Kompetenznetz Maligne Lymphome

Lymphom Kompetenz KOMPAKT

KML KONGRESSE

Expert:innen berichten zu Lymphomen & Leukämien

Amy Spartwasser, Stock-Fotografie-ID: 1455291856

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Prof. Dr. med. Kai Hübel
Uniklinik Köln

Follikuläre Lymphome (FL)

Offenlegung potentieller Interessenskonflikte

LymphomKompetenz KOMPAKT – ASH2025 wird in Kooperation mit acht unterstützenden Firmen durchgeführt.
Meine persönlichen Disclosures betreffen:

Anstellungsverhältnis, Führungsposition	Oberarzt, Uniklinik Köln
Beratungs-/ Gutachtertätigkeit	Roche, BMS, Incyte, Recordati, AbbVie, Novartis, Gilead, Miltenyi Biotec, BeOne, Sandoz
Besitz von Geschäftsanteilen, Aktien oder Fonds	entfällt
Patent, Urheberrecht, Verkaufslizenz	entfällt
Honorare	Amgen, Roche, Incyte, Recordati, Sandoz, Novartis, BeOne, AbbVie
Finanzierung wissenschaftlicher Untersuchungen	Roche, Gilead, Incyte
Andere finanzielle Beziehungen	entfällt
Immaterielle Interessenkonflikte	entfällt

Kapitel 1

Die neue Zweitlinie:

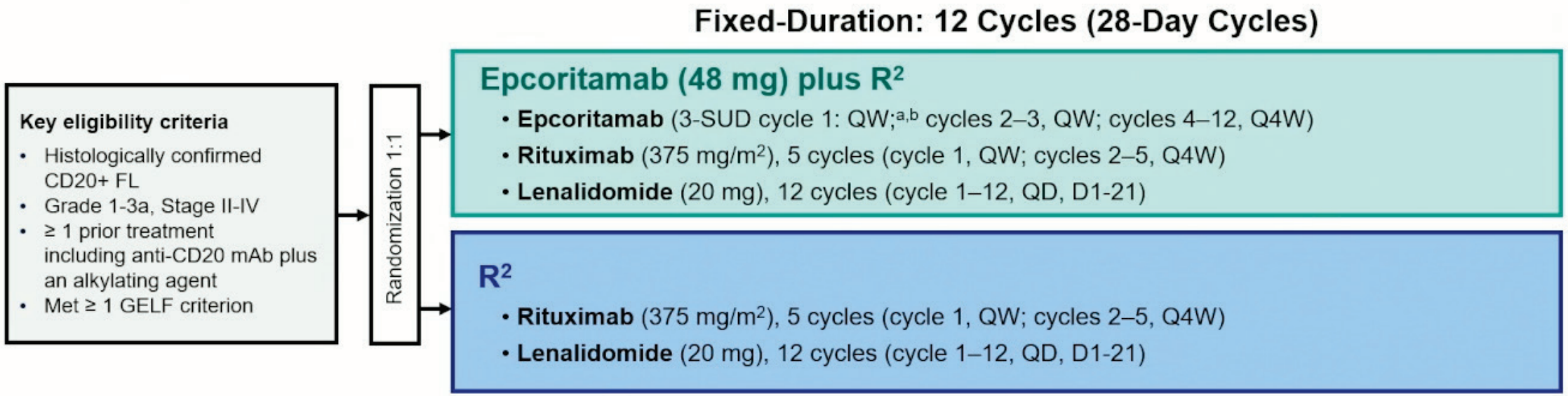
CD19-Antikörper oder Bispezifische?

Primary Phase 3 Results from the EPCORE FL-1 Trial of Epcoritamab with Rituximab and Lenalidomide (R^2) versus R^2 for Relapsed or Refractory Follicular Lymphoma

Presentation ID: 466

Lorenzo Falchi et al.

EPCORE FL-1: Studiendesign



Stratification factors

- Disease status:
  - 2L: > or ≤ 2 years since last therapy
  - 3L+: > or < 6 months since last therapy
- Region: US/EU vs Rest of World

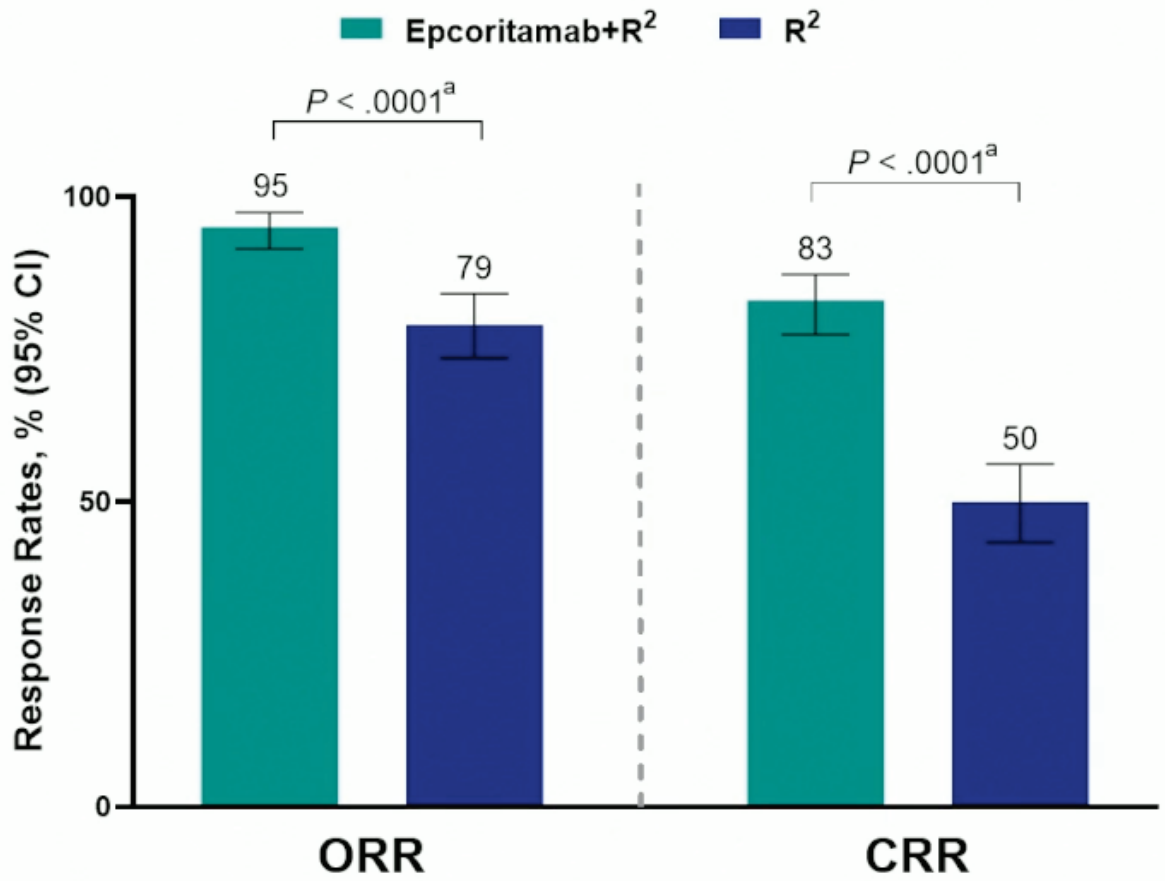
- **Dual primary endpoints: ORR per IRC and PFS per IRC**
- Key secondary endpoints: CR rate per IRC, OS, and MRD[c]
- Additional secondary endpoints: DOR, DOCR, TTNLT, safety, and PRO assessments

Data cutoff: May 24, 2025; median follow-up: 14.8 months[d]
Enrollment period: October 2022 - January 2025

[a]Two step-up dosing (SUD) regimens during cycle 1 to mitigate the risk of cytokine release syndrome: either a 2-SUD (0.16 mg on cycle 1 day 1, 0.8 mg on cycle 1 day 8), or 3-SUD (0.16 mg on cycle 1 day 1, 0.8 mg on cycle 1 day 8, 3 mg on cycle 1 day 15) regimen, followed by full dose 48 mg. The 3-SUD regimen was implemented after reduced CRS severity and incidence had been observed in the EPCORE NHL-1 FL trial (NCT03625037).[1] [b]The 24 mg epcoritamab plus R2 arm was closed to enrollment based on the superior efficacy for the 48 mg dose from EPCORE NHL-2.[2] Only the data for the optimal dose explored (48 mg) are presented here. [c]Minimal residual disease data are forthcoming in a future analysis. [d]The data presented here are from the second planned interim analysis (May 24, 2025) after 78% Information Fraction for PFS had occurred.

1. Vose J, et al. *J Clin Oncol*. 2024;42(16_suppl):7015–7015. 2. Falchi L, et al. *Blood*. 2024;144(Supplement 1):342–342.

EPCORE FL-1: Therapieansprechen



	Epcoritamab+R² (N = 243)	R² (N = 245)
ORR, n (%)	231 (95)	194 (79)
CRR, n (%)	201 (83)	122 (50)
PR, n (%)	30 (12)	72 (29)
SD, n (%)	1 (< 1)	17 (7)
PD, n (%)	7 (3)	16 (7)
NE,[b] n (%)	4 (2)	18 (7)

The first planned interim analysis (January 10, 2025) achieved statistical significance for ORR (N = 232; 95.7% vs 81.0%; *P* < 0.0001, with a 1-sided significance level of 0.005) and CR (74.5% vs 43.3%; *P* < 0.0001, with a 1-sided significance level of 0.025).

[a]Nominal *P* value by stratified Cochran-Mantel-Haenszel method. [b]Patients with no post-baseline disease assessment were also included.

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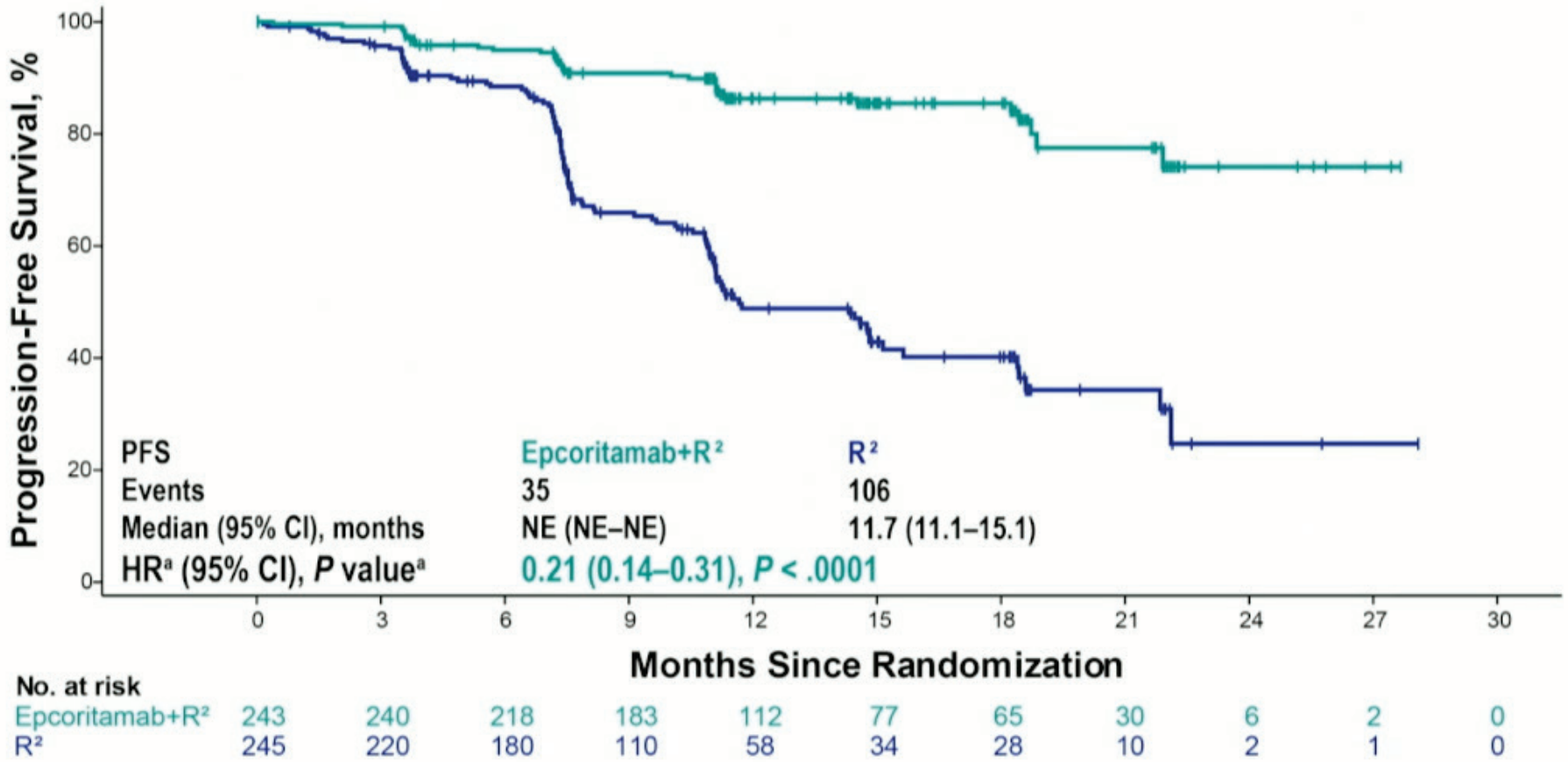
EPCORE FL-1: PFS



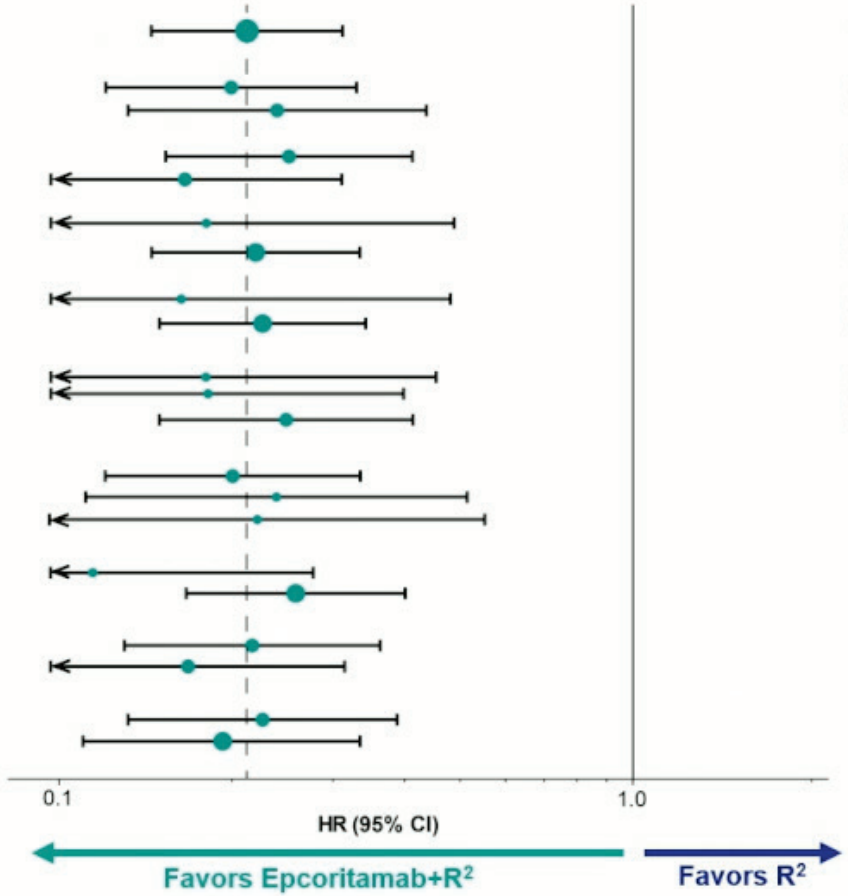
- Concordance rate was 94% for PFS between IRC and investigator assessment
- The estimated 16-month PFS was 85.5% (95% CI: 79.7, 89.7) for epcoritamab+R² and 40.2% (95% CI: 31.8, 48.4) for R²

Median follow-up for PFS: epcoritamab+R² (14.4m), R² (11.5m). The first planned interim analysis (January 10, 2025) achieved statistical significance on PFS, HR 0.21 (95% CI 0.13, 0.33) $P < 0.0001$, with a 1-sided significance level of 0.0023.

[a]Nominal P value is based on stratified log-rank test. Hazard ratio is estimated using stratified Cox proportional hazards model. This analysis was performed on the 78% information fraction.

EPCORE FL-1: PFS in Subgruppen

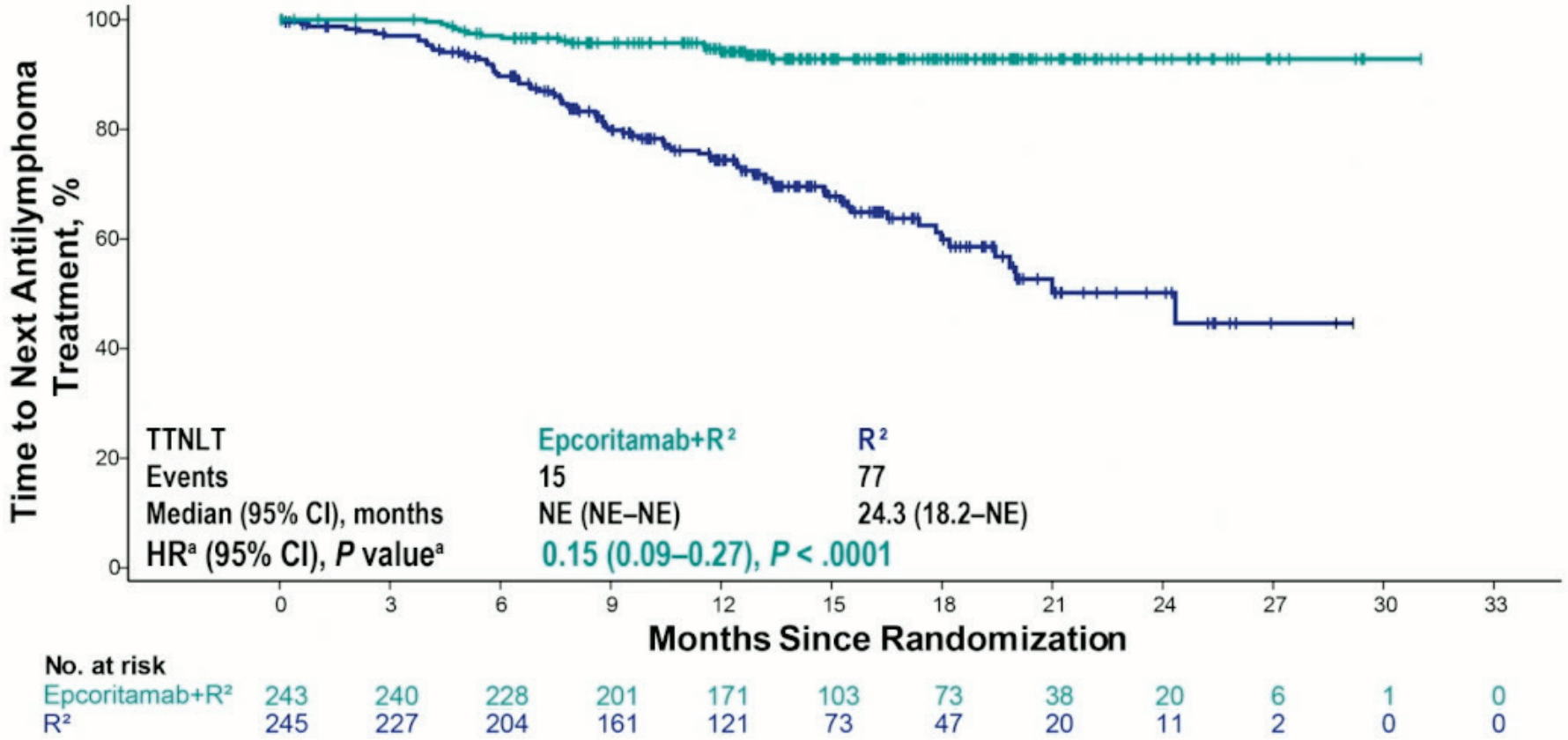
Prespecified Subgroups	Epcoritamab+R² Event/N (%)	R² Event/N (%)	HR (95% CI)
All patients	35/243 (14)	106/245 (43)	0.22 (0.15, 0.32)
Age (years)			
< 65	21/155 (13)	58/139 (42)	0.20 (0.12, 0.33)
≥ 65	14/88 (16)	48/106 (45)	0.24 (0.13, 0.44)
Sex			
Male	23/139 (17)	54/138 (39)	0.25 (0.15, 0.42)
Female	12/104 (12)	52/107 (49)	0.17 (0.09, 0.31)
Region			
US/Western Europe	5/58 (9)	18/60 (30)	0.18 (0.07, 0.49)
Rest of World	30/185 (16)	88/185 (48)	0.22 (0.15, 0.34)
Ann Arbor stage			
II	4/37 (11)	21/44 (48)	0.16 (0.06, 0.49)
III+IV	31/206 (15)	85/201 (42)	0.23 (0.15, 0.35)
FLIPI score at baseline			
0-1	6/63 (10)	19/56 (34)	0.18 (0.07, 0.46)
2	8/79 (10)	30/76 (39)	0.18 (0.08, 0.40)
3-5	21/100 (21)	57/113 (50)	0.25 (0.15, 0.42)
Number of prior lines			
1	20/145 (14)	58/141 (41)	0.20 (0.12, 0.34)
2	9/58 (16)	26/61 (43)	0.24 (0.11, 0.52)
≥ 3	6/40 (15)	22/43 (51)	0.23 (0.09, 0.56)
Bulky disease (≥ 7 cm)			
Yes	6/47 (13)	31/61 (51)	0.12 (0.05, 0.28)
No	28/191 (15)	71/176 (40)	0.26 (0.17, 0.41)
POD24			
Yes	22/106 (21)	47/93 (51)	0.22 (0.13, 0.37)
No	12/131 (9)	54/144 (38)	0.17 (0.09, 0.32)
Double refractory			
Yes	19/91 (21)	47/91 (52)	0.23 (0.13, 0.39)
No	16/152 (11)	59/154 (38)	0.19 (0.11, 0.34)



- Trends in favor of epcoritamab+R² were shown for all prespecified subgroups and ORR, CR, and DOR endpoints

N represents the total number of patients within each category in each arm. Arrows indicate that the confidence interval is extended more than current range. 95% CI is by unstratified Cox proportional hazard model.

EPCORE FL-1: TTNT



- At 16 months, 92.8% of patients treated with epcoritamab+R² remained free from new antilymphoma treatment compared with 64.9% of patients treated with R²

Median follow-up for TTNLT: epcoritamab+R² (14.6m), R² (14.1m). TTNLT results are for descriptive purposes only.
[a]Nominal *P* value is based on stratified log-rank test. Hazard ratio is estimated using stratified Cox proportional hazards model.

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EPCORE FL-1: Sicherheit

Adverse Event, n (%)	Epcoritamab+R² (N = 243)		R² (N = 238)	
	Any Grade	Grade ≥ 3	Any Grade	Grade ≥ 3
Any adverse event	242 (100)	219 (90)	235 (99)	161 (68)
Serious adverse event	135 (56)	-	69 (29)	-
Adverse event leading to treatment discontinuation	46 (19)	-	29 (12)	-
Epcoritamab	21 (9)	-	-	-
Rituximab	7 (3)	-	12 (5)	-
Lenalidomide	45 (19)	-	29 (12)	-
Adverse event of clinical interest > 20%[a,b]				
Infections[c]	188 (77)	81 (33)	125 (53)	37 (16)
Neutropenia	180 (74)	167 (69)	123 (52)	100 (42)
Cytokine release syndrome	85 (35)	-	1 (< 1)	-
Anemia	68 (28)	19 (8)	41 (17)	11 (5)
Thrombocytopenia	67 (28)	23 (9)	44 (18)	15 (6)
Pyrexia	58 (24)	1 (< 1)	33 (14)	3 (1)
Rash	58 (24)	19 (8)	53 (22)	9 (4)
COVID-19	54 (22)	7 (3)	32 (13)	4 (2)

- Neutropenia was manageable and few patients discontinued any study drug (epcoritamab+R², 3%; R², 2%)
  - Incidence of febrile neutropenia: epcoritamab+R², 6%; R², 3%
- Infections were manageable and few patients discontinued any study drug (epcoritamab+R², 6%; R², 1%)
- Fatal adverse events were rare (epcoritamab+R², 2%; R², 4%)
- Despite higher rates of AEs in the epcoritamab+R² arm, most patients completed the prescribed regimen (median relative dose intensity ≥ 90% for epcoritamab+R²)

[a]Neutropenia, anemia, pyrexia, rash and COVID-19 are grouped terms comprising multiple clinically related Preferred Terms. [b]This includes the AESI of CRS. [c]Events were in the MedDRA system organ class "Infections and Infestations." No grade 5 infections were reported.

Tafasitamab plus Lenalidomide and Rituximab for Relapsed and Refractory Follicular Lymphoma: Results from a Phase 3 Study (inMIND)

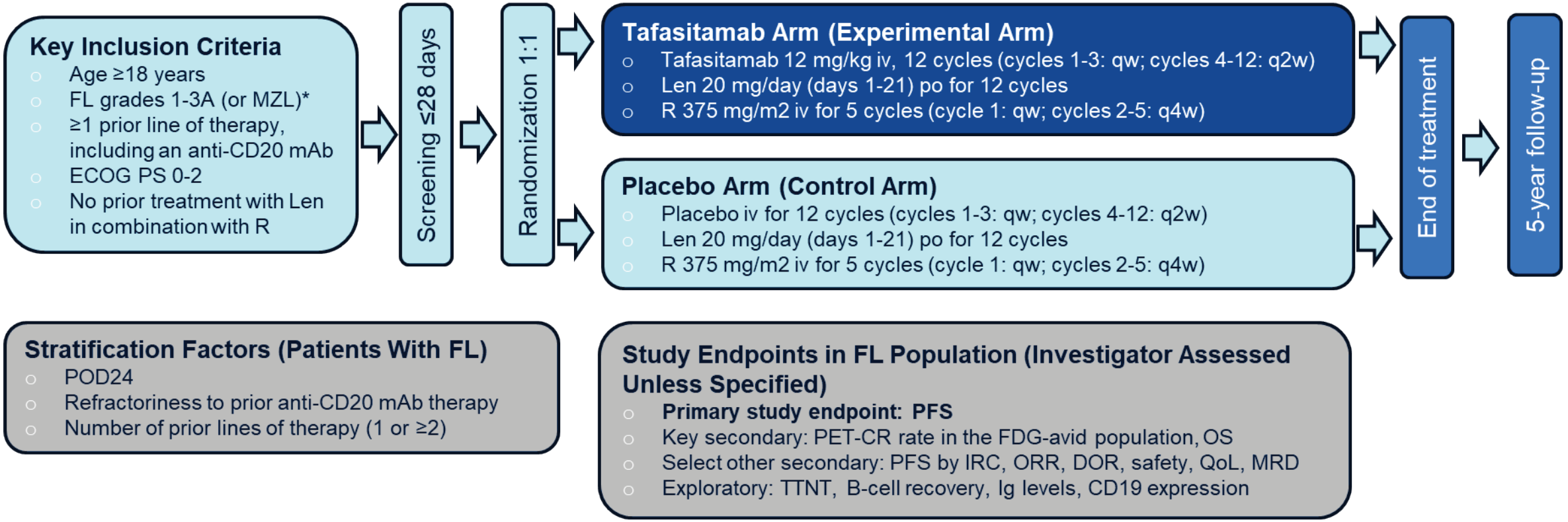
Presentation ID: 5367, 3582, 1819

Kai Hübel et al.

Christina Poh et al.

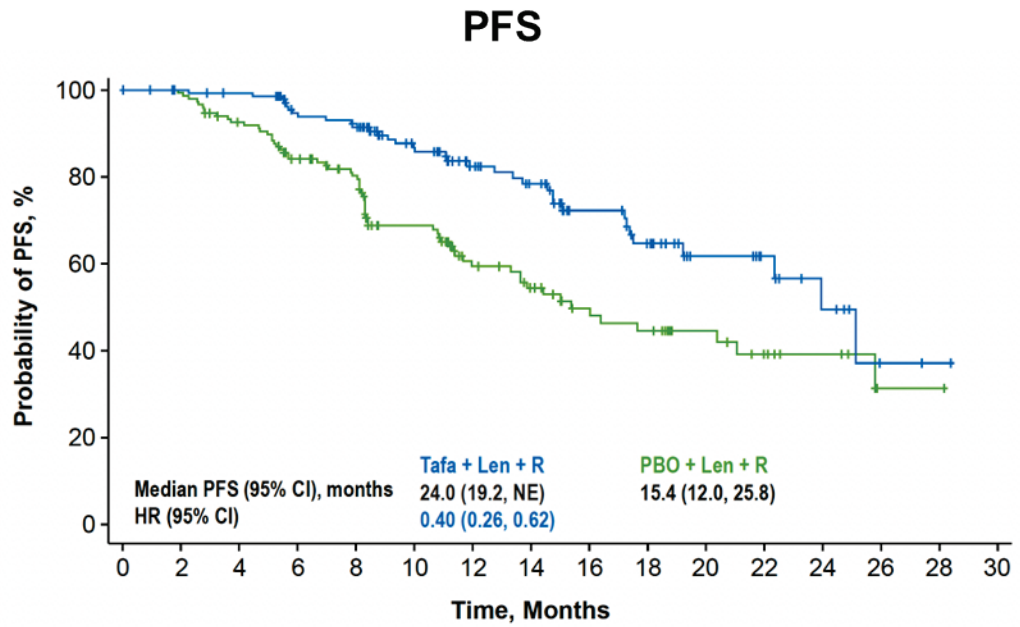
Ajay Gopal et al.

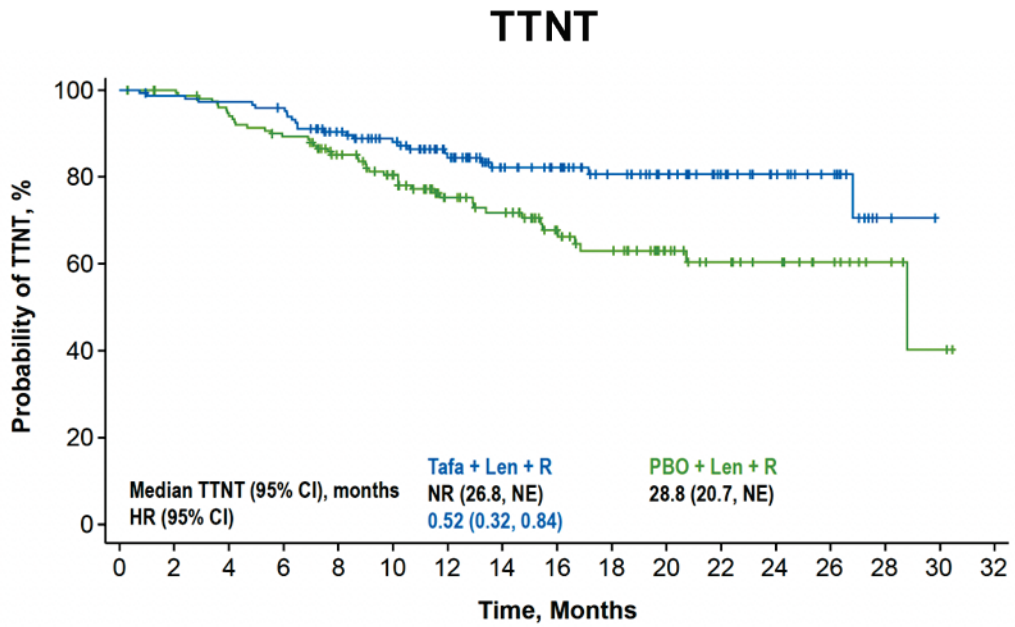
inMIND: Studiendesgin



- For the primary analysis, 174 investigator assessed progression-free survival events in the FL population were required to detect a HR of 0.65 with 80% power, using a 2-sided log-rank test at an alpha level of 5%
- Final analysis for overall survival is planned at 5 years of follow-up

inMIND: PFS und TTNT in der zweiten Therapielinie (n=300)



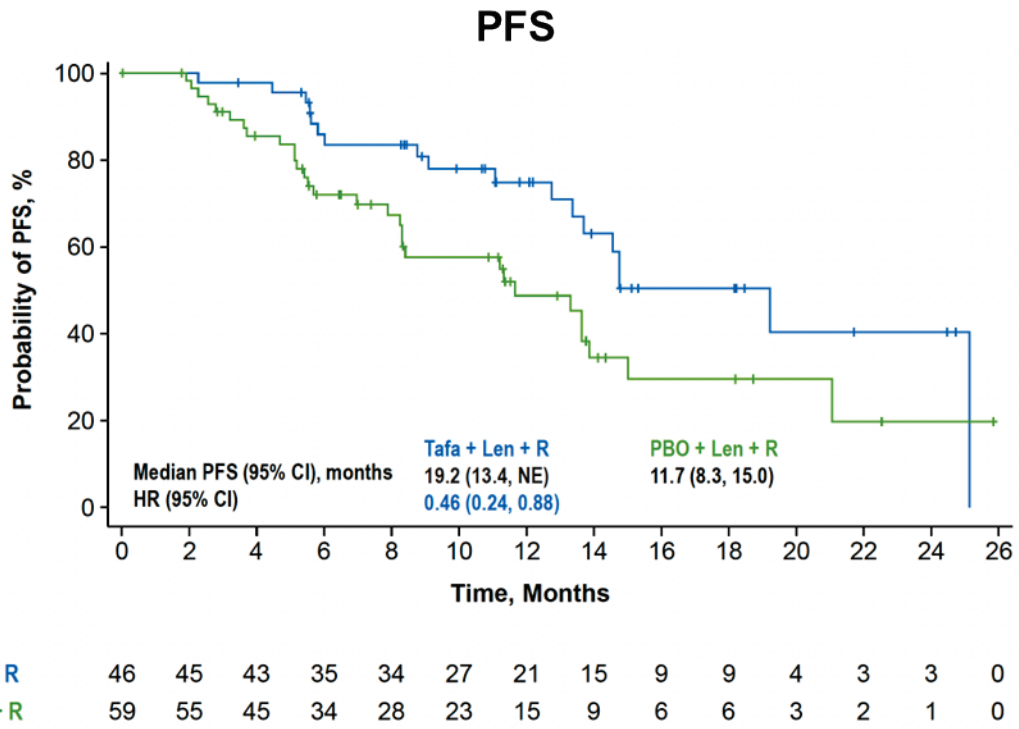


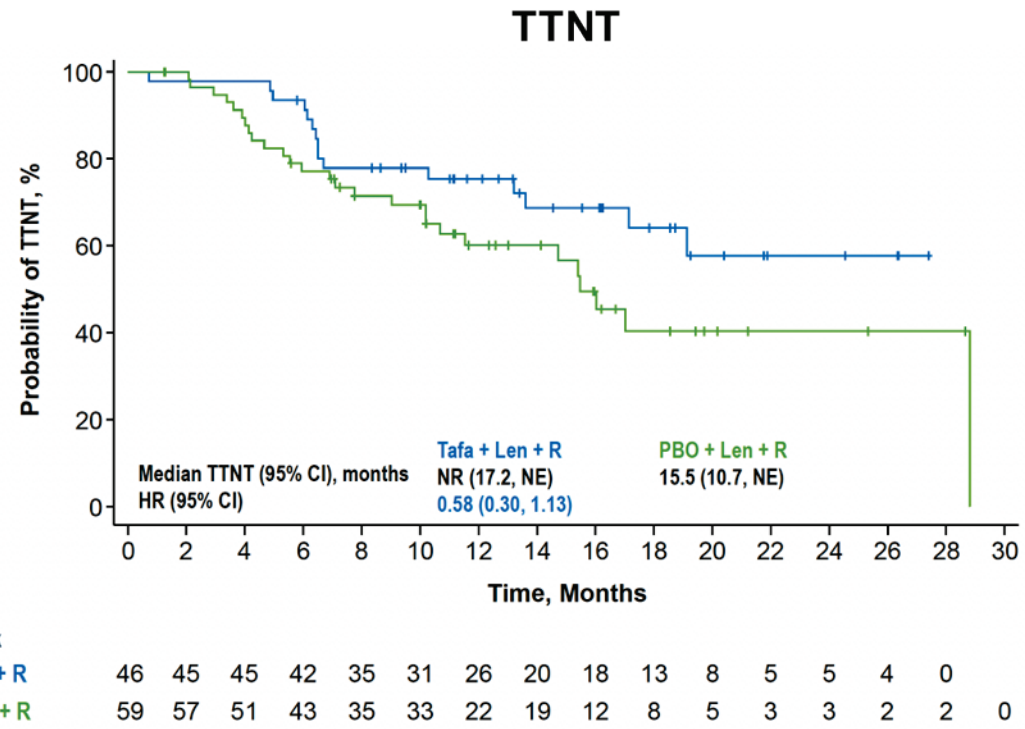
No. at Risk																
Tafa + len + R	147	140	137	117	113	90	65	57	40	32	18	12	7	2	1	0
PBO + len + R	153	148	133	113	102	74	50	42	29	26	17	12	8	2	2	0

No. at Risk																													
Tafa + len + R	147	144	142	139	122	108	87	68	60	49	39	27	20	14	2	0													
PBO + len + R	153	150	141	132	116	100	70	61	46	38	27	19	15	10	5	2	0												

ITT population. Analysis by investigator assessment.
2L, second-line; CI, confidence interval; FL, follicular lymphoma; HR, hazard ratio; ITT, intention-to-treat; len, lenalidomide; NE, not evaluable; NR, not reached; PBO, placebo; PFS, progression-free survival; R, rituximab; tafa, tafasitamab; TTNT, time to next treatment.

inMIND: PFS und TTNT bei POD24-Patienten in der zweiten Therapielinie (n=105)

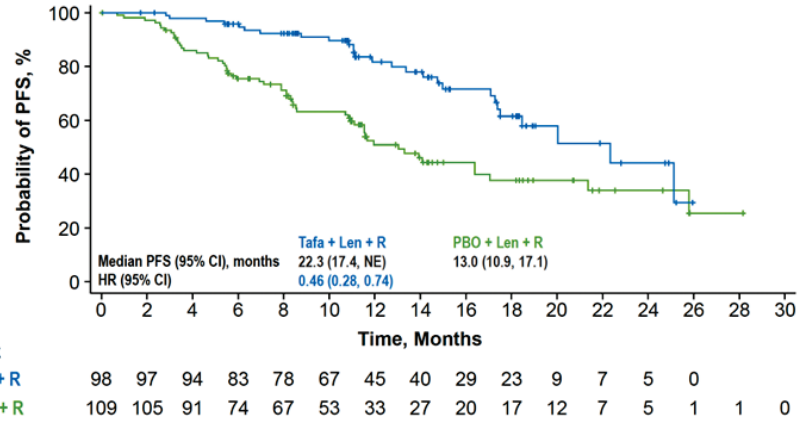




ITT population. Analysis by investigator assessment.
1L, first-line; 2L, second-line; CI, confidence interval; FL, follicular lymphoma; HR, hazard ratio; ITT, intention-to-treat; len, lenalidomide; NE, not evaluable; NR, not reached; PBO, placebo; PFS, progression-free survival; POD24, progression of disease within 24 months from the start of initial treatment; R, rituximab; tafa, tafasitamab; TTNT, time to next treatment..

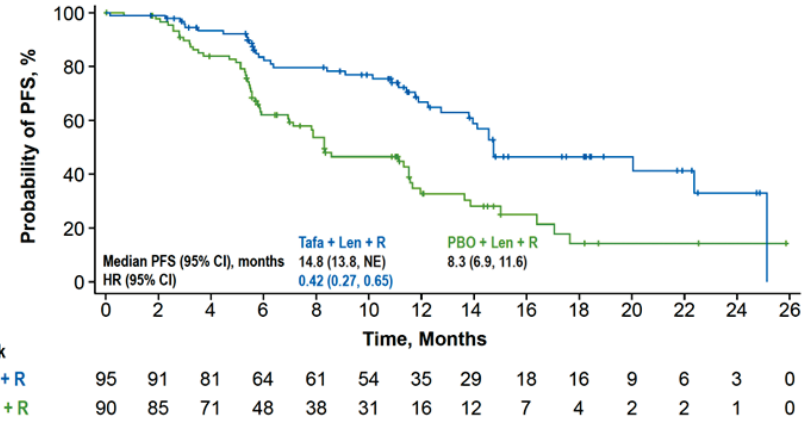
inMIND: PFS in weiteren Risikogruppen (ab 2. Linie)

Bulky Disease



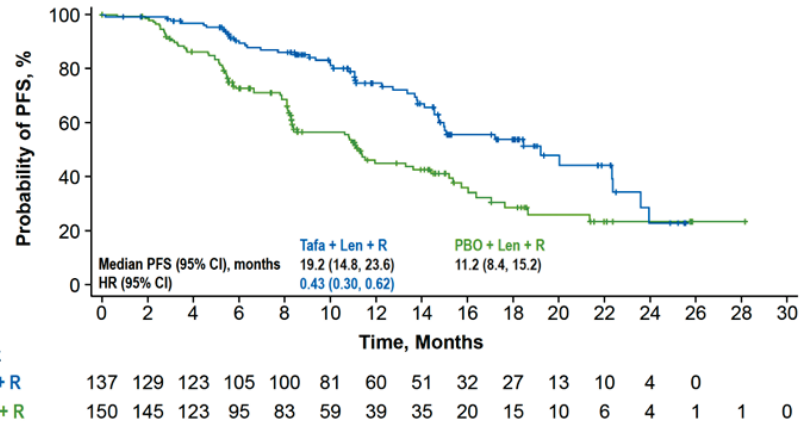
No. at Risk															
Tafa + len + R	98	97	94	83	78	67	45	40	29	23	9	7	5	0	
PBO + len + R	109	105	91	74	67	53	33	27	20	17	12	7	5	1	1	0

CIT Refractory



No. at Risk														
Tafa + len + R	95	91	81	64	61	54	35	29	18	16	9	6	3	0
PBO + len + R	90	85	71	48	38	31	16	12	7	4	2	2	1	0

FLIPI Score 3-5

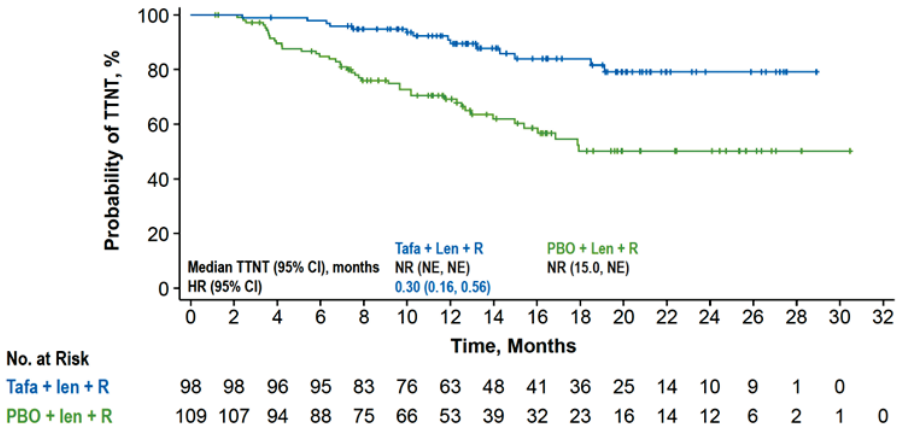


No. at Risk																
Tafa + len + R	137	129	123	105	100	81	60	51	32	27	13	10	4	0		
PBO + len + R	150	145	123	95	83	59	39	35	20	15	10	6	4	1	1	0

ITT population. Analysis by investigator assessment.
CI, confidence interval; CIT, chemoimmunotherapy; FLIPI, Follicular Lymphoma International Prognostic Index; HR, hazard ratio; ITT, intention-to-treat; len, lenalidomide; NE, not evaluable; NR, not reached; PBO, placebo; R, rituximab; tafa, tafasitamab; TTNT, time to next treatment.

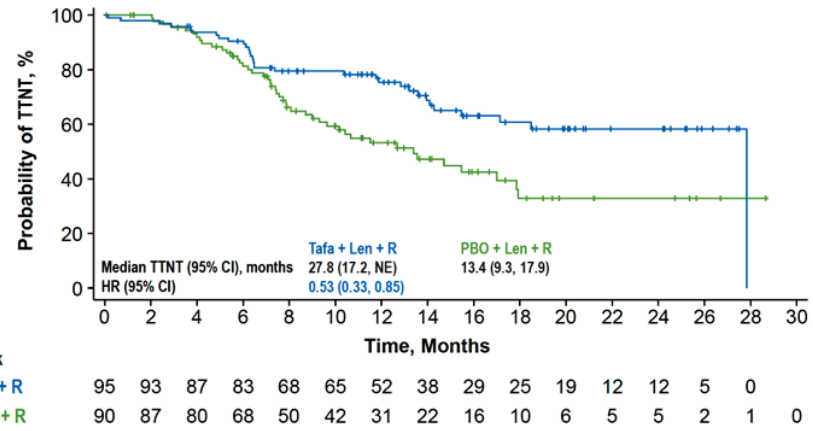
inMIND: TTNT in weiteren Risikogruppen (ab 2. Linie)

Bulky Disease



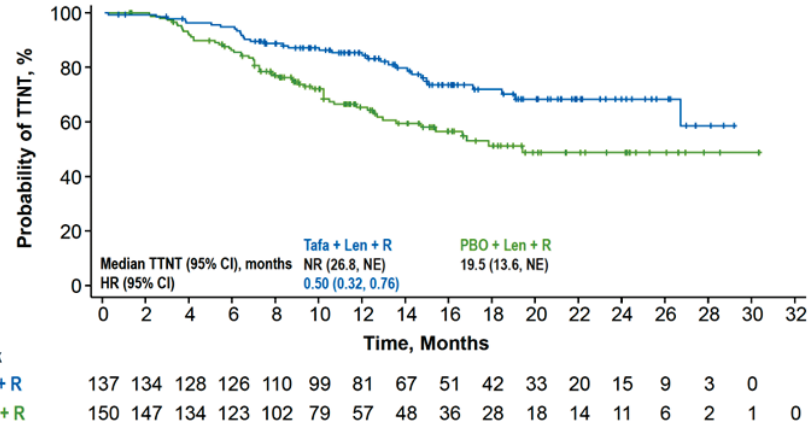
No. at Risk																
Tafa + len + R	98	98	96	95	83	76	63	48	41	36	25	14	10	9	1	0
PBO + len + R	109	107	94	88	75	66	53	39	32	23	16	14	12	6	2	1	0

CIT Refractory



No. at Risk																
Tafa + len + R	95	93	87	83	68	65	52	38	29	25	19	12	12	5	0	
PBO + len + R	90	87	80	68	50	42	31	22	16	10	6	5	5	2	1	0

FLIPI Score 3-5

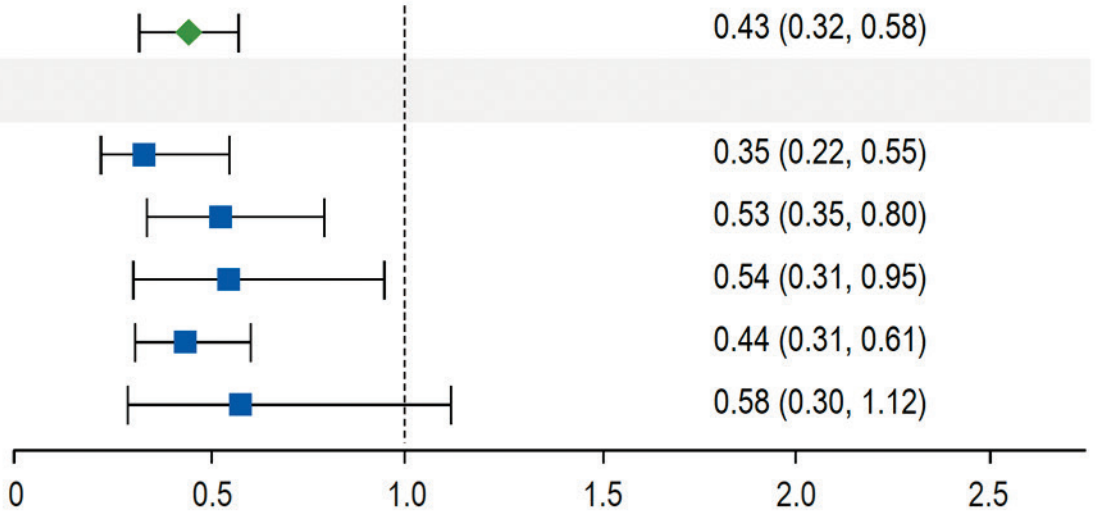


No. at Risk																
Tafa + len + R	137	134	128	126	110	99	81	67	51	42	33	20	15	9	3	0
PBO + len + R	150	147	134	123	102	79	57	48	36	28	18	14	11	6	2	1	0

ITT population. Analysis by investigator assessment.
CI, confidence interval; CIT, chemoimmunotherapy; FLIPI, Follicular Lymphoma International Prognostic Index; HR, hazard ratio; ITT, intention-to-treat; len, lenalidomide; NE, not evaluable; NR, not reached; PBO, placebo; R, rituximab; tafa, tafasitamab; TTNT, time to next treatment.

inMIND: PFS in verschiedenen Altersgruppen

Subgroup	Tafa + Len + R # Events/# Patients Censored	PBO + Len + R # Events/# Patients Censored	HR (95% CI)
Overall	75/198	131/144	0.43 (0.32, 0.58)
Age Group			
<65 years	29/108	69/70	0.35 (0.22, 0.55)
≥65 years	46/90	62/74	0.53 (0.35, 0.80)
≥65 to <75 years	26/56	33/49	0.54 (0.31, 0.95)
<75 years	55/164	102/119	0.44 (0.31, 0.61)
≥75 years	20/34	29/25	0.58 (0.30, 1.12)



ITT population. Analysis by investigator assessment.
CI, confidence interval; HR, hazard ratio; ITT, intention-to-treat; len, lenalidomide; PBO, placebo; PFS, progression-free survival; R, rituximab; tafa, tafasitamab.

Kapitel 2

Langzeitdaten zu Behandlungen in der Drittlinie:

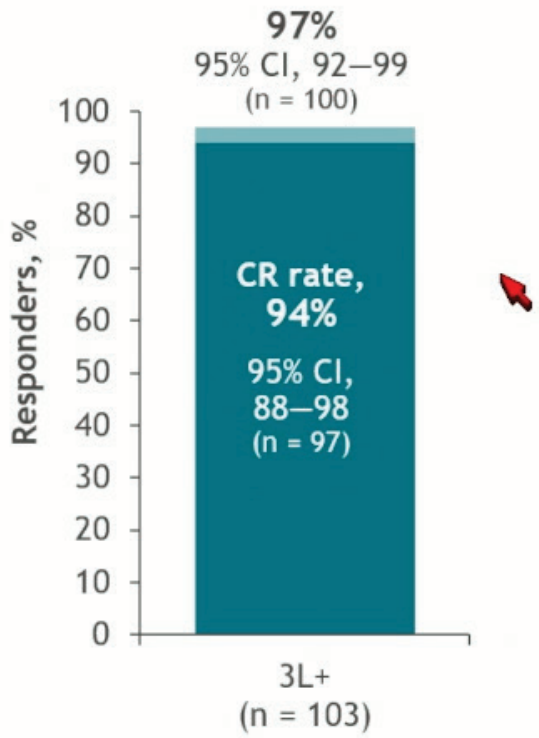
CARs und BTK-Inhibitoren

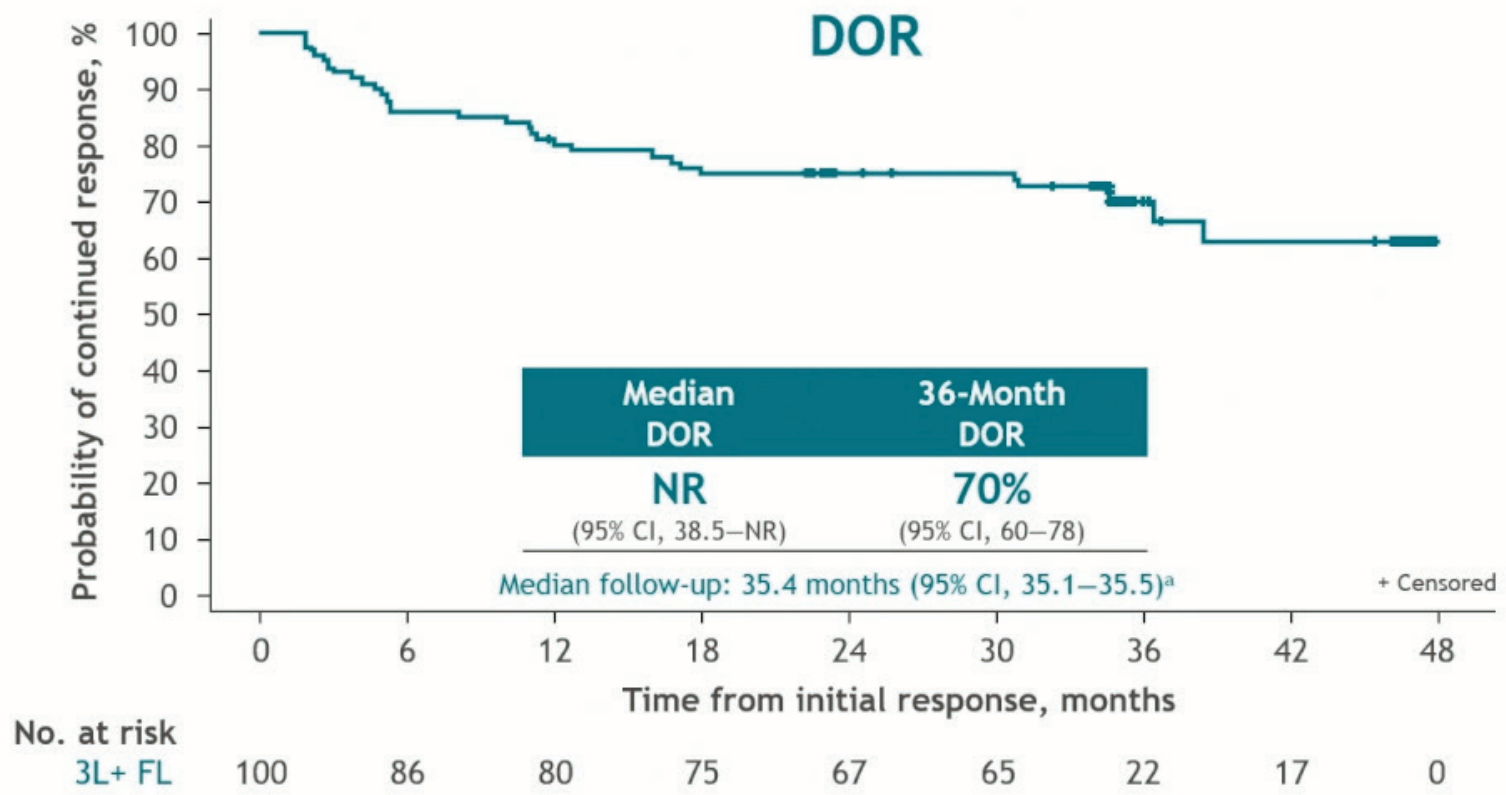
Three-Year Efficacy and Longitudinal Safety of Lisocabtagene Maraleucel (liso-cel) in Patients With Third-Line or later (3L+) Follicular Lymphoma (FL) from TRANSCEND FL

Presentation ID: 467

Sairah Ahmed et al.

TRANSCEND FL: Ansprechen und DOR





- Median DOR continued to be not reached with longer follow-up, and 70% remained in response at 36 months

[a]Reverse KM method was used to obtain the median follow-up and 95% CI.
NR, not reached.

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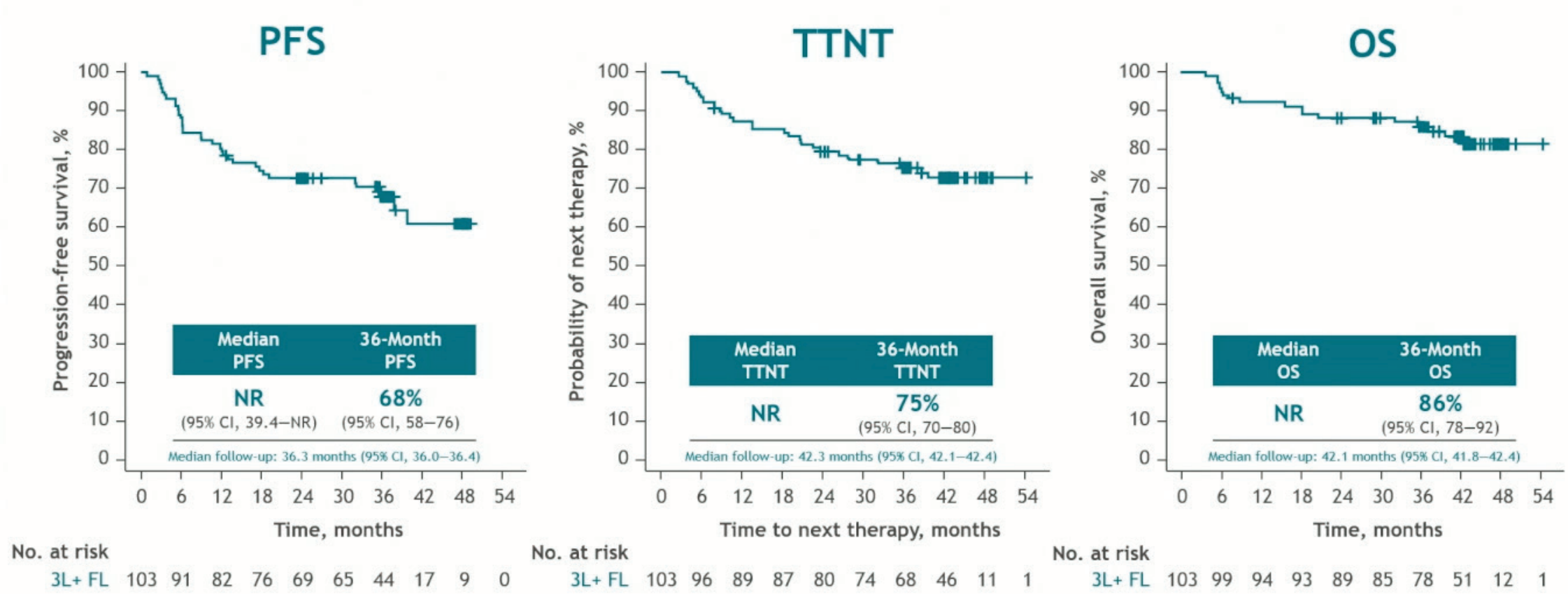
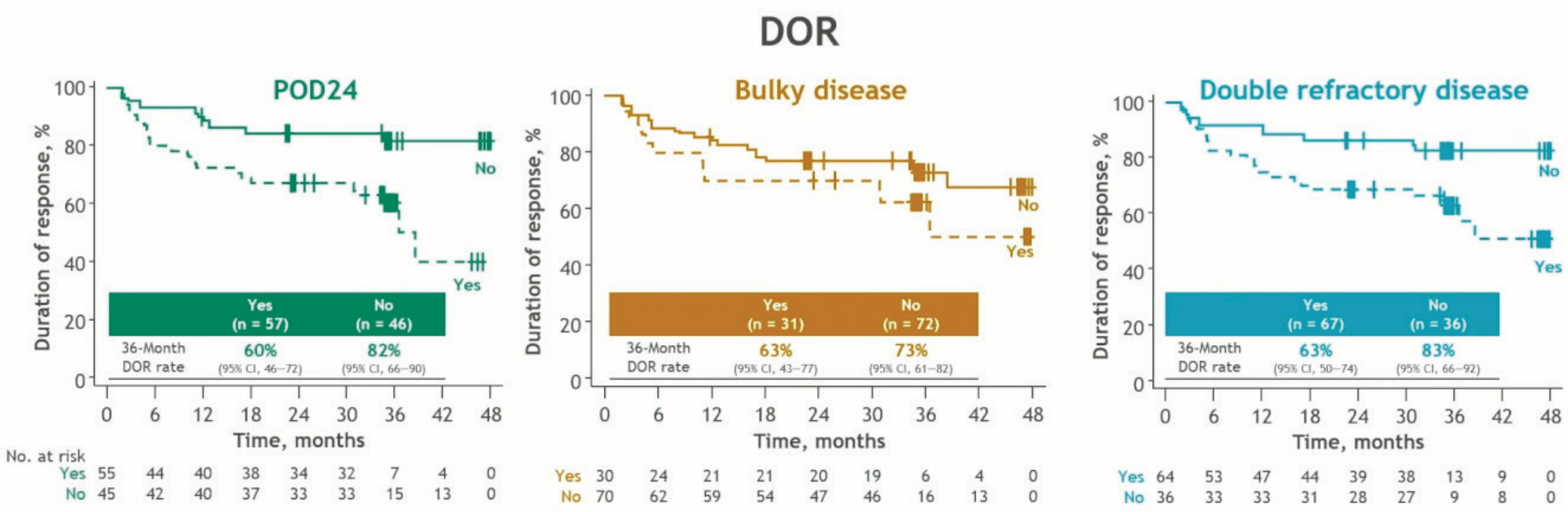
TRANSCEND FL: PFS, TTNT und OS nach 36 Mo



- Median PFS, TTNT, and OS all continued to be not reached with longer follow-up

TRANSCEND FL: DOR und PFS bei Risikopatienten

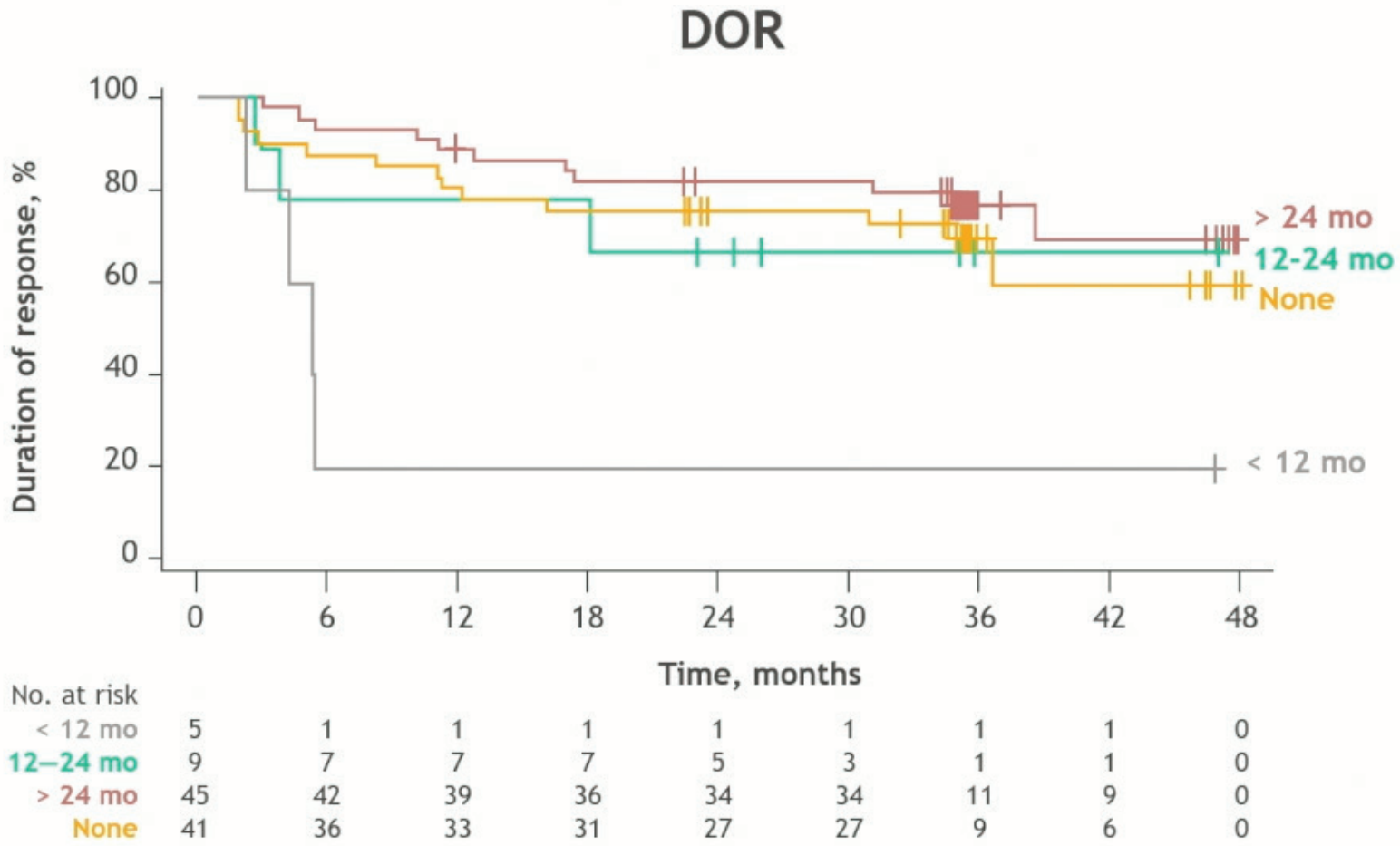


36-Month PFS rate

POD24 (n = 57)	No POD24 (n = 46)	Bulky disease (n = 31)	No bulky disease (n = 72)	Double refractory (n = 67)	Not double refractory (n = 36)
58% (95% CI, 43–70)	80% (95% CI, 65–89)	61% (95% CI, 41–75)	71% (95% CI, 58–80)	60% (95% CI, 47–71)	83% (95% CI, 66–92)

Median DOR was not reached across all these subgroups except patients with POD24 (38.5 months [95% CI, 31.0–NR]).

TRANSCEND FL: DOR nach Bendamustin-Vorbehandlung



36-Month rates

DOR	
< 12 mo (n = 5)	20% (95% CI, 1–58)
12–24 mo (n = 9)	67% (95% CI, 28–88)
> 24 mo (n = 47)	77% (95% CI, 61.5–87)
None (n = 42)	69% (95% CI, 52–81)
PFS	
< 12 mo (n = 5)	20% (95% CI, 1–58)
12–24 mo (n = 9)	67% (95% CI, 28–88)
> 24 mo (n = 47)	74% (95% CI, 58–84)
None (n = 42)	67.5% (95% CI, 50–80)

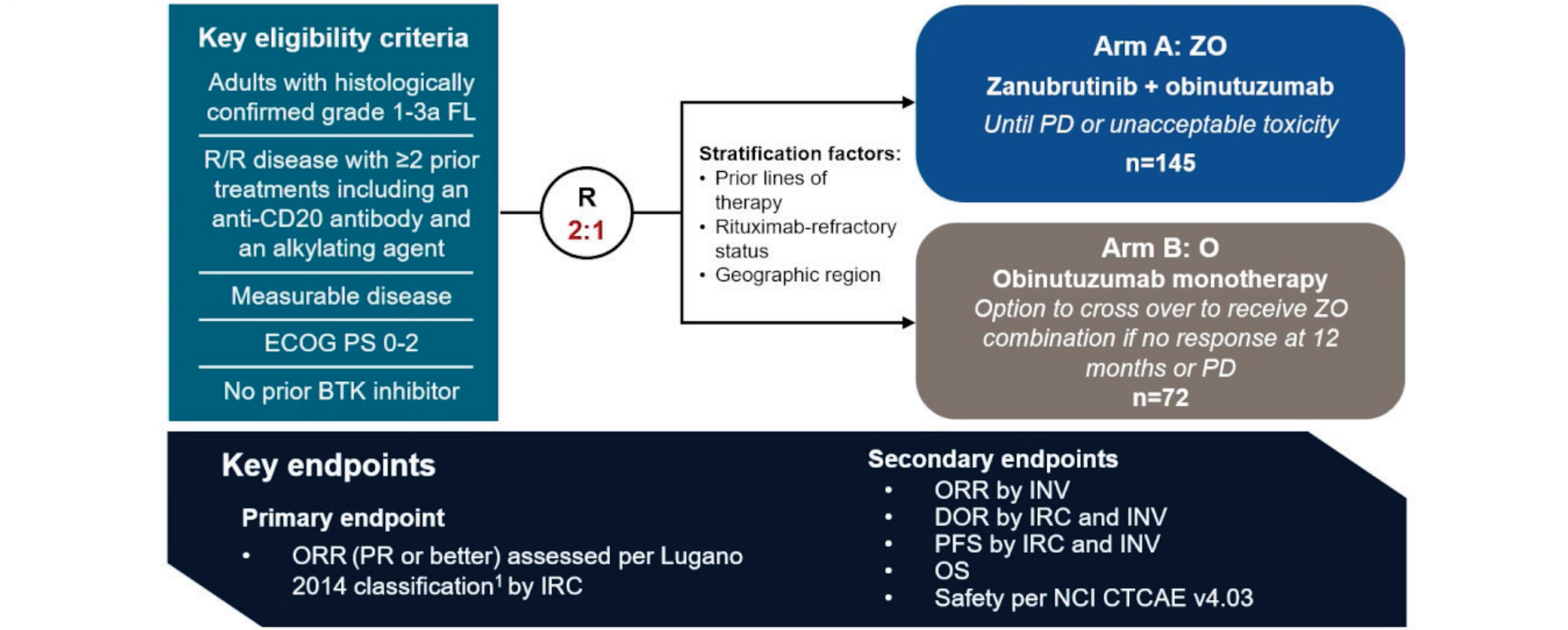
Median DOR was not reached across all these subgroups except patients with prior bendamustine < 12 months before leukapheresis (5.2 months [95% CI, 2.2–NR]).

Final Analysis of the Randomized Phase 2 ROSEWOOD Study of Zanubrutinib + Obinutuzumab vs Obinutuzumab Monotherapy in Patients with Relapsed/Refractory Follicular Lymphoma

Presentation ID: 227

Pier Luigi Zinzani et al.

ROSEWOOD: Studiendesign



BTK, Bruton tyrosine kinase; CD, cluster of differentiation; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; FL, follicular lymphoma; INV, investigator; IRC, independent review committee; NCI CTCAE, National Cancer Institute Common Terminology Criteria for Adverse Events; O, obinutuzumab; ORR, overall response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PR, partial response; R, randomized; R/R, relapsed/refractory; ZO, zanubrutinib + obinutuzumab.

1. Cheson BD, et al. *J Clin Oncol.* 2014;32(27):3059-3068.

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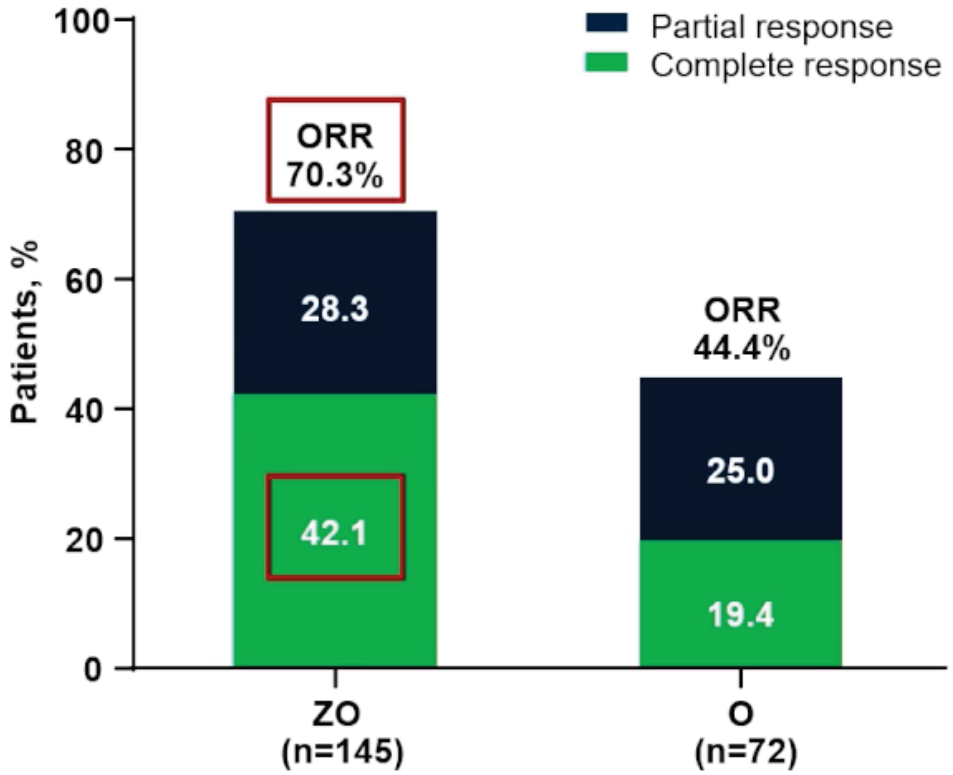
Medianes Follow-up: 34,6 Mo

ROSEWOOD: Therapieansprechen



- ORRs per INV were similar to ORRs per IRC (ZO, 68.3%; O, 43.1%)

	ZO (n=145)	O (n=72)
Overall response rate, n (%)	102 (**70.3**)	32 (**44.4**)
95% CI	62.2-77.6	32.7-56.6
Risk difference (95% CI), %	25.5 (11.8-39.3)	
2-sided *P* value[a]	.0003	
Complete response rate, n (%)	61 (**42.1**)	14 (**19.4**)
95% CI	33.9-50.5	11.1-30.5
2-sided *P* value[a]	.0009	
Other responses, n (%)		
Stable disease	21 (14.5)	14 (19.4)
Indeterminate due to zanubrutinib hold	1 (0.7)	0
Non-progressive disease[b]	6 (4.1)	9 (12.5)
Progressive disease	13 (9.0)	16 (22.2)
Discontinued prior to first assessment/NE	2 (1.4)	1 (1.4)

[a]*P* value is descriptive. [b]Defined as PET assessment missing or not evaluable, and CT assessment showed no progressive disease.
CT, computed tomography; INV, investigator; IRC, independent review committee; O, obinutuzumab; ORR, overall response rate; PET, positron emission tomography; ZO, zanubrutinib + obinutuzumab.

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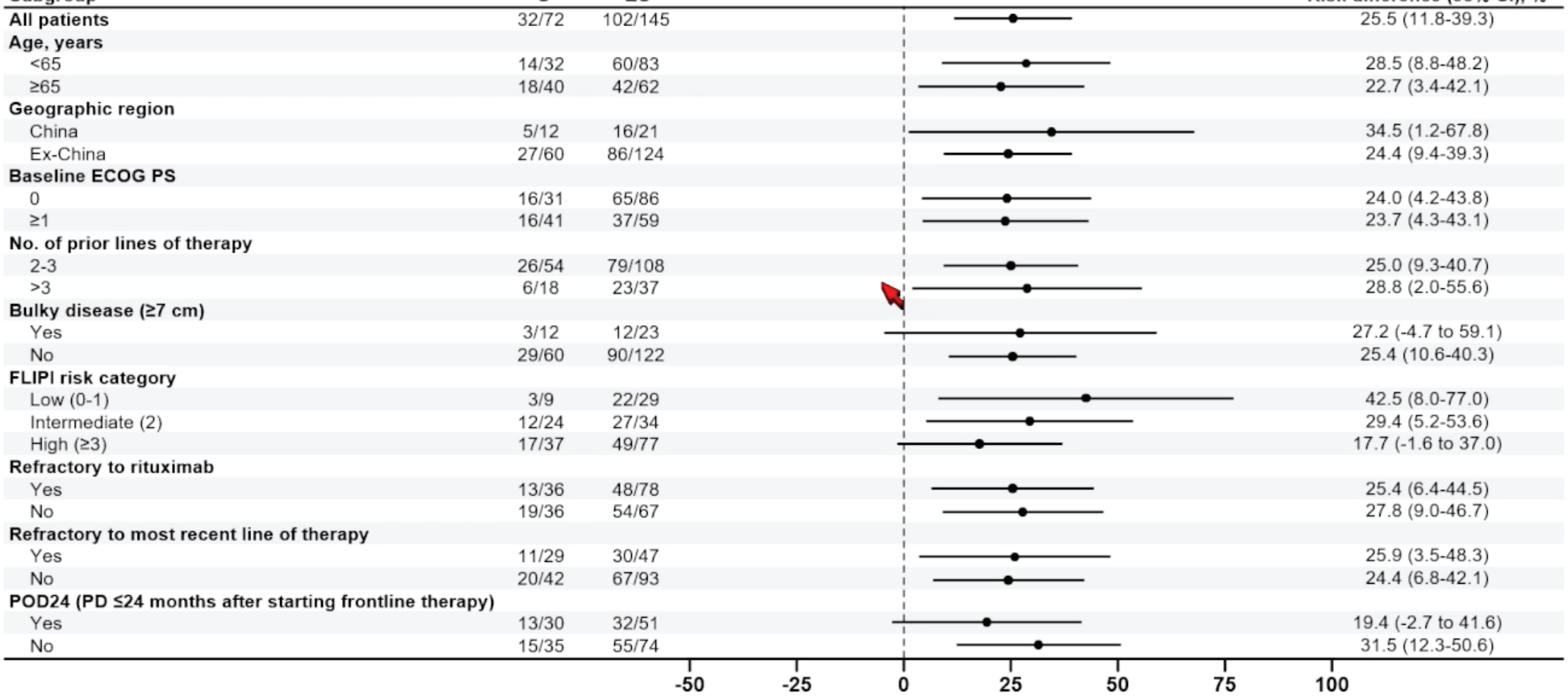
ROSEWOOD: Therapieansprechen in Subgruppen

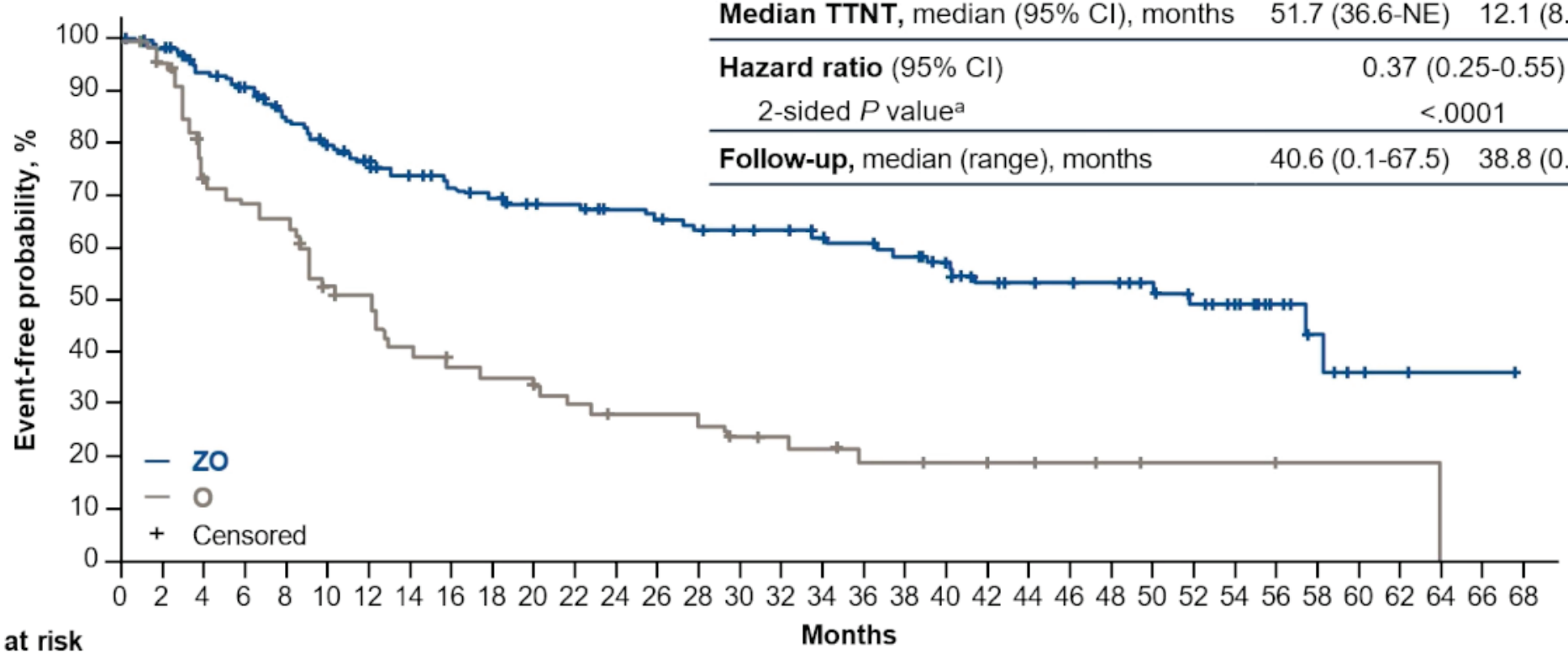
Subgroup	Responders/Patients O	Responders/Patients ZO	Risk difference (95% CI), %
All patients	32/72	102/145	25.5 (11.8-39.3)
Age, years			
<65	14/32	60/83	28.5 (8.8-48.2)
≥65	18/40	42/62	22.7 (3.4-42.1)
Geographic region			
China	5/12	16/21	34.5 (1.2-67.8)
Ex-China	27/60	86/124	24.4 (9.4-39.3)
Baseline ECOG PS			
0	16/31	65/86	24.0 (4.2-43.8)
≥1	16/41	37/59	23.7 (4.3-43.1)
No. of prior lines of therapy			
2-3	26/54	79/108	25.0 (9.3-40.7)
>3	6/18	23/37	28.8 (2.0-55.6)
Bulky disease (≥7 cm)			
Yes	3/12	12/23	27.2 (-4.7 to 59.1)
No	29/60	90/122	25.4 (10.6-40.3)
FLIPI risk category			
Low (0-1)	3/9	22/29	42.5 (8.0-77.0)
Intermediate (2)	12/24	27/34	29.4 (5.2-53.6)
High (≥3)	17/37	49/77	17.7 (-1.6 to 37.0)
Refractory to rituximab			
Yes	13/36	48/78	25.4 (6.4-44.5)
No	19/36	54/67	27.8 (9.0-46.7)
Refractory to most recent line of therapy			
Yes	11/29	30/47	25.9 (3.5-48.3)
No	20/42	67/93	24.4 (6.8-42.1)
POD24 (PD ≤24 months after starting frontline therapy)			
Yes	13/30	32/51	19.4 (-2.7 to 41.6)
No	15/35	55/74	31.5 (12.3-50.6)



FLIPI, Follicular Lymphoma International Prognostic Index; O, obinutuzumab; PD, progressive disease; ZO, zanubrutinib + obinutuzumab.

ROSEWOOD: TTNT

	ZO	O
Median TTNT, median (95% CI), months	51.7 (36.6-NE)	12.1 (8.3-15.9)
Hazard ratio (95% CI)	0.37 (0.25-0.55)	
2-sided *P* value[a]	<.0001	
Follow-up, median (range), months	40.6 (0.1-67.5)	38.8 (0.1-63.9)



No. at risk

ZO	145	137	126	118	107	99	91	84	80	76	71	70	66	64	61	58	57	54	52	49	43	37	34	33	31	27	22	16	11	6	3	2	1	1	0
O	72	65	49	44	42	32	30	24	21	20	18	16	14	14	13	11	10	9	7	7	6	6	5	4	3	2	2	2	1	1	1	1	0		

[a]*P* value is descriptive.
TTNT, time to new anticancer therapy or crossover; NE, not estimable; O, obinutuzumab; ZO, zanubrutinib + obinutuzumab.

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ROSEWOOD: Sicherheit

- With a longer median duration of exposure (ZO, 12.4 months; O, 6.5 months), the incidence of TEAEs and treatment-related TEAEs was generally higher in the ZO arm vs the O arm

n (%)	ZO n=143	O n=71
Any TEAE	137 (95.8)	65 (91.5)
Any treatment-related TEAE	110 (76.9)	49 (69.0)
Grade ≥3	103 (72.0)	34 (47.9)
Treatment-related grade ≥3	62 (43.4)	19 (26.8)
Serious	75 (52.4)	22 (31.0)
Treatment-related serious	29 (20.3)	8 (11.3)
Leading to death	15 (10.5)	7 (9.9)
Treatment-related leading to death	2 (1.4)	1 (1.4)
Leading to treatment discontinuation	31 (21.7)	9 (12.7)
Treatment-related leading to treatment discontinuation	14 (9.8)	3 (4.2)

O, obinutuzumab; TEAE, treatment-emergent adverse event; ZO, zanubrutinib + obinutuzumab.

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Zusammenfassung | Take-Home-Messages

- Der CD3xCD20 bispezifische Antikörper Epcoritamab dokumentiert in der Kombination mit R^2 in einer randomisierten Studie eine Überlegenheit gegenüber einer Standard-Zweitlininentherapie.

- Die Kombination von Tafasitamab plus R^2 zeigt eine gute Effektivität auch in Risikogruppen und wird einen neuen Therapiestandard in der Zweitlinie des FL darstellen.

- Liso-Cel zeigt auch nach drei Jahren eine hervorragende Effektivität und Verträglichkeit.

- Die Langzeitdaten von Zanubrutinib und Obinutuzumab bestätigen die Kombination als wichtige Therapieoption ab der dritten Therapielinie des FL.

Die Kurzpräsentationen sind online unter

www.lymphome.de/ash2025

Für den Inhalt verantwortlich:

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Lymphom Kompetenz KOMPAKT

KML KONGRESSE

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