Tafasitamab

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New Drugs in Hematology
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DISCLOSURES OF COMMERCIAL SUPPORT

Name of Company	Research support	Employee	Consultant	Stockholder	Speaker's Bureau	Scientific Advisory Board	Other
Regeneron	x						
Morphosys			x			x	
Incyte	x					x	

Overview

- Tafasitamab mode of action and clinical data
- Tafasitamab real world
- Tafasitamab experience including CD19 therapie sequencing

CRS, cytokine release syndrome

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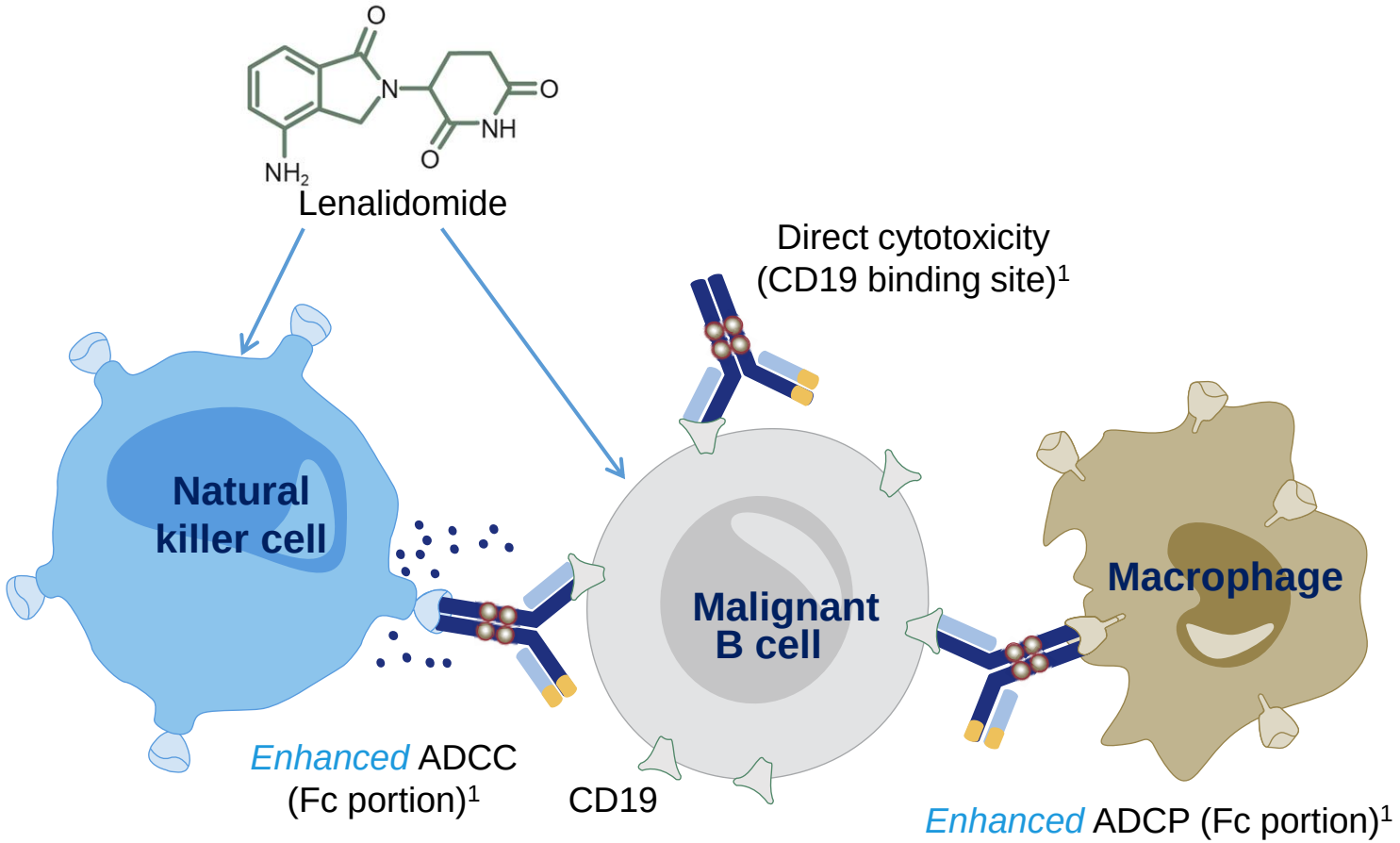
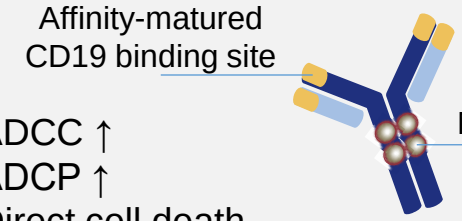
CRS, cytokine release syndrome

Tafasitamab mode of action



Tafasitamab (Fc-modified, anti-CD19 mAb)[1–4]



- ADCC ↑
- ADCP ↑
- Direct cell death
- Encouraging single-agent activity in patients with R/R DLBCL and iNHL

Lenalidomide[5,6]

- T-cell and NK-cell activation/expansion
- Direct cell death
- Well-studied as an anti-lymphoma agent, alone or in combination

- ADCC, antibody-dependent cellular cytotoxicity; ADCP, antibody-dependent cellular phagocytosis; iNHL, indolent non-Hodgkin's lymphoma.

- 1. Horton HM, et al. *Cancer Res.* 2008;68:8049–57; 2. Woyach JA, et al. *Blood.* 2014;124:3553–60; 3. Jurczak W, et al. *Ann Oncol.* 2018;29:1266–72; 4. Awan FT, et al. *Blood.* 2010;115:1204–13; 5. Witzig TE, et al. *Ann Oncol.* 2015;26:1667–77; 6. Czuczman MS, et al. *Clin Cancer Res.* 2017;23:4127–37.

Clinical data

Five-year efficacy and safety of tafasitamab in patients with relapsed or refractory DLBCL:

Final results from the Phase II L-MIND study

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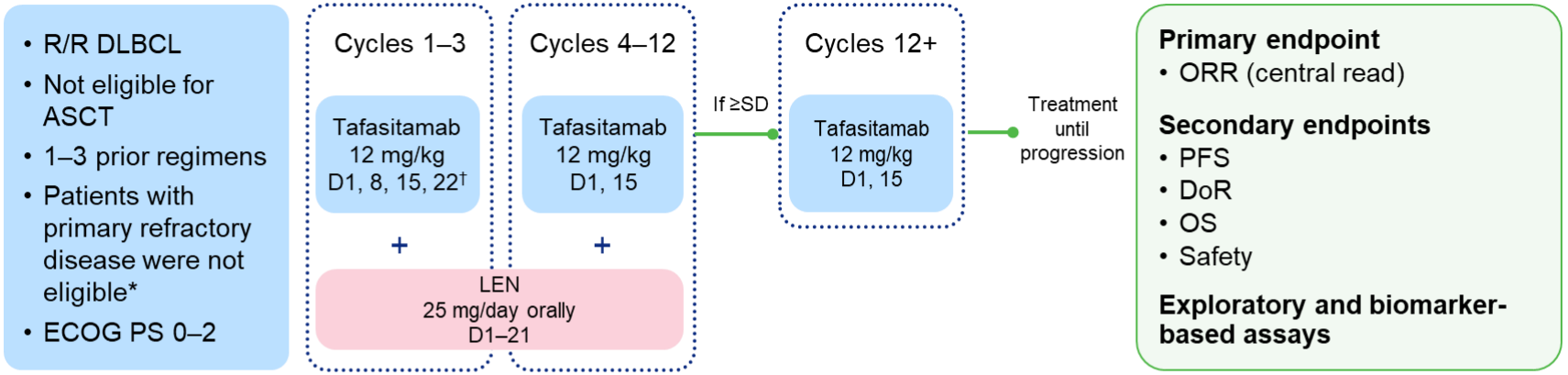
Clinical data

L-MIND: Study Design

Open-label, single-arm, multicenter, global, Phase II study; **N=81**



NCT02399085[1]

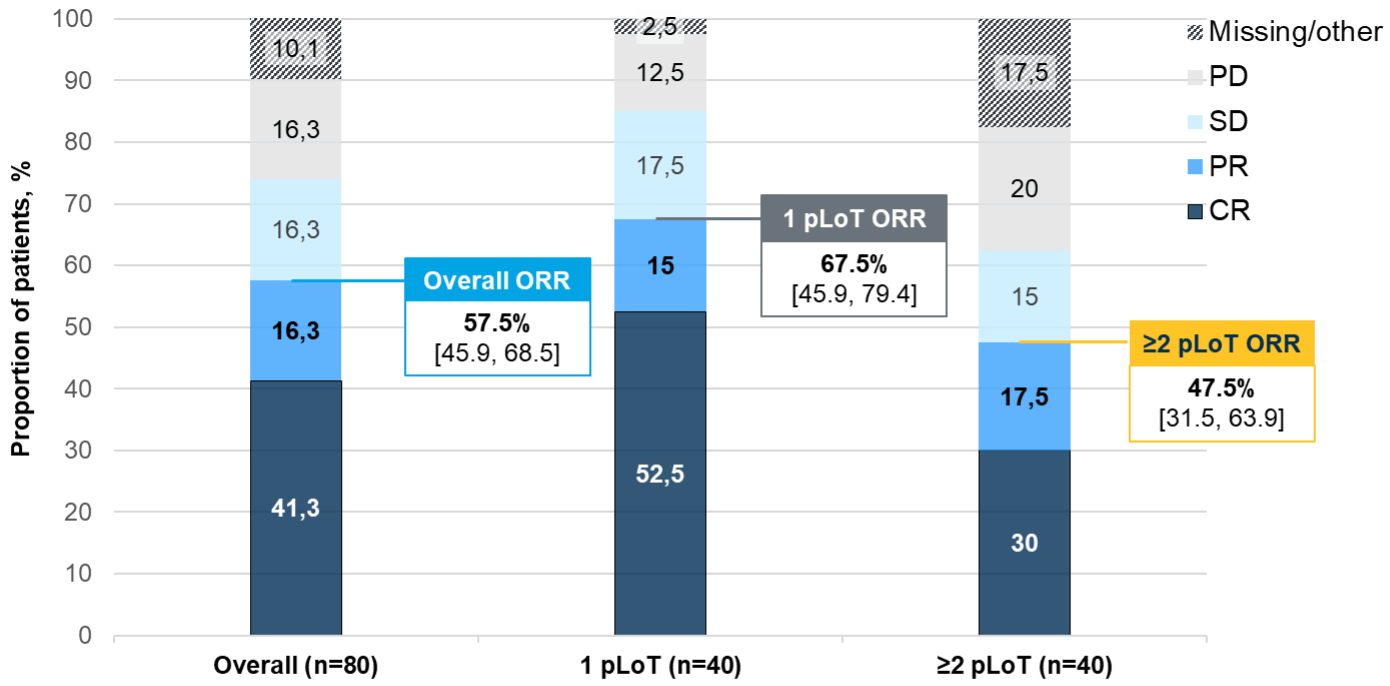
*Primary refractory is defined as no response to, or progression/relapse during/within 6 months of, front-line therapy; 15 patients with refractory disease were included under an early version of the protocol.

†A loading dose of tafasitamab was administered on Day 4 of Cycle 1.
ASCT, autologous stem cell transplantation; D, days; DLBCL, diffuse large B-cell lymphoma; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; HDC, high-dose chemotherapy; LEN, lenalidomide; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; R/R, relapsed or refractory; SD, stable disease.
1. ClinicalTrials.gov NCT02399085 (accessed Apr 2023).

Duell J, et al. AACR 2023. Abstract 9810.

Clinical data

Efficacy Results: Best Response at 5-year Follow-up

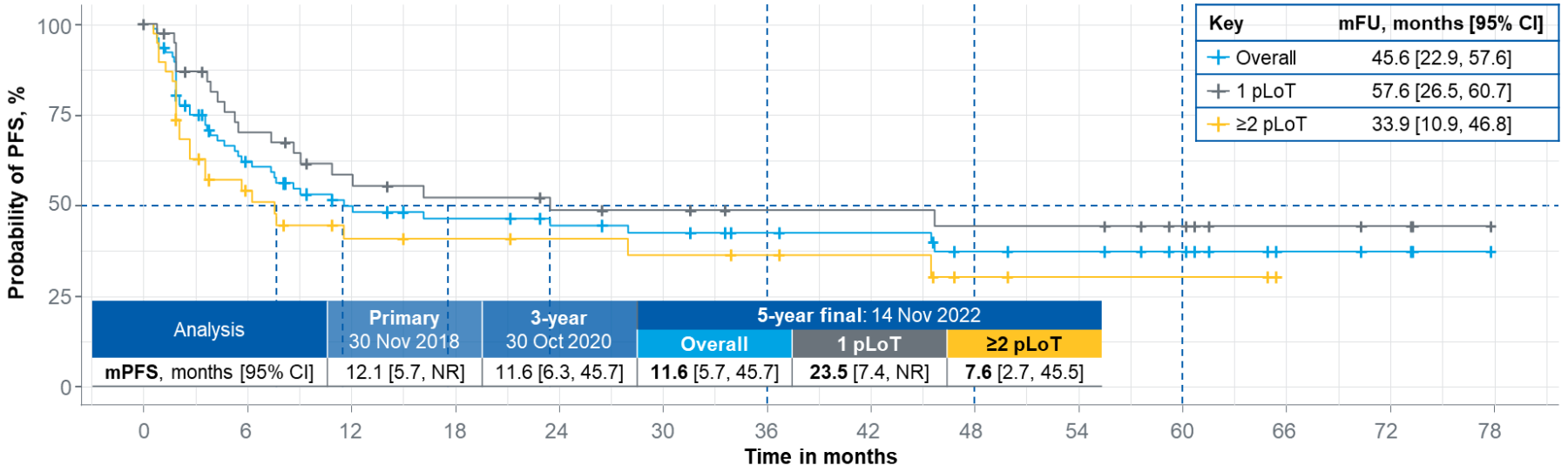


CR, complete response; ORR, objective response rate; PD, progressive disease; pLoT, prior line of therapy; PR, partial response; SD, stable disease.

Duell J, et al. AACR 2023. Abstract 9810.

Clinical data

Efficacy Results: PFS at 5-year Follow-up



Number at risk:

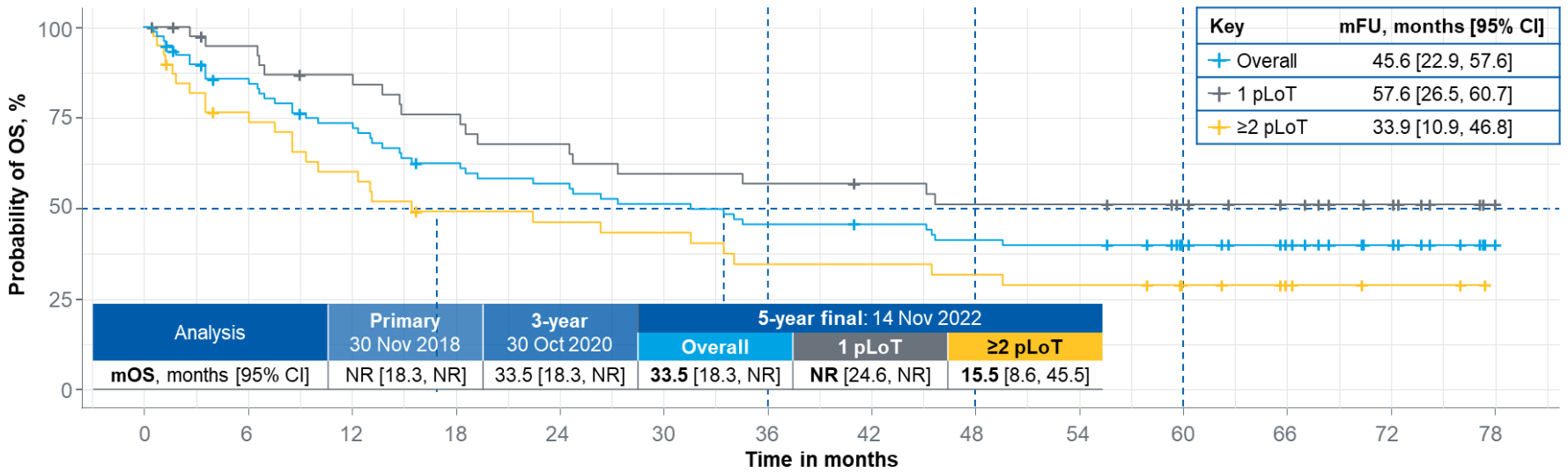
Overall	80	42	30	26	23	21	18	17	13	12	9	4	3	0
1 pLoT	40	25	19	16	14	13	11	11	10	10	7	4	3	0
≥2 pLoT	40	17	11	10	9	8	7	6	3	2	2	0	0	0

mFU, median follow-up; mPFS, median PFS; NR, not reached; PFS, progression-free survival; pLoT, prior line of therapy.

Duell J, et al. AACR 2023. Abstract 9810.

Clinical data

Efficacy Results: OS at 5-year Follow-up



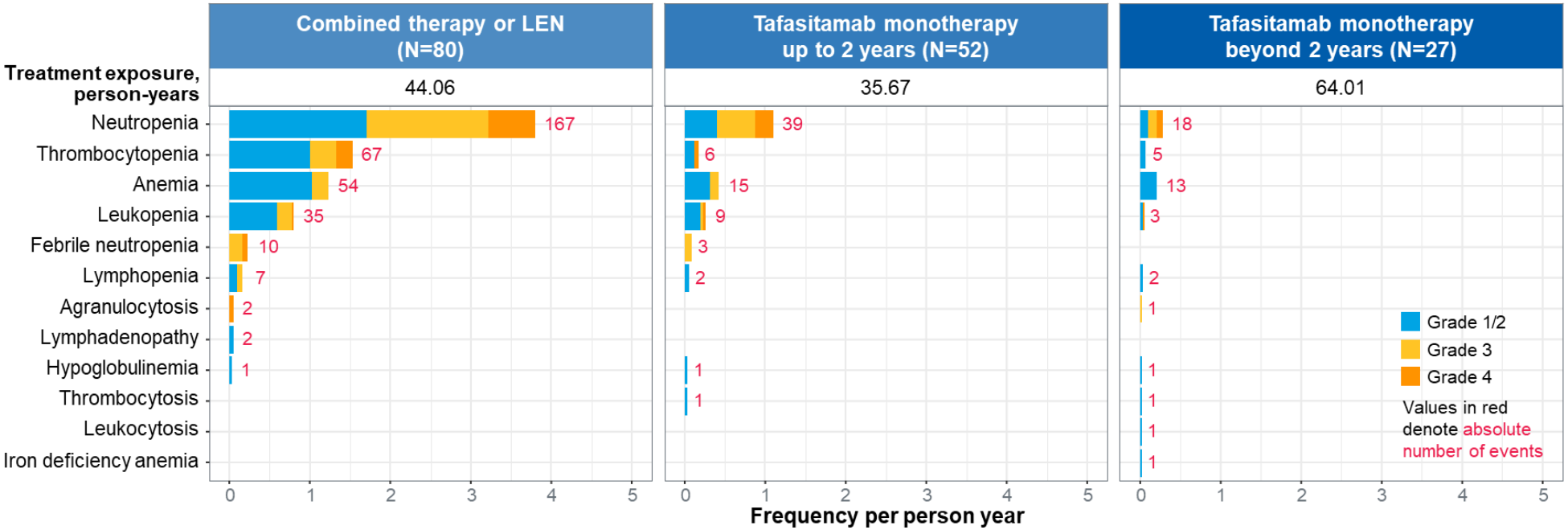
Number at risk:

Overall	80	64	54	45	41	37	33	32	29	28	21	15	9	1
1 pLoT	40	36	32	28	25	22	21	20	18	18	14	11	7	1
≥2 pLoT	40	28	22	17	16	15	12	12	11	10	7	4	2	0

mFU, median follow-up; mOS, median OS; NR, not reached; OS, overall survival; pLoT, prior line of therapy.

Clinical data

Hematological TEAEs



- Hematological TEAEs were less frequent during tafasitamab monotherapy compared with tafasitamab + LEN combination therapy
- The low incidence of TEAEs with tafasitamab monotherapy up to 2 years was maintained or further reduced from 2 years onwards

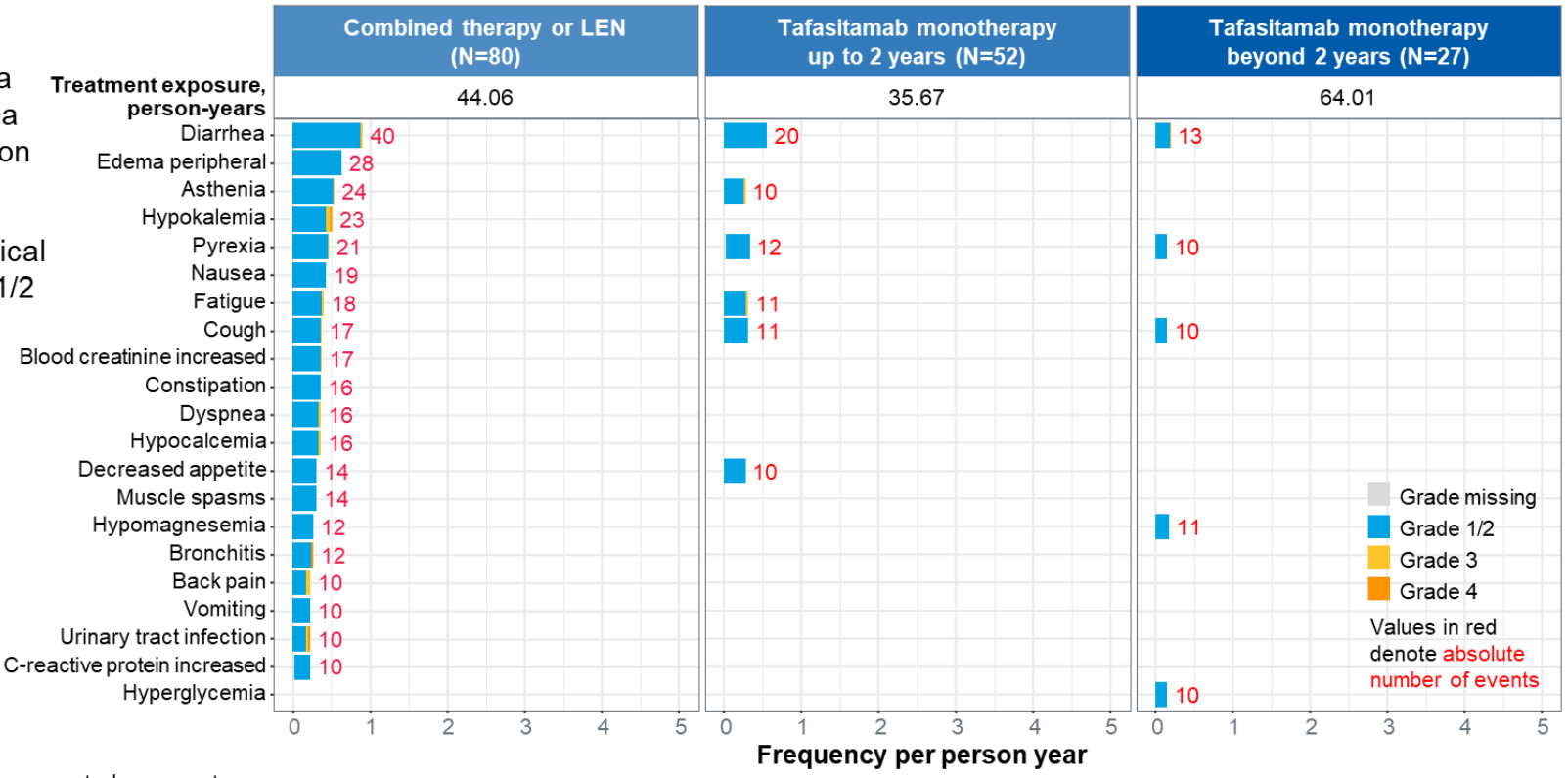
CTCAE grading system.
LEN, lenalidomide; TEAE, treatment-emergent adverse event.

Duell J, et al. AACR 2023. Abstract 9810.

Clinical data

Non-hematological TEAEs (cut-off: ≥10 events in any treatment period)

- The most common TEAEs were diarrhea and peripheral edema during the combination therapy phase
- Most non-hematological TEAEs were Grade 1/2



CTCAE grading system.
LEN, lenalidomide; TEAE, treatment-emergent adverse event.

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Clinical data

Conclusions

- The **5-year analysis of Phase II L-MIND** study showed **durable responses** in patients with R/R DLBCL who are not eligible for ASCT
  - **Median DoR was not reached** after 44 months of median follow-up
  - As expected, patients with **1 pLoT** had better outcomes than those with **≥2 pLoT**
  - **mDoR was not reached in either subgroup** indicating durability of response irrespective of treatment line
- The frequency of **TEAEs decreased** after **patients transitioned** from combination therapy to tafasitamab monotherapy, up to 2 years (previous analysis) and further beyond 2 years
- **No new safety signals** were identified, confirming the tolerable safety profile seen with earlier data cuts
- These long-term data suggest that **this immunotherapy may have curative potential**, which is being explored in further studies

ASCT, autologous stem cell transplantation; DLBCL, diffuse large B-cell lymphoma; DoR, duration of response; pLoT, prior line of therapy; R/R, relapsed or refractory; TEAE, treatment-emergent adverse event.

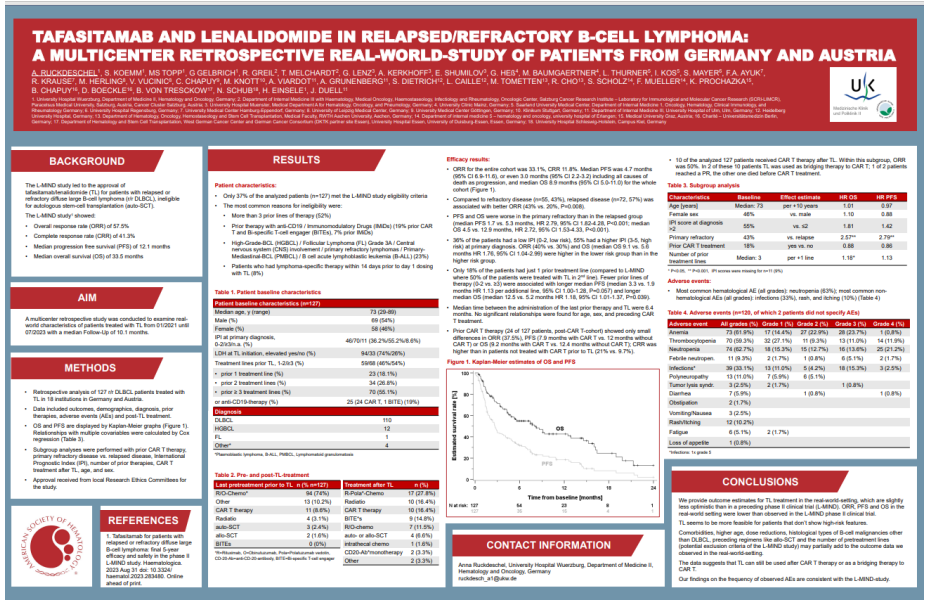
Overview

- Tafasitamab mode of action and clinical data
- Tafasitamab real world
- Tafasitamab experience including CD19 therapie sequencing

CRS, cytokine release syndrome

TAFASITAMAB AND LENALIDOMIDE IN RELAPSED/REFRACTORY B-CELL LYMPHOMA: A MULTICENTER RETROSPECTIVE REAL-WORLD-STUDY OF PATIENTS FROM GERMANY AND AUSTRIA

A. RUCKDESCHEL[1], S. KOEMM[1], MS TOPP[1], G GELBRICH[1], R. GREIL[2], T. MELCHARDT[2], G. LENZ[3], A. KERKHOFF[3], E. SHUMILOV[3], G. HEß[4], M. BAUMGAERTNER[4], L. THURNER[5], I. KOS[5], S. MAYER[6], F.A. AYUK[7], R. KRAUSE[7], M. HERLING[8], V. VUCINIC[8], C. CHAPUY[9], M. KNOTT[10], A. VIARDOT[11], A. GRUNENBERG[11], S. DIETRICH[12], L. CAILLE[12], M. TOMETTEN[13], R. CHO[13], S. SCHOLZ[14], F. MUELLER[14], K. PROCHAZKA[15], B. CHAPUY[16], D. BOECKLE[16], B. VON TRESCKOW[17], N. SCHUB[18], H. EINSELE[1], J. DUELL[11]



ASH2023

Medizinische Klinik und Poliklinik II

TAFASITAMAB AND LENALIDOMIDE IN RELAPSED/REFRACTORY B-CELL LYMPHOMA: A MULTICENTER RETROSPECTIVE REAL-WORLD-STUDY OF PATIENTS FROM GERMANY AND AUSTRIA

- **Aim:** **A multicenter retrospective study** to examine real-world characteristics of patients treated with Tafasitamab and Lenalidomide (Tafa-Len)
  - **Treated with Tafa-Len** from 03/2020 until 07/2023
  - **Median follow-up time of 10.1 months**

- **Methods:** Retrospective analysis of **127 R/R DLBCL patients**
  - **18 institutions, mainly academic hospitals**, in Germany and Austria contributed patient data
  - Data included outcomes, demographics, diagnosis, prior therapies, adverse events (AEs) and post- Tafa-Len treatment

- **L-MIND study eligibility:** **Only 37% of patients were L-MIND eligible,** most common **reasons for ineligibility** were:
  - More than **half of study population in 5L+**
  - Prior anti-CD19 therapy (**CAR T/ Bispecific Antibody**) and/or **IMiDs**
  - **Primary refractory disease**/ other diagnosis (e.g. **High-Grade-BCL**)

Ruckdeschel A, et al. ASH annual meeting 2023, poster #1771.
5L+, fifth line of therapy or higher, BCL, B-cell lymphoma; DLBCL, diffuse large B-cell lymphoma; IMiDs, immunomodulatory imide drugs; R/R, relapsed or refractory; Tafa-Len, Tafasitamab and Lenalidomide.

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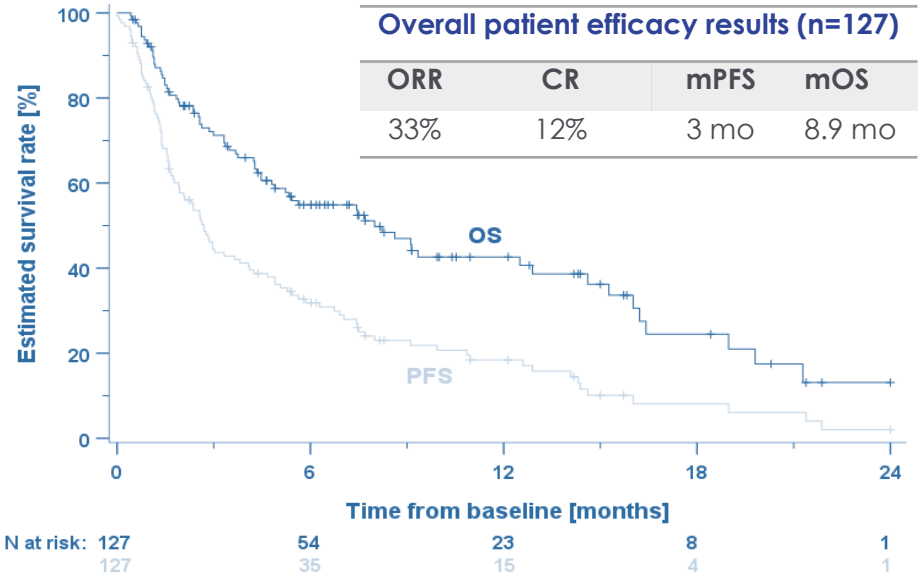
Summary of patient baseline characteristics (n=127)	
Median age in years (range)	73 (29-89)
IPI ≥3 at primary diagnosis	55%
Elevated LDH at initiation of Tafa-Len	74%
≥ 4 prior lines of therapy†	52%
Prior Anti-CD19 CAR T/ BITE†	19%
Other diagnosis than DLBCL (e.g. HGBCL) †	13%



Overall patient efficacy results (n=127)			
ORR	**CR**	**mPFS**	**mOS**
33%	12%	3 mo	8.9 mo

Subgroup analysis

Characteristics	Baseline	Effect estimate	HR OS	HR PFS
Age [years]	Median: 73	per +10 years	1.01	0.97
Female sex	46%	vs. male	1.10	0.88
IPI score at diagnosis >2	55%	vs. ≤2	1.81	1.42
Primary refractory†	**43%**	**vs. relapse**	**2.57****	**2.79****
Prior CAR T treatment	18%	yes vs. no	0.88	0.86
Number of prior treatment lines	**Median: 3**	**per +1 line**	**1.18***	1.13

*** P<0.05, ** P<0.001**, IPI scores were missing for n=11 (9%)

†Exclusion criteria for L-MIND

(figures and tables adapted from) Ruckdeschel A, et al. ASH annual meeting 2023, poster #1771.
CRR, complete response; BCL, B-cell lymphoma; DLBCL, diffuse large B-cell lymphoma; BITE, Bi-specific T-cell engagers; HGBCL, High-Grade B-cell lymphoma; IPI, International Prognostic Index; LDH, lactate dehydrogenase; mo, months; ORR, overall response rate; mOS, median overall survival; mPFS, median progression-free survival; R/R, relapsed or refractory; Tafa-Len, Tafasitamab and Lenalidomide.

TAFASITAMAB AND LENALIDOMIDE IN RELAPSED/REFRACTORY B-CELL LYMPHOMA: A MULTICENTER RETROSPECTIVE REAL-WORLD-STUDY OF PATIENTS FROM GERMANY AND AUSTRIA

Further results and conclusions summary

Efficacy outcome estimates for this real-world cohort were lower compared to L-MIND study

- Only 37% of the patients were L-MIND eligible (**52% of overall patients in 5L+, 18% prior CAR T**)
- **Fewer prior lines of therapy** were associated with **longer mPFS** and **mOS**
- e.g. histological subtypes other than DLBCL (**HGBCL**), comorbidities or dose reductions may partially add to the outcome

Tafa-Len seems to be more feasible for patients that don't show high-risk features

- **Relapsed vs. refractory** disease **ORR**: **43% vs. 20%**, P=0.008
- **Relapsed vs. primary refractory** disease **mPFS: 5.3 vs. 1.7 mo** , P<0.001 and **mOS: 12.9 vs. 4.5 mo**, P<0.001

Data suggests that Tafa-Len can still be used after CAR T therapy or as a bridging therapy to CAR T

- **Prior CAR T therapy** (n=24) showed **only small differences in ORR, PFS or OS; CRR was reduced**
- **n=10** patients received **CAR T after Tafa-Len** (n=2 as bridging therapy): **ORR 50%**
- No significant relationships were found for age, sex, and prior CAR T therapy

Frequency of observed adverse events are consistent with the L-MIND study

Ruckdeschel A, et al. ASH annual meeting 2023, poster #1771.
CRR, complete response; DLBCL, diffuse large B-cell lymphoma; HGBCL, High-Grade B-cell lymphoma; mo, months; ORR, overall response rate; mOS, median overall survival; mPFS, median progression-free survival; R/R, relapsed or refractory; Tafa-Len, Tafasitamab and Lenalidomide.

Tafasitamab for the Treatment of Relapsed or Refractory Diffuse Large B-Cell Lymphoma in the US Real-World Setting

- **Kim Saverno**,[1] Kristin M. Zimmerman Savill,[2] Bruce Feinberg,[2] John Galvin,[1] Prathamesh Pathak,[2] Sarah Gordon,[2] Theresa Amoloja,[1] Narendranath Epperla,[3] Loretta J. Nastoupil[4]

- [1]Incyte Corporation, Wilmington, DE, USA; [2]Cardinal Health, Dublin, OH, USA; [3]The Ohio State University, Columbus, OH, USA; [4]The University of Texas MD Anderson Cancer Center, Houston, TX, USA

Presented at the 65th ASH Annual Meeting & Exposition • San Diego, CA, USA • December 9-12, 2023 (Presentation 265)

Tafasitamab for the treatment of relapsed/refractory diffuse large B-cell lymphoma in the US real-world setting

- **Study Design:** A retrospective, physician-abstracted, multisite, medical chart review*
  - 24 physicians/sites across the United States contributed patient data
  - 83% (n = 20) of participating physicians were from community oncology practices

- **Objectives:** Among R/R DLBCL patients who received Tafasitamab in real-world setting, describe:
  - Primary: Patient demographic and clinical characteristics, treatment and utilization patterns
  - Secondary: Clinical effectiveness

- **Inclusion criteria**: Initiation of Tafasitamab for R/R DLBCL from October 21, 2020, outside of a clinical trial
  - Concomitant use of lenalidomide was not a requirement for study eligibility

Median follow-up time was 6.5 months [range: 0.9-27.4]
since initiating Tafasitamab for the overall study population

Saverno K, et al. ASH annual meeting 2023, oral presentation #265.
*Data source: Cardinal Health's OPEN is a community of >7000 private practice and hospital-based oncologists/hematologists, including approximately 800 composing the real-world research community.
DLBCL, diffuse large B-cell lymphoma; R/R, relapsed or refractory

Patient Demographics

Characteristic	All Patients (N=181)	Tafasitamab 2L (n=130)	Tafasitamab 3L (n=43)
Sex at birth, male, n (%)	102 (56.4)	68 (52.3)	30 (69.8)
Age at tafasitamab initiation, years, median (IQR)	71.1 (65.0-75.5)	72.1 (67.2-77.1)	67.7 (62.2-73.9)
Race, n (%)			
White	116 (64.1)	80 (61.5)	29 (67.4)
Black	40 (22.1)	31 (23.8)	9 (20.9)
Asian	11 (6.1)	10 (7.7)	1 (2.3)
Other*	3 (1.7)	2 (1.5)	1 (2.3)
Unknown	11 (6.1)	7 (5.4)	3 (7.0)
Ethnicity, n (%)			
Hispanic/Latino/Latina	31 (17.1)	20 (15.4)	8 (18.6)
Non-Hispanic/Non-Latino/Non-Latina	149 (82.3)	109 (83.8)	35 (81.4)
Unknown	1 (0.6)	1 (0.8)	0

- The median follow-up time since initiating tafasitamab for the overall study population was 6.5 (range, 0.9-27.4) months

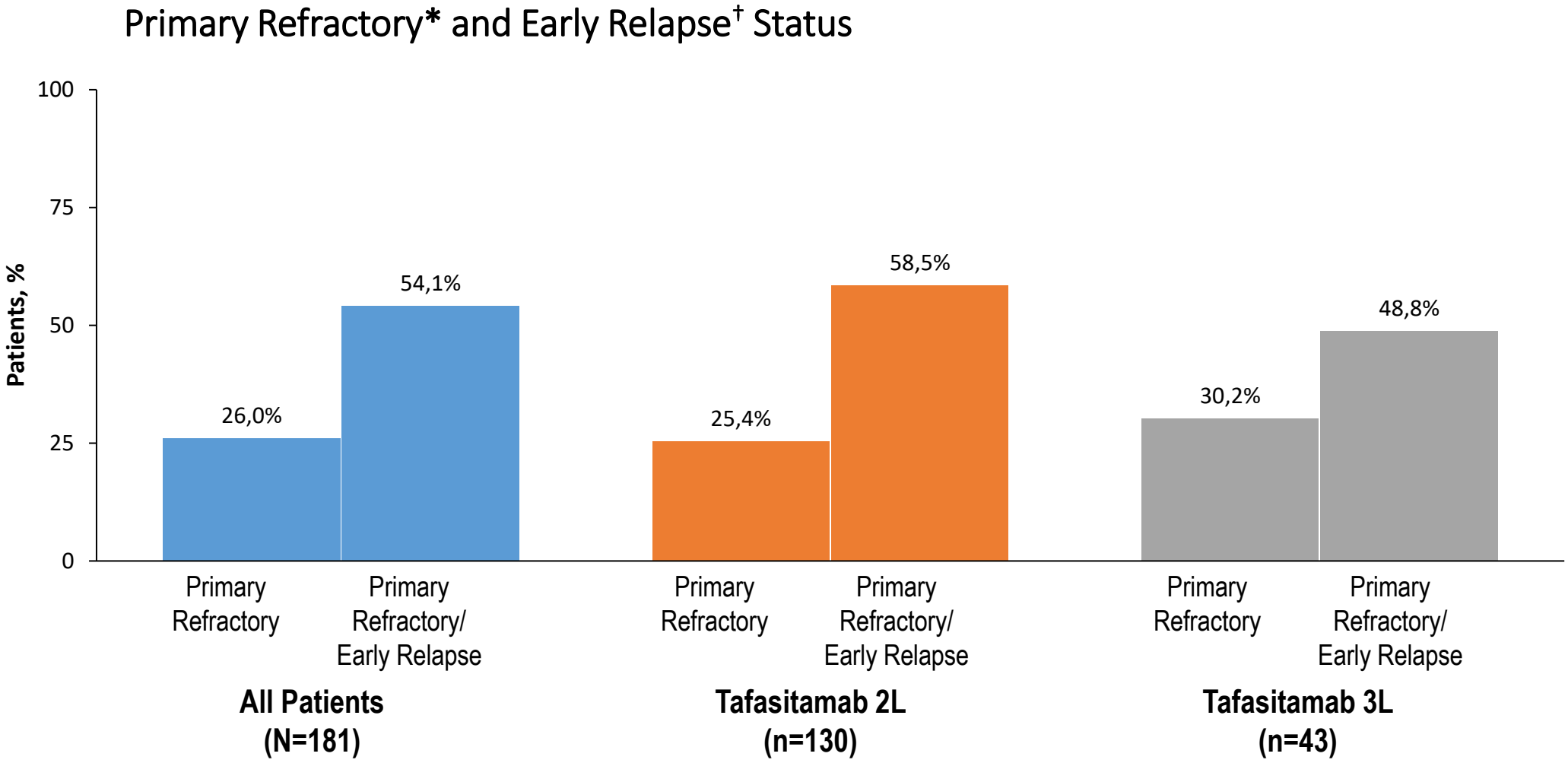
*Including Native Hawaiian or Other Pacific Islander, American Indian or Alaska Native, or mixed race (Alaska Native + Asian + Black).
2L, second line; 3L, third line; IQR, interquartile range.

Patient Clinical Characteristics

Characteristic	All Patients (N=181)	Tafasitamab 2L (n=130)	Tafasitamab 3L (n=43)
ECOG PS at tafasitamab initiation, n (%)			
0-1	95 (52.5)	69 (53.1)	21 (48.8)
≥2	86 (47.5)	61 (46.9)	22 (51.2)
Ann Arbor stage at tafasitamab initiation, n (%)			
Stage I/II	10 (5.5)	9 (6.9)	1 (2.3)
Stage III	58 (32.0)	50 (38.5)	7 (16.3)
Stage IV	111 (61.3)	70 (53.8)	35 (81.4)
Unknown	2 (1.1)	1 (0.8)	0
R-IPI at tafasitamab initiation, n (% of patients with data available)*			
1-2 (good prognosis)	33 (19.5)	22 (18.3)	8 (19.0)
3-5 (poor prognosis)	136 (80.5)	98 (81.7)	34 (81.0)
Double-hit or triple-hit at tafasitamab initiation, n (%)			
Yes, double-/triple-hit	22 (12.2)	14 (10.8)	8 (18.6)
Tested, found to be negative	130 (71.8)	103 (79.2)	26 (60.5)
Unknown	29 (16.0)	13 (10.0)	9 (20.9)
Cell of origin information, n (%)			
GCB	81 (44.8)	60 (46.2)	17 (39.5)
Non-GCB/ABC	39 (21.5)	28 (21.5)	9 (20.9)
Unknown	61 (33.7)	42 (32.3)	17 (39.5)
Refractory to line prior to tafasitamab†	59 (32.6)	33 (25.4)	19 (44.2)

*There were no patients with an R-IPI score of 0 (very good prognosis) at tafasitamab initiation. †Defined as disease progression while receiving line of therapy prior to tafasitamab or disease progression occurring ≤6 months after the completion of the line of therapy prior to tafasitamab. 2L, second line; 3L, third line; ABC, activated B cell; GCB, germinal center B cell; ECOG PS, Eastern Cooperative Oncology Group performance status; R-IPI, revised International Prognostic Index.

54.1 % R/R < 12 month/ 45.9% late relapse > 12 month



*Defined as disease progression while receiving first-line therapy or disease progression occurring ≤6 months after the completion of first-line therapy.
†Defined as disease progression while receiving first-line therapy or disease progression occurring ≤12 months after the completion of first-line therapy.
2L, second line; 3L, third line.

Treatment and Utilization Patterns

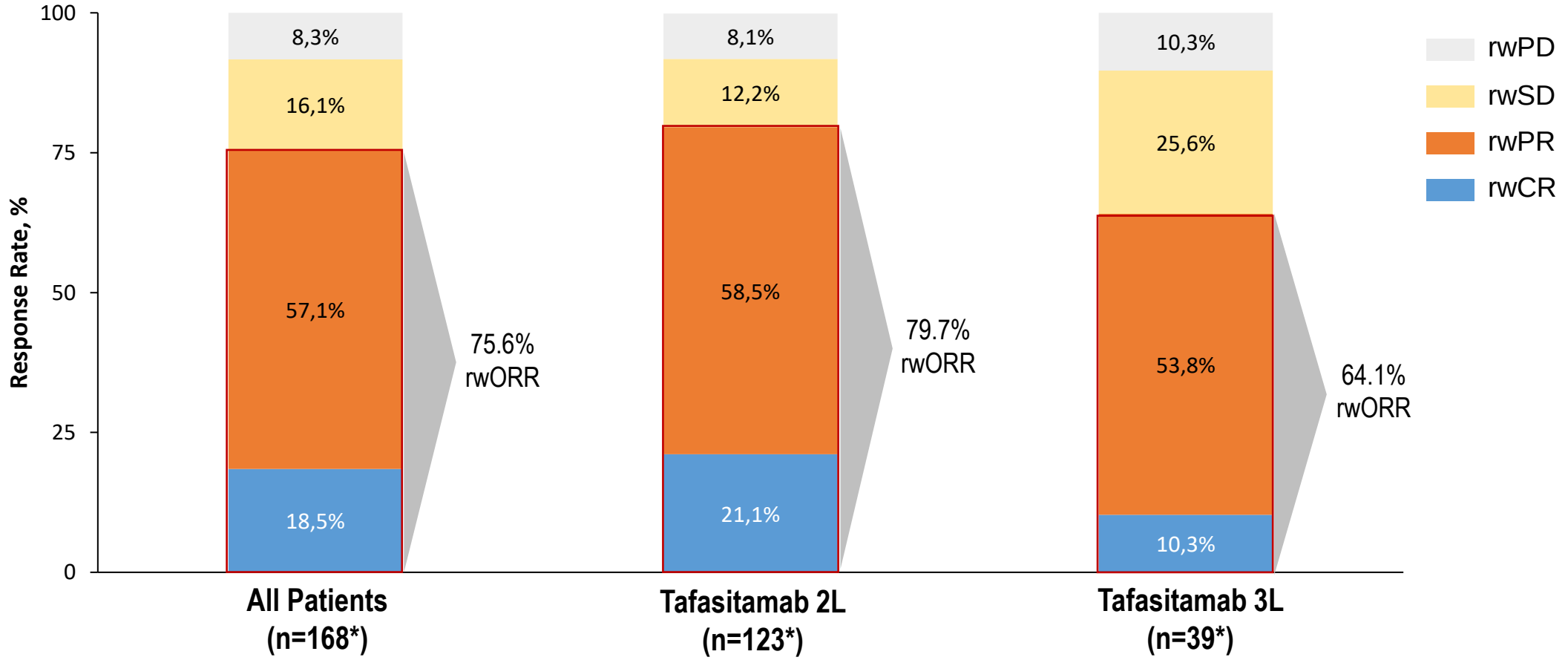
- At data collection (median follow-up time of 6.5 months), 80% (n=144) of patients were still alive, of whom 84% (n=121) were still receiving tafasitamab

- Among the 60 patients who discontinued tafasitamab, reasons for discontinuation included progression confirmed by scan (50%), progression defined clinically (17%), toxicity (15%), patient/caregiver request (3%), complete response (2%), and other reasons (13%)

	All Patients (N=181)
Prior ASCT therapy, n (%)	21 (11.6)
Prior CAR-T therapy, n (%)	6 (3.3)
Subsequent CAR-T therapy, n (%)	5 (2.8)

ASCT, autologous stem cell transplantation; CAR-T, chimeric antigen receptor T cell.

Real-World Best Response



- Response criteria used for assessing best response (% among those with best response available) included: Cheson 2007 (26.8%), Lugano (72.6%), and other (0.6%)

*Patient denominators represent those with available best disease response data.

2L, second line; 3L, third line; rwCR, real-world complete response; rwORR, real-world overall response rate; rwPD, real-world progressive disease; rwPR, real-world partial response; rwSD, real-world stable disease.

Real-World Progression-Free Survival (rwPFS)

Probability of rwPFS at Various Time Points From Time of Tafasitamab Initiation

	All Patients (N=181)	Tafasitamab 2L (n=130)	Tafasitamab 3L (n=43)
3-month rwPFS probability			
Point-estimate	0.93	0.92	0.95
(lower 95%-upper 95%)	(0.88-0.96)	(0.86-0.96)	(0.83-0.99)
6-month rwPFS probability			
Point-estimate	0.80	0.83	0.72
(lower 95%-upper 95%)	(0.73-0.85)	(0.75-0.89)	(0.54-0.84)

2L, second line; 3L, third line; rwPFS, real-world progression-free survival.

Conclusions

- Findings from this real-world analysis support the clinical benefit of tafasitamab when used in early lines of treatment of R/R DLBCL, as demonstrated in L-MIND[1,2]
- The study included a racially and ethnically diverse patient population; nearly one-third of patients were from typically underrepresented racial groups and approximately one-sixth were of Hispanic ethnicity
- Patients were treated predominantly at community oncology settings, where most treatment for DLBCL is administered in the United States
- Most patients were still on tafasitamab at the time of data collection and follow-up was limited in duration
- Longer follow-up of these patients is warranted to better understand long-term outcomes of tafasitamab and treatment sequencing among this diverse patient population

1. Salles G, et al. *Lancet Oncol.* 2020;21:978-88. **2.** Duell J, et al. *Haematologica.* 2021;106:2417-26.
DLBCL, diffuse large B-cell lymphoma; R/R, relapsed or refractory.

Overview

- Tafasitamab mode of action and clinical data
- Tafasitamab real world
- Tafasitamab experience including CD19 therapy sequencing

CRS, cytokine release syndrome

Therapy sequencing

Tafa/Len prior CAR T

Tafa/Len -> **CAR T**	US (Qualls et al.) 14 pts	Germany (Ruckdeschel et al.) 8 pts
ORR	n/a	50%
CR	n/a	10%
PFS	EFS: 3.7 months (after CAR T)	2.6 months
OS	8.1 months (after CAR T)	6.4 months

Tafa/Len post CAR T

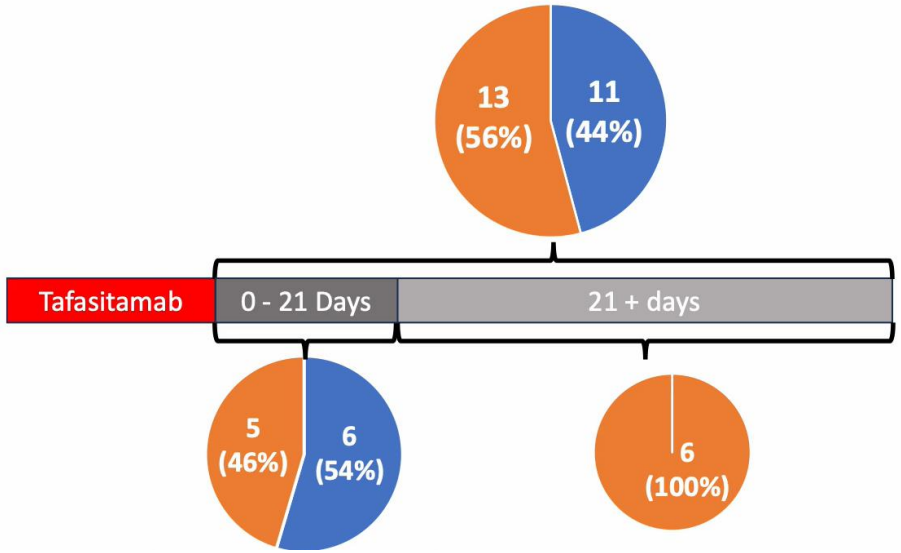
CAR T -> **Tafa/Len**	US (Qualls et al.) 52 pts	Germany (Ruckdeschel et al.) 24 pts
ORR	15 %	37,5 %
CR	15 %	21 %
PFS	1.6 months	7.9 months
OS	n/a	9.2 months

CD19 expression post Tafa/Len

CD19 expression after Tafasitamab

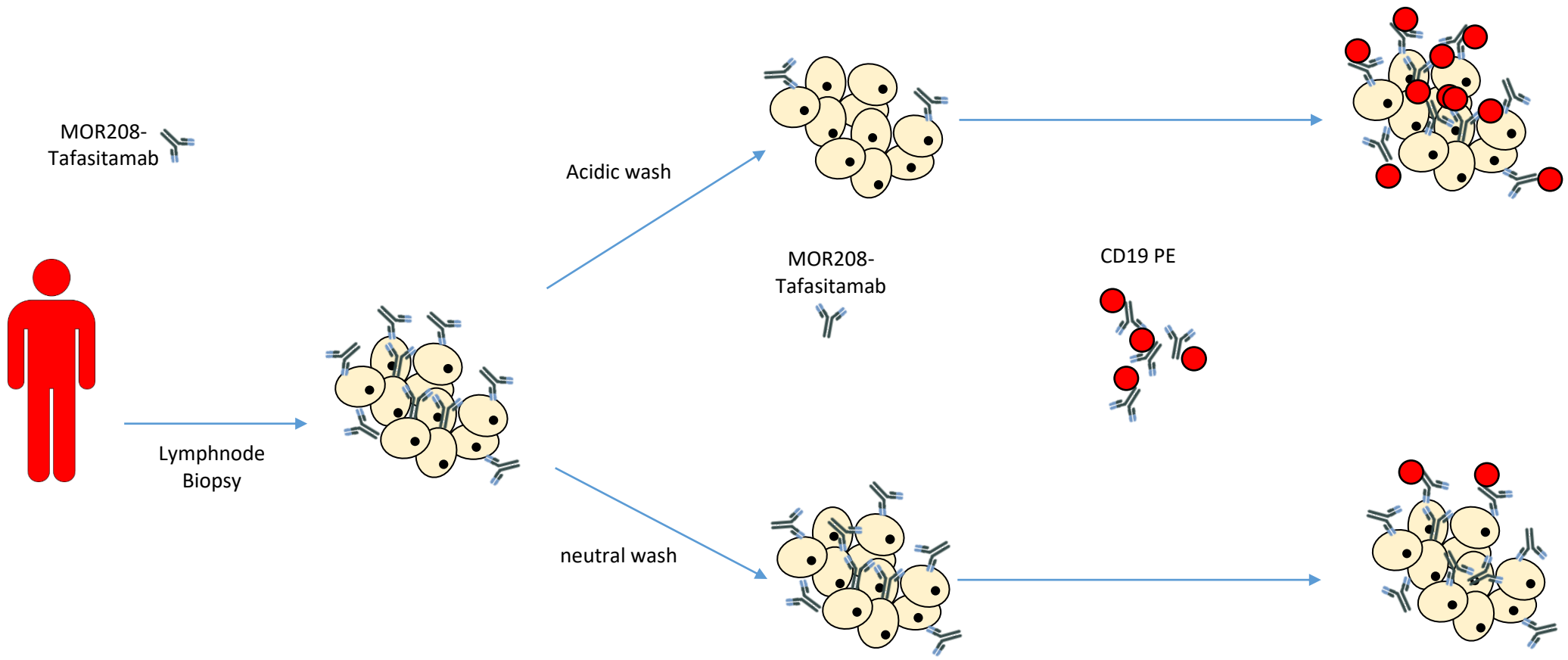
- 24 patients biopsied after last dose of tafasitamab, a median of 18 days after last infusion
- 13 (54%) were CD19-positive and 11 (46%) were CD19-negative*
- All samples obtained more than 21 days after tafasitamab (6/6) were CD19-positive, while 46% obtained within 21 days were CD19-positive.

*Determined using IHC or flow cytometry per local institutional protocols.



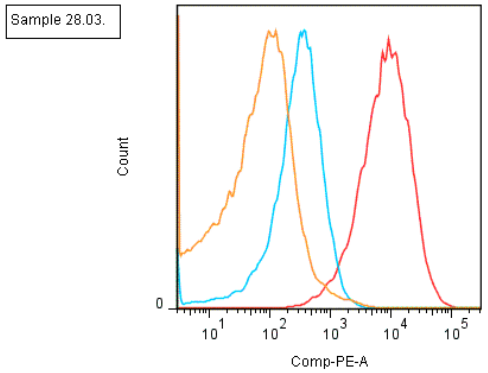
Qualls et al ASH 2023 Abstract 3136

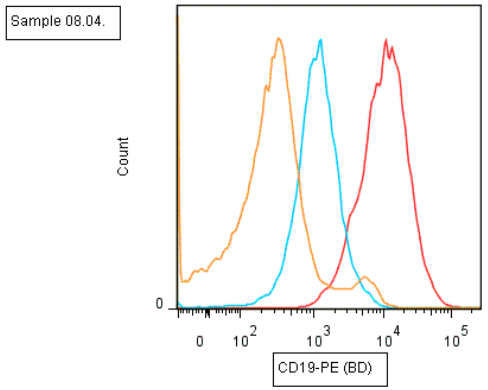
Case study – CD19 expression levels

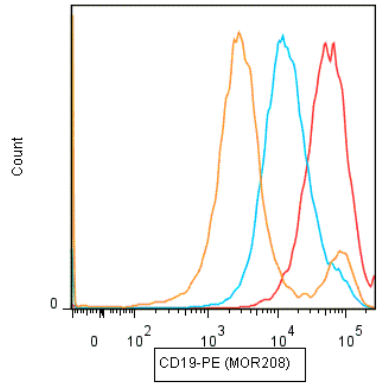


PE, phycoerythrin

Acidic wash procedure demasks ABC post treatment







- Negative ctrl. (CD3+)
- Neutral wash
- Acidic wash

- After treatment with tafasitamab only few CD19 epitopes on cell surface available
- However there is no downregulation of CD19 expression during treatment
- **Acidic wash demasks epitopes and allows quantification of CD19 surface expression**

Free CD19 epitopes: after 1 week: 5%
after 2 weeks 10%
after 3 weeks 60%

unpublished data: Dülls Lab

Conclusion CD19 sequencing thrapies

- **Tafa/Len is possible prior and post CD19 CAR T**
- **Take biopsies! (30 % of the non relapse patients after CAR T are CD19 loss variants)**
- **No CD19 loss variants for Tafa already described**
- **CD19 occupancy after Tafasitamab with CD19 recovery after 3 weeks post CD19 AB infusion**

The patients and their families!

Hermann Einsele, Würzburg
Florian Eisele, Würzburg
Max Topp, Würzburg
Leo Rasche, Würzburg

Study team Würzburg

Thank you!

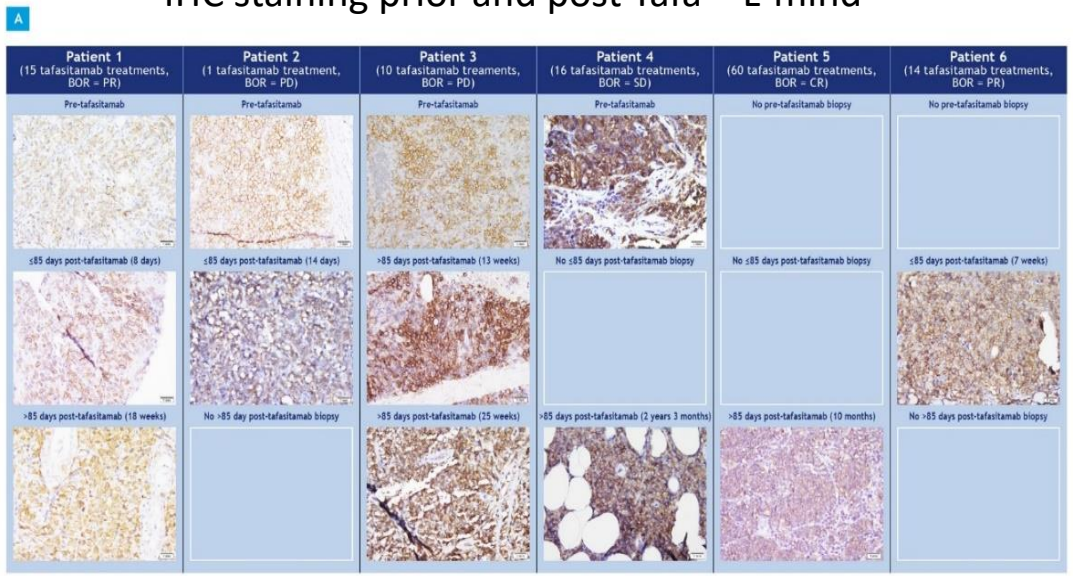
IZKF Würzburg

CD19 loss after Tafasitamab?

CD19 expression is maintained in DLBCL patients after treatment with tafasitamab plus lenalidomide in the L-MIND study

→ DNA whole exome and RNA exome sequencing
→ CD19 IHC staining

IHC staining prior and post Tafa – L-mind



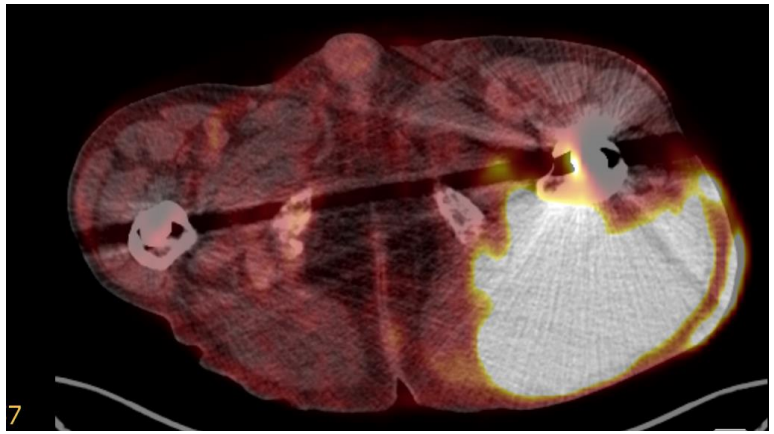
(A) IHC data CD19 from serial core needle lymph node FFPE biopsies of six L-MIND patients

Duell et al: Leuk Lymphoma. 2021 Nov 15;1-5

IHC, immune histochemistry; FFPE, formaline-fixed paraffin embedded

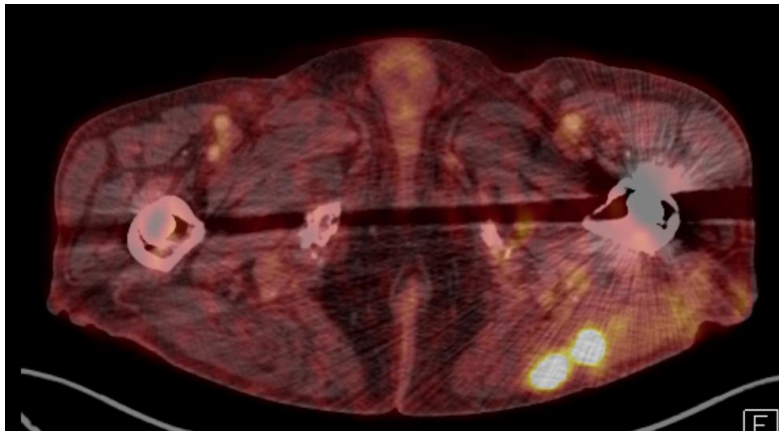
Case study – FDG PET

Prior Tafa/Len



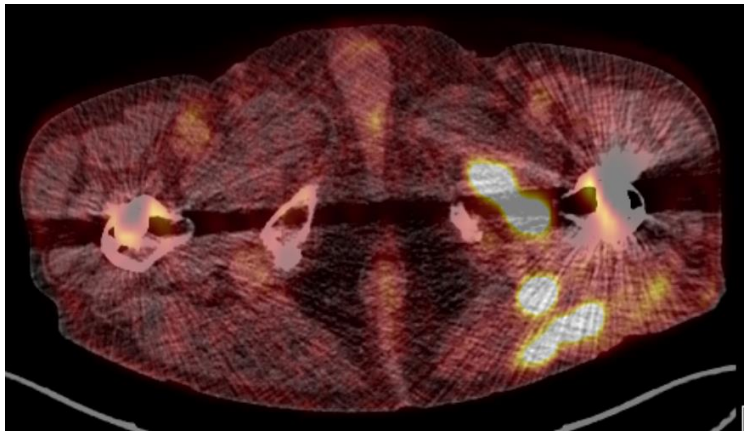
After 3 cycles

PR



After 6 cycles

PD



Pictures: Nuclear Medicine Universitätsklinik Würzburg

PD, progressive disease; PR, partial response

MINJUVI 200 mg Pulver für ein Konzentrat zur Herstellung einer Infusionslösung
Wirkstoff: Tafasitamab

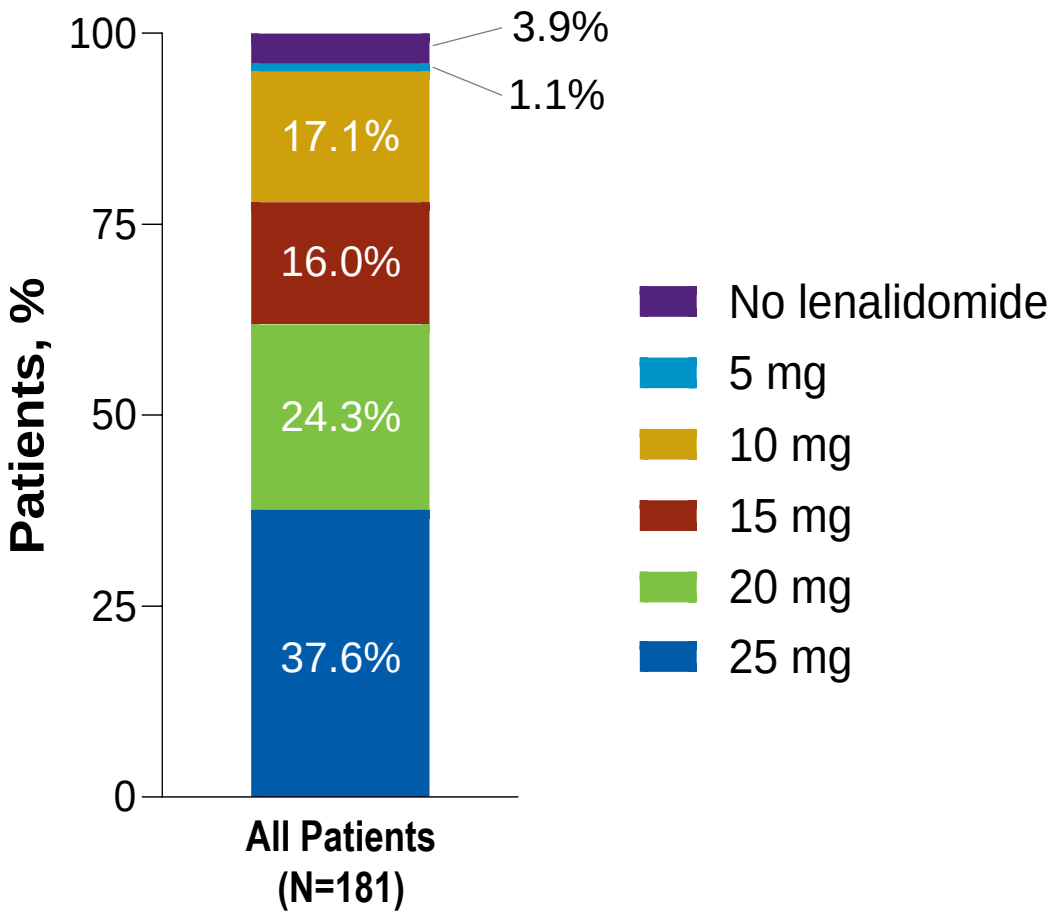
▼ Dieses Arzneimittel unterliegt einer zusätzlichen Überwachung. Dies ermöglicht eine schnelle Identifizierung neuer Erkenntnisse über die Sicherheit. Angehörige von Gesundheitsberufen sind aufgefordert, jeden Verdachtsfall einer Nebenwirkung zu melden. Hinweise zur Meldung von Nebenwirkungen, siehe Abschnitt 4.8 der Fachinformation.

Bevor Sie MINJUVI verschreiben, lesen Sie bitte die vollständige Fachinformation (Zusammenfassung der Merkmale des Arzneimittels).

Qualitative und quantitative Zusammensetzung: Eine Durchstechflasche mit Pulver enthält 200 mg Tafasitamab. Nach Rekonstitution enthält jeder ml der Lösung 40 mg Tafasitamab. Tafasitamab ist ein humanisierter CD19-spezifischer monoklonaler Antikörper, der Immunglobulin-G (IgG)-Subklasse, hergestellt in Säugetierzellen (Ovarialzellen des chinesischen Hamsters) mittels rekombinanter DNATechnologie. Sonstiger Bestandteil mit bekannter Wirkung: Jede Durchstechflasche von MINJUVI enthält 7,4 mg Natrium. Vollständige Auflistung der sonstigen Bestandteile: Natriumcitrat (Ph.Eur.), Citronensäure-Monohydrat, Trehalose-Dihydrat, Polysorbat 20. **Anwendungsgebiete:** MINJUVI wird angewendet in Kombination mit Lenalidomid gefolgt von einer MINJUVI-Monotherapie für die Behandlung bei erwachsenen Patienten mit rezidiviertem oder refraktärem diffusem großzelligem B-Zell-Lymphom (diffuse large B-cell lymphoma, DLBCL), für die eine autologe Stammzelltransplantation (ASZT) nicht infrage kommt. **Gegenanzeigen:** Überempfindlichkeit gegen den Wirkstoff oder einen der sonstigen Bestandteile. **Nebenwirkungen:** *Sehr häufige Nebenwirkungen* (≥ 1/10): Bakterielle, Virus- und Pilzinfektionen, einschließlich opportunistische Infektionen mit tödlichem Ausgang (z. B. bronchopulmonale Aspergillose, Bronchitis, Pneumonie und Harnwegsinfektion), Febrile Neutropenie, Neutropenie, Thrombozytopenie, Anämie, Leukopenie, Hypokaliämie, Appetit vermindert, Dyspnoe, Husten, Diarrhoe, Obstipation, Erbrechen, Übelkeit, Abdominalschmerz, Ausschlag (beinhaltet verschiedene Arten von Ausschlag, z. B. Ausschlag, makulo-papulöser Ausschlag, Ausschlag mit Juckreiz, erythematöser Hautausschlag), Rückenschmerzen, Muskelspasmen, Asthenie (einschließlich Unwohlsein), Ermüdung, Ödem peripher, Fieber. *Häufige Nebenwirkungen* (≥ 1/100, < 1/10): Sepsis (einschließlich neutropenische Sepsis), Basalzellkarzinom, Lymphopenie, Hypogammaglobulinämie, Hypokalzämie, Hypomagnesiämie, Kopfschmerzen, Parästhesie, Dysgeusie, Exazerbation einer chronisch-obstruktiven Lungenerkrankung, Nasenverstopfung, Hyperbilirubinämie, Transaminasen erhöht (beinhaltet ALT und/oder AST erhöht), Gamma-Glutamyltransferase erhöht, Pruritus, Alopezie, Erythem, Hyperhidrosis, Arthralgie, Schmerz in einer Extremität, Schmerzen des Muskel- und Skelettsystems, Kreatinin im Blut erhöht, Schleimhautentzündung, Gewicht erniedrigt, C-reaktives Protein erhöht, Reaktion im Zusammenhang mit einer Infusion. **Verkaufsabgrenzung:** Deutschland: Verschreibungspflichtig. Österreich: Rezept- und apothekenpflichtig, wiederholte Abgabe verboten. **Pharmakotherapeutische Gruppe:** Antineoplastische Mittel, monoklonale Antikörper, ATC-Code: L01FX12. **Inhaber der Zulassung:** Incyte Biosciences Distribution B.V., Paasheuvelweg 25, 1105 BP Amsterdam, Niederlande. **Weitere Informationen:** Ausführliche Informationen zu Warnhinweisen und Vorsichtsmaßnahmen für die Anwendung, Wechselwirkungen, Schwangerschaft und Stillzeit, Nebenwirkungen sowie Dosierung und Art/Dauer der Anwendung entnehmen Sie bitte der veröffentlichten Fachinformation (Zusammenfassung der Merkmale des Arzneimittels). **Stand:** 03/2022

Lenalidomide Treatment With Tafasitamab

Lenalidomide Starting Dose



- During treatment, 33 patients (19%) had ≥1 lenalidomide dose reduction
  - The most common reasons for any dose reductions were neutropenia (73%), thrombocytopenia (33%), performance status/patient frailty (27%), and renal dysfunction (18%)

Study Limitations

- The median follow-up time was relatively short (6.5 months), and many patients were still on tafasitamab at time of data collection
- As with any RWS, this study may be limited by unobserved data and missing data bias
- Source document verification was not conducted; however, all physicians were required to submit to data validation checks
- The study included data abstracted by a limited number of oncologists (n=24)
  - Treatment patterns may not reflect those of all oncologists managing patients with DLBCL
- Findings from this study may be impacted by a lack of uniform assessment criteria for certain variables such as disease response

DLBCL, diffuse large B-cell lymphoma; RWS, real-world study.