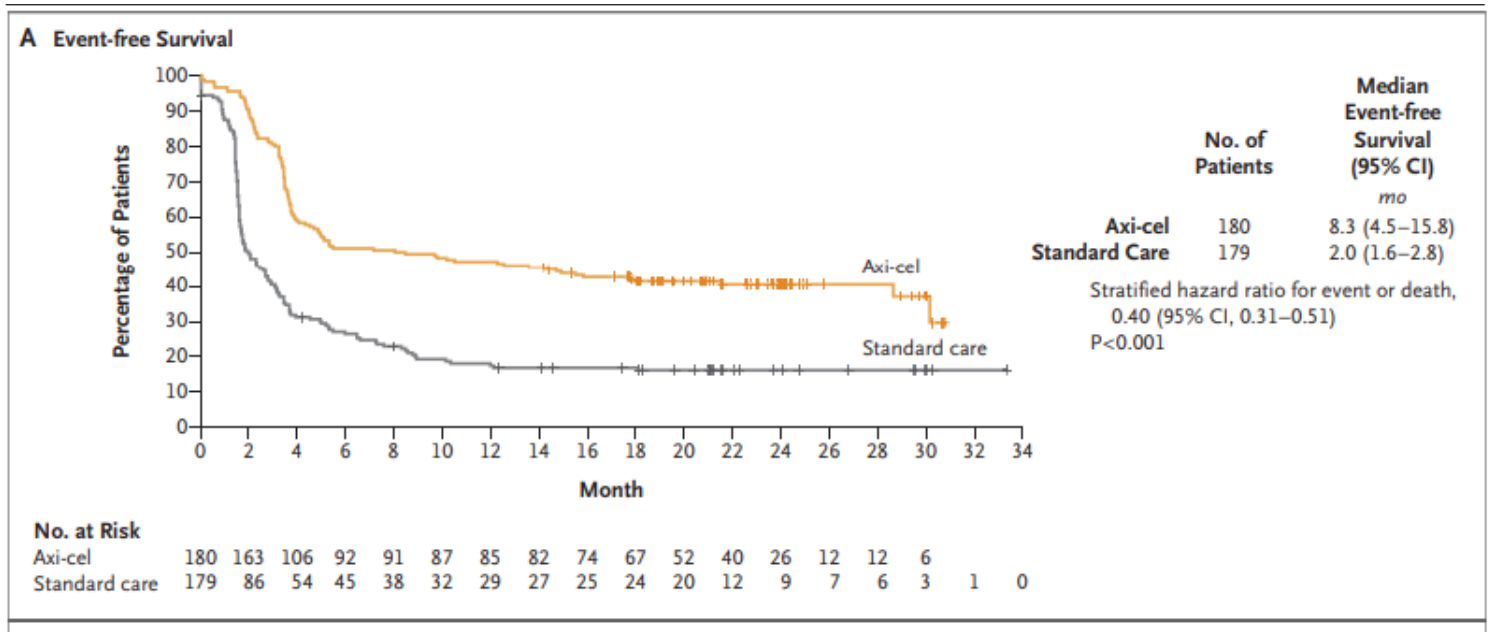
Company name	Research support	Employee	Consultant	Stockholder	Speakers bureau	Advisory board	Other
Janssen-Cilag			x			x	
Gilead			x			x	
Roche						x	
Italfarmaco						x	
Takeda						x	
AbbVie						x	
Incyte			x			x	
Astrazeneca						x	
MorphoSys						x	

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Axicabtagene Ciloleucel as Second-Line Therapy for Large B-Cell Lymphoma

F.L. Locke, D.B. Miklos, C.A. Jacobson, M.-A. Perales, M.-J. Kersten,



NEJM 386;February 17, 2022

JACC: CARDIOONCOLOGY
VOL. 5, NO. 3, 2023

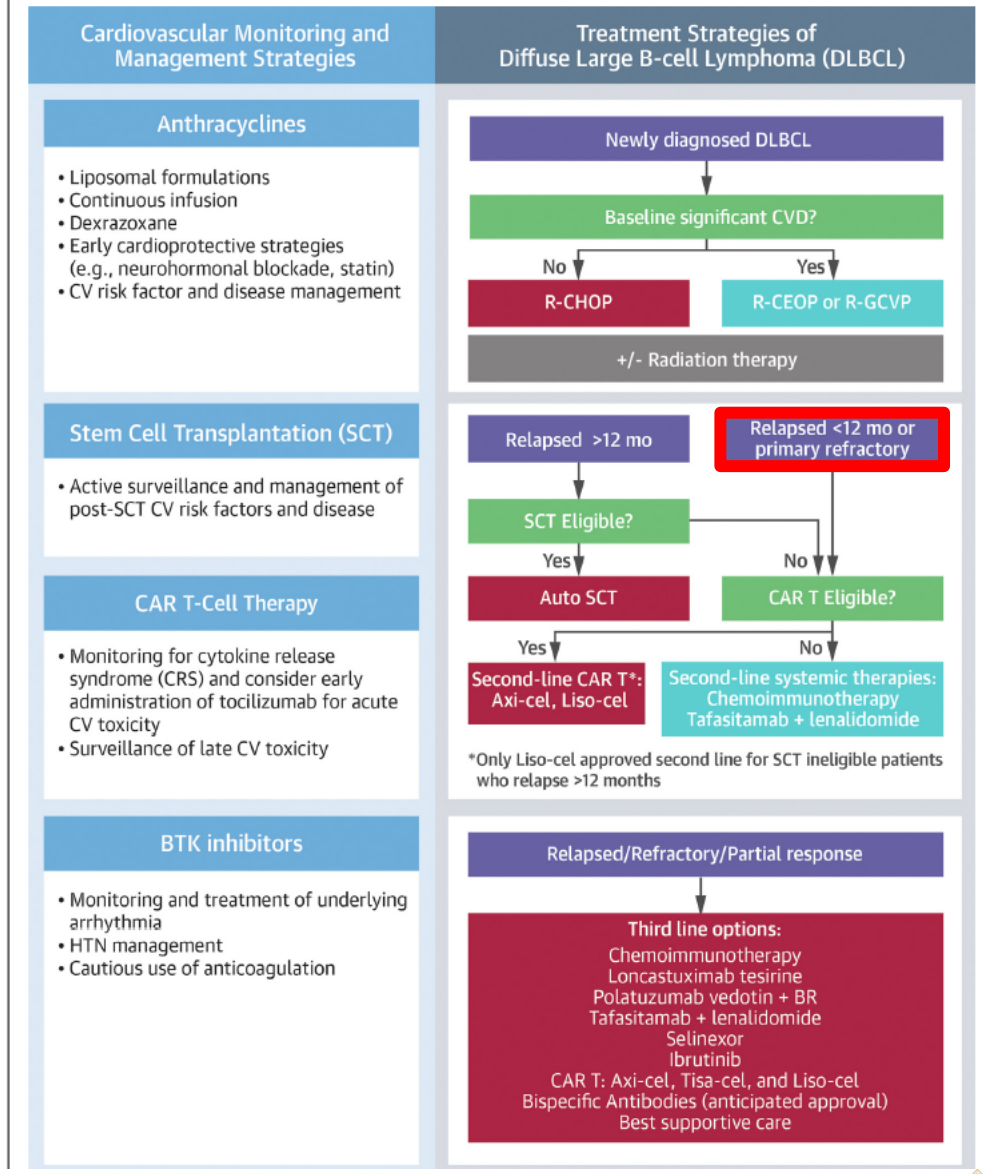
PRIMERS IN CARDIO-ONCOLOGY

How to Treat Diffuse Large B-Cell Lymphoma

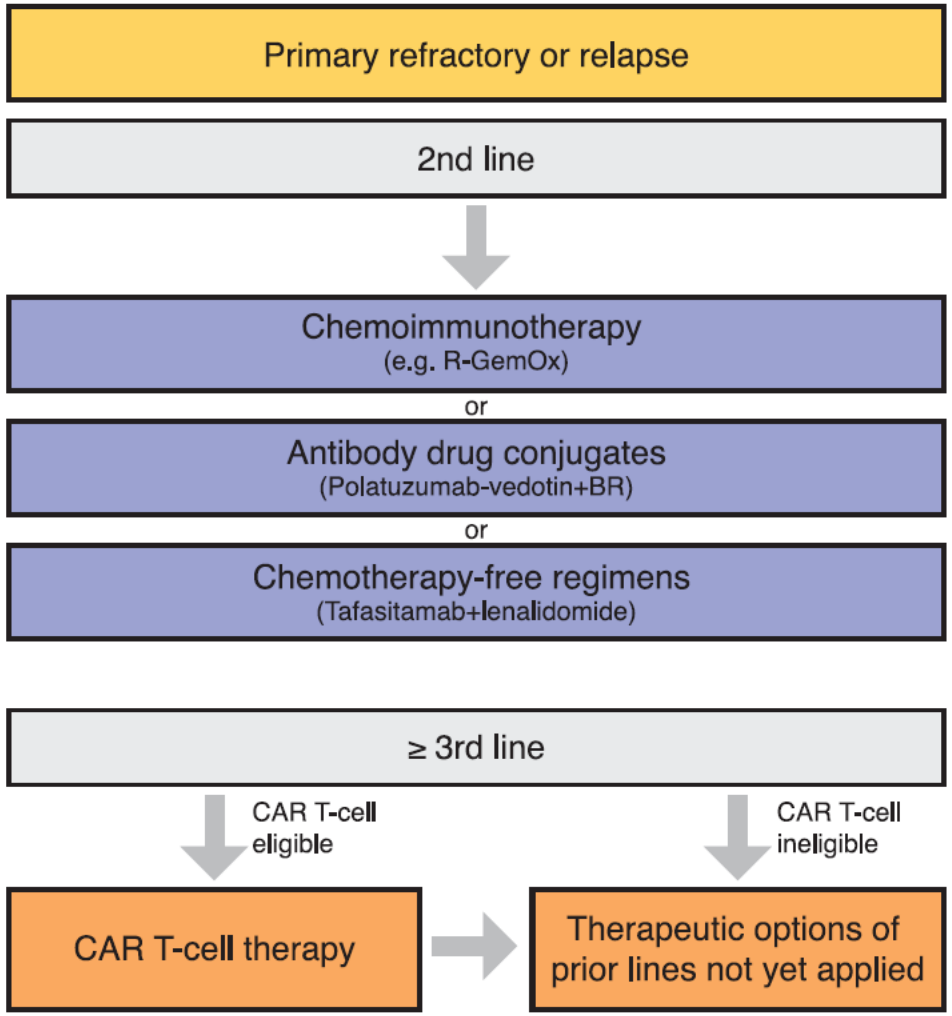
Oncologic and Cardiovascular Considerations

Swetha Kambhampati, MD,[a] Alex F. Herrera, MD,[a] June-Wha Rhee, MD[b]

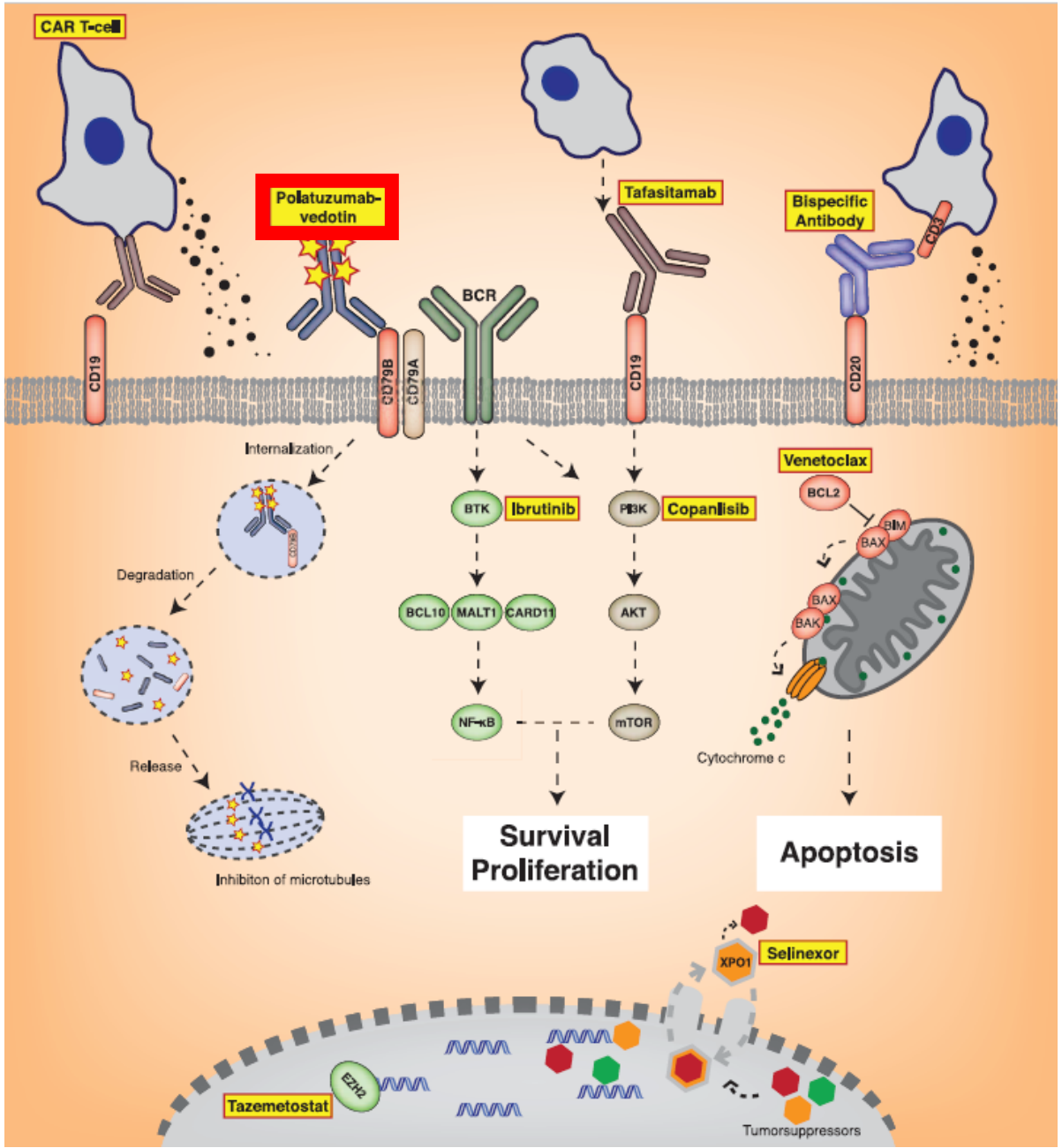
FIGURE 1 Schema Outlining Treatment Strategies for DLBCL and Cardiovascular Considerations



Transplant-ineligible patients



Fabian Frontzek *Ther Adv Hematol* 2022, Vol. 13: 1–19

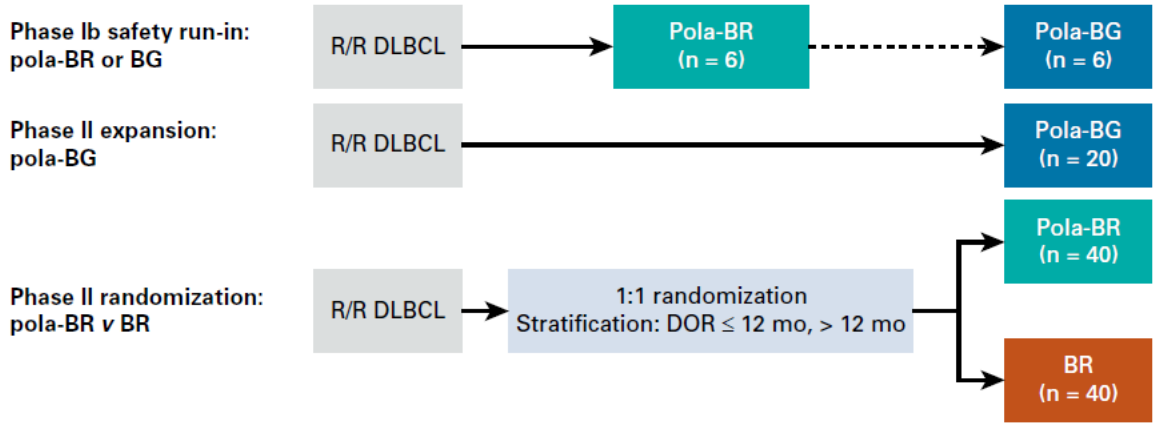


Fabian Frontzek. *Ther Adv Hematol.* 2022, Vol. 13: 1–19

Polatuzumab Vedotin in Relapsed or Refractory Diffuse Large B-Cell Lymphoma

Laurie H. Sehn, MD, MPH[1]; Alex F. Herrera, MD[2]; Christopher R. Flowers, MD, MSc[3]; Manali K. Kamdar, MD, MBBS[4];

Patients with transplantation-ineligible R/R DLBCL



The **median number of prior lines** of therapy was **2**

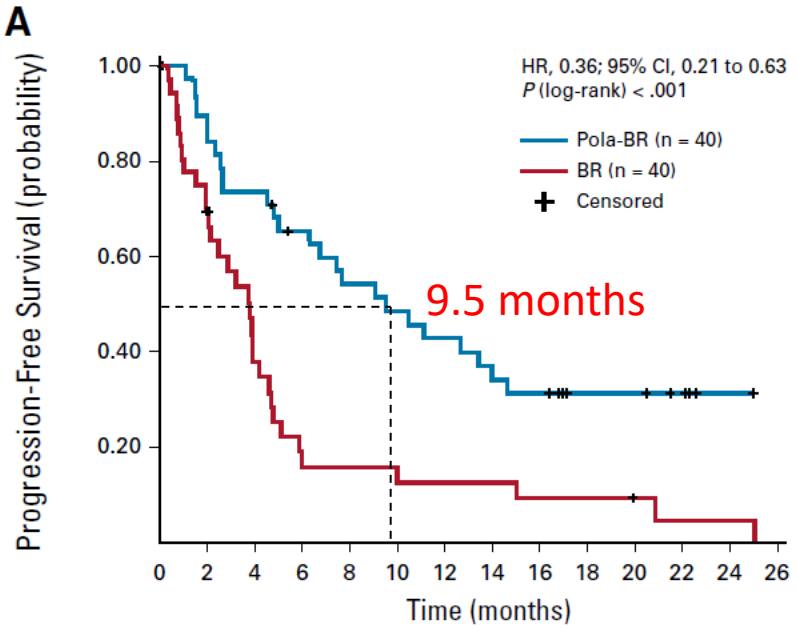
Patients refractory to the **last treatment**: **75% pola-BR** and **85% BR**

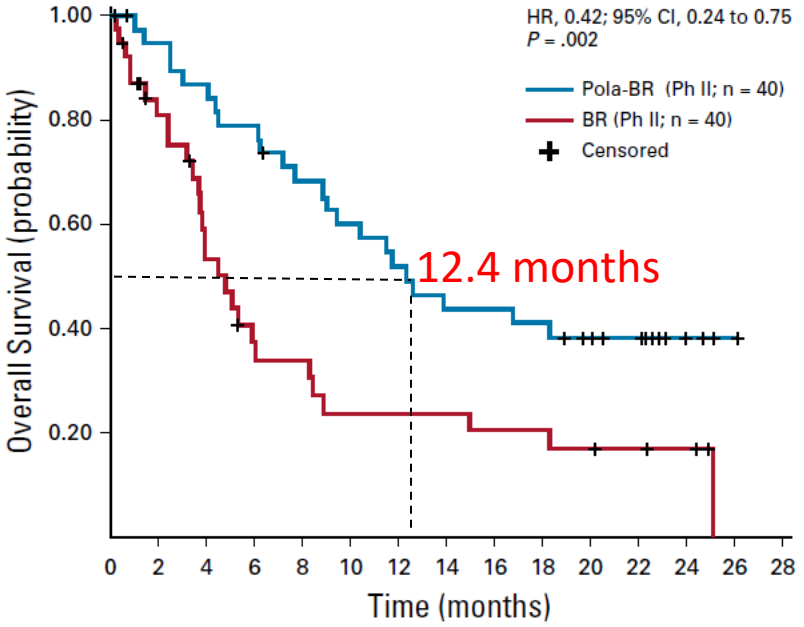
J Clin Oncol 38:155-165. © 2019

Polatuzumab Vedotin in Relapsed or Refractory Diffuse Large B-Cell Lymphoma

Laurie H. Sehn, MD, MPH[1]; Alex F. Herrera, MD[2]; Christopher R. Flowers, MD, MSc[3]; Manali K. Kamdar, MD, MBBS[4];

	Phase II Randomized	
Outcome	**Pola-BR (n = 40)**	**BR (n = 40)**
End of treatment		
IRC, objective response	18 (45.0)	7 (17.5)
Complete response	16 (40.0)	7 (17.5)
Partial response	2 (5.0)	0
Stable disease	6 (15.0)	1 (2.5)
Progressive disease	8 (20.0)	10 (25.0)





J Clin Oncol 38:155-165. © 2019

Polatuzumab Vedotin in Relapsed or Refractory Diffuse Large B-Cell Lymphoma

Laurie H. Sehn, MD, MPH[1]; Alex F. Herrera, MD[2]; Christopher R. Flowers, MD, MSc[3]; Manali K. Kamdar, MD, MBBS[4];

TABLE 3. Adverse Events in Patients Treated With Pola-BR Compared With BR

	Pola-BR (n = 39)*		BR (n = 39)*	
Adverse Event	**All Grades, No. (%)**	**Grades 3-4, No. (%)**	**All Grades, No. (%)**	**Grades 3-4, No. (%)**
Blood and lymphatic system disorders				
Anemia	21 (53.8)	11 (28.2)	10 (25.6)	7 (17.9)
Neutropenia	21 (53.8)	18 (46.2)	15 (38.5)	13 (33.3)
Thrombocytopenia	19 (48.7)	16 (41.0)	11 (28.2)	9 (23.1)
Lymphopenia	5 (12.8)	5 (12.8)	0	0
Febrile neutropenia	4 (10.3)	4 (10.3)	5 (12.8)	5 (12.8)
GI disorders				
Diarrhea	15 (38.5)	1 (2.6)	11 (28.2)	1 (2.6)
Nausea	12 (30.8)	0	16 (41.0)	0
Constipation	7 (17.9)	0	8 (20.5)	1 (2.6)
General disorders and administration site conditions				
Fatigue	14 (35.9)	1 (2.6)	14 (35.9)	1 (2.6)
Pyrexia	13 (33.3)	1 (2.6)	9 (23.1)	0
Metabolism and nutrition disorders				
Decreased appetite	10 (25.6)	1 (2.6)	8 (20.5)	0
Peripheral neuropathy				
Peripheral neuropathy†	17 (43.6)	0	3 (7.7)	0

Peripheral neuropathy (43.6%) was the only reason for Pola dose reduction

J Clin Oncol 38:155-165. © 2019

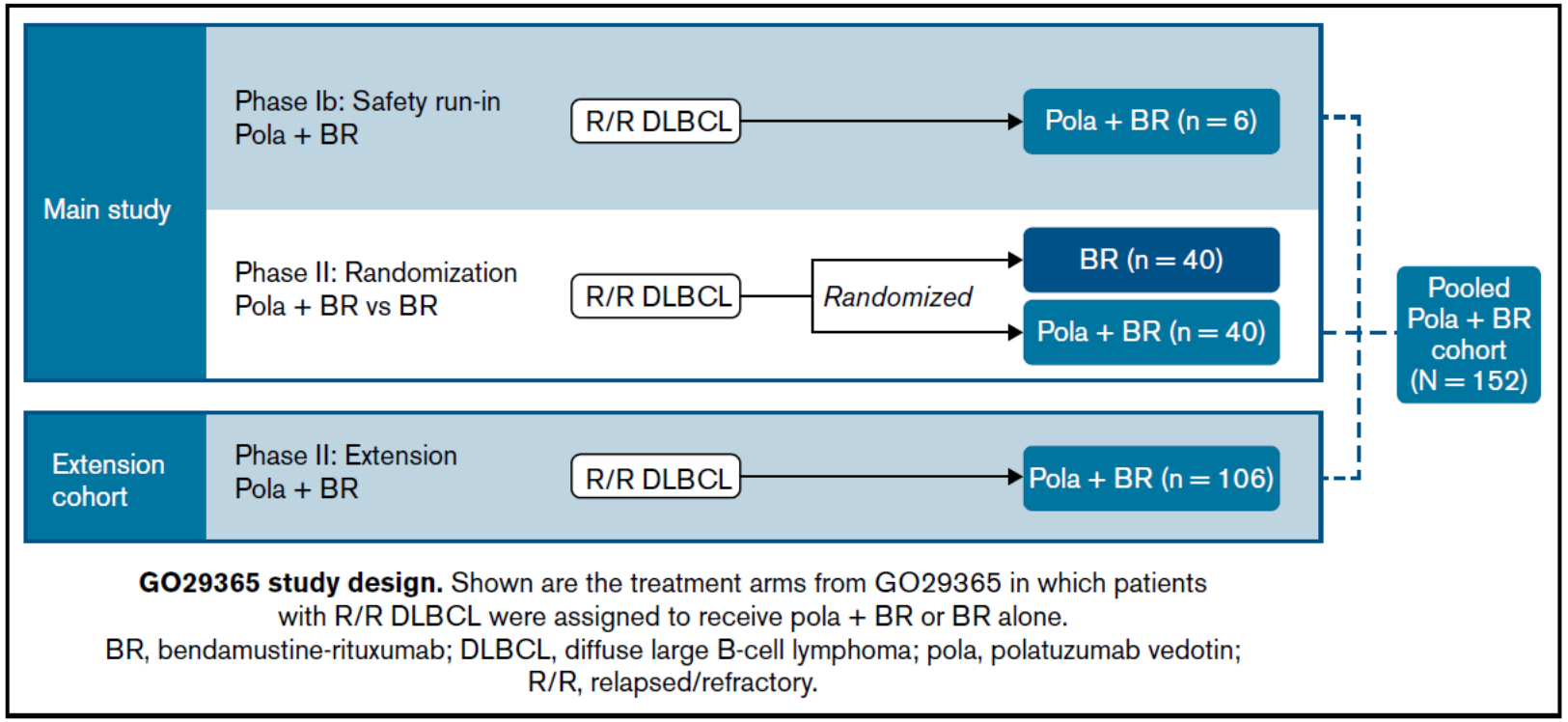
REGULAR ARTICLE

blood advances

Check for updates

Polatuzumab vedotin plus bendamustine and rituximab in relapsed/refractory DLBCL: survival update and new extension cohort data

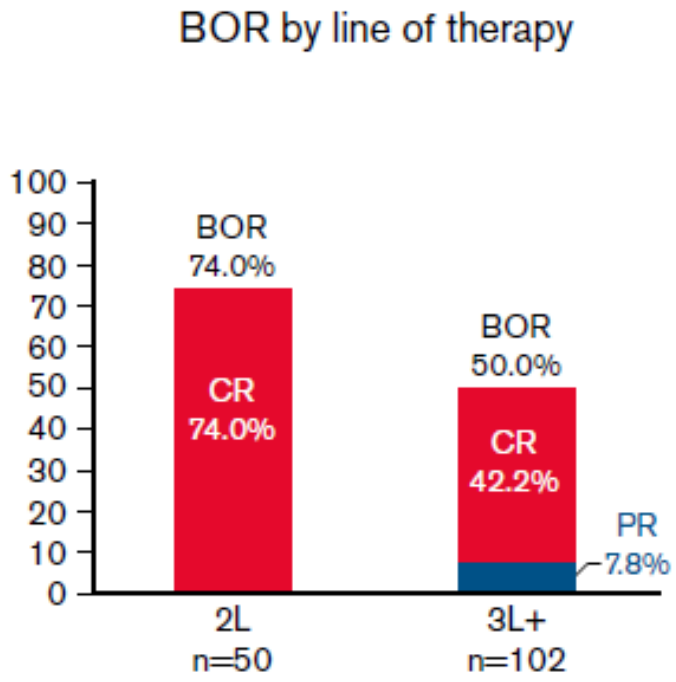
Laurie H. Sehn,[1] Mark Hertzberg,[2] Stephen Opat,[3] Alex F. Herrera,[4] Sarit Assouline,[5] Christopher R. Flowers,[6] Tae Min Kim,[7]

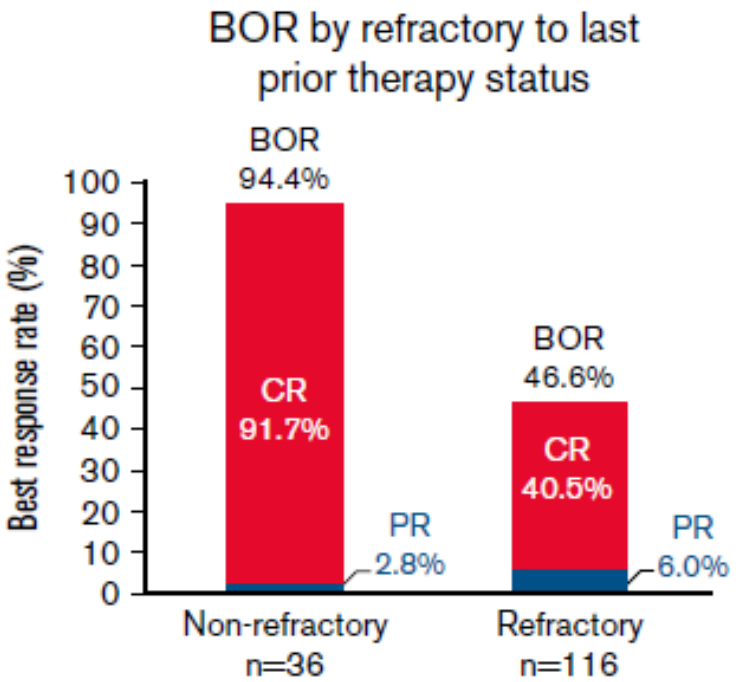


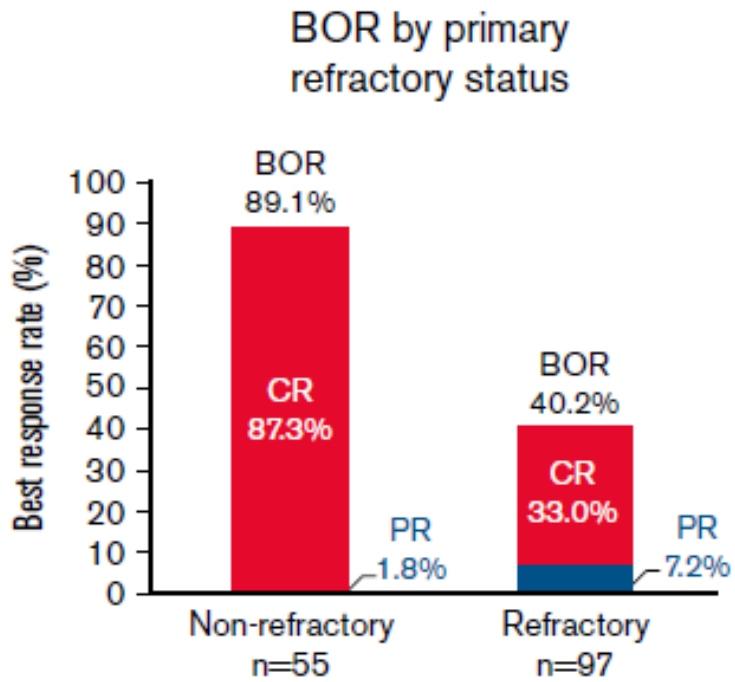
GO29365 study design. Shown are the treatment arms from GO29365 in which patients with R/R DLBCL were assigned to receive pola + BR or BR alone.
BR, bendamustine-rituximab; DLBCL, diffuse large B-cell lymphoma; pola, polatuzumab vedotin; R/R, relapsed/refractory.

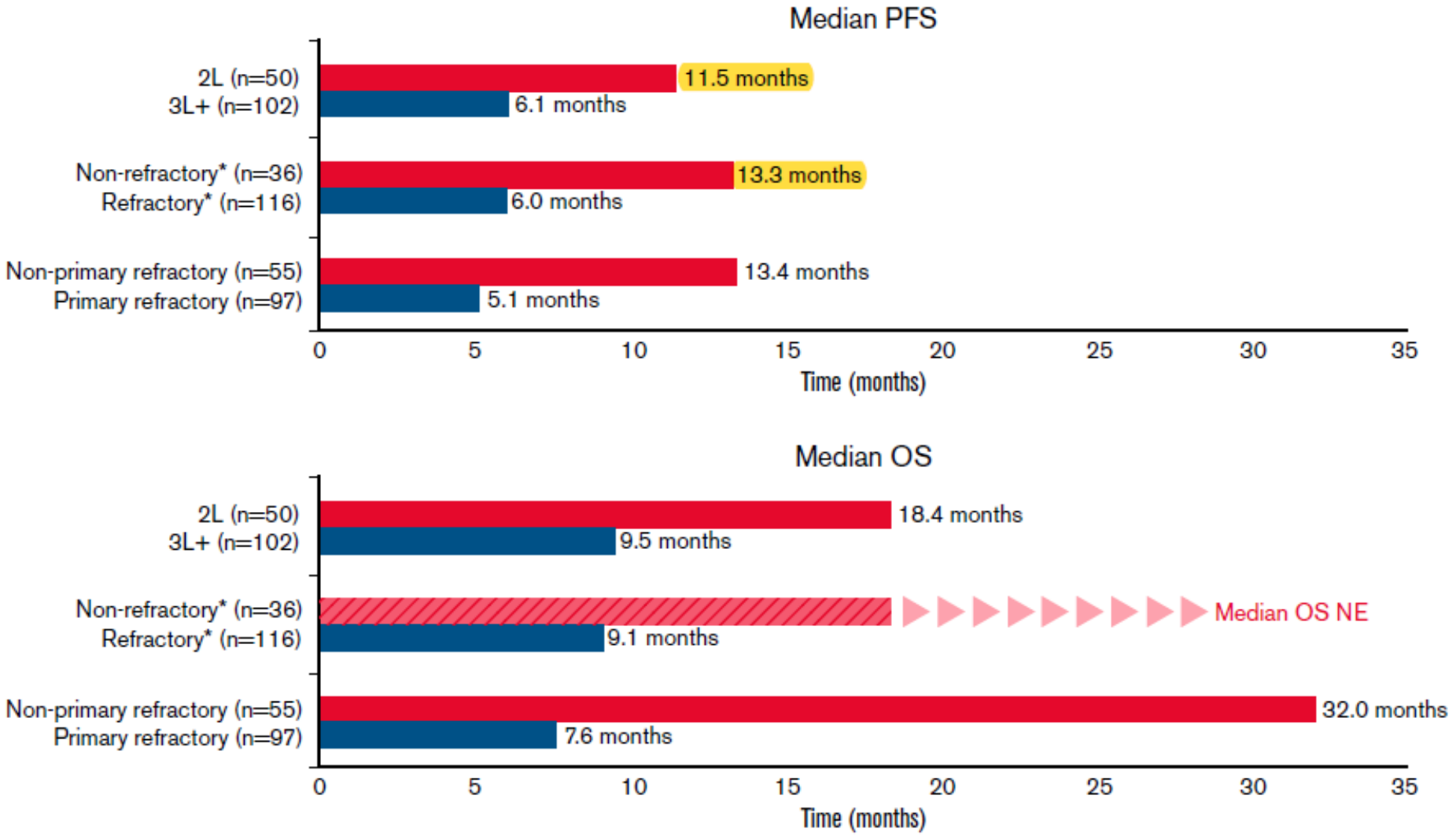
Table 1. Patient demographic and baseline clinical characteristics

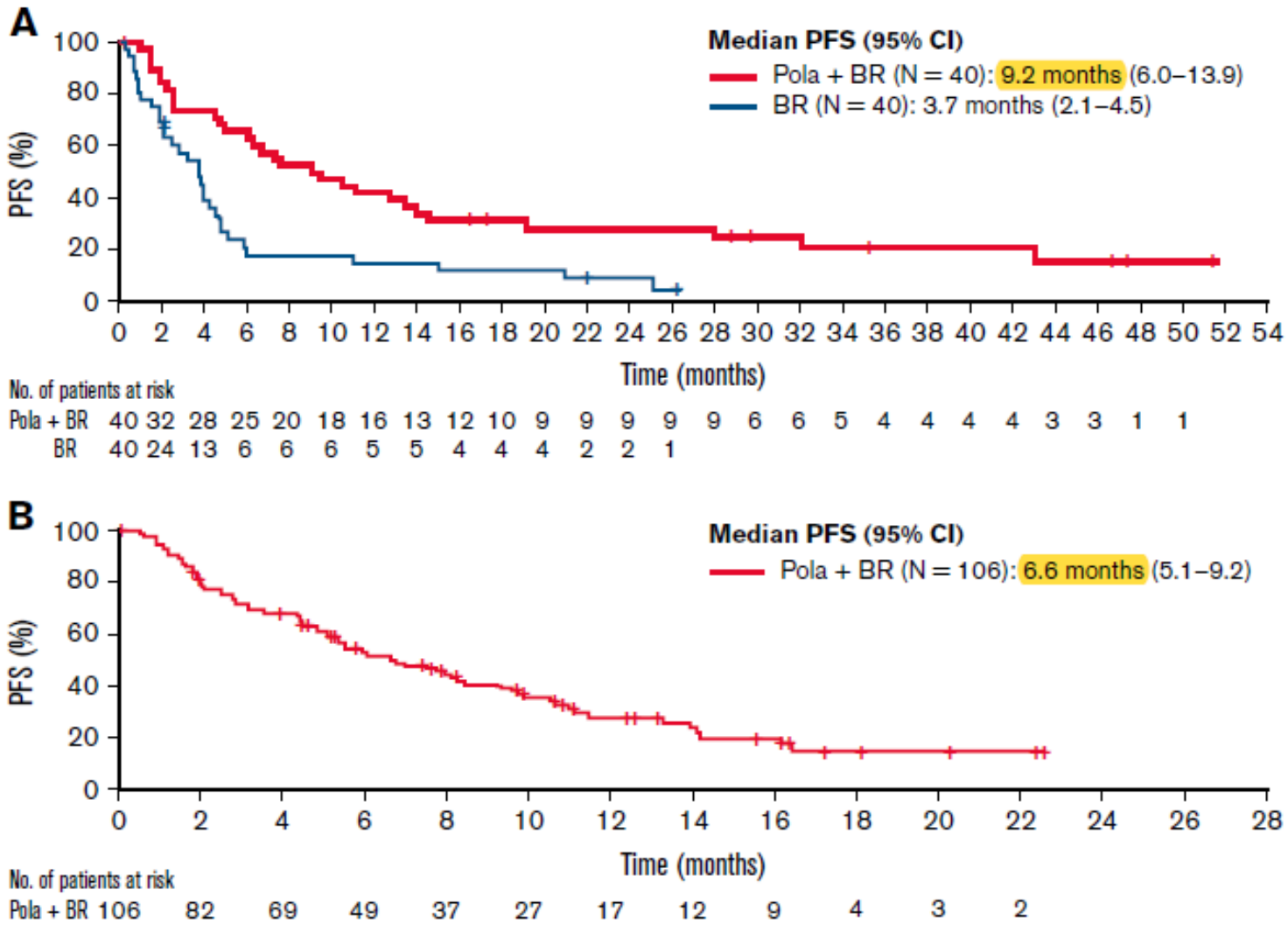
ITT	Randomized		Extension cohort, pola + BR (n = 106)	Pooled, pola + BR (N = 152)
	BR (n = 40)	pola + BR (n = 40)		
Median (range) age, y	71 (30-84)	67 (33-86)	70 (24-94)	69 (24-94)
Age ≥65 y	26 (65)	23 (58)	77 (73)	103 (68)
Male sex	25 (63)	28 (70)	52 (49)	84 (55)
ECOG PS score				
0	17 (43)	12 (30)	30 (28)	44 (29)
1	14 (35)	21 (53)	62 (59)	87 (57)
2	8 (20)	6 (15)	14 (13)	20 (13)
Ann Arbor stage III/IV	36 (90)	34 (85)	84 (79)	122 (80)
Bulky disease	14 (35.0)	10 (25)	28 (26)	39 (26)
IPI score 3-5 at enrollment	29 (73)	22 (55)	70 (66)	94 (62)
Median no. of prior therapies (range)	2 (1-5)	2 (1-7)	2 (1-7)	2 (1-7)
1 line	12 (30)	11 (28)	37 (35)	50 (33)
2 lines	9 (23)	11 (28)	27 (26)	42 (28)
≥3 lines	19 (48)	18 (45)	42 (40)	60 (39)
WHO 2016 classification (central pathology review)*	40	40	104	150
DLBCL NOS	40 (100)	38 (95)	98 (94)	142 (95)
ABC	20 (50)	19 (48)	50 (48)	73 (49)
GCB	17 (43)	15 (38)	42 (40)	58 (39)
Follicular lymphoma	0	1 (3)	0	1 (1)
Burkitt lymphoma	0	1 (3)	0	1 (1)
T-cell/histiocyte-rich large B-cell lymphoma	0	0	1 (1)	1 (1)
High-grade B-cell lymphoma with *MYC* and *BCL2*, and/or *BCL6* rearrangements (DLBCL morphology)	0	0	5 (5)	5 (3)
Prior SCT	6 (15)	10 (25)	17 (16)	27 (18)
Prior CAR T-cell therapy	0	0	1 (1)	1 (1)
DOR of last treatment ≤12 mo	34 (85)	32 (80)	92 (87)	129 (85)
Median (range) time from last treatment, mo	2.7 (1-97)	4.3 (1-386)	3.2 (1-232)	3.4 (1-386)
Primary refractory†	28 (70)	21 (53)	73 (69)	97 (64)
Refractory to last prior therapy‡	33 (83)	30 (75)	81 (76)	116 (76)

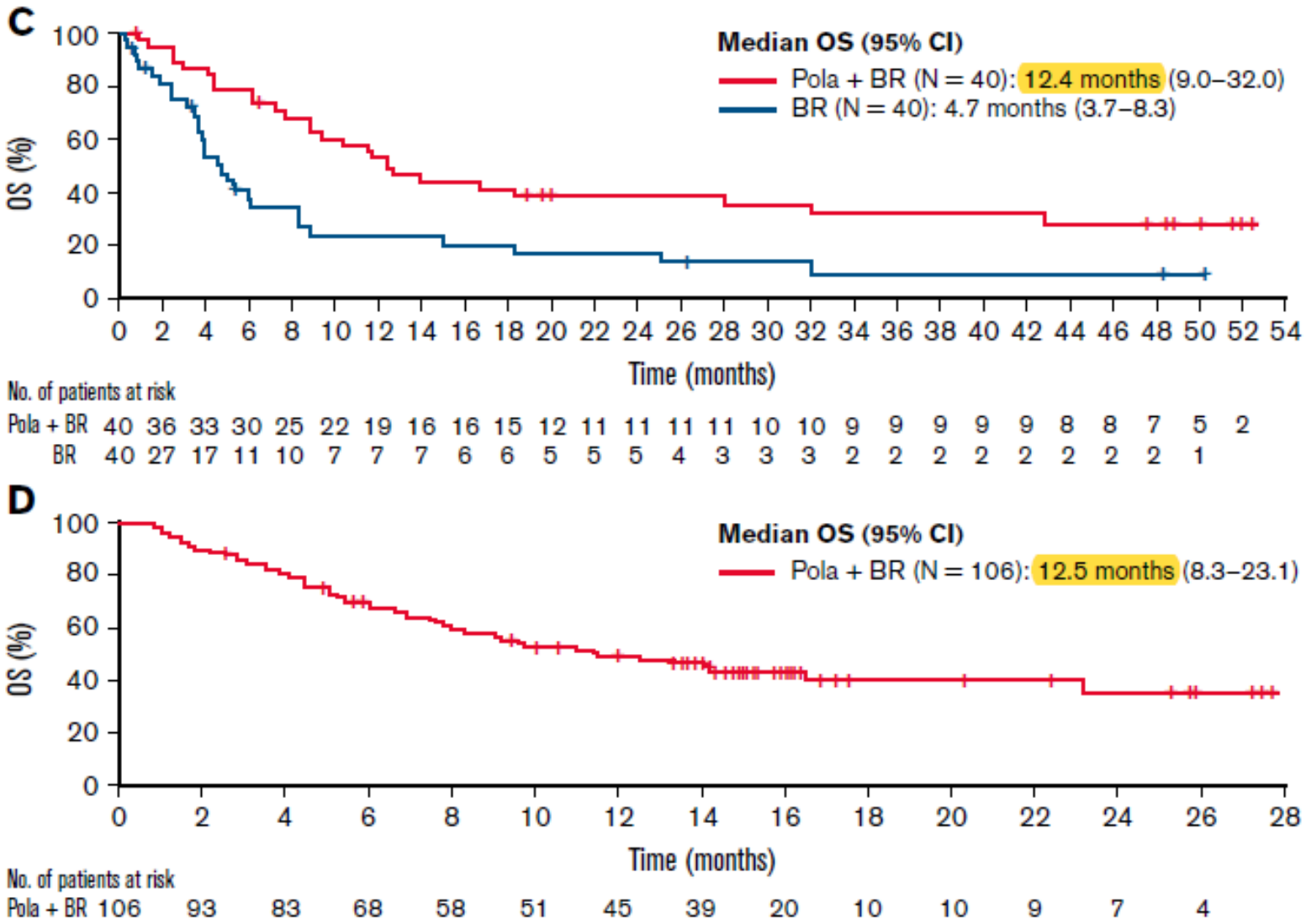

BOR by line of therapy
100
90
80
70
60
50
40
30
20
10
0
BOR
74.0%
CR
74.0%
BOR
50.0%
CR
42.2%
PR
7.8%
2L
n=50
3L+
n=102


BOR by refractory to last prior therapy status
Best response rate (%)
100
90
80
70
60
50
40
30
20
10
0
BOR
94.4%
CR
91.7%
PR
2.8%
BOR
46.6%
CR
40.5%
PR
6.0%
Non-refractory
n=36
Refractory
n=116


BOR by primary refractory status
Best response rate (%)
100
90
80
70
60
50
40
30
20
10
0
BOR
89.1%
CR
87.3%
PR
1.8%
BOR
40.2%
CR
33.0%
PR
7.2%
Non-refractory
n=55
Refractory
n=97


Median PFS
2L (n=50)
3L+ (n=102)
11.5 months
6.1 months
Non-refractory* (n=36)
Refractory* (n=116)
13.3 months
6.0 months
Non-primary refractory (n=55)
Primary refractory (n=97)
13.4 months
5.1 months
0
5
10
15
20
25
30
35
Time (months)
Median OS
2L (n=50)
3L+ (n=102)
18.4 months
9.5 months
Non-refractory* (n=36)
Refractory* (n=116)
Median OS NE
9.1 months
Non-primary refractory (n=55)
Primary refractory (n=97)
32.0 months
7.6 months
0
5
10
15
20
25
30
35
Time (months)


A
Median PFS (95% CI)
Pola + BR (N = 40): 9.2 months (6.0–13.9)
BR (N = 40): 3.7 months (2.1–4.5)
PFS (%)
Time (months)
No. of patients at risk
Pola + BR 40 32 28 25 20 18 16 13 12 10 9 9 9 9 9 6 6 5 4 4 4 4 3 3 1 1
BR 40 24 13 6 6 6 5 5 4 4 4 2 2 1
B
Median PFS (95% CI)
Pola + BR (N = 106): 6.6 months (5.1–9.2)
PFS (%)
Time (months)
No. of patients at risk
Pola + BR 106 82 69 49 37 27 17 12 9 4 3 2


C
Median OS (95% CI)
Pola + BR (N = 40): 12.4 months (9.0–32.0)
BR (N = 40): 4.7 months (3.7–8.3)
OS (%)
Time (months)
No. of patients at risk
Pola + BR 40 36 33 30 25 22 19 16 16 15 12 11 11 11 11 10 10 9 9 9 9 9 8 8 7 5 2
BR 40 27 17 11 10 7 7 7 6 6 5 5 5 4 3 3 3 2 2 2 2 2 2 2 2 1
D
Median OS (95% CI)
Pola + BR (N = 106): 12.5 months (8.3–23.1)
OS (%)
Time (months)
No. of patients at risk
Pola + BR 106 93 83 68 58 51 45 39 20 10 10 9 7 4

Named Patient Program

HemaSphere

EHA EUROPEAN HEMATOLOGY ASSOCIATION

Article
Open Access

Real-world Outcomes of Relapsed/Refractory Diffuse Large B-cell Lymphoma Treated With Polatuzumab Vedotin-based Therapy

Lisa Argnani[1,2], Alessandro Broccoli[1,2], Cinzia Pellegrini[1], Alberto Fabbri[3], Benedetta Puccini[4], Riccardo Bruna[5], Maria Chiara Tisi[6], Francesco Masia[7], Leonardo Flenghi[8], Maria Elena Nizzoli[9], Maurizio Musso[10], Marilena Salerno[11], Potito Rosario Scalzulli[12], Daniela Dessi[13], Isacco Ferrarini[14], Elsa Pennese[15], Elisa Lucchini[16], Francesca Gaia Rossi[17], Carla Minoia[18], Filippo Gherlinzoni[19], Pellegrino Musto[20], Caterina Patti[21], Vittorio Stefoni[1,2], Pier Luigi Zinzani[1,2]

	Total (n = 55)	PolaBR (n = 36)	PolaR (n = 19)	P
Sex, female/male, n(%)	26/29 (47.3/52.7)	17/19 (47.2/52.8)	9/10 (47.4/52.6)	ns
Age at diagnosis, y, median (range)	63.6 (29.2-84.2)	61.5 (29.2-84.2)	67.6 (30.4-81.8)	ns
Pathology classification at diagnosis, n (%)				ns
GCB	22 (40.0)	15 (41.7)	7 (36.7)	
ABC	6 (10.9)	5 (13.9)	1 (5.3)	
Non-GCB	17 (30.9)	11 (30.6)	4 (21.5)	
DLBCL-nos	10 (18.2)	8 (22.2)	2 (10.5)	
DLBCL subtypes, n (%)				ns
Double-hit	3 (5.5)	2 (5.6)	1 (5.3)	
Triple-hit	1 (1.8)	1 (2.8)	0 (0.0)	
Double expressor	3 (5.5)	2 (5.6)	1 (5.3)	
Ann Arbor stage, n (%)				ns
I	0	0	0	
II	11 (20.0)	6 (16.7)	5 (26.3)	
III	14 (25.5)	11 (30.6)	6 (31.6)	
IV	30 (54.5)	19 (52.8)	8 (42.1)	
Bone marrow involvement, n (%)	10 (18.2)	9 (25.0)	1 (5.2)	0.021
B symptoms, n (%)	11 (20.0)	7 (19.4)	4 (21.1)	ns
Outcome first line, n (%)				ns
Relapsed	23 (41.8)	16 (44.4)	7 (36.8)	
Refractory	32 (58.2)	20 (55.6)	12 (63.2)	
Outcome last line, n (%)				ns
Relapsed	10 (18.2)	6 (16.7)	4 (21.1)	
Refractory	45 (81.8)	30 (83.3)	15 (78.9)	
Previous therapies, median (range)	3 (1–6)	3 (1–6)	3 (2–5)	ns
ECOG score at Pola, n (%)				ns
0	22 (40.0)	13 (36.1)	8 (42.1)	
1	21 (38.2)	15 (41.7)	7 (36.8)	
2	9 (16.4)	6 (16.7)	3 (15.8)	
3	3 (5.4)	2 (5.5)	1 (5.3)	
Age at Pola, y median (range)	67.0 (29.9–85.1)	63.8 (29.9–85.1)	72.3 (32.1–83.4)	ns

HemaSphere

EHA EUROPEAN HEMATOLOGY ASSOCIATION

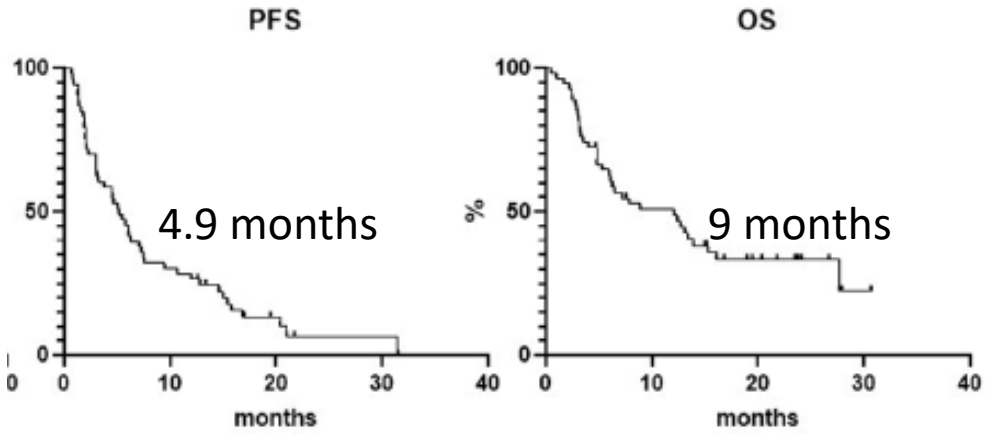
Article
Open Access

Real-world Outcomes of Relapsed/Refractory Diffuse Large B-cell Lymphoma Treated With Polatuzumab Vedotin-based Therapy

Lisa Argnani[1,2], Alessandro Broccoli[1,2], Cinzia Pellegrini[1], Alberto Fabbri[3], Benedetta Puccini[4], Riccardo Bruna[5], Maria Chiara Tisi[6], Francesco Masia[7], Leonardo Flenghi[8], Maria Elena Nizzoli[9], Maurizio Musso[10], Marilena Salerno[11], Potito Rosario Scalzulli[12], Daniela Dessi'[13], Isacco Ferrarini[14], Elsa Pennese[15], Elisa Lucchini[16], Francesca Gaia Rossi[17], Carla Minoia[18], Filippo Gherlinzoni[19], Pellegrino Musto[20], Caterina Patti[21], Vittorio Stefoni[1,2], Pier Luigi Zinzani[1,2]

Response Rates and Comparison Between the 2 Treatment Groups

	Total (n = 55)	PolaBR (n = 36)	PolaR (n = 19)	*P*
ORR, %	32.7	30.6	36.9	ns
CR, n (%)	10 (18.2)	7 (19.4)	3 (15.8)	
PR, n	8	4	4	
Best response rate, %	49.1	47.2	52.6	ns
CR, n (%)	15 (27.3)	10 (27.8)	5 (26.3)	
PR, n	12	7	5	



HemaSphere

EHA EUROPEAN HEMATOLOGY ASSOCIATION

Article
Open Access

Real-world Outcomes of Relapsed/Refractory Diffuse Large B-cell Lymphoma Treated With Polatuzumab Vedotin-based Therapy

Lisa Argnani[1,2], Alessandro Broccoli[1,2], Cinzia Pellegrini[1], Alberto Fabbri[3], Benedetta Puccini[4], Riccardo Bruna[5], Maria Chiara Tisi[6], Francesco Masia[7], Leonardo Flenghi[8], Maria Elena Nizzoli[9], Maurizio Musso[10], Marilena Salerno[11], Potito Rosario Scalzulli[12], Daniela Dessi'[13], Isacco Ferrarini[14], Elsa Pennese[15], Elisa Lucchini[16], Francesca Gaia Rossi[17], Carla Minoia[18], Filippo Gherlinzoni[19], Pellegrino Musto[20], Caterina Patti[21], Vittorio Stefoni[1,2], Pier Luigi Zinzani[1,2]

Table 4

Real-life Studies Comparison

	n	Refractory to Last Prior Therapy	mOS, mo	mPFS, mo	CR Rate	ORR	mFUP, mo
Vodicka et al[8]	21	76.2	8.7	3.8	23.8	33.3	6.8
Dimou et al[9]	49[a]	78.0	8.5	4.0	20.0	35.0	10.8
Segman et al[10]	47	23.0	8.3	5.6	40.0	61.0	6.8
Northend et al[11]	133	68.4	8.2	4.8	31.6 (best)	57.0 (best)	7.7
Present study	55	81.8	9.0	4.9	18.2 27.3 (best)	32.7 49.1 (best)	11

RESEARCH LETTER

blood advances

TO THE EDITOR:

Results of a United Kingdom real-world study of polatuzumab vedotin, bendamustine, and rituximab for relapsed/refractory DLBCL

Michael Northend,[1,2] William Wilson,[2] Wendy Osborne,[3] Christopher P. Fox,[4] Andrew J. Davies,[5] Dima El-Sharkawi,[6]

Characteristic	All patients (N = 133)
Median age, y (range)	72 (18-88)
Sex	
Male	87 (65.4)
Female	46 (34.6)
ECOG PS	
0-1	90 (67.7)
≥2	40 (30.1)
Unknown	3 (2.3)
Diagnosis	
DLBCL (transformed low-grade lymphoma)	31 (23.3)
DLBCL, not otherwise specified	78 (58.6)
Double-hit or triple-hit DLBCL	14 (10.5)
Posttransplant lymphoproliferative disorder	1 (0.8)
Plasmablastic lymphoma	2 (1.5)
Primary cutaneous DLBCL, leg type	1 (0.8)
Primary mediastinal large B-cell lymphoma	4 (3.0)
T-cell rich/histiocyte rich large B-cell lymphoma	1 (0.8)
Previous CAR T-cell therapy	
Yes	16 (12.0)
No	117 (88.0)

10 MAY 2022 • VOLUME 6, NUMBER 9

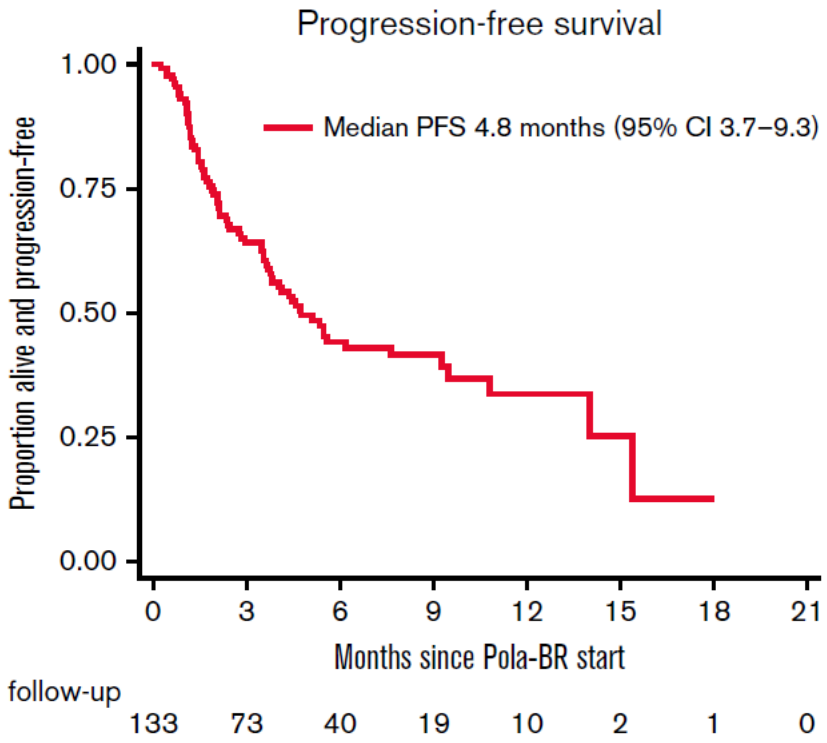
RESEARCH LETTER

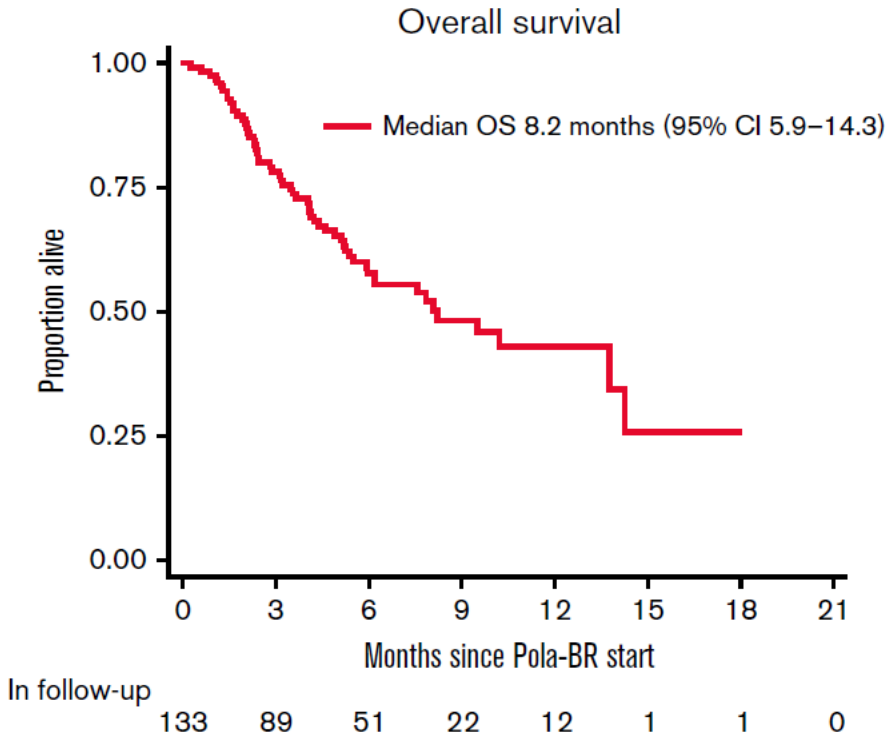
blood advances

TO THE EDITOR:

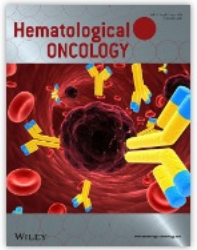
Results of a United Kingdom real-world study of polatuzumab vedotin, bendamustine, and rituximab for relapsed/refractory DLBCL

Michael Northend,[1,2] William Wilson,[2] Wendy Osborne,[3] Christopher P. Fox,[4] Andrew J. Davies,[5] Dima El-Sharkawi,[6]





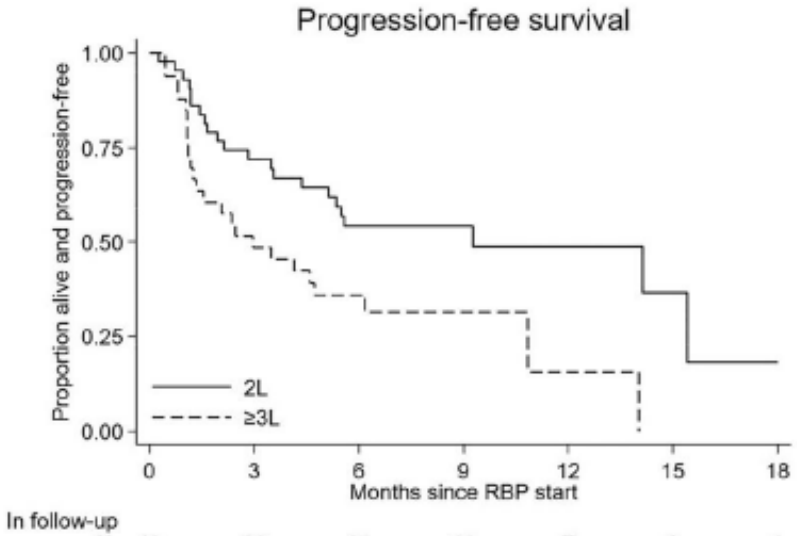
10 MAY 2022 • VOLUME 6, NUMBER 9

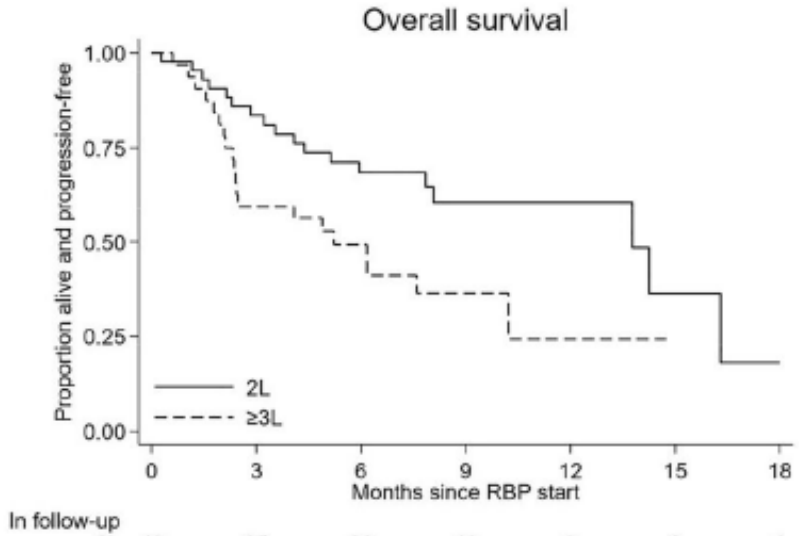


Volume 41, Issue S2
Supplement: 17th International Conference on Malignant Lymphoma, Palazzo dei Congressi, Lugano, Switzerland, 13 - 17 June, 2023
June 2023
Pages 716-717

571 | INFERIOR OUTCOMES WITH POLATUZUMAB VEDOTIN, BENDAMUSTINE AND RITUXIMAB FOR TREATMENT OF RELAPSED/REFRACTORY LARGE B-CELL LYMPHOMA AFTER >1 PRIOR LINE OF THERAPY

M. Northend[1], W. Wilson[2], K. Ediriwickrema[2], W. Osborne[3], R. Auer[4], C. Burton[5], A. Davies[6], D. El-Sharkawi[7], C. Fox[8], R. Karim[9], A. Kuhnl[10], P. McKay[11], Y. Y. Peng[12], E. Phillips[13], N. Phillips[14], W. Townsend[2]





Survival is limited after 2 or more prior lines and more effective approaches are needed for this difficult to treat group

RESEARCH LETTER

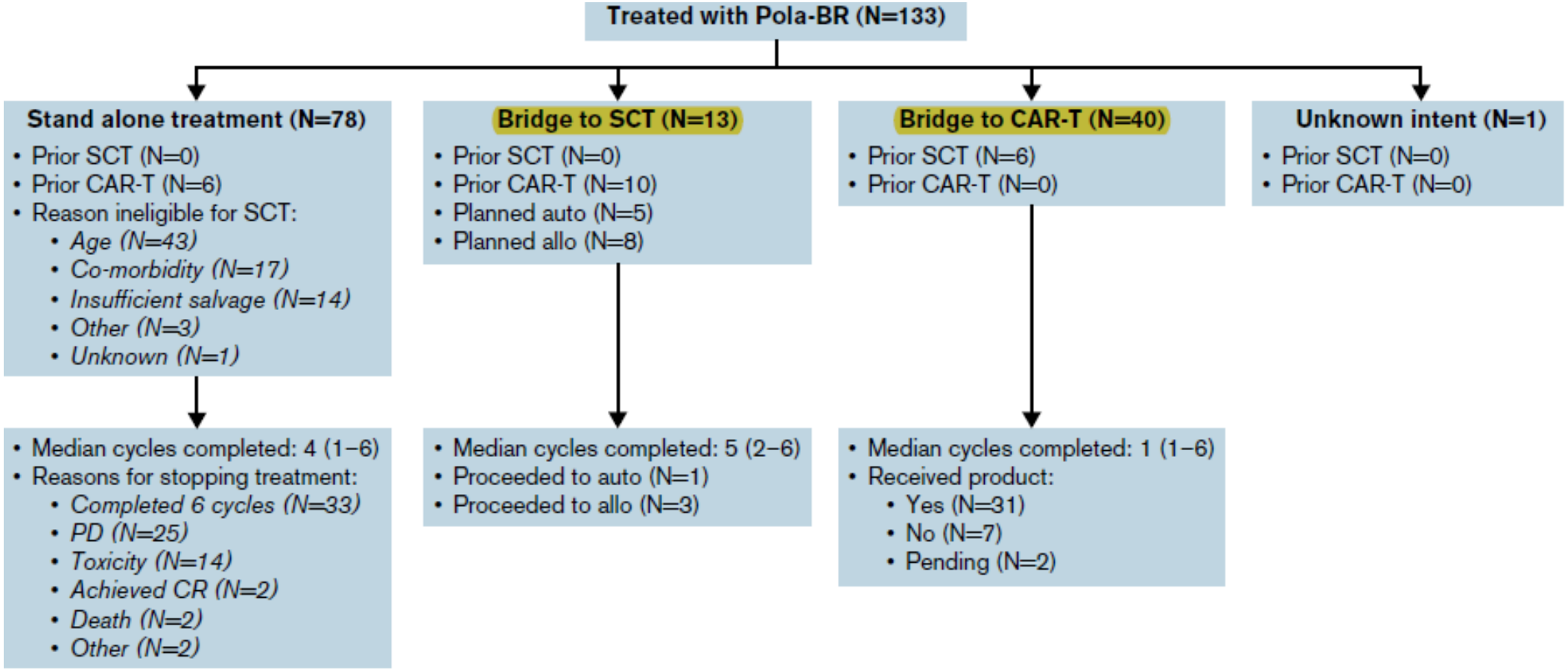
blood advances

Check for updat

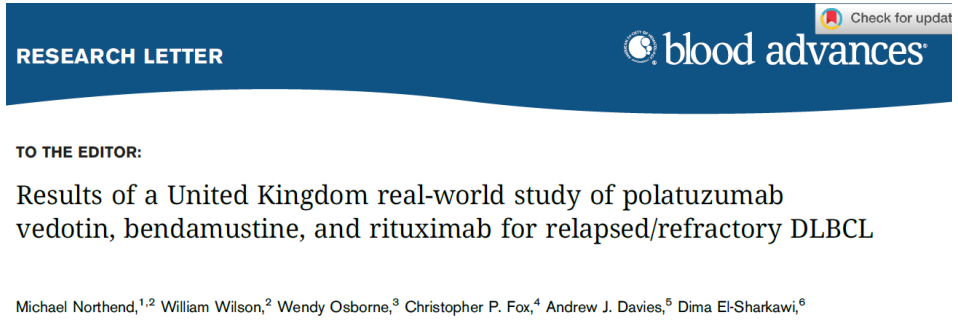
TO THE EDITOR:

Results of a United Kingdom real-world study of polatuzumab vedotin, bendamustine, and rituximab for relapsed/refractory DLBCL

Michael Northend,[1,2] William Wilson,[2] Wendy Osborne,[3] Christopher P. Fox,[4] Andrew J. Davies,[5] Dima El-Sharkawi,[6]



10 MAY 2022 • VOLUME 6, NUMBER 9



RESEARCH LETTER

blood advances

Check for updat

TO THE EDITOR:

Results of a United Kingdom real-world study of polatuzumab vedotin, bendamustine, and rituximab for relapsed/refractory DLBCL

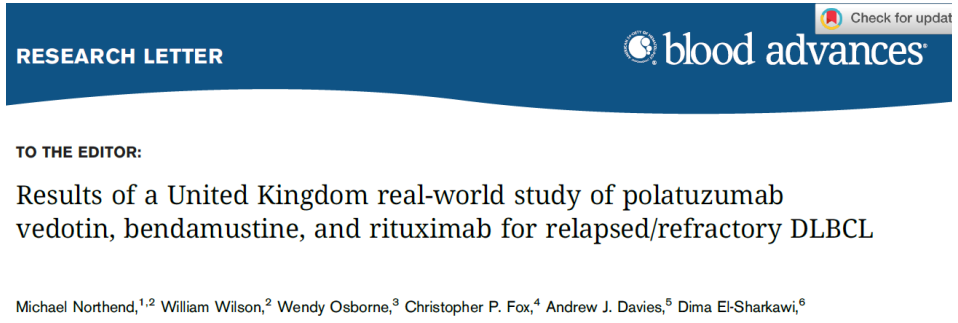
Michael Northend,[1,2] William Wilson,[2] Wendy Osborne,[3] Christopher P. Fox,[4] Andrew J. Davies,[5] Dima El-Sharkawi,[6]

Bridging to CAR T-cell therapy for 40 pts

- **ORR: 42.1%** and **CR: 17.5%**

- 31 received cell infusion; 5 died as a result of PD; 1 died as a result of infection during bridging, 2 was pending
- 36 leukapheresis before bridging
- **3 leukapheresis after at least 1 cycle of Pola-BR**

10 MAY 2022 • VOLUME 6, NUMBER 9



RESEARCH LETTER

blood advances

Check for updat

TO THE EDITOR:

Results of a United Kingdom real-world study of polatuzumab vedotin, bendamustine, and rituximab for relapsed/refractory DLBCL

Michael Northend,[1,2] William Wilson,[2] Wendy Osborne,[3] Christopher P. Fox,[4] Andrew J. Davies,[5] Dima El-Sharkawi,[6]

Pola-BR after CAR T-cell therapy for 16 pts

- ORR: 43.8% and CR:18.8%
- 3/16 ⟶ allogeneic SCT

10 MAY 2022 • VOLUME 6, NUMBER 9

Journal of clinical and experimental hematopathology
Vol. 63 No. 3, 201-204, 2023

Short Communication

Poor clinical outcome of relapsed/refractory diffuse large B-cell lymphoma with MYC translocation treated with polatuzumab vedotin, bendamustine, and rituximab

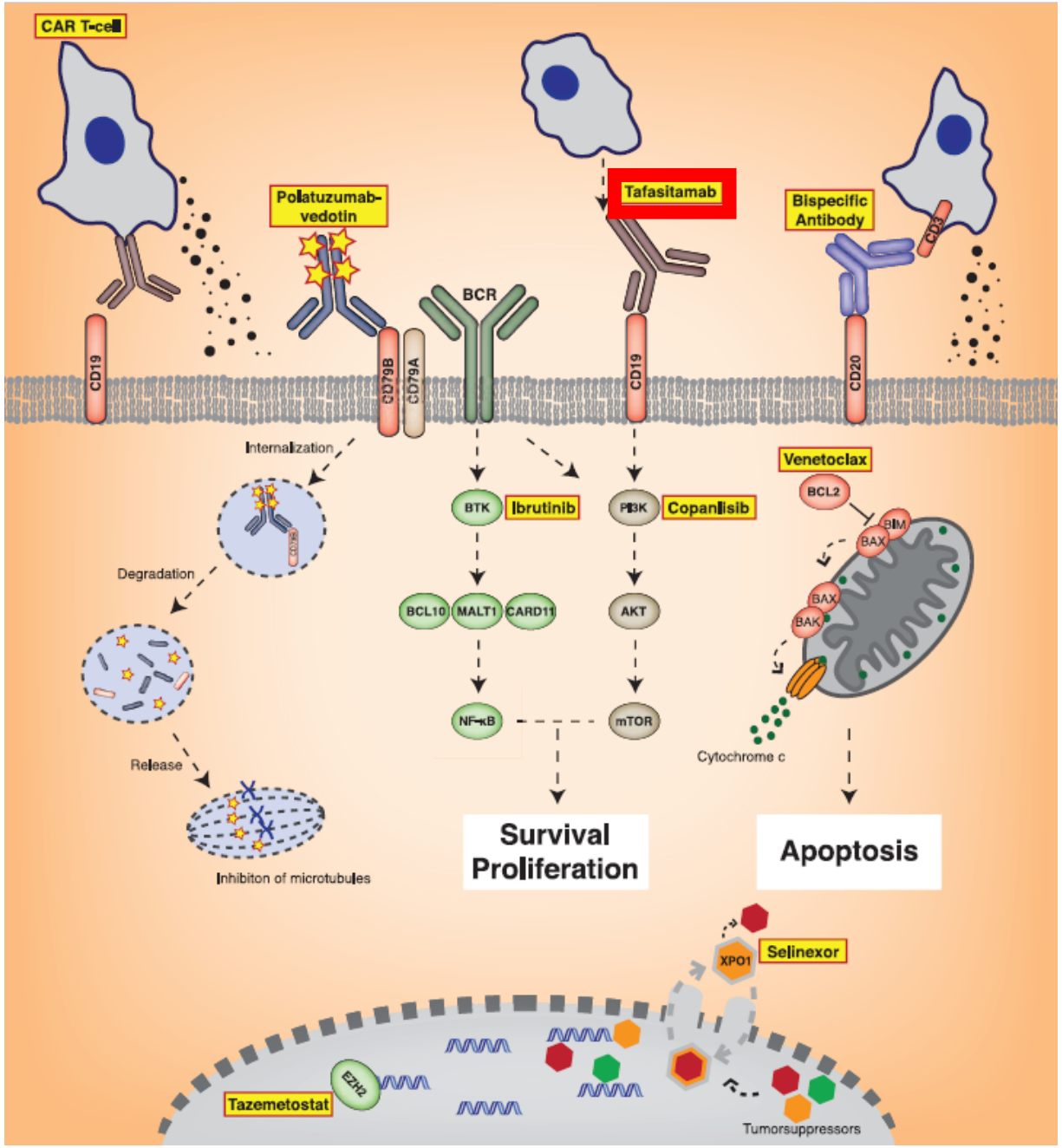
Masuho Saburi,[1)] Masanori Sakata,[1)] Yousuke Kodama,[1)] Keiichi Uraisami,[1)] Hiroyuki Takata,[1)]

Table 1. Univariate and multivariate analyses of overall survival and progression-free survival

		OS				PFS			
		Univariate		Multivariate		Univariate		Multivariate	
	N=26	HR (95% CI)	p value	HR (95% CI)	p value	HR (95% CI)	p value	HR (95% CI)	p value
Age									
<70 years	11	Reference	0.17	-	-	Reference	0.081	Reference	0.30
≥70 years	15	2.81 (0.58–13.59)		-		3.55 (0.76–16.52)		2.38 (0.45–12.51)	
NCCN-IPI									
Low / LI	10	Reference	0.033	Reference	0.14	Reference	0.042	Reference	0.11
HI / High	16	6.98 (0.86–56.38)		4.92 (0.56–42.73)		4.41 (0.92–21.14)		3.88 (0.71–21.09)	
Prior lines of chemotherapy									
<3 lines	19	Reference	0.93	-	-	Reference	0.63	-	-
≥3 lines	7	0.93 (0.19–4.52)		-		0.69 (0.14–3.23)		-	
Primary refractory									
Non-refractory	21	Reference	0.24	-	-	Reference	0.068	Reference	0.058
Refractory	5	2.21 (0.55–8.87)		-		2.96 (0.86–10.20)		3.58 (0.95–13.48)	
Cell of origin									
GCB	14	Reference	0.50	-	-	Reference	0.80	-	-
Non-GCB	11	0.62 (0.14–2.60)		-		1.17 (0.33–4.07)		-	
MYC translocation									
Negative / unavailable	23	Reference	<0.001	Reference	0.035	Reference	0.002	Reference	0.098
Positive	3	9.73 (1.93–49.04)		5.87 (1.12–30.75)		7.41 (1.62–33.80)		4.02 (0.77–20.98)	

Table 2. Characteristics, treatments, responses, and outcomes in three patients with MYC translocation

	Age/sex	Histological subtype	Assessment of MYC translocation	NCCN-IPI at PBR	Relapse/ refractory	Prior lines of chemotherapy	Course of PBR	Best response of PBR	Survival from start of PBR (months)	Outcome	Cause of death
1	74/M	DLBCL-NOS	G-banding*1	High intermediate	Relapsed	2	6	SD	6.4	Died	Lymphoma
2	78/M	DLBCL transformed of FL	G-banding*2 and FISH	High	Relapsed	2	4	PR	4.1	Died	Lymphoma
3	77/F	HGBCL with MYC and BCL6 translocation	G-banding*3 and FISH	High	Primary refractory	3	3	PD	1.9	Died	Lymphoma

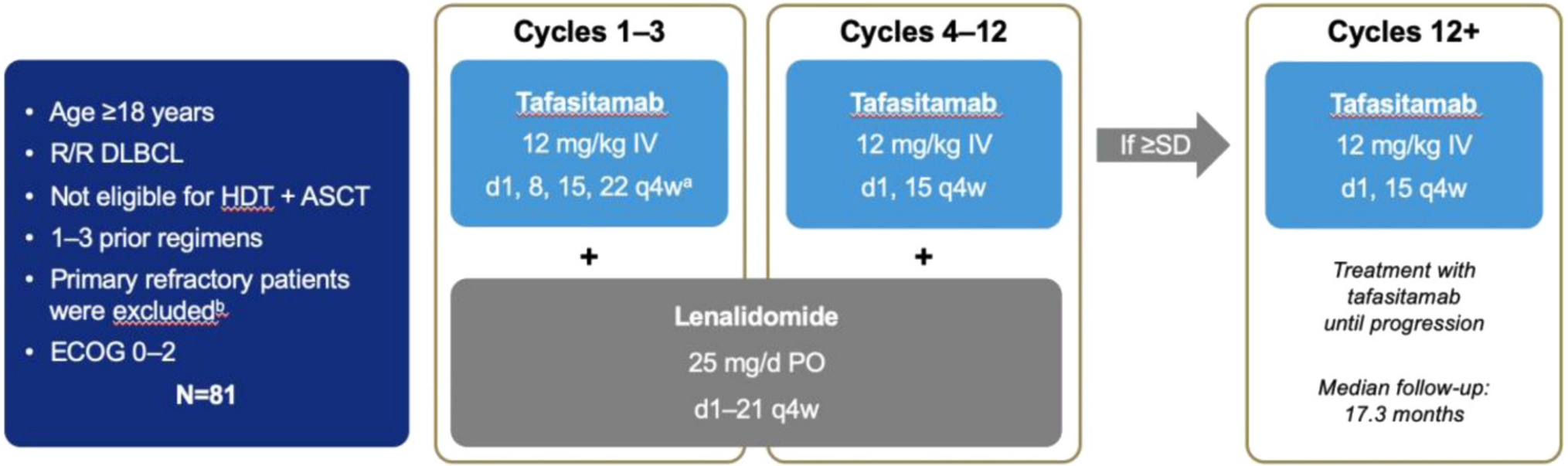


Fabian Frontzek. *Ther Adv Hematol* 2022, Vol. 13: 1–19

Tafasitamab plus lenalidomide in relapsed or refractory diffuse large B-cell lymphoma (L-MIND): a multicentre, prospective, single-arm, phase 2 study

Gilles Salles*, Johannes Duell*, Eva González Barca, Olivier Tournilhac, Wojciech Jurczak, Anna Marina Liberati, Zsolt Nagy, Aleš Obr,

Lancet Oncol 2020



haematologica
Journal of The Ferrata Storti Foundation

Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety in the phase II L-MIND study

by Johannes Duell, Pau Abrisqueta, Marc Andre, Gianluca Gaidano, Eva Gonzales-Barca, Wojciech Jurczak, Nagesh Kalakonda, Anna Marina Liberati, Kami J. Maddocks, Tobias Menne, Zsolt Nagy, Olivier Tournilhac, Christian Kuffer, Abhishek Bakuli, Aasim Amin, Konstantin Gurbanov, and Gilles Salles

	All patients (FAS)	1 pLoT	≥2 pLoT
N	80	40	40
Median age, years (range)	72.0 (41.0–86.0)	72.0 (53.0–86.0)	70.5 (41.0–82.0)
Age >70 years, n (%)	45 (56.2)	25 (62.5)	20 (50.0)
Sex, n (%)			
Female	37 (46.2)	19 (47.5)	18 (45.0)
Male	43 (53.8)	21 (52.5)	22 (55.0)
Ann Arbor stage, n (%)			
I–II	20 (25.0)	11 (27.5)	9 (22.5)
III–IV	60 (75.0)	29 (72.5)	31 (77.5)
IPI score, n (%)			
0–2	40 (50.0)	25 (62.5)	15 (37.5)
3–5	40 (50.0)	15 (37.5)	25 (62.5)
Elevated LDH, n (%)			
Yes	44 (55.0)	18 (45.0)	26 (65.0)
No	36 (45.0)	22 (55.0)	14 (35.0)
Prior lines, n (%)			
1	40 (50.0)		
2	34 (42.5)		
3	5 (6.3)		
4	1 (1.3)		
Prior lines, n (%)			
1	40 (50.0)		
2	34 (42.5)		
3	5 (6.3)		
4	1 (1.3)		
Primary refractory*, n (%)			
Yes	15 (18.8)	6 (15.0)	9 (22.5)
No	65 (81.2)	34 (85.0)	31 (77.5)
Refractory to previous therapy line, n (%)			
Yes	35 (43.8)	6 (15.0)	29 (72.5)
No	45 (56.2)	34 (85.0)	11 (27.5)
Prior ASCT, n (%)			
Yes	9 (11.2)	2 (5.0)	7 (17.5)
No	71 (88.8)	38 (95.0)	33 (82.5)
Cell of origin (by IHC), n (%)			
GCB	38 (47.5)	16 (40.0)	22 (55.0)
Non-GCB	22 (27.5)	14 (35.0)	8 (20.0)
Unknown/NE	20 (25.0)	10 (25.0)	10 (25.0)

Haematologica. 2023 Aug 31

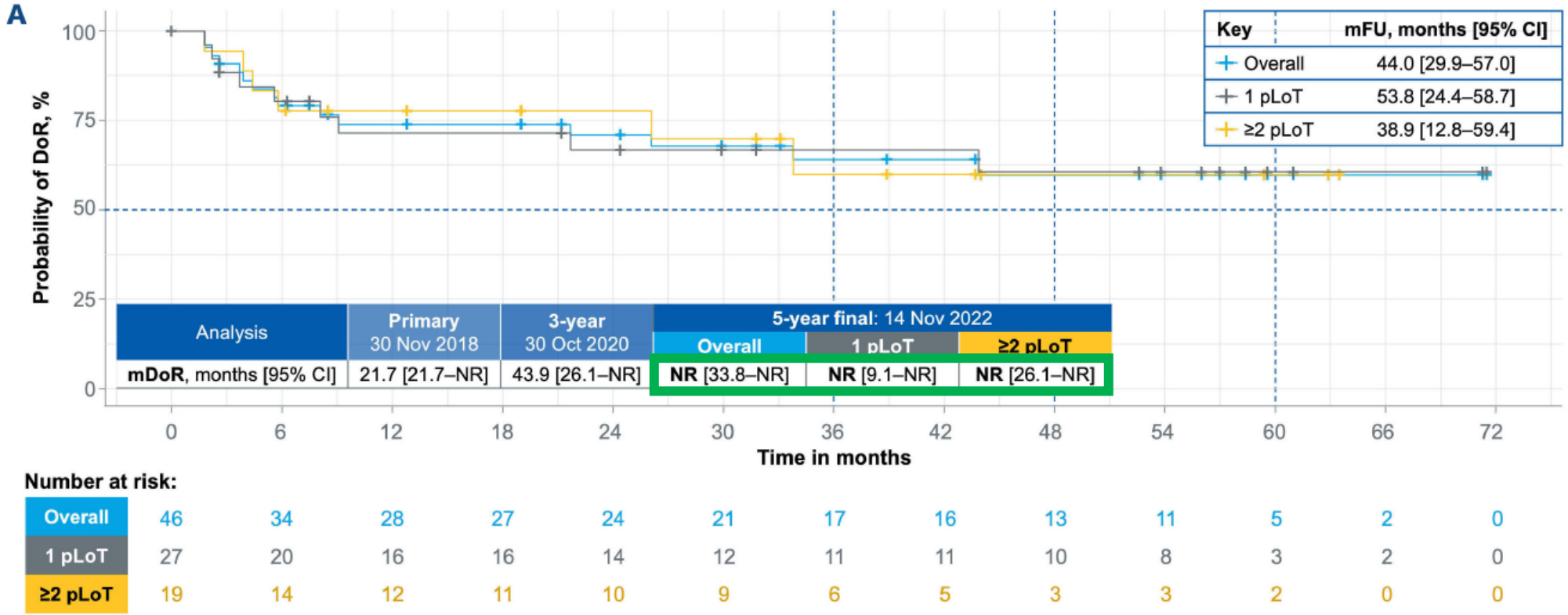
haematologica
Journal of The Ferrata Storti Foundation

ORR: 57.5%

CR: 41.3%

Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety in the phase II L-MIND study

by Johannes Duell, Pau Abrisqueta, Marc Andre, Gianluca Gaidano, Eva Gonzales-Barca, Wojciech Jurczak, Nagesh Kalakonda, Anna Marina Liberati, Kami J. Maddocks, Tobias Menne, Zsolt Nagy, Olivier Tournilhac, Christian Kuffer, Abhishek Bakuli, Aasim Amin, Konstantin Gurbanov, and Gilles Salles

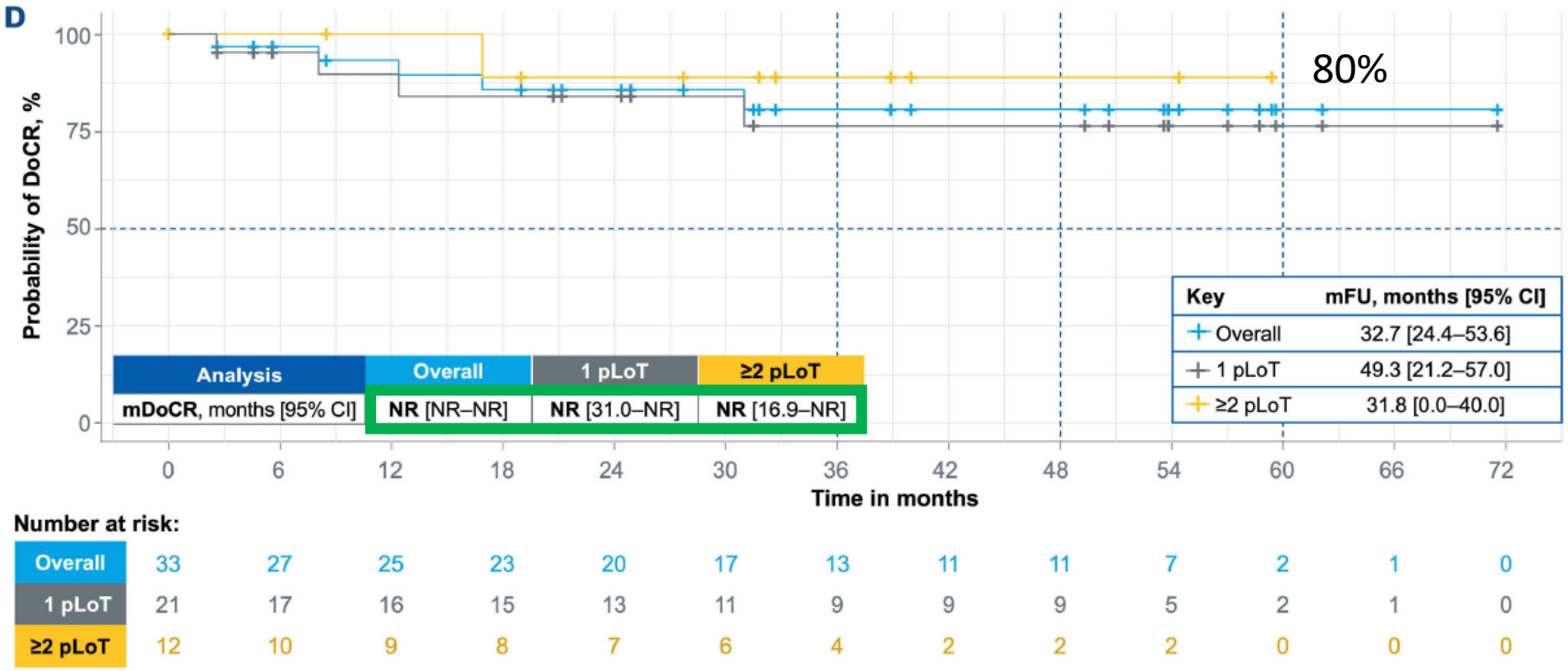


Haematologica. 2023 Aug 31

haematologica
Journal of The Ferrata Storti Foundation

Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety in the phase II L-MIND study

by Johannes Duell, Pau Abrisqueta, Marc Andre, Gianluca Gaidano, Eva Gonzales-Barca, Wojciech Jurczak, Nagesh Kalakonda, Anna Marina Liberati, Kami J. Maddocks, Tobias Menne, Zsolt Nagy, Olivier Tournilhac, Christian Kuffer, Abhishek Bakuli, Aasim Amin, Konstantin Gurbanov, and Gilles Salles

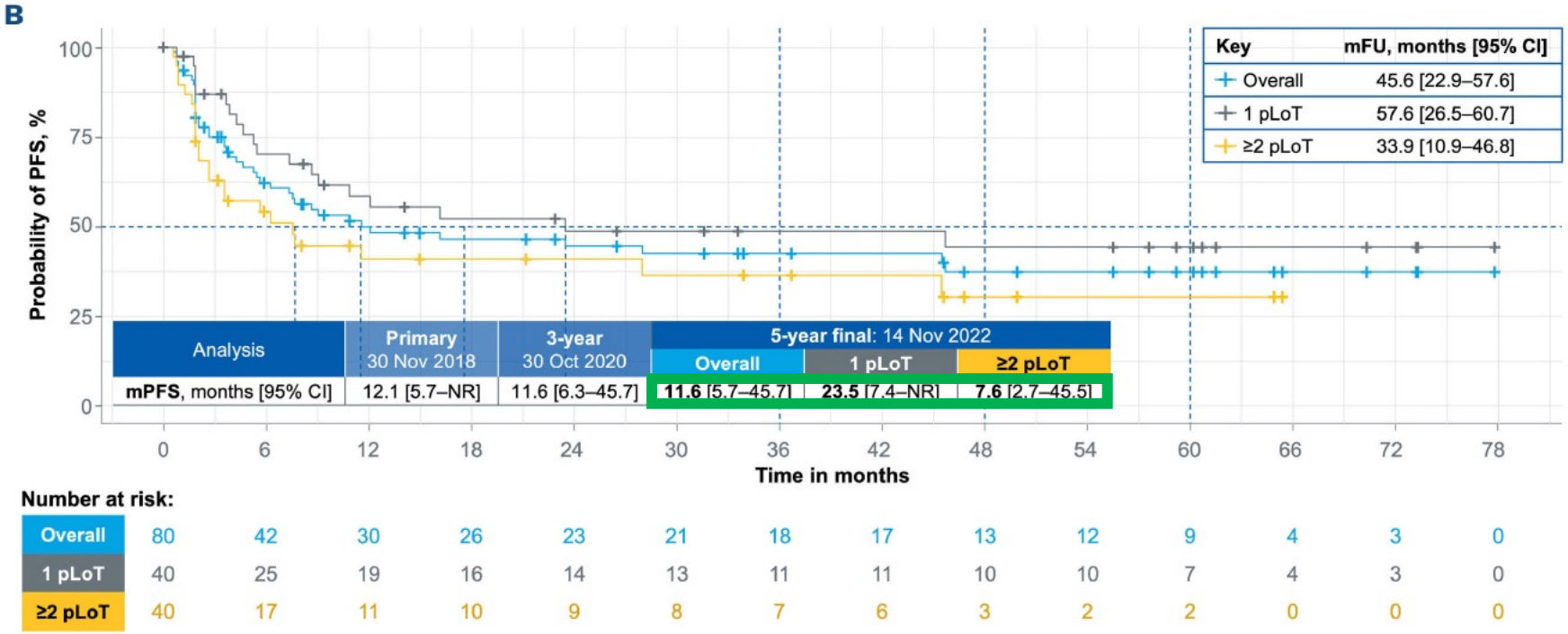


Haematologica. 2023 Aug 31

haematologica
Journal of The Ferrata Storti Foundation

Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety in the phase II L-MIND study

by Johannes Duell, Pau Abrisqueta, Marc Andre, Gianluca Gaidano, Eva Gonzales-Barca, Wojciech Jurczak, Nagesh Kalakonda, Anna Marina Liberati, Kami J. Maddocks, Tobias Menne, Zsolt Nagy, Olivier Tournilhac, Christian Kuffer, Abhishek Bakuli, Aasim Amin, Konstantin Gurbanov, and Gilles Salles

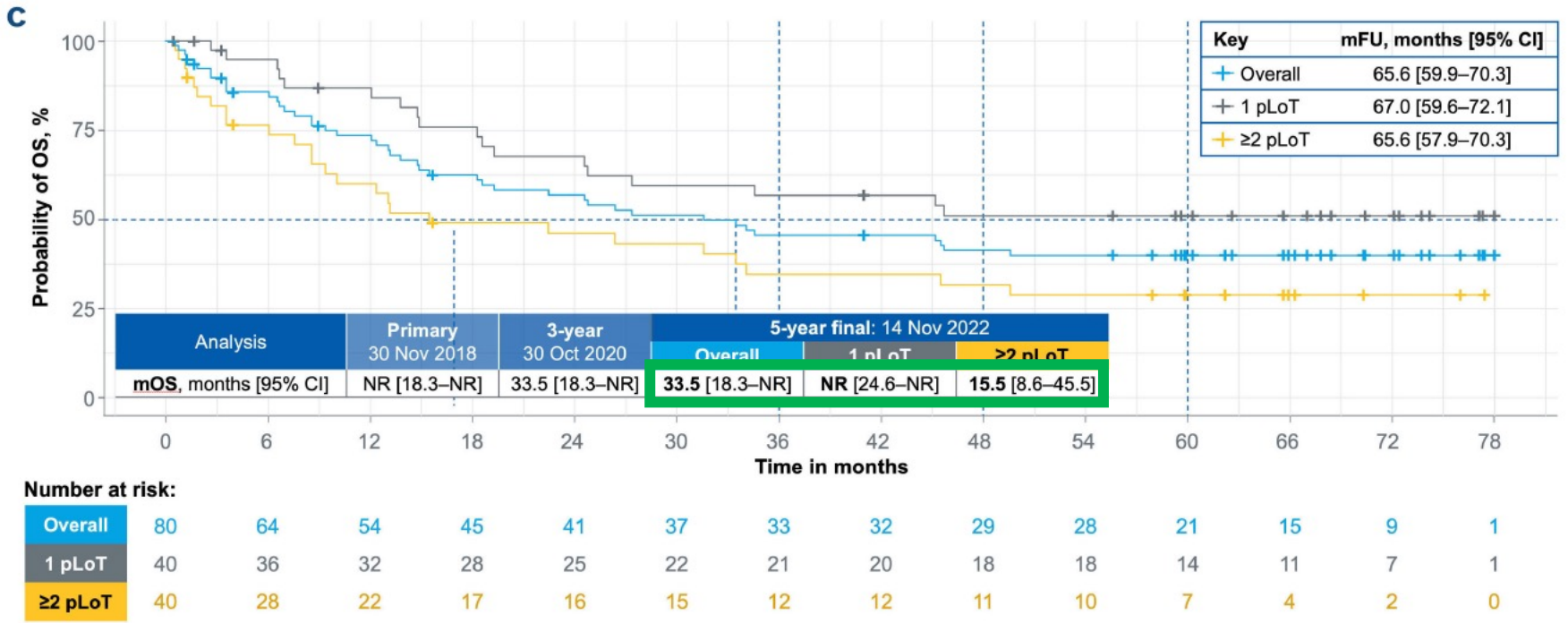


Haematologica. 2023 Aug 31

haematologica
Journal of The Ferrata Storti Foundation

Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety in the phase II L-MIND study

by Johannes Duell, Pau Abrisqueta, Marc Andre, Gianluca Gaidano, Eva Gonzales-Barca, Wojciech Jurczak, Nagesh Kalakonda, Anna Marina Liberati, Kami J. Maddocks, Tobias Menne, Zsolt Nagy, Olivier Tournilhac, Christian Kuffer, Abhishek Bakuli, Aasim Amin, Konstantin Gurbanov, and Gilles Salles

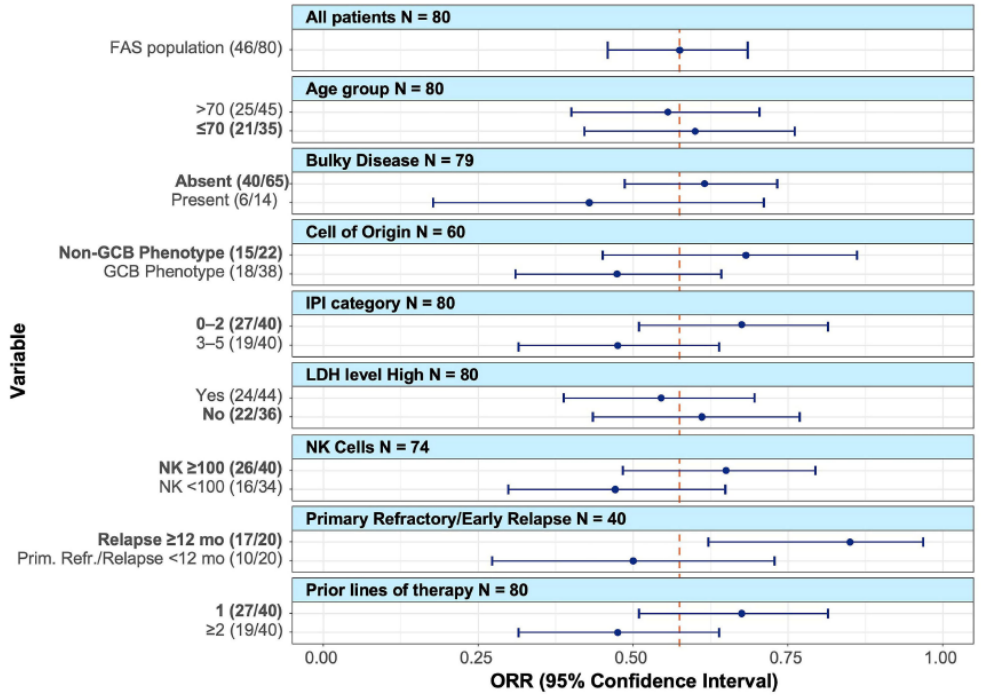


Haematologica. 2023 Aug 31

haematologica
Journal of The Ferrata Storti Foundation

Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety in the phase II L-MIND study

by Johannes Duell, Pau Abrisqueta, Marc Andre, Gianluca Gaidano, Eva Gonzales-Barca, Wojciech Jurczak, Nagesh Kalakonda, Anna Marina Liberati, Kami J. Maddocks, Tobias Menne, Zsolt Nagy, Olivier Tournilhac, Christian Kuffer, Abhishek Bakuli, Aasim Amin, Konstantin Gurbanov, and Gilles Salles

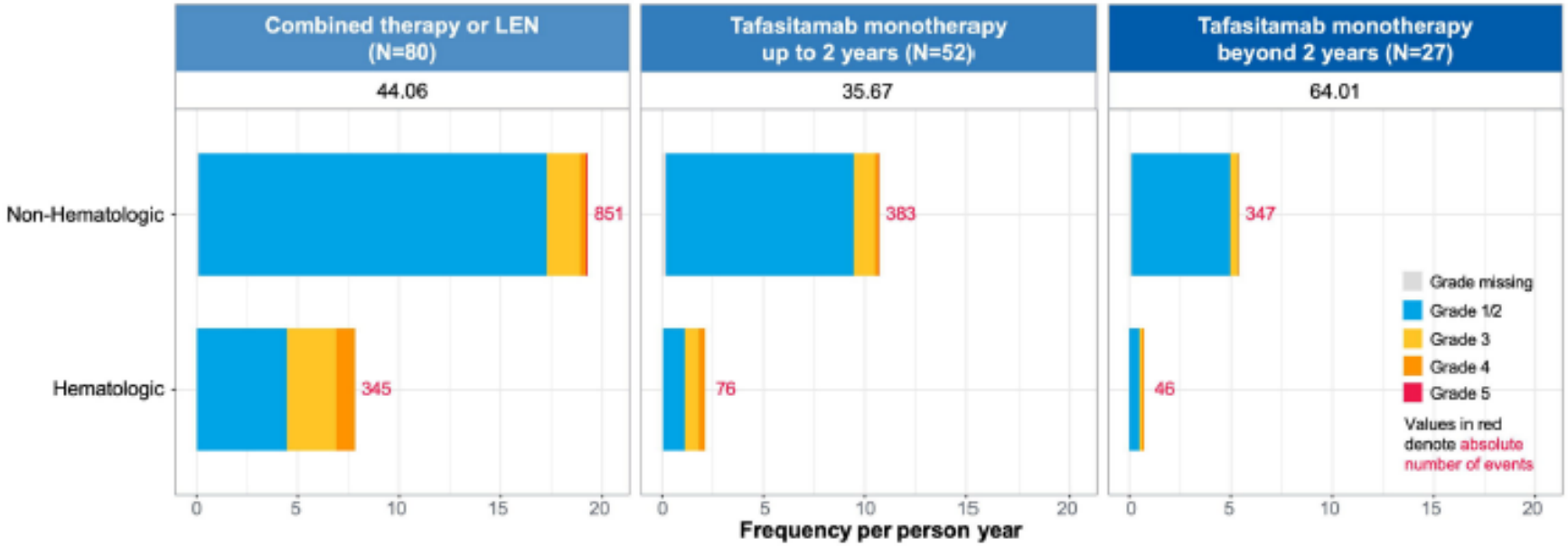


Haematologica. 2023 Aug 31

haematologica
Journal of The Ferrata Storti Foundation

Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety in the phase II L-MIND study

by Johannes Duell, Pau Abrisqueta, Marc Andre, Gianluca Gaidano, Eva Gonzales-Barca, Wojciech Jurczak, Nagesh Kalakonda, Anna Marina Liberati, Kami J. Maddocks, Tobias Menne, Zsolt Nagy, Olivier Tournilhac, Christian Kuffer, Abhishek Bakuli, Aasim Amin, Konstantin Gurbanov, and Gilles Salles



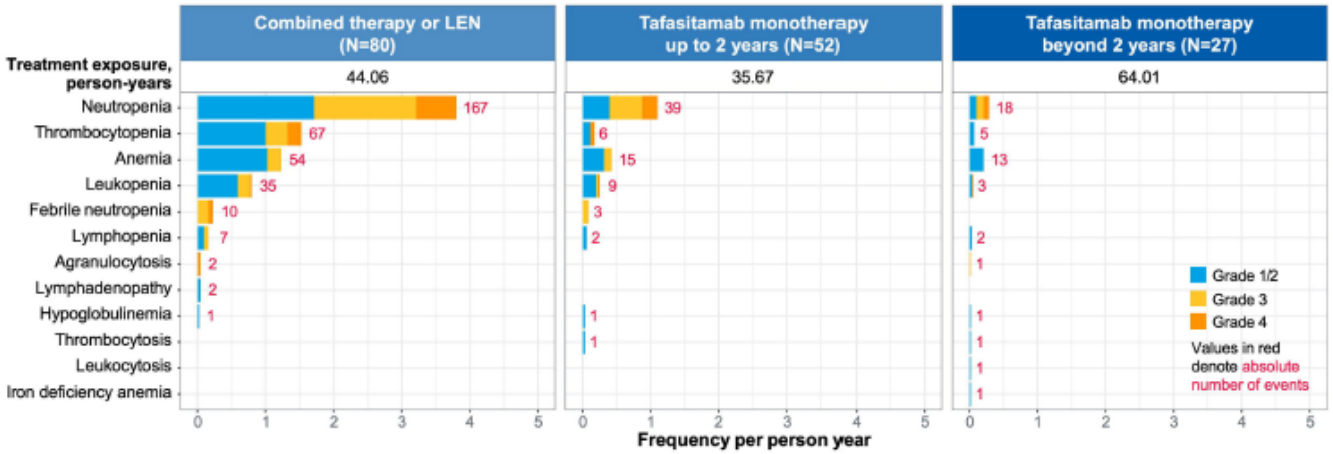
Haematologica. 2023 Aug 31

haematologica
Journal of The Ferrata Storti Foundation

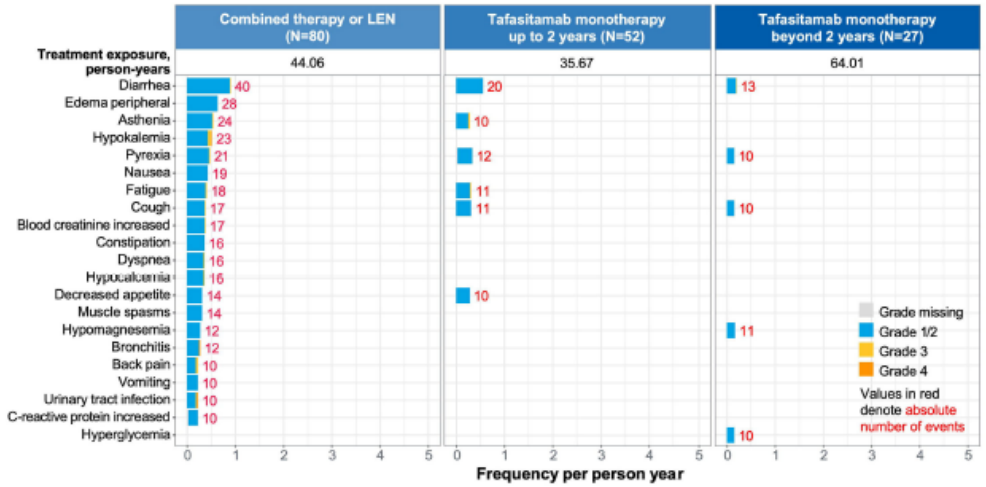
Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety in the phase II L-MIND study

by Johannes Duell, Pau Abrisqueta, Marc Andre, Gianluca Gaidano, Eva Gonzales-Barca, Wojciech Jurczak, Nagesh Kalakonda, Anna Marina Liberati, Kami J. Maddocks, Tobias Menne, Zsolt Nagy, Olivier Tournilhac, Christian Kuffer, Abhishek Bakuli, Aasim Amin, Konstantin Gurbanov, and Gilles Salles

B. Hematologic TEAEs



C. Non-hematologic TEAEs (cut-off: ≥10 events in any treatment period)



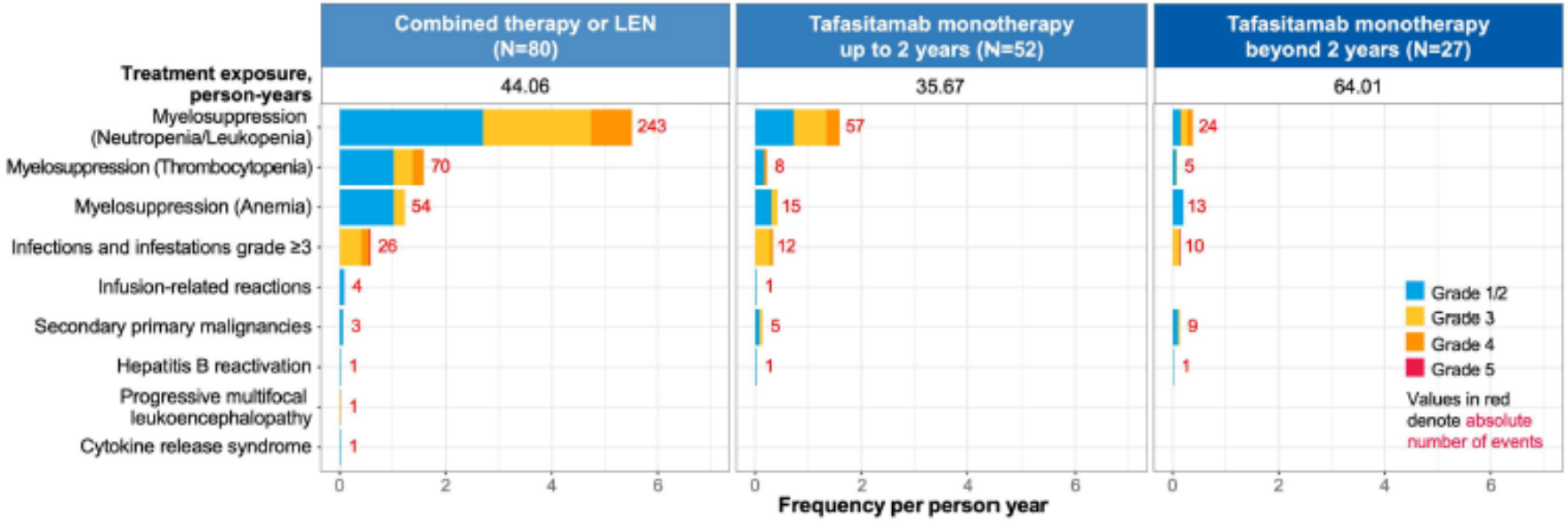
Haematologica. 2023 Aug 31

haematologica
Journal of The Ferrata Storti Foundation

Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety in the phase II L-MIND study

by Johannes Duell, Pau Abrisqueta, Marc Andre, Gianluca Gaidano, Eva Gonzales-Barca, Wojciech Jurczak, Nagesh Kalakonda, Anna Marina Liberati, Kami J. Maddocks, Tobias Menne, Zsolt Nagy, Olivier Tournilhac, Christian Kuffer, Abhishek Bakuli, Aasim Amin, Konstantin Gurbanov, and Gilles Salles

D. Important TEAEs of interest



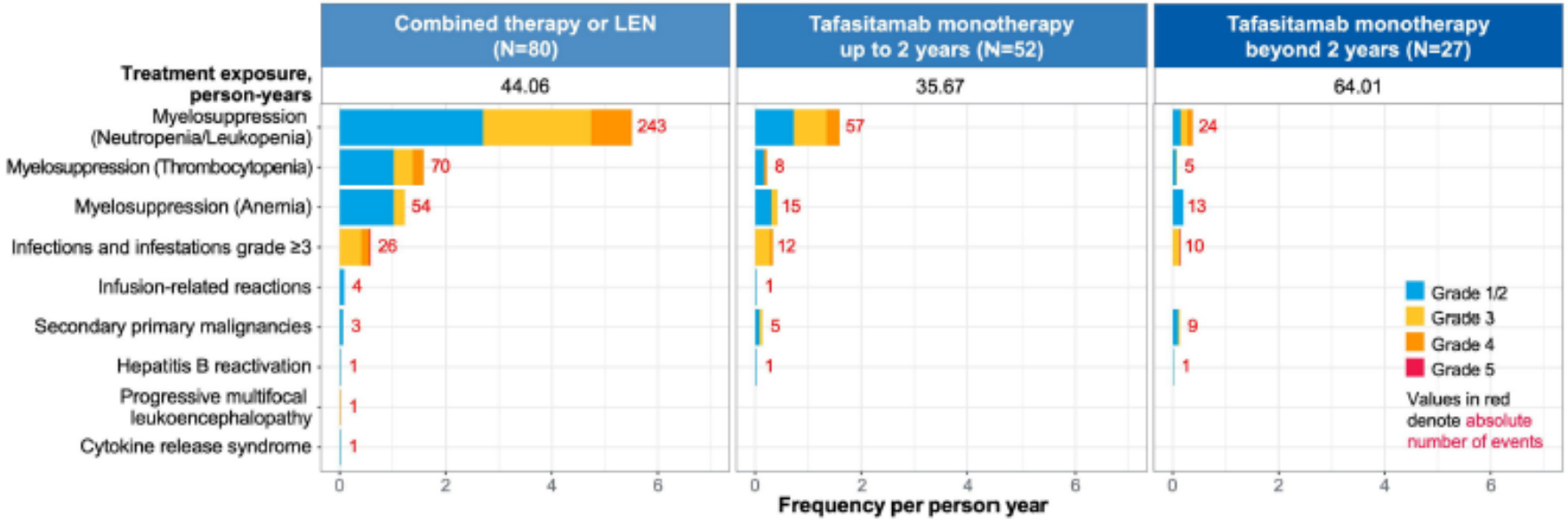
Haematologica. 2023 Aug 31

haematologica
Journal of The Ferrata Storti Foundation

Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety in the phase II L-MIND study

by Johannes Duell, Pau Abrisqueta, Marc Andre, Gianluca Gaidano, Eva Gonzales-Barca, Wojciech Jurczak, Nagesh Kalakonda, Anna Marina Liberati, Kami J. Maddocks, Tobias Menne, Zsolt Nagy, Olivier Tournilhac, Christian Kuffer, Abhishek Bakuli, Aasim Amin, Konstantin Gurbanov, and Gilles Salles

D. Important TEAEs of interest



Haematologica. 2023 Aug 31

Tafasitamab plus lenalidomide in relapsed or refractory diffuse large B-cell lymphoma (L-MIND): a multicentre, prospective, single-arm, phase 2 study

Gilles Salles, Johannes Duell*, Eva González Barca, Olivier Tournilhac, Wojciech Jurczak, Anna Marina Liberati, Zsolt Nagy, Aleš Obr,*

Lancet Oncol 2020

- **2 pts** subsequently received salvage treatment consolidation with **SCT**:

1 with autologous stem cell transplantation and 1 with allogeneic stem-cell transplantation

- **1** received **CD19 CAR T-cell therapy** after disease progression in this study: **CR**

- **7** with ***c-MYC*** **translocation**: **3 CR** and 1 PR

RE-MIND: Comparing Tafasitamab + Lenalidomide (L-MIND) with a Real-world Lenalidomide Monotherapy Cohort in Relapsed or Refractory Diffuse Large B-cell Lymphoma

Pier Luigi Zinzani[1], Thomas Rodgers[2], Dario Marino[3], Maurizio Frezzato[4], Anna Maria Barbui[5], Claudia Castellino[6], Erika Meli[7], Nathan H. Fowler[8], Gilles Salles[9], Bruce Feinberg[10], Nuwan C. Kurukulasuriya[11], Sascha Tillmanns[12], Stephan Parche[11], Debarshi Dey[11], Günter Fingerle-Rowson[11], Sumeet Ambarkhane[11], Mark Winderlich[11], and Grzegorz S. Nowakowski[12]

Aligned Inclusion/Exclusion Criteria

Same histologies, 1-3 prior systemic therapies, not eligible for ASCT

L-MIND: tafasitamab+ LEN, n=80

Find Matching Patients for
- Age
- Tumor stage
- Response to prior therapies
- Number of prior therapies
- Blood laboratory parameters
- Lenalidomide treatment dose

RE-MIND: LEN monotherapy, n~500 (50%/50% from US/EU)

Matched Comparison Cohort: tafasitamab+LEN vs. LEN monotherapy

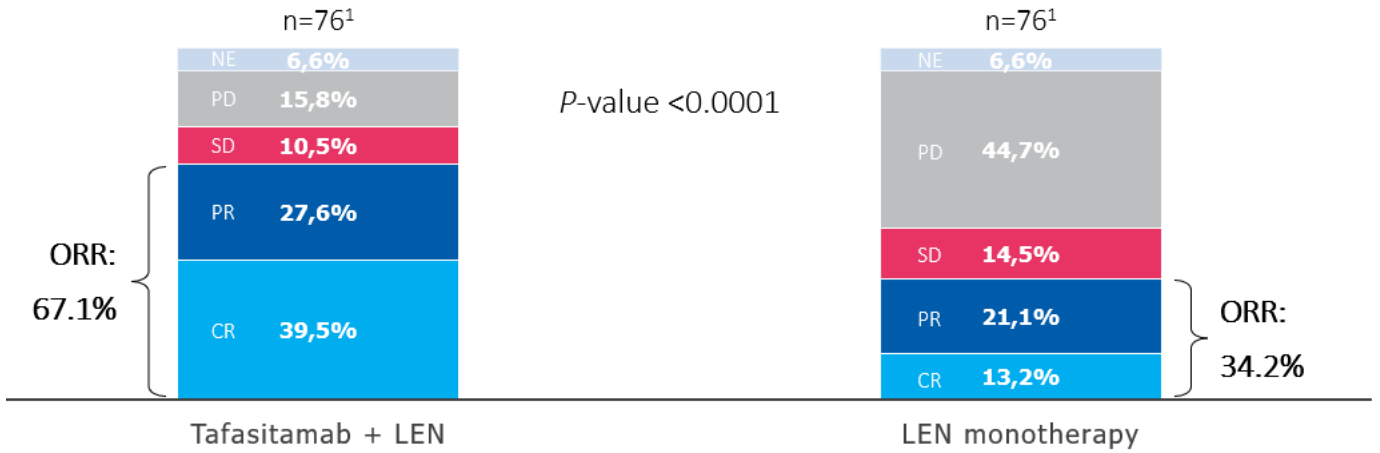
76 patients

Key Endpoints
- Difference in
  - Response rates (Primary Endpoint)
  - Complete response rates
  - Duration of Response
  - Progression-free survival
  - Survival

Grzegorz S. Et al; ASCO 2020 Abstract 8020

RE-MIND: Comparing Tafasitamab + Lenalidomide (L-MIND) with a Real-world Lenalidomide Monotherapy Cohort in Relapsed or Refractory Diffuse Large B-cell Lymphoma

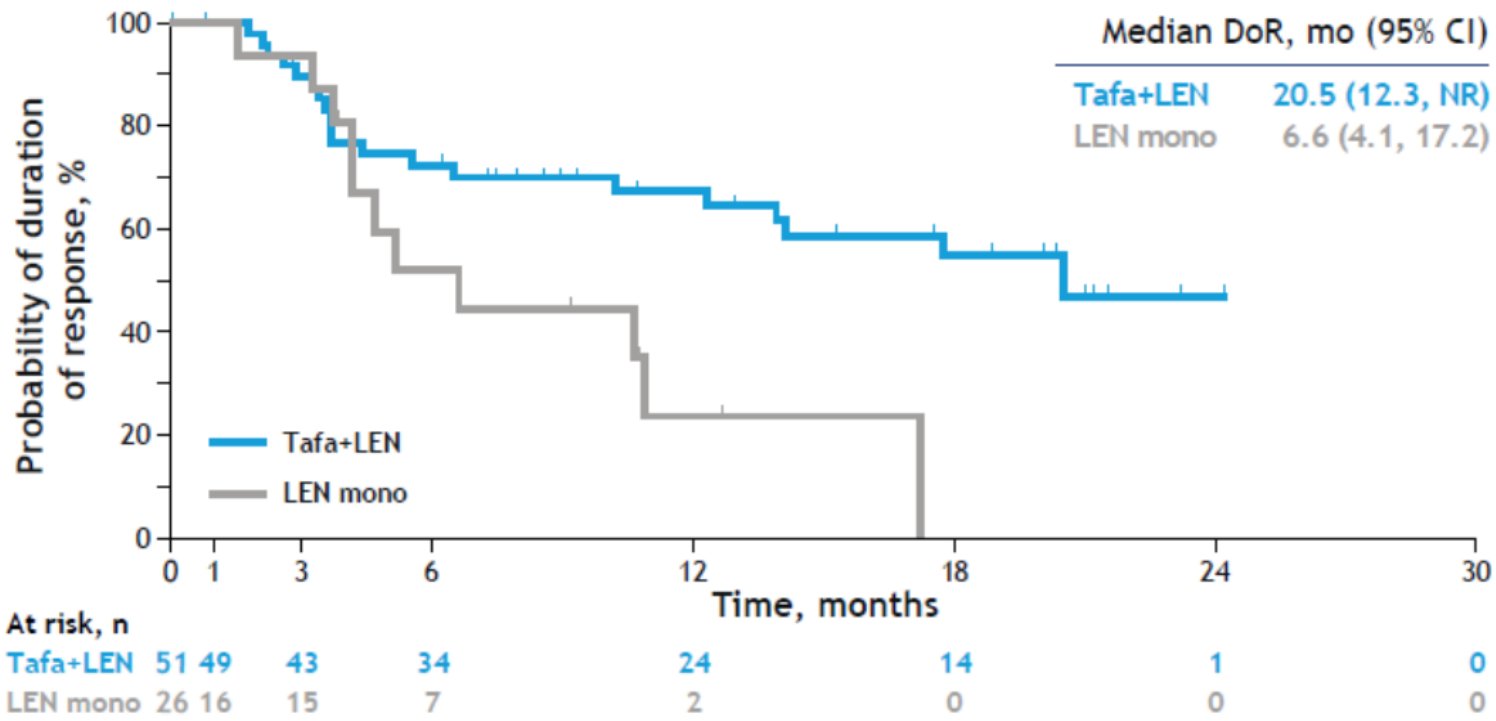
Pier Luigi Zinzani[1], Thomas Rodgers[2], Dario Marino[3], Maurizio Frezzato[4], Anna Maria Barbui[5], Claudia Castellino[6], Erika Meli[7], Nathan H. Fowler[8], Gilles Salles[9], Bruce Feinberg[10], Nuwan C. Kurukulasuriya[11], Sascha Tillmanns[12], Stephan Parche[11], Debarshi Dey[11], Günter Fingerle-Rowson[11], Sumeet Ambarkhane[11], Mark Winderlich[11], and Grzegorz S. Nowakowski[12]



Zinzani PL et al. 2021

RE-MIND: Comparing Tafasitamab + Lenalidomide (L-MIND) with a Real-world Lenalidomide Monotherapy Cohort in Relapsed or Refractory Diffuse Large B-cell Lymphoma

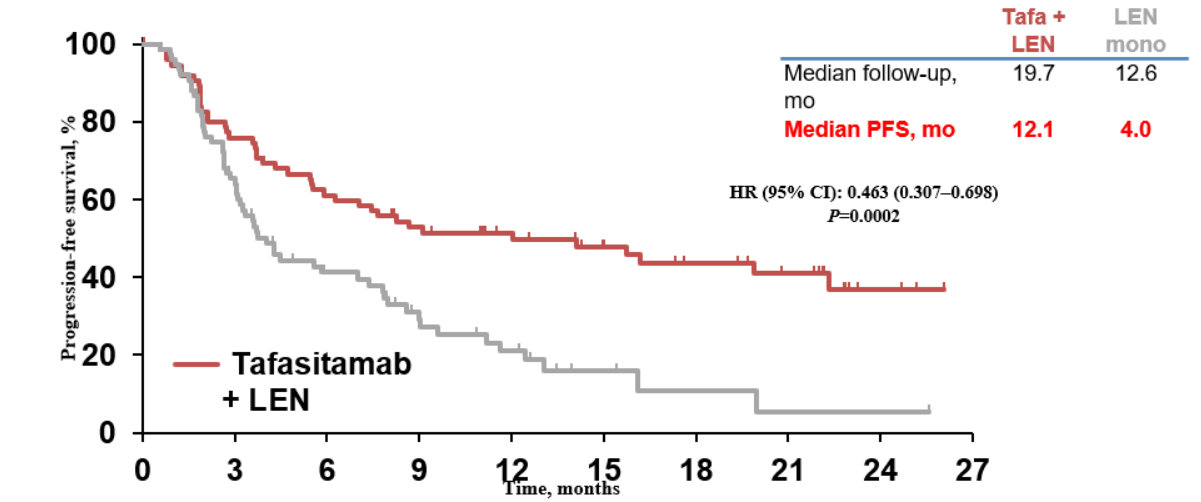
Pier Luigi Zinzani[1], Thomas Rodgers[2], Dario Marino[3], Maurizio Frezzato[4], Anna Maria Barbui[5], Claudia Castellino[6], Erika Meli[7], Nathan H. Fowler[8], Gilles Salles[9], Bruce Feinberg[10], Nuwan C. Kurukulasuriya[11], Sascha Tillmanns[12], Stephan Parche[11], Debarshi Dey[11], Günter Fingerle-Rowson[11], Sumeet Ambarkhane[11], Mark Winderlich[11], and Grzegorz S. Nowakowski[12]



RE-MIND: Comparing Tafasitamab + Lenalidomide (L-MIND) with a Real-world Lenalidomide Monotherapy Cohort in Relapsed or Refractory Diffuse Large B-cell Lymphoma

Pier Luigi Zinzani[1], Thomas Rodgers[2], Dario Marino[3], Maurizio Frezzato[4], Anna Maria Barbui[5], Claudia Castellino[6], Erika Meli[7], Nathan H. Fowler[8], Gilles Salles[9], Bruce Feinberg[10], Nuwan C. Kurukulasuriya[11], Sascha Tillmanns[12], Stephan Parche[11], Debarshi Dey[11], Günter Fingerle-Rowson[11], Sumeet Ambarkhane[11], Mark Winderlich[11], and Grzegorz S. Nowakowski[12]

SECONDARY ENDPOINTS: PROGRESSION-FREE SURVIVAL



	Tafa + LEN	LEN mono
Median follow-up, mo	19.7	12.6
Median PFS, mo	**12.1**	**4.0**

HR (95% CI): 0.463 (0.307–0.698)
P=0.0002

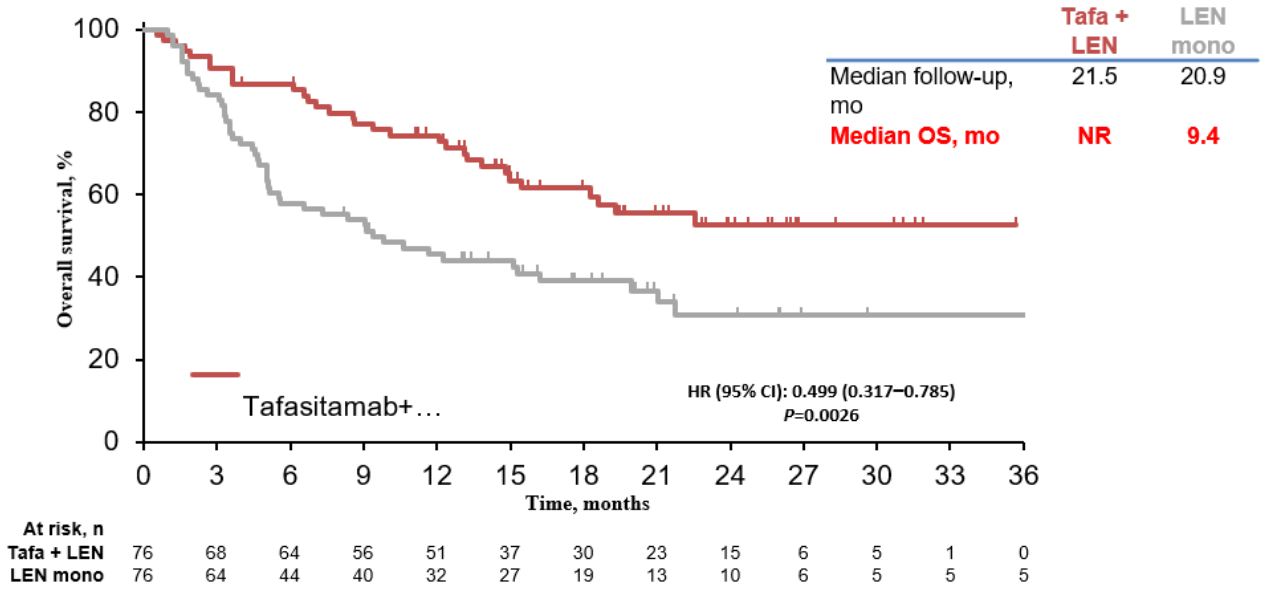
At risk, n										
Tafa + LEN	76	57	45	37	30	24	19	14	3	0
LEN mono	76	48	25	16	10	4	2	1	1	0

CI, confidence interval; HR, hazard ratio; LEN, lenalidomide; mo, month(s); mono, monotherapy; NR, not reached; PFS, progression-free survival.
Nowakowski G, et al. Poster presentation at ASCO 2020; Abstract 8020.

RE-MIND: Comparing Tafasitamab + Lenalidomide (L-MIND) with a Real-world Lenalidomide Monotherapy Cohort in Relapsed or Refractory Diffuse Large B-cell Lymphoma

Pier Luigi Zinzani[1], Thomas Rodgers[2], Dario Marino[3], Maurizio Frezzato[4], Anna Maria Barbui[5], Claudia Castellino[6], Erika Meli[7], Nathan H. Fowler[8], Gilles Salles[9], Bruce Feinberg[10], Nuwan C. Kurukulasuriya[11], Sascha Tillmanns[12], Stephan Parche[11], Debarshi Dey[11], Günter Fingerle-Rowson[11], Sumeet Ambarkhane[11], Mark Winderlich[11], and Grzegorz S. Nowakowski[12]

SECONDARY ENDPOINTS: OVERALL SURVIVAL



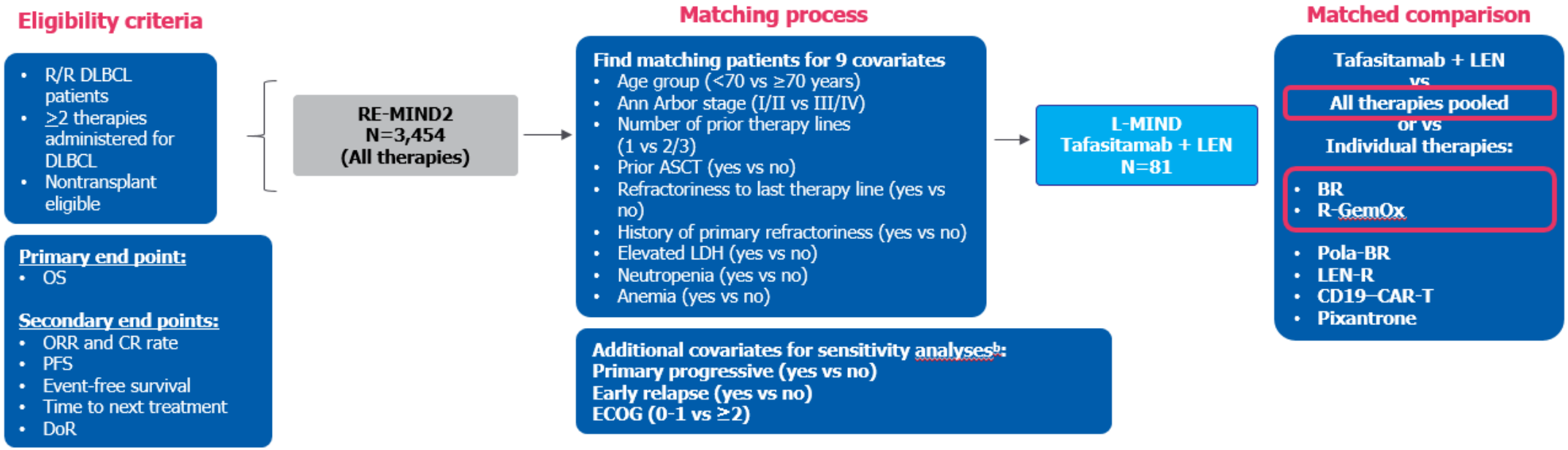
	Tafa + LEN	LEN mono
Median follow-up, mo	21.5	20.9
Median OS, mo	**NR**	**9.4**

At risk, n													
Tafa + LEN	76	68	64	56	51	37	30	23	15	6	5	1	0
LEN mono	76	64	44	40	32	27	19	13	10	6	5	5	5

CI, confidence interval; HR, hazard ratio; LEN, lenalidomide; mo, month(s); mono, monotherapy; NR, not reached; OS, overall survival.
Nowakowski G, et al. Poster presentation at ASCO 2020; Abstract 8020.

RE-MIND2: STUDY DESIGN AND METHODS

Matching criteria and estimated propensity score (ePS)-based method were applied and efficacy outcomes from the L-MIND cohort were compared with those treated with the observational cohort of patients enrolled in RE-MIND2 database



Grzegorz S. Nowakowski et al, SOHO September 8-11, 2021: Poster number ABCL-346

REMIND2: ORR

Table 2. ORR and CR rate for tafasitamab + LEN vs systemic therapies pooled, BR, and R-GemOx

	MAS for systemic therapies pooled		MAS for BR		MAS for R-GemOx	
	Tafasitamab + LEN (n=76)	Systemic therapies pooled (n=76)	Tafasitamab + LEN (n=75)	BR (n=75)	Tafasitamab + LEN (n=74)	R-GemOx (n=74)
ORR, n (%) (95% CI)	51 (67.1) (55.4–77.5)	37 (48.7) (37.0–60.4)	50 (66.7) (54.8–77.1)	41 (54.7) (42.7–66.2)	51 (68.9) (57.1–79.2)	34 (45.9) (34.3–57.9)
Fisher's exact test p-value of ORR	0.032		0.181		0.007	
CR rate as best response, n (%) (95% CI)	29 (38.2) (27.2–50.0)	16 (21.1) (12.5–31.9)	29 (38.7) (27.6–50.6)	21 (28.0) (18.2–39.6)	29 (39.2) (28.0–51.2)	17 (23.0) (14.0–34.2)
Fisher's exact p-value of CR rate	0.032		0.225		0.050	

BR, bendamustine + rituximab; CI, confidence interval; CR, complete response; LEN, lenalidomide; MAS, matched analysis set; ORR, overall response rate; R-GemOx, rituximab + gemcitabine + oxaliplatin.

Tafasitamab + LEN vs therapies pooled and R-GemOx: ORR and CR significantly higher

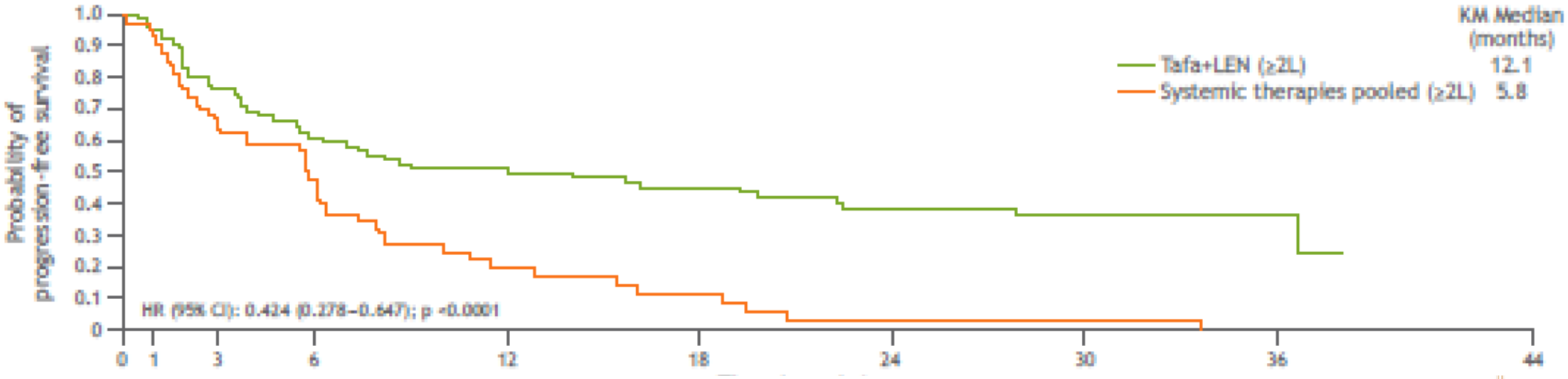
A numerical improvement was observed for tafasitamab + LEN vs BR but no statistically significant

Grzegorz S. Nowakowski et al, SOHO September 8-11, 2021: Poster number ABCL-346

Improved Efficacy of Tafasitamab plus Lenalidomide versus Systemic Therapies for Relapsed/Refractory DLBCL: RE-MIND2, an Observational Retrospective Matched Cohort Study

Grzegorz S. Nowakowski[1], Dok Hyun Yoon[2], Anthea Peters[3], Patrizia Mondello[4], Erel Joffe[4], Isabelle Fleury[5], Richard Greil[6], Matthew Ku[7], Reinhard Marks[8], Kibum Kim[9,10], Pier Luigi Zinzani[11], Judith Trotman[12], Dan Huang[13], Eva E. Waltl[13], Mark Winderlich[13], Nuwan C. Kurukulasuriya[14], Sumeet Ambarkhane[13], Georg Hess[15], and Gilles Salles[4]

RE-MIND2: PROGRESSION FREE SURVIVAL VS POOLED THERAPIES

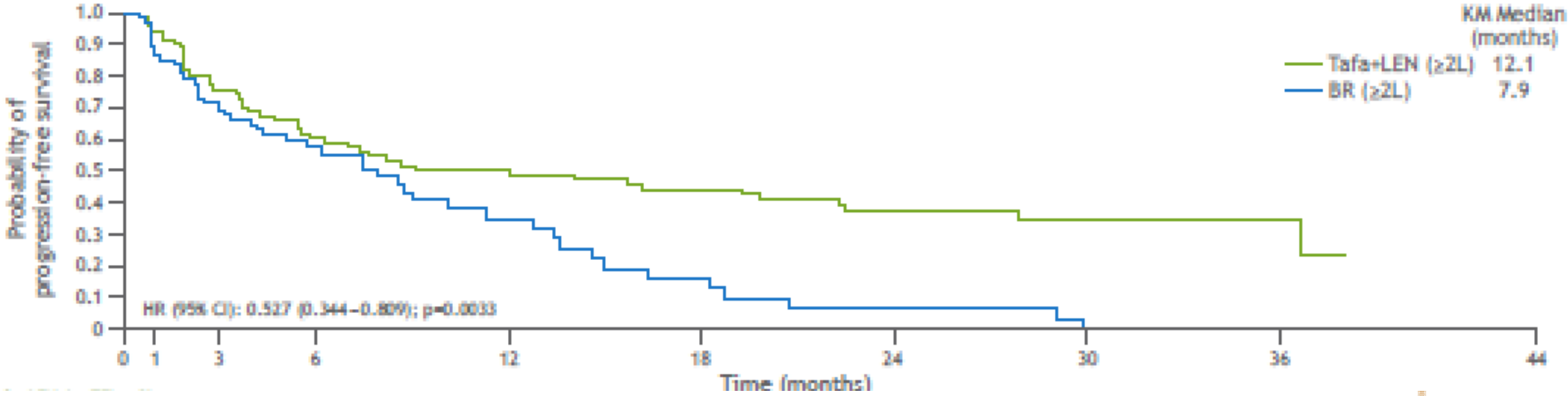


Clin Cancer Res; 28(18) September 15, 2022

Improved Efficacy of Tafasitamab plus Lenalidomide versus Systemic Therapies for Relapsed/Refractory DLBCL: RE-MIND2, an Observational Retrospective Matched Cohort Study

Grzegorz S. Nowakowski[1], Dok Hyun Yoon[2], Anthea Peters[3], Patrizia Mondello[4], Erel Joffe[4], Isabelle Fleury[5], Richard Greil[6], Matthew Ku[7], Reinhard Marks[8], Kibum Kim[9,10], Pier Luigi Zinzani[11], Judith Trotman[12], Dan Huang[13], Eva E. Waltl[13], Mark Winderlich[13], Nuwan C. Kurukulasuriya[14], Sumeet Ambarkhane[13], Georg Hess[15], and Gilles Salles[4]

RE-MIND2: PROGRESSION FREE SURVIVAL VS BR

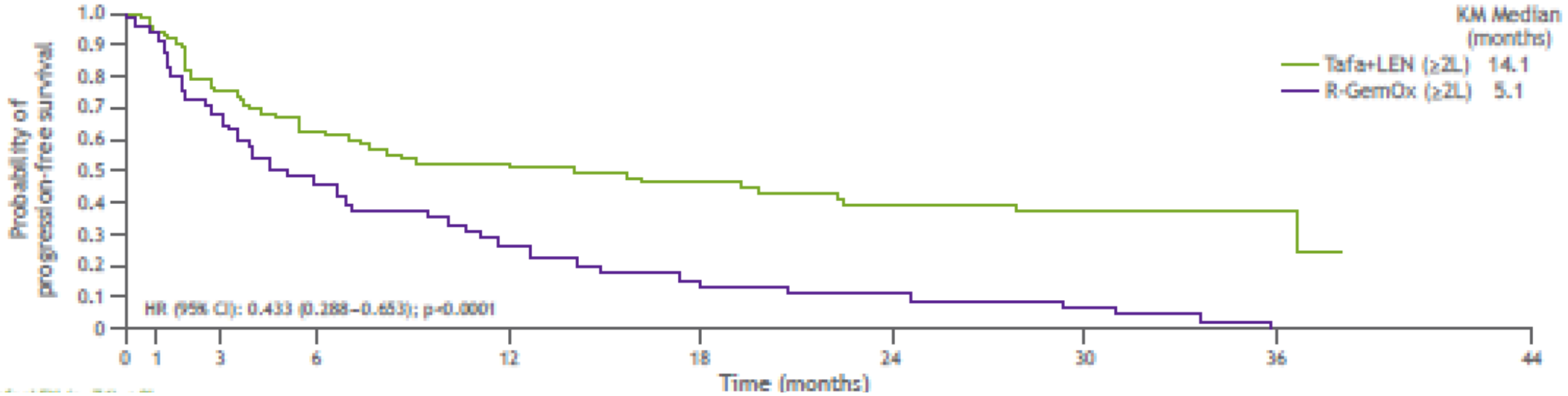


Clin Cancer Res; 28(18) September 15, 2022

Improved Efficacy of Tafasitamab plus Lenalidomide versus Systemic Therapies for Relapsed/Refractory DLBCL: RE-MIND2, an Observational Retrospective Matched Cohort Study

Grzegorz S. Nowakowski[1], Dok Hyun Yoon[2], Anthea Peters[3], Patrizia Mondello[4], Erel Joffe[4], Isabelle Fleury[5], Richard Greil[6], Matthew Ku[7], Reinhard Marks[8], Kibum Kim[9,10], Pier Luigi Zinzani[11], Judith Trotman[12], Dan Huang[13], Eva E. Waltl[13], Mark Winderlich[13], Nuwan C. Kurukulasuriya[14], Sumeet Ambarkhane[13], Georg Hess[15], and Gilles Salles[4]

RE-MIND2: PROGRESSION FREE SURVIVAL VS R-GEMOX

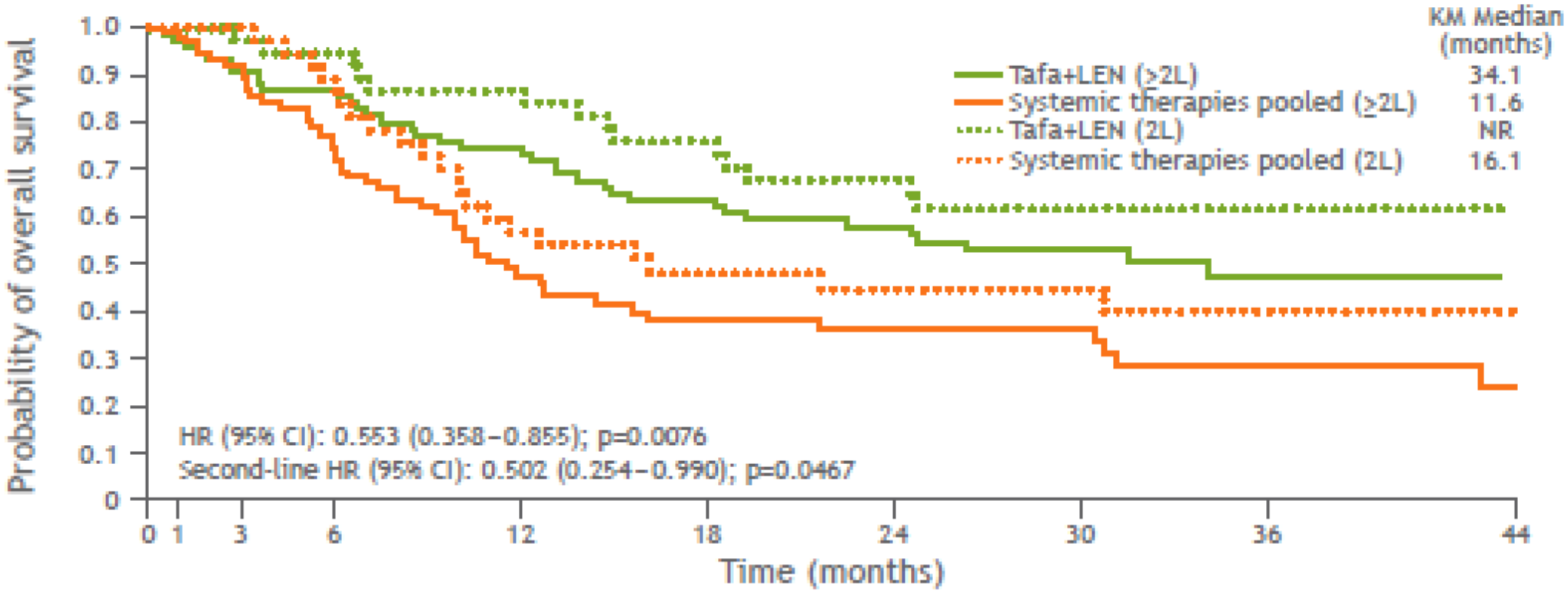


Clin Cancer Res; 28(18) September 15, 2022

Improved Efficacy of Tafasitamab plus Lenalidomide versus Systemic Therapies for Relapsed/Refractory DLBCL: RE-MIND2, an Observational Retrospective Matched Cohort Study

Grzegorz S. Nowakowski[1], Dok Hyun Yoon[2], Anthea Peters[3], Patrizia Mondello[4], Erel Joffe[4], Isabelle Fleury[5], Richard Greil[6], Matthew Ku[7], Reinhard Marks[8], Kibum Kim[9,10], Pier Luigi Zinzani[11], Judith Trotman[12], Dan Huang[13], Eva E. Waltl[13], Mark Winderlich[13], Nuwan C. Kurukulasuriya[14], Sumeet Ambarkhane[13], Georg Hess[15], and Gilles Salles[4]

RE-MIND2: OVERALL SURVIVAL VS POOLED THERAPIES

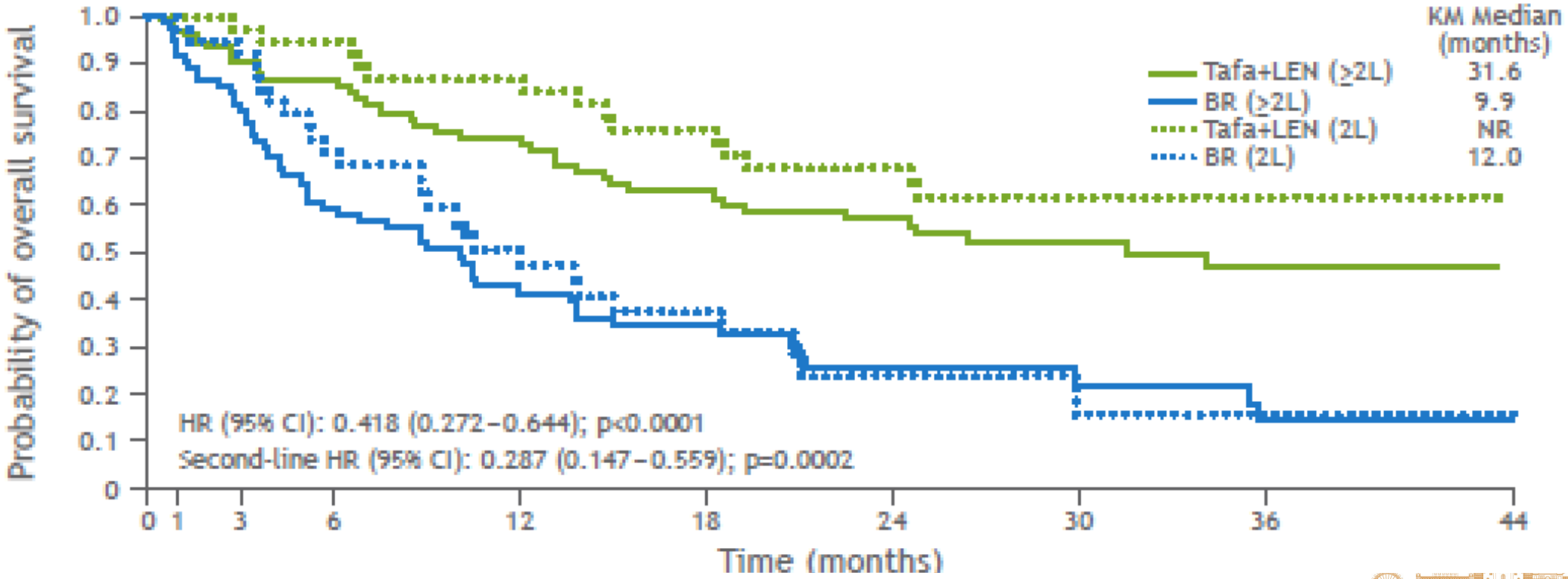


Clin Cancer Res; 28(18) September 15, 2022

Improved Efficacy of Tafasitamab plus Lenalidomide versus Systemic Therapies for Relapsed/Refractory DLBCL: RE-MIND2, an Observational Retrospective Matched Cohort Study

Grzegorz S. Nowakowski[1], Dok Hyun Yoon[2], Anthea Peters[3], Patrizia Mondello[4], Erel Joffe[4], Isabelle Fleury[5], Richard Greil[6], Matthew Ku[7], Reinhard Marks[8], Kibum Kim[9,10], Pier Luigi Zinzani[11], Judith Trotman[12], Dan Huang[13], Eva E. Waltl[13], Mark Winderlich[13], Nuwan C. Kurukulasuriya[14], Sumeet Ambarkhane[13], Georg Hess[15], and Gilles Salles[4]

RE-MIND2: OVERALL SURVIVAL VS BR

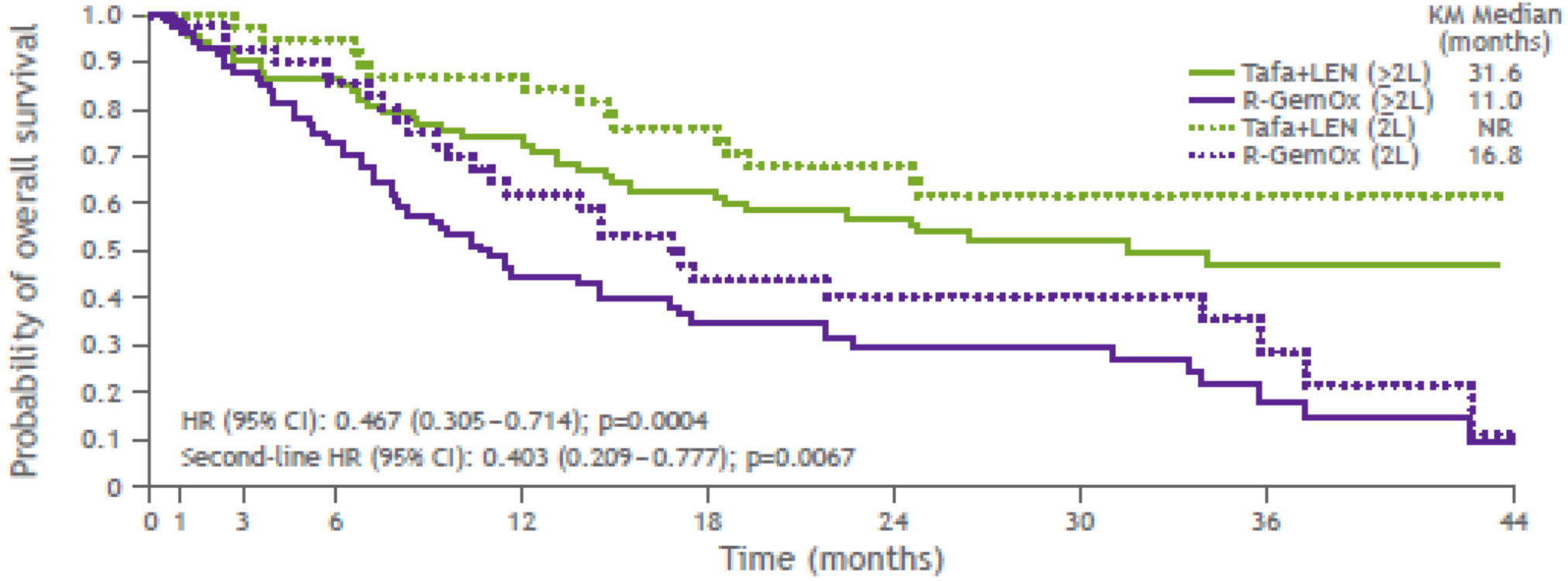


Clin Cancer Res; 28(18) September 15, 2022

Improved Efficacy of Tafasitamab plus Lenalidomide versus Systemic Therapies for Relapsed/Refractory DLBCL: RE-MIND2, an Observational Retrospective Matched Cohort Study

Grzegorz S. Nowakowski[1], Dok Hyun Yoon[2], Anthea Peters[3], Patrizia Mondello[4], Erel Joffe[4], Isabelle Fleury[5], Richard Greil[6], Matthew Ku[7], Reinhard Marks[8], Kibum Kim[9,10], Pier Luigi Zinzani[11], Judith Trotman[12], Dan Huang[13], Eva E. Waltl[13], Mark Winderlich[13], Nuwan C. Kurukulasuriya[14], Sumeet Ambarkhane[13], Georg Hess[15], and Gilles Salles[4]

RE-MIND2: OVERALL SURVIVAL VS R-GEMOX



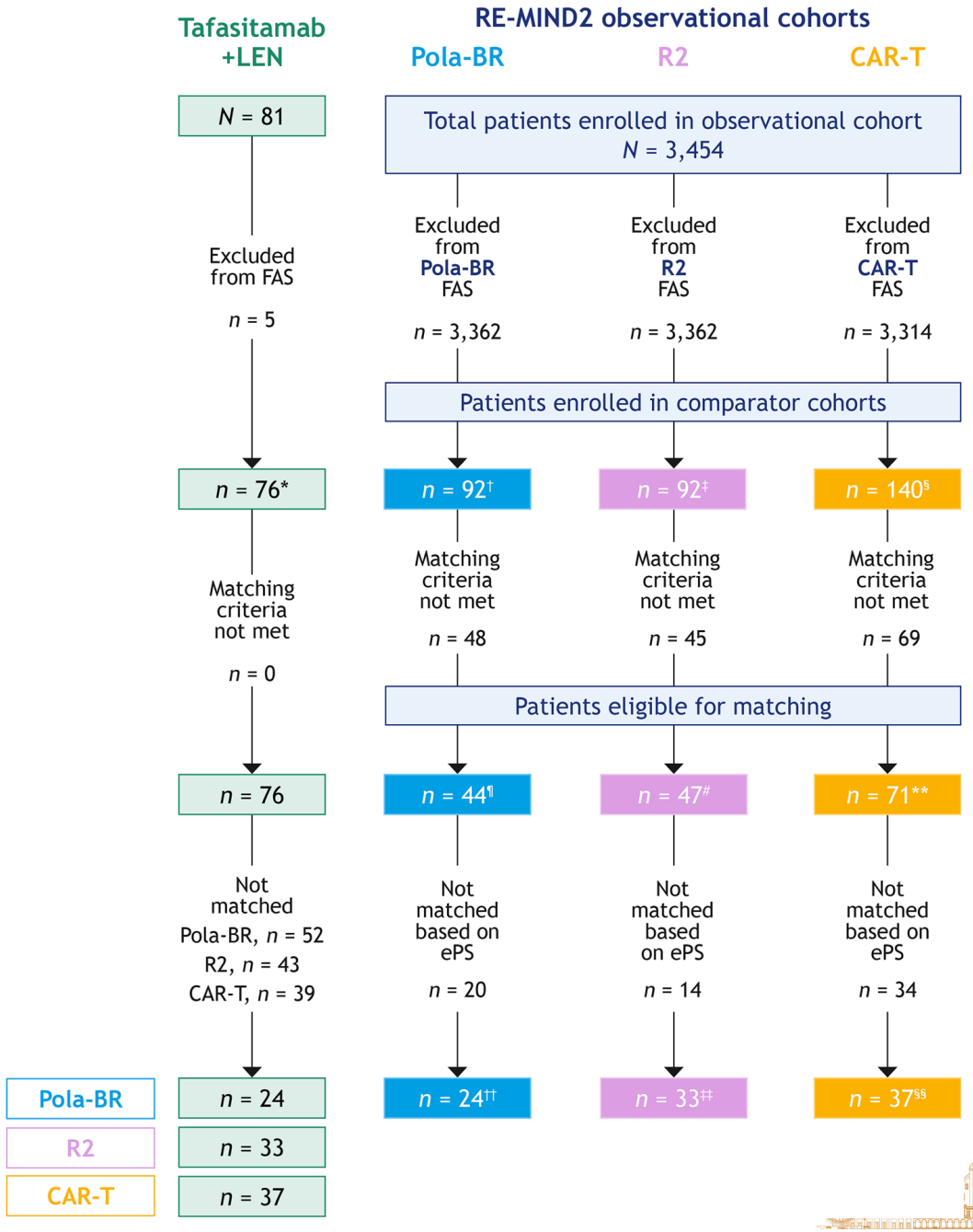
Clin Cancer Res; 28(18) September 15, 2022

Annals of Hematology (2023) 102:1773–1787
https://doi.org/10.1007/s00277-023-05196-4

ORIGINAL ARTICLE

RE-MIND2: comparative effectiveness of tafasitamab plus lenalidomide versus polatuzumab vedotin/bendamustine/rituximab (pola-BR), CAR-T therapies, and lenalidomide/rituximab (R2) based on real-world data in patients with relapsed/refractory diffuse large B-cell lymphoma

Grzegorz S. Nowakowski[1] · Dok Hyun Yoon[2] · Patrizia Mondello[3] · Erel Joffe[3] · Anthea Peters[4] · Isabelle Fleury[5] · Richard Greil[6] · Matthew Ku[7] · Reinhard Marks[8] · Kibum Kim[9,10] · Pier Luigi Zinzani[11,12] · Judith Trotman[13] · Lorenzo Sabatelli[14] · Eva E. Waltl[15] · Mark Winderlich[15] · Andrea Sporchia[15] · Nuwan C. Kurukulasuriya[16] · Raul Cordoba[17] · Georg Hess[18] · Gilles Salles[3]



Eligibility criteria

- R/R DLBCL patients
- ≥2 therapies administered for DLBCL
- Transplant ineligible

RE-MIND2
N=3,454
(All therapies)

Matching process

Find matching patients for 6 covariates*

- Age group (<70 years vs ≥70 years)
- Number of prior therapy lines (1 vs 2/3)
- Prior ASCT (yes vs no)
- History of primary refractoriness (yes vs no)
- Refractoriness to last therapy line (yes vs no)
- ECOG (0–1 vs ≥2)

L-MIND
Tafasitamab + LEN
N=81
Cut-off date: November 2019

Matched comparison

Tafasitamab + LEN vs

- Pola-BR
- R2
- CAR-T

Primary endpoint:

- OS

Key secondary endpoints:

- ORR and CR rate
- DoR
- PFS

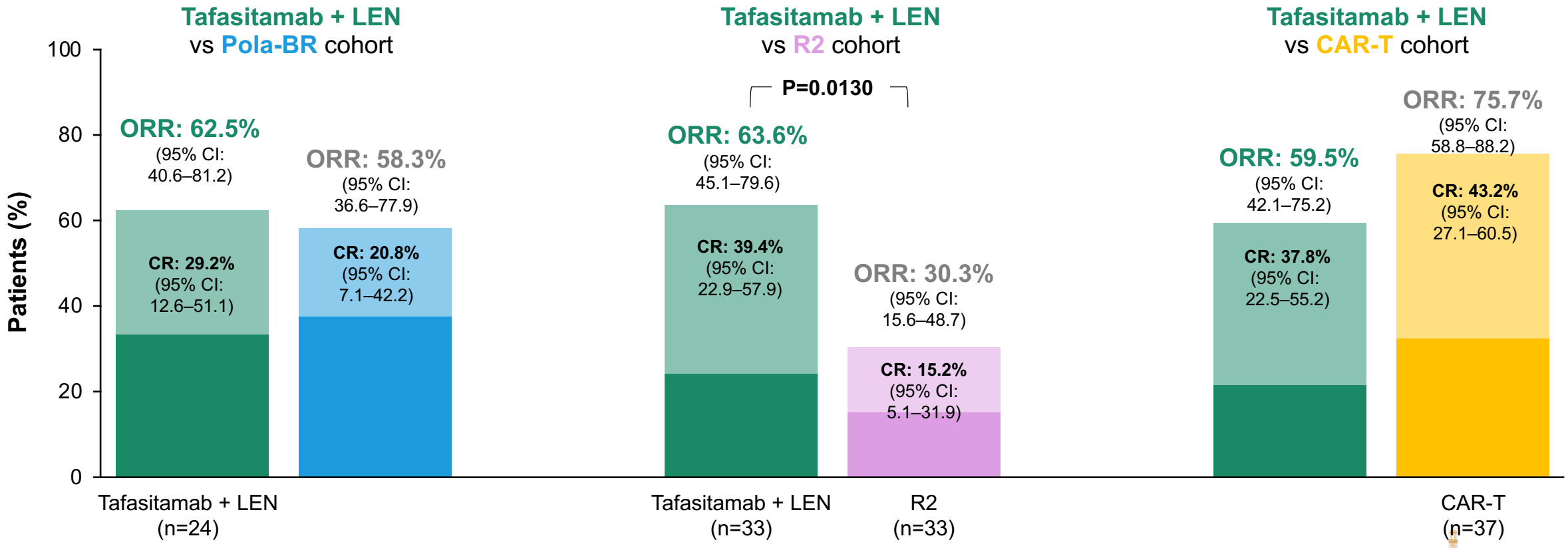
G. S. Nowakowski, Saturday, ASH December 11, 2021

Annals of Hematology (2023) 102:1773–1787
https://doi.org/10.1007/s00277-023-05196-4

ORIGINAL ARTICLE

RE-MIND2: comparative effectiveness of tafasitamab plus lenalidomide versus polatuzumab vedotin/bendamustine/rituximab (pola-BR), CAR-T therapies, and lenalidomide/rituximab (R2) based on real-world data in patients with relapsed/refractory diffuse large B-cell lymphoma

Grzegorz S. Nowakowski[1] · Dok Hyun Yoon[2] · Patrizia Mondello[3] · Erel Joffe[3] · Anthea Peters[4] · Isabelle Fleury[5] · Richard Greil[6] · Matthew Ku[7] · Reinhard Marks[8] · Kibum Kim[9,10] · Pier Luigi Zinzani[11,12] · Judith Trotman[13] · Lorenzo Sabatelli[14] · Eva E. Waltl[15] · Mark Winderlich[15] · Andrea Sporchia[15] · Nuwan C. Kurukulasuriya[16] · Raul Cordoba[17] · Georg Hess[18] · Gilles Salles[3]

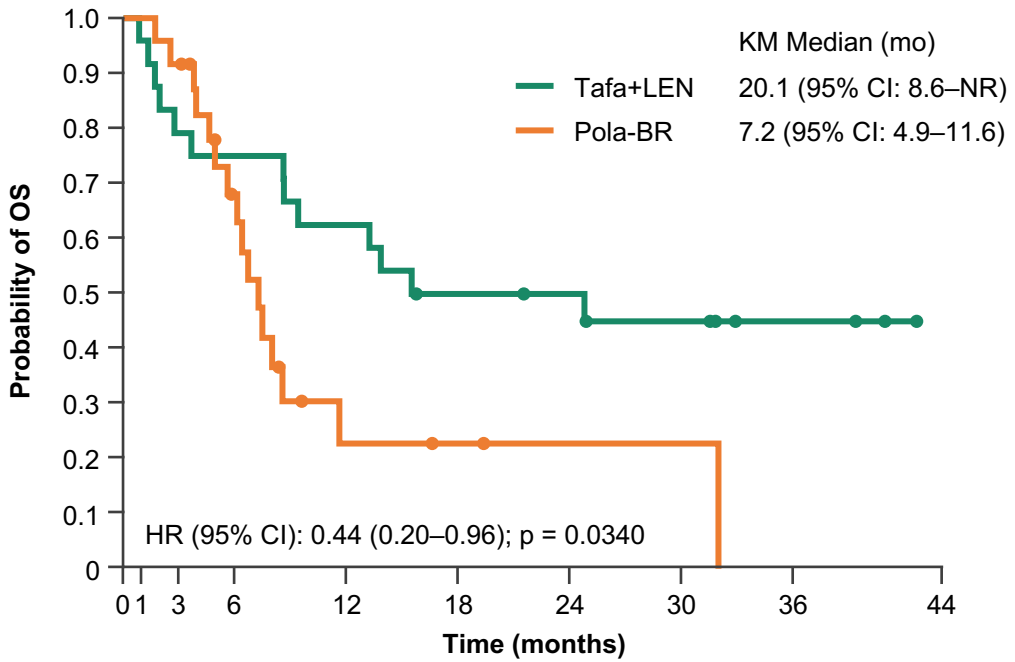


Annals of Hematology (2023) 102:1773–1787
https://doi.org/10.1007/s00277-023-05196-4

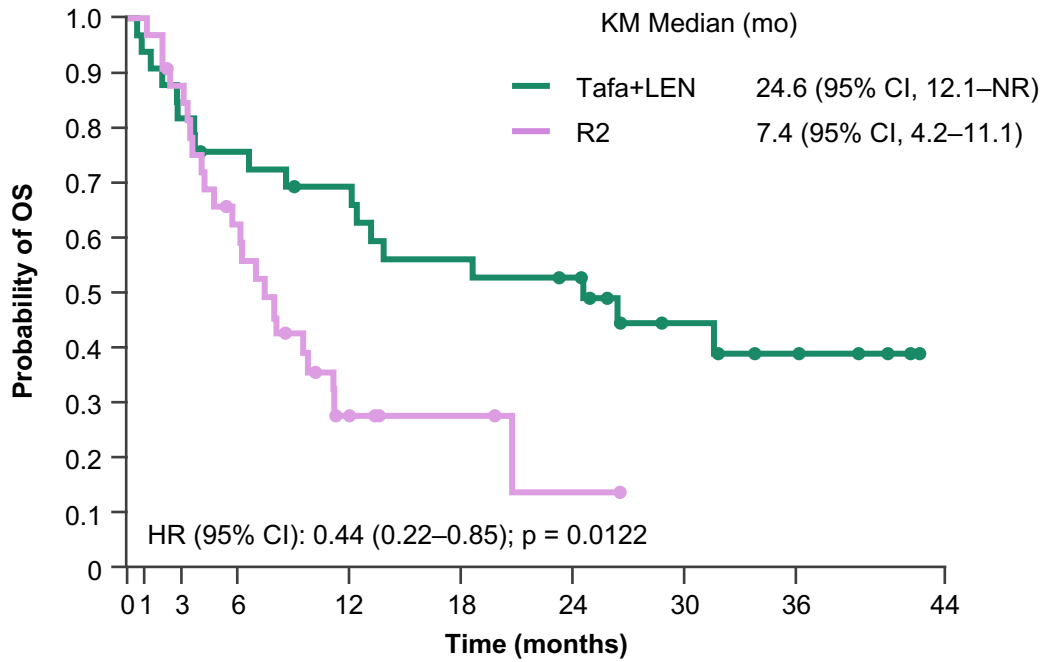
ORIGINAL ARTICLE

RE-MIND2: comparative effectiveness of tafasitamab plus lenalidomide versus polatuzumab vedotin/bendamustine/rituximab (pola-BR), CAR-T therapies, and lenalidomide/rituximab (R2) based on real-world data in patients with relapsed/refractory diffuse large B-cell lymphoma

Grzegorz S. Nowakowski[1] · Dok Hyun Yoon[2] · Patrizia Mondello[3] · Erel Joffe[3] · Anthea Peters[4] · Isabelle Fleury[5] · Richard Greil[6] · Matthew Ku[7] · Reinhard Marks[8] · Kibum Kim[9,10] · Pier Luigi Zinzani[11,12] · Judith Trotman[13] · Lorenzo Sabatelli[14] · Eva E. Waltl[15] · Mark Winderlich[15] · Andrea Sporchia[15] · Nuwan C. Kurukulasuriya[16] · Raul Cordoba[17] · Georg Hess[18] · Gilles Salles[3]



Median duration of follow-up: tafasitamab plus + LEN: 32 mo; Pola-BR: 16.6 mo



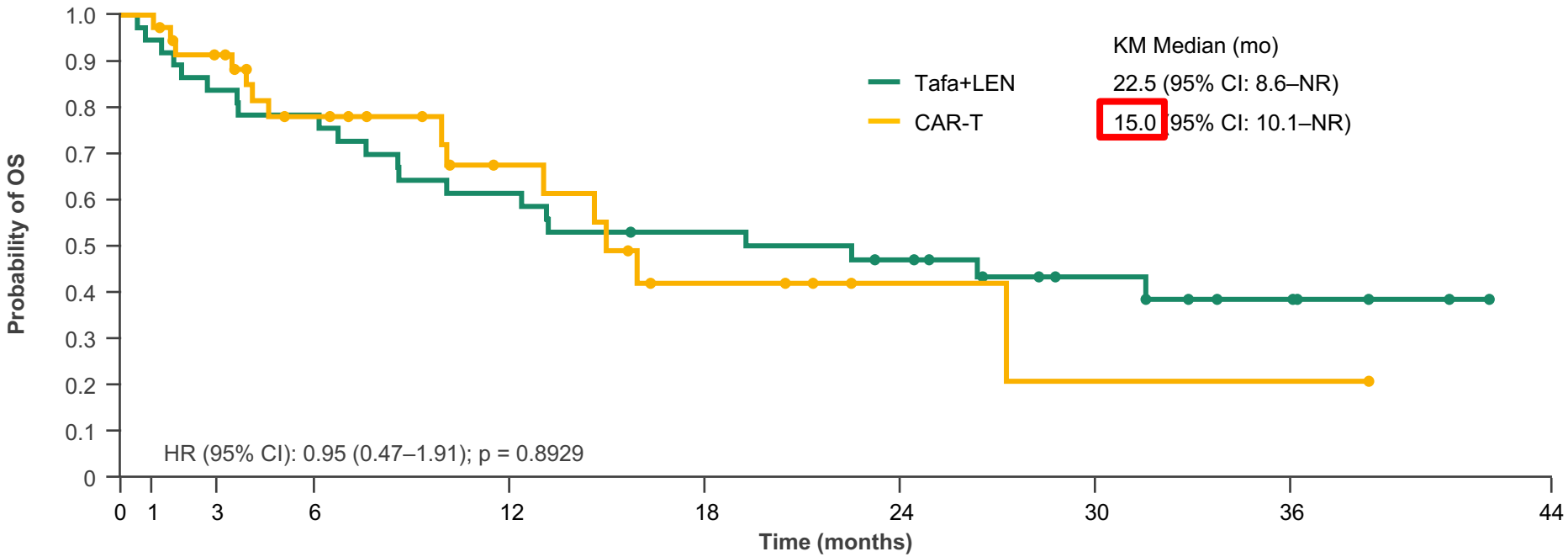
Median duration of follow-up: tafasitamab plus + LEN: 32; mo; R2: 13.4 mo

Annals of Hematology (2023) 102:1773–1787
https://doi.org/10.1007/s00277-023-05196-4

ORIGINAL ARTICLE

RE-MIND2: comparative effectiveness of tafasitamab plus lenalidomide versus polatuzumab vedotin/bendamustine/rituximab (pola-BR), CAR-T therapies, and lenalidomide/rituximab (R2) based on real-world data in patients with relapsed/refractory diffuse large B-cell lymphoma

Grzegorz S. Nowakowski[1] · Dok Hyun Yoon[2] · Patrizia Mondello[3] · Erel Joffe[3] · Anthea Peters[4] · Isabelle Fleury[5] · Richard Greil[6] · Matthew Ku[7] · Reinhard Marks[8] · Kibum Kim[9,10] · Pier Luigi Zinzani[11,12] · Judith Trotman[13] · Lorenzo Sabatelli[14] · Eva E. Waltl[15] · Mark Winderlich[15] · Andrea Sporchia[15] · Nuwan C. Kurukulasuriya[16] · Raul Cordoba[17] · Georg Hess[18] · Gilles Salles[3]



???

Median duration of follow-up: tafasitamab plus + LEN: 32 mo; CAR-T: 10.2 mo

G. S. Nowakowski, Saturday, ASH December 11, 2021

Annals of Hematology (2023) 102:1773–1787
https://doi.org/10.1007/s00277-023-05196-4

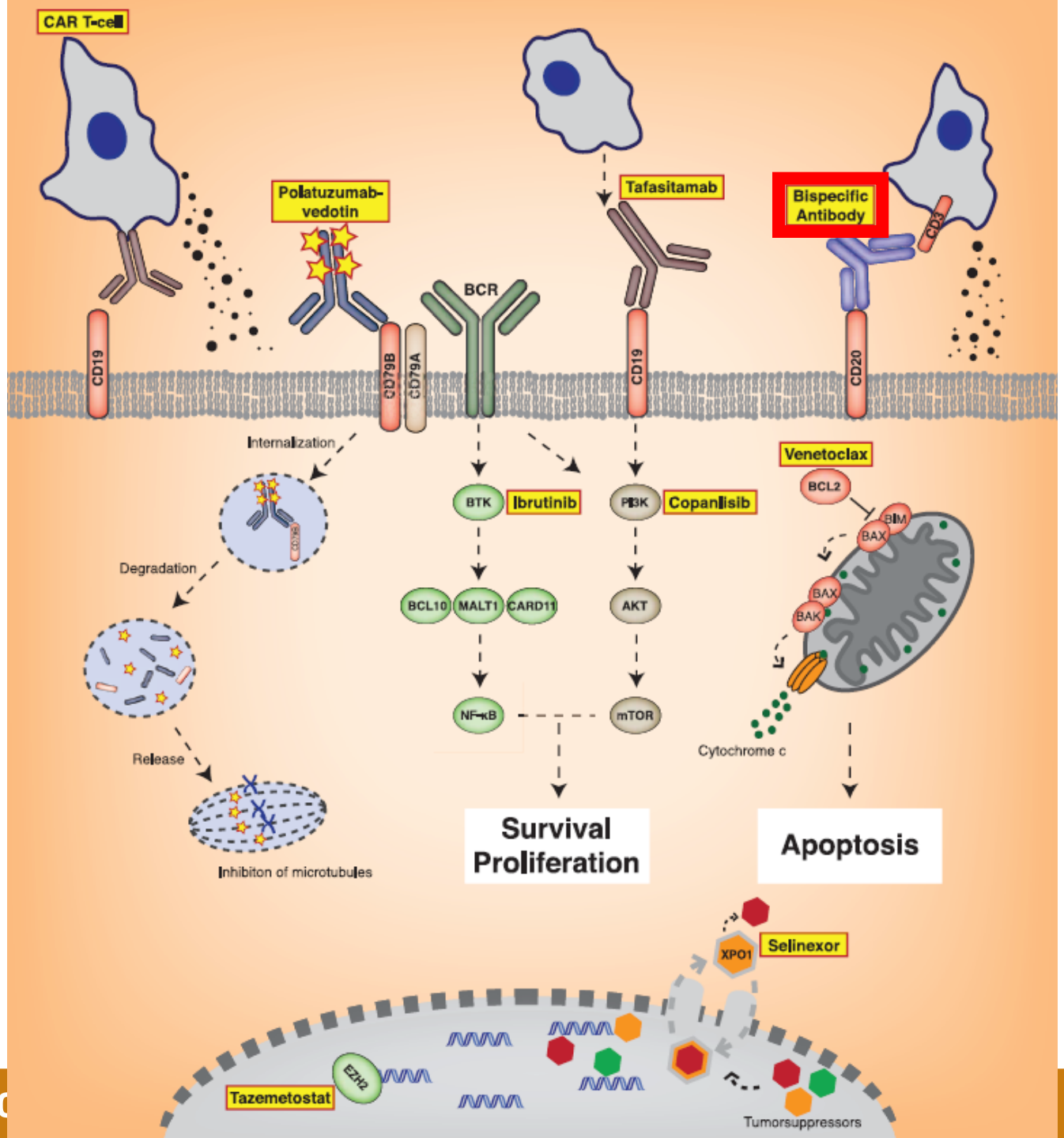
ORIGINAL ARTICLE

RE-MIND2: comparative effectiveness of tafasitamab plus lenalidomide versus polatuzumab vedotin/bendamustine/rituximab (pola-BR), CAR-T therapies, and lenalidomide/rituximab (R2) based on real-world data in patients with relapsed/refractory diffuse large B-cell lymphoma

Grzegorz S. Nowakowski[1] · Dok Hyun Yoon[2] · Patrizia Mondello[3] · Erel Joffe[3] · Anthea Peters[4] · Isabelle Fleury[5] · Richard Greil[6] · Matthew Ku[7] · Reinhard Marks[8] · Kibum Kim[9,10] · Pier Luigi Zinzani[11,12] · Judith Trotman[13] · Lorenzo Sabatelli[14] · Eva E. Waltl[15] · Mark Winderlich[15] · Andrea Sporchia[15] · Nuwan C. Kurukulasuriya[16] · Raul Cordoba[17] · Georg Hess[18] · Gilles Salles[3]

"The patients from **these pivotal studies** served as the reference populations for regulatory approval and were (on average) **younger**…"

"…Patients included in the CAR-T therapies cohort in the present study were **not transplant eligible"**



Fabian Frontzek. *Ther Adv Hematol* 2022, Vol. 13: 1–19

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

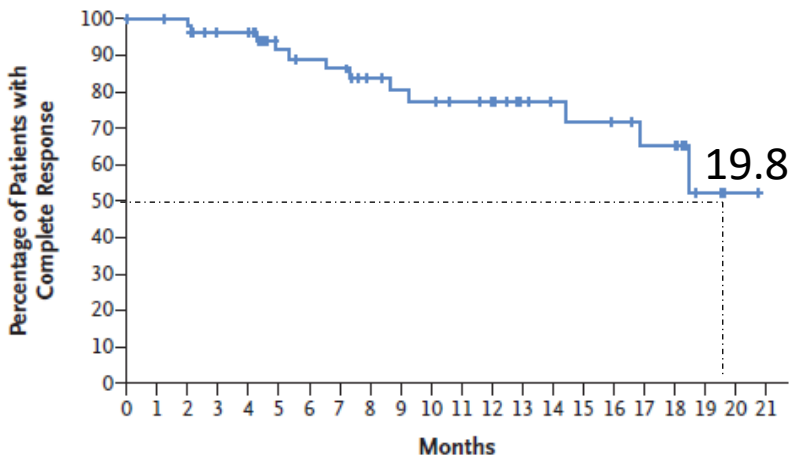
Glofitamab for Relapsed or Refractory Diffuse Large B-Cell Lymphoma

Michael J. Dickinson, M.B., B.S., D.Med.Sc., Carmelo Carlo-Stella, M.D.,

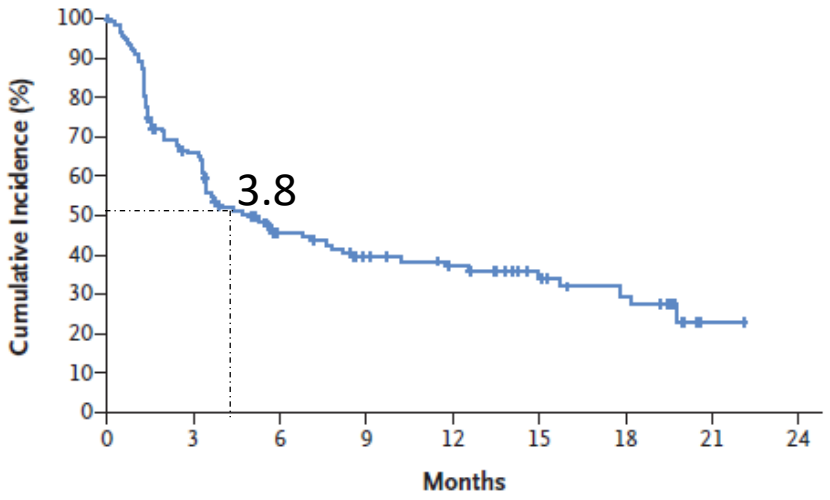
Pretreatment with **obinutuzumab** (1000 mg) was administered intravenously 7 days before
Glofitamab EV: on day 8 (2.5 mg) and day 15 (10 mg) of cycle 1, dose of 30 mg on day 1 of cycles 2 through 12 (cycles lasted 21 days)

ORR: 89%
CR: 58%

Duration of Complete Response among Patients with a Complete Response in the Main Analysis Cohort



Progression-free Survival in the Main Analysis Cohort



CRS: 63%
serious adverse events CRS: 21%

Table 1. Demographic and Clinical Characteristics at Baseline of All 154 Patients Treated at the Phase 2 Dose (Safety Population).*

Characteristic	Value
Median age (range) — yr	66 (21–90)
Male sex — no. (%)	100 (65)
ECOG performance-status score — no. (%)†	
0	69 (45)
1	84 (55)
Ann Arbor stage at time of study entry — no. (%)	
I	10 (6)
II	25 (16)
III	31 (20)
IV	85 (55)
Missing data	3 (2)
Non-Hodgkin's lymphoma subtype — no. (%)	
Diffuse large B-cell lymphoma, not otherwise specified	110 (71)
Transformed follicular lymphoma	27 (18)
High-grade B-cell lymphoma	11 (7)
Primary mediastinal B-cell lymphoma	6 (4)
Bulky disease at study entry	
>6 cm	64 (42)
>10 cm	18 (12)
Previous lines of therapy	
Median no. of lines (range)	3 (2–7)
Only 2 previous lines — no. (%)	62 (40)
≥3 previous lines — no. (%)	92 (60)
Previous therapy for lymphoma — no. (%)	
Anti-CD20 antibody	154 (100)
Anthracycline	149 (97)
CAR T-cell therapy	51 (33)
Autologous stem-cell transplantation — no. (%)	28 (18)
Relapsed or refractory status — no. (%)‡	
Refractory to any previous therapy	139 (90)
Refractory to last previous therapy	132 (86)
Primary refractory	90 (58)
Refractory to any previous anti-CD20 therapy	128 (83)
Refractory to previous CAR T-cell therapy	46 (30)

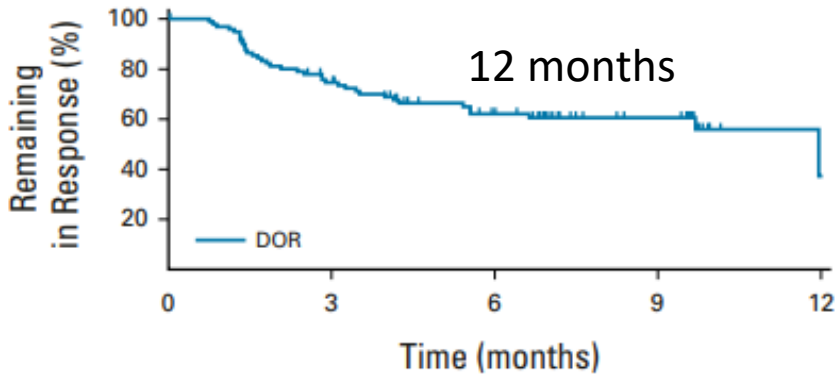
original report

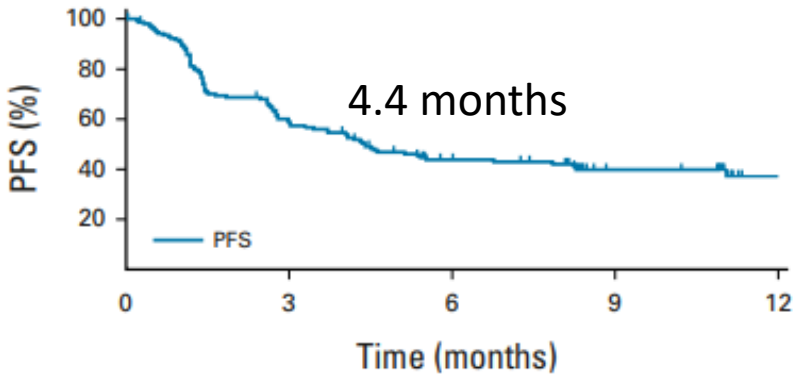
Epcoritamab, a Novel, Subcutaneous CD3xCD20 Bispecific T-Cell–Engaging Antibody, in Relapsed or Refractory Large B-Cell Lymphoma: Dose Expansion in a Phase I/II Trial

Catherine Thieblemont, MD, PhD[1]; Tycel Phillips, MD[2]; Herve Ghesquieres, MD, PhD[3]; Chan Y. Cheah, MBBS, DMSc[4,5];

Median prior lines of antilymphoma therapy: 3
Primary refractory disease: 61.1%
Refractory to last systemic therapy: 82.8%
DHL and THL: 13%
Prior CAR T-cell therapy: 38.9%
ORR: 63%
CR: 38.9%

CRS any grade: 49.7%
CRS G3-4: 2.5%





J Clin Oncol 41:2238-2247. © 2022

Meeting Abstract | 2023 ASCO Annual Meeting I

Real-world outcomes with novel therapies in R/R DLBCL.

Jennifer Leigh Crombie, Monika P. Jun, Tongsheng Wang, Alex Mutebi, Anthony Wang, Anindit Chibber, Rajesh Kamalakar, Jon Ukropec, Julie Blædel, Anupama Kalsekar; Dana-Farber Cancer Institute, Boston, MA; Genmab US, Inc., Plainsboro, NJ; AbbVie Inc., North Chicago, IL

Database (2010–2021)
A total of 175 R/R DLBCL patients
A total of **73 pts** treated with **CAR-T**,
69 pts with **Pola-BR**
27 pts with **Tafa-lena**
6 pts with Lonca

"…Outcomes of pola-BR and tafa-len regimens in the 2L+ and 3L+ R/R DLBCL setting remain suboptimal, with worse outcomes as patients advance through lines of therapy.

Outcomes are particularly poor when these agents are used following CAR T therapy…"

Clinical outcomes by line of therapy and treatment type.

	Treatment in the 2L+ setting			Treatment in the 3L+ setting		
Outcome (95% CI)	**CAR T (n=73)**	**Pola-BR (n=69)**	**Tafa-len (n=27)**	**CAR T (n=55)**	**Pola-BR (n=37)**	**Tafa-len (n=20)**
ORR (%)	76.7 (65.4, 85.8)	59.4 (46.9, 71.1)	40.7 (22.4, 61.2)	74.6 (61.0, 85.3)	62.2 (44.8, 77.5)	35.0 (15.4, 59.2)
CR (%)	52.1 (40.0, 63.9)	18.8 (10.4, 30.1)	11.1 (2.4, 29.2)	41.8 (28.7, 55.9)	13.5 (4.5, 28.8)	10.0 (1.2, 31.7)
mPFS (mo)	6.7 (4.0, 10.0)	3.1 (1.9, 3.8)	1.9 (0.8, 3.5)	5.6 (2.9, 7.4)	3.4 (2.1, 4.4)	1.7 (0.7, 4.4)
mOS (mo)	26.5 (13.6, NE)	7.8 (5.6, 11.4)	6.3 (1.6, 16.2)	17.8 (9.6, NE)	7.4 (4.3, 10.9)	6.3 (1.6, 16.2)

Vol 41, Issue 16 suppl

GF Nove Colli di Cesenatico

Congratulazioni, questa attività ha completato la S...

7.500 m

Distanza	Dislivello positivo
168,93 km	2.492 m
Tempo in movimento	**Potenza media**
6:37:15	190 W
Velocità media	**Calorie**
25,5 km/h	5.163 kcal