ER Congressi

9th Postgraduate Lymphoma Conference
Florence, Hotel Brunelleschi, March 20-21, 2025
Responsabile Scientifico: Pier Luigi Zinzani

Session IV : Follicular lymphoma

The scaling dynamics of chemo-free regimens to the second line

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FL – Second lines

SUGGESTED TREATMENT REGIMENS[a,b,c]

SECOND-LINE THERAPY[h]

Preferred regimens (in alphabetical order)
- Bendamustine[d,i] + obinutuzumab[j] or rituximab (not recommended if treated with prior bendamustine)
- CHOP + obinutuzumab[j] or rituximab
- CVP + obinutuzumab[j] or rituximab
- Lenalidomide + rituximab
- Tafasitamab-cxix[k] + lenalidomide + rituximab (≥1 prior systemic therapy including an anti-CD20 mAb)

Other recommended regimens (in alphabetical order)
- Lenalidomide (if not a candidate for anti-CD20 mAb therapy)
- Lenalidomide + obinutuzumab
- Obinutuzumab
- Rituximab

SECOND-LINE THERAPY FOR OLDER OR INFIRM
(if none of the therapies are expected to be tolerable in the opinion of treating physician)

Preferred regimens
- Rituximab (375 mg/m^2 weekly for 4 doses)
- Tazemetostat[l] (irrespective of *EZH2* mutation status)

Other recommended regimen
- Cyclophosphamide ± rituximab

SECOND-LINE EXTENDED THERAPY (optional)

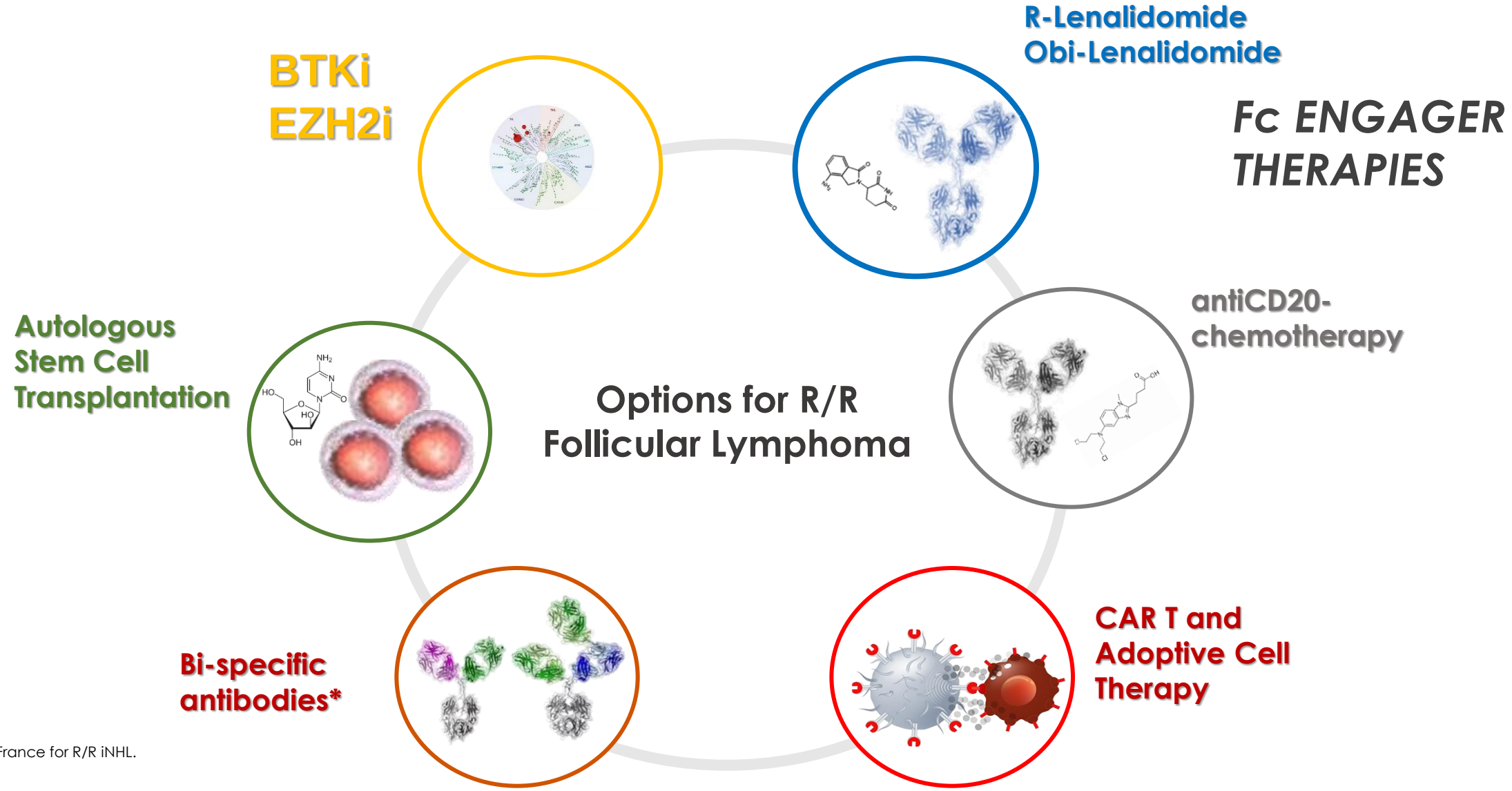
Preferred regimens
- Rituximab maintenance 375 mg/m^2 one dose every 12 weeks for 2 years (category 1)
- Obinutuzumab maintenance for rituximab-refractory disease (1 g every 8 weeks for total of 12 doses)

SECOND-LINE CONSOLIDATION THERAPY (optional)

- High-dose therapy with autologous stem cell rescue (HDT/ASCR)

NCCN guidelines - Version 10 Feb 2025

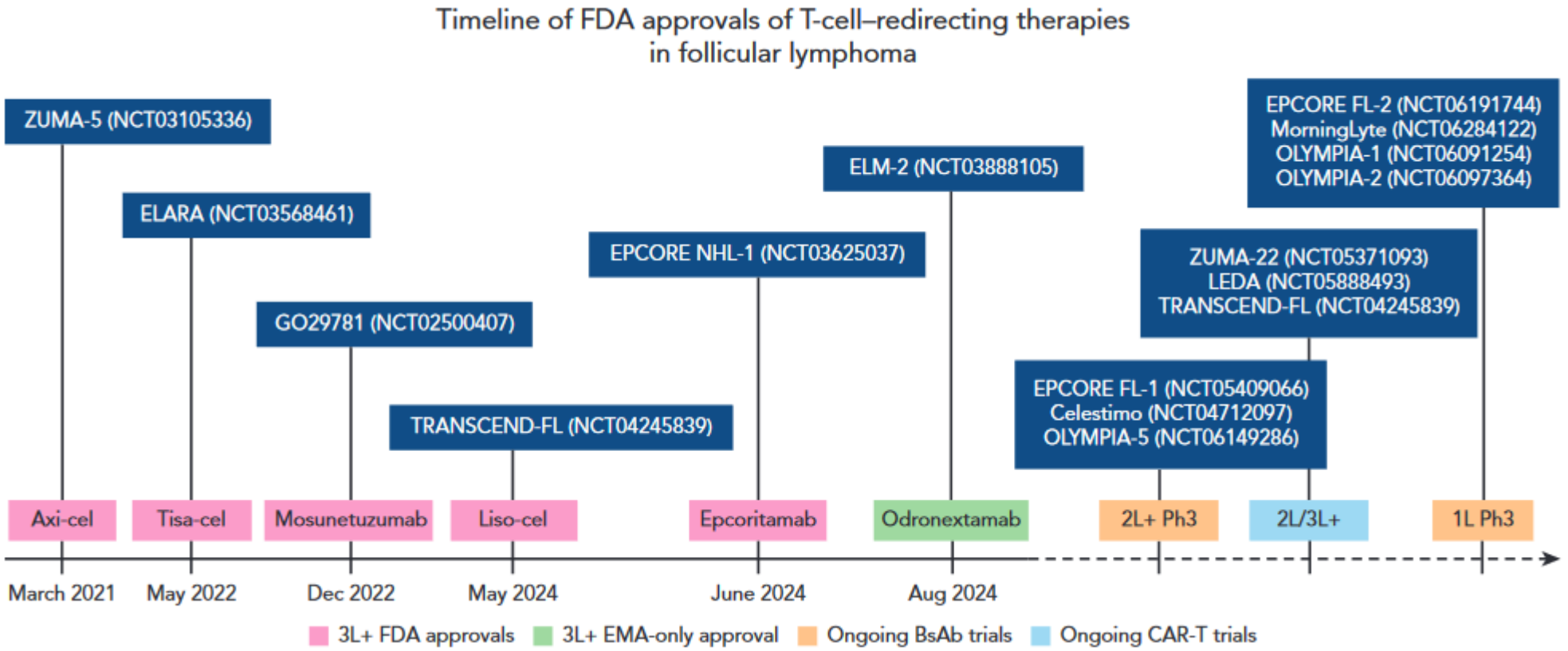
Novel options for R/R Lymphoma



* Not approved in France for R/R iNHL.

Courtesy of Guillaume Cartron

Timeline of FDA approvals of T-cell–redirecting therapies in FL



Iacoboni G and Morschhauser F. Blood 2025

Chemo-free regimens

- AUGMENT : R2
- inMIND : Tafa-R2
- CELESTIMO : Mosun-Len
- EPCORE FL : Epco-R2
- OLYMPIA-5 : Odro-Len
- SYMPHONY 1 : Taz-R2
- SELENE, ROSEWOOD, MAHOGANY : BTKi

Chemo-free regimens

- **AUGMENT : R2**
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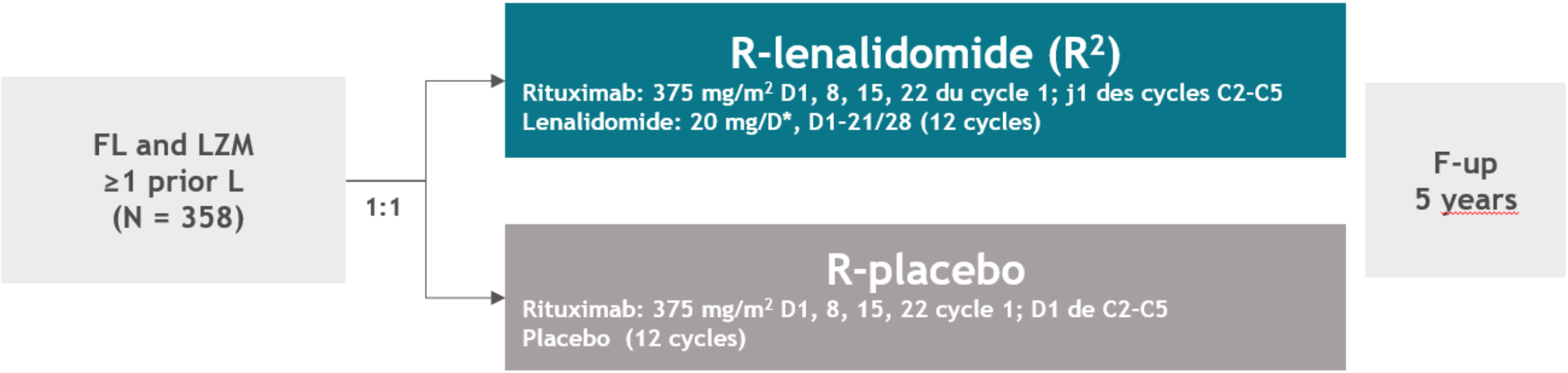
AUGMENT (NCT01938001) : R2 vs placebo-R

double-blind, phase III trial, 1:1



Leonard JP, et al: J Clin Oncol . 2019 May 10;37(14):1188-1199

AUGMENT (NCT01938001)

double-blind, phase III trial, 1:1

FL population, n = 295

Characteristic, n (%)	Patients with FL	
	R² (n = 147)	R-placebo (n = 148)
Age, median (range), years	62 (26–86)	61 (35–88)
Sex, male	61 (42)	80 (54)
ECOG PS[a]		
0	99 (67)	105 (71)
1	47 (32)	42 (28)
2	1 (1)	1 (1)
Positive bone marrow involvement	20 (24)	22 (25)
Biopsy not done	64 (44)	59 (40)
Ann Arbor stage at enrollment[b]		
I or II	34 (23)	42 (28)
III or IV	113 (77)	106 (72)
Bulky disease[c]	39 (27)	43 (29)
Baseline creatinine clearance (≥30—59 mL/minute)	20 (14)	16 (11)
High tumor burden	77 (52)	68 (46)
Histology[d]		
FL	147 (100)	148 (00)
MZL	0	0
Lactate dehydrogenase >ULN	34 (23)	33 22)
B symptoms[e]	12 (8)	11 (7)

Characteristic, n (%)	Patients with FL	
	R² (n = 147)	R-placebo (n = 148)
FLIPI score[f]		
0 or 1	45 (31)	53 (36)
2	46 (31)	48 (32)
3–5	54 (37)	46 (31)
Number of prior lines therapy		
1	78 (53)	79 (53)
2	25 (17)	33 (22)
3	24 (16)	16 (11)
4+	20 (14)	20 (14)
Prior rituximab treatment	125 (85)	124 (84)
Prior rituximab-containing chemotherapy regimen	108 (74)	108 (73)
Time since last anti-lymphoma therapy		
≤2 years	77 (52)	78 (53)
>2 years	70 (48)	70 (47)
Relapse/progression ≤2 years of initial diagnosis	49 (33)	50 (34)
Refractory to last regimen	26 (18)	25 (17)

R² was approved for the treatment of adult patients with previously treated FL or MZL in the USA, Japan, and Brazil, and for FL in Europe

Leonard JP, et al: J Clin Oncol . 2019 May 10;37(14):1188-1199

AUGMENT (NCT01938001)

Variable	Lenalidomide + Rituximab (n = 147)	Placebo + Rituximab (n = 148)	*P**
Best response, as assessed by IRC			
ORR, No. (% [95% CI])	118 (80 [73 to 86])	82 (55 [47 to 64])	< .0001
CR, No. (% [95% CI])	51 (35 [27 to 43])	29 (20 [14 to 27])	.0040
PR, No. (%)	67 (46)	53 (36)	
SD, No. (%)	14 (10)	44 (30)	
PD/death, No. (%)	7 (5)	19 (13)	
Not done/missing/no evidence of di No. (%)	8 (5)	3 (2)	

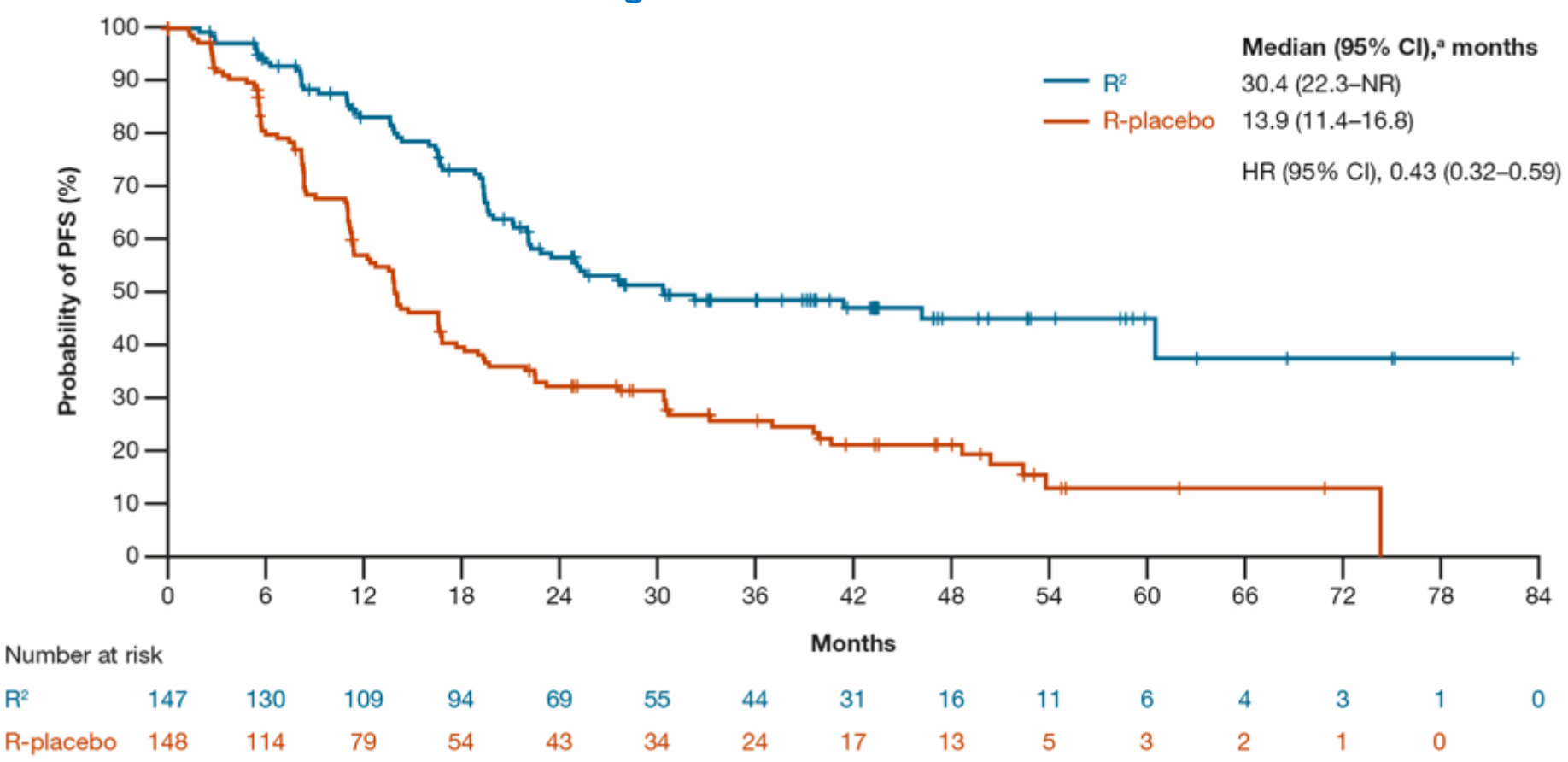
Leonard JP, et al: J Clin Oncol . 2019 May 10;37(14):1188-1199

AUGMENT : long-term results

FL population

median follow-up of 65.9 months

Progression – free survival



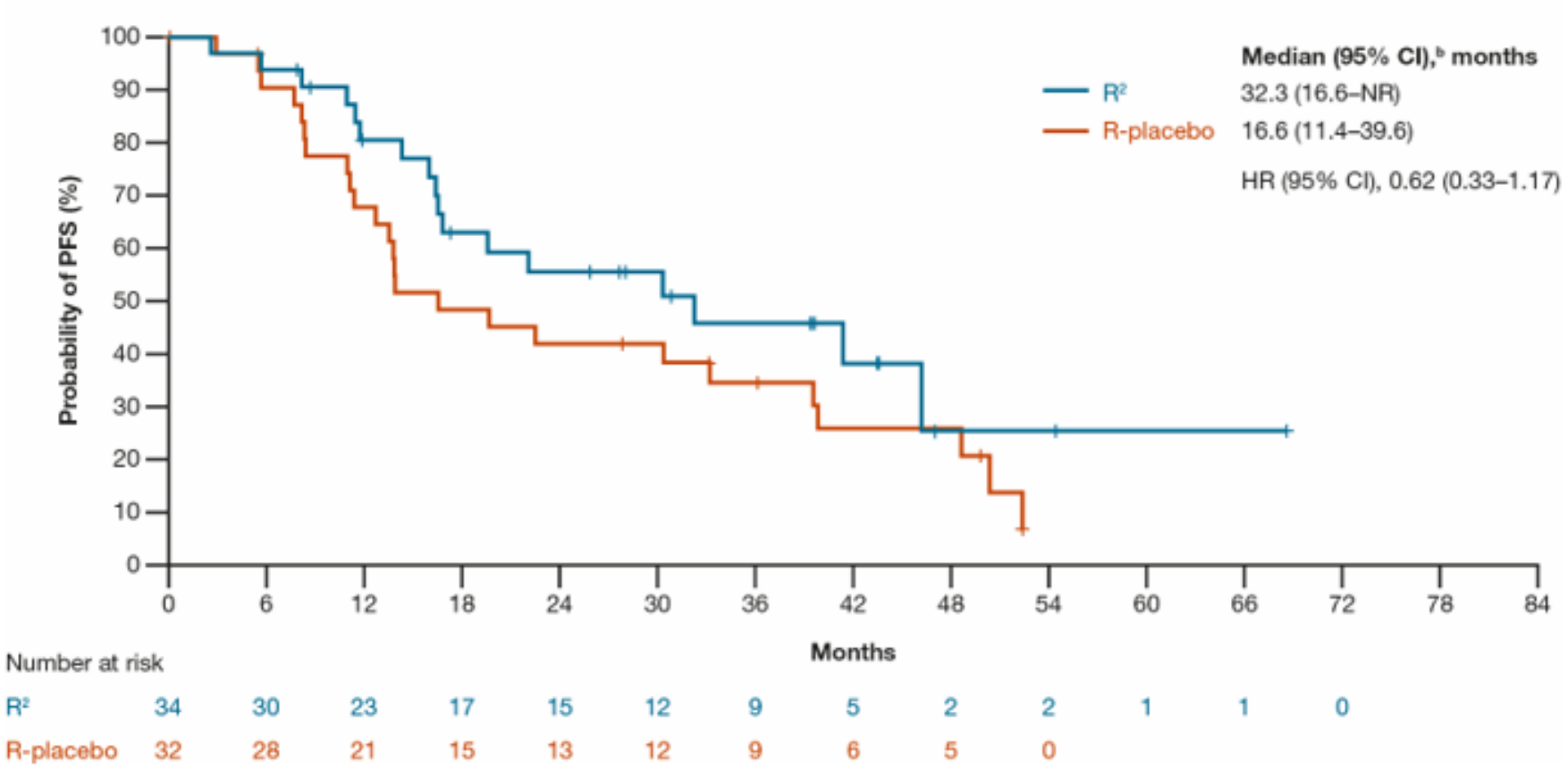
Leonard JP, et al: submitted

AUGMENT : long-term results

FL population <u>> 70 yo</u>

median follow-up of 65.9 months

Progression – free survival

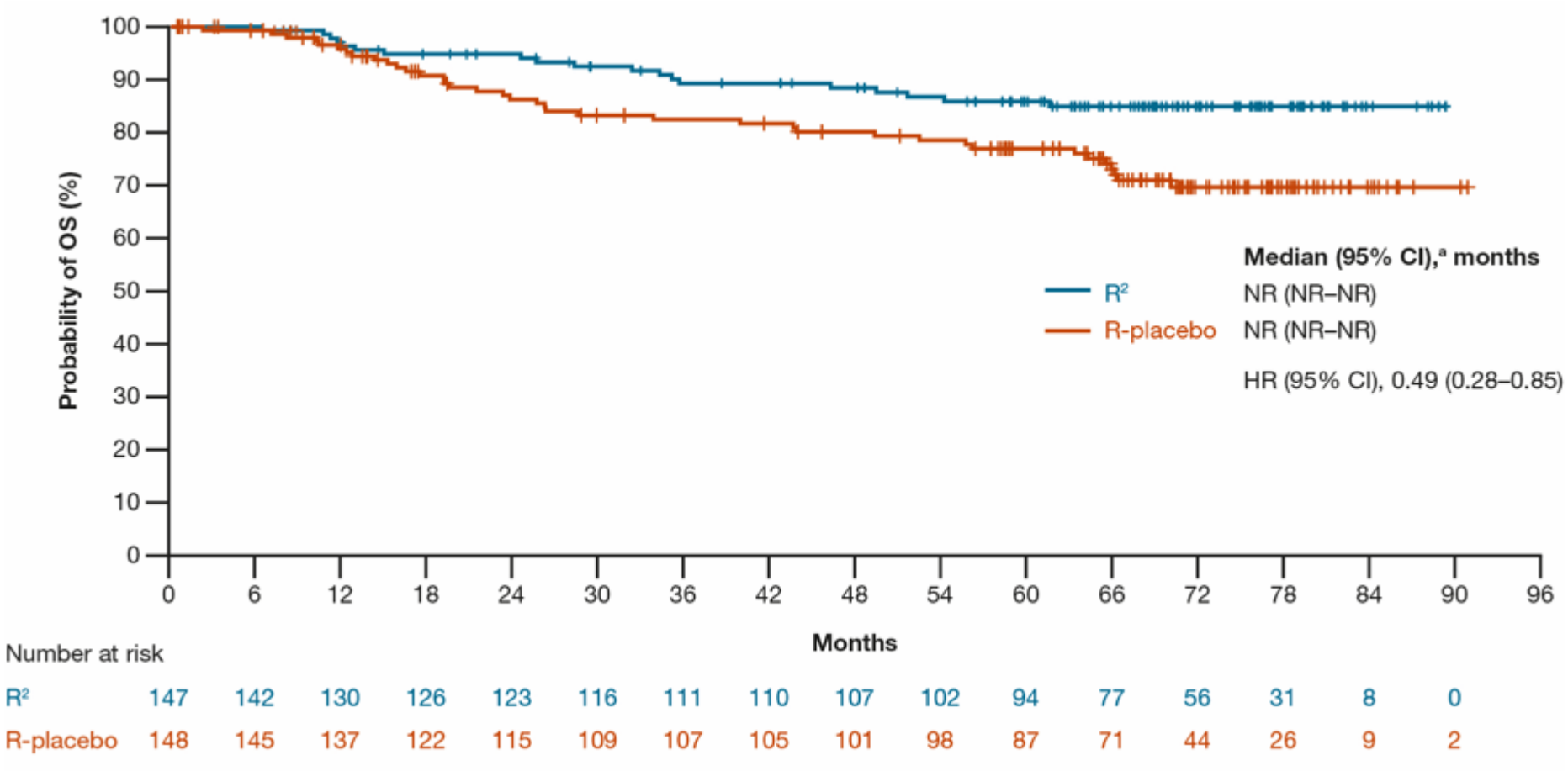


Leonard JP, et al: submitted

AUGMENT : long-term results

FL population

median follow-up of 65.9 months
overall survival



Leonard JP, et al: submitted

AUGMENT : long-term results

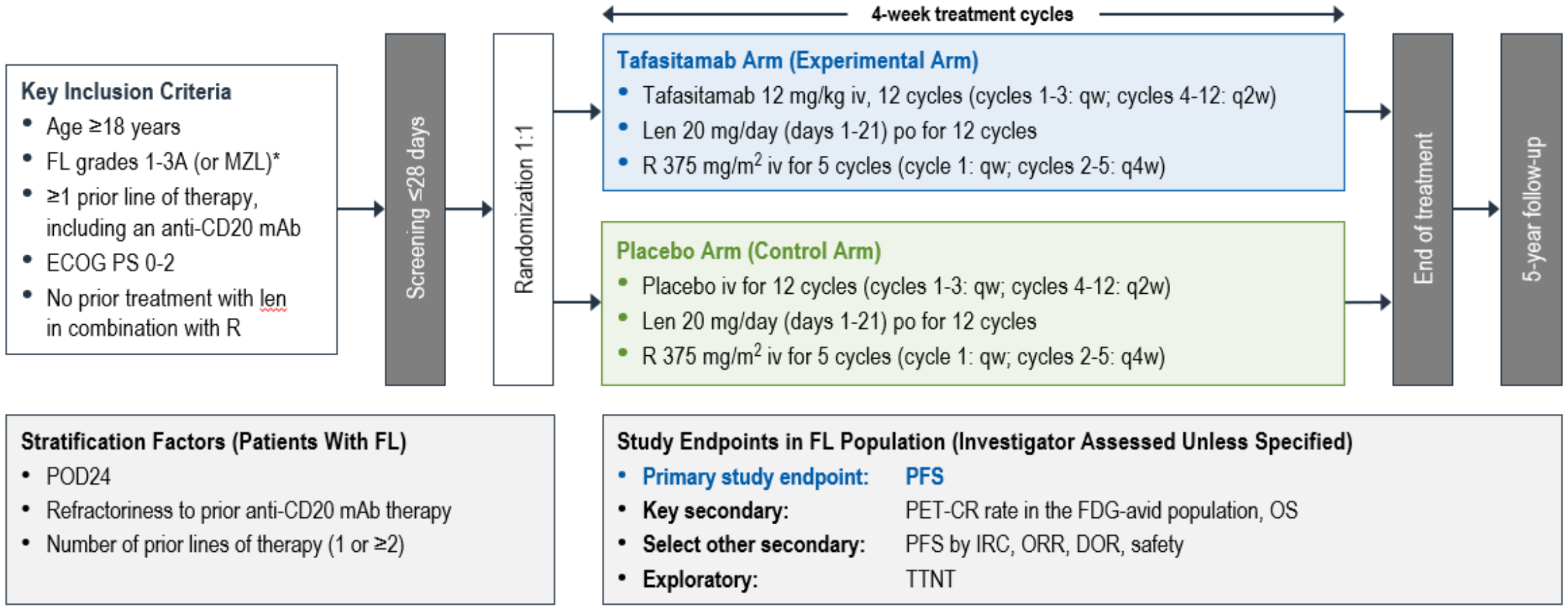
- **R^2 => long-term disease control** as a second-line or later therapy
- including in patients with FL and those **who aged ≥70 years**
- These data continue to support R^2 as a standard of care for patients with R/R iNHL

Chemo-free regimens

- **AUGMENT : R2**
- **inMIND : Tafa-R2**
- **CELESTIMO : Mosun-Len**
- **EPCORE FL : Epco-R2**
- **OLYMPIA-5 : Odro-len**
- **SYMPHONY 1 : Taz-R2**
- **SELENE, ROSEWOOD, MAHOGANY : BTKi**

inMIND (NCT04680052) : Tafa-R2 vs placebo-R2

Phase 3, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study



Sehn L et al. ASH 2024; Abstract #LBA-1

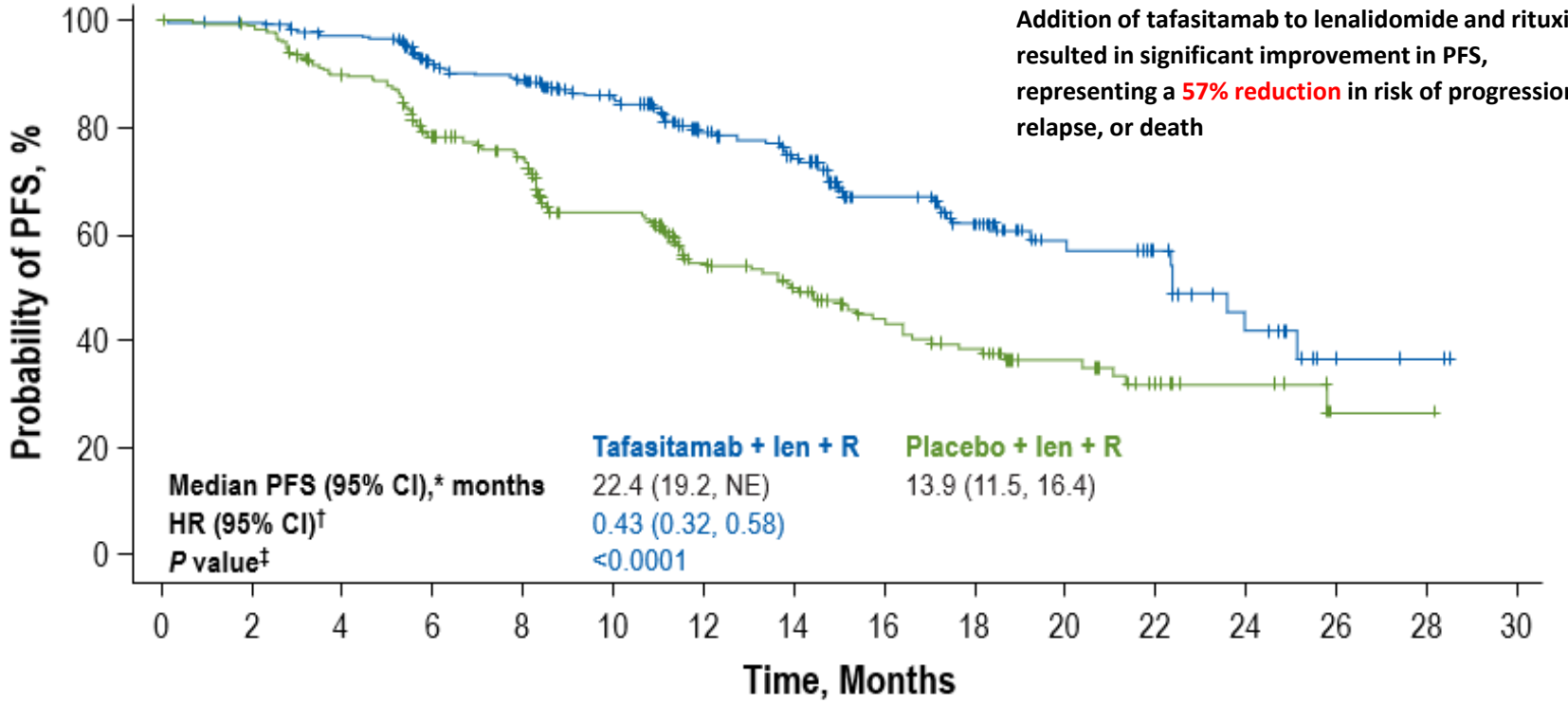
inMIND (NCT04680052) : Tafa-R2 vs placebo-R2

Variable	Tafasitamab + Len + R (n=273)	Placebo + Len + R (n=275)	Total (N=548)
Median age, years (range)	64.0 (36, 88)	64.0 (31, 85)	64.0 (31, 88)
≥75, n (%)	54 (19.8)	54 (19.6)	108 (19.7)
Male sex	150 (54.9)	149 (54.2)	299 (54.6)
Median time since initial diagnosis of FL, years (range)	5.2 (0, 34)	5.5 (1, 33)	5.3 (0, 34)
ECOG PS at screening, n (%)			
0	181 (66.3)	192 (69.8)	373 (68.1)
1-2	92 (33.7)	83 (30.2)	175 (31.9)
Ann Arbor stage, n (%)			
I or II/III or IV	52 (19.0)/221 (81.0)	50 (18.2)/225 (81.8)	102 (18.6)/446 (81.4)
FL grade, n (%)			
1 or 2/3A	203 (74.4)/67 (24.5)	203 (73.8)/71 (25.8)	406 (74.1)/138 (25.2)
B symptoms, n (%)	63 (23.1)	67 (24.4)	130 (23.7)
FLIPI score, n (%)			
0-1	57 (20.9)	57 (20.7)	114 (20.8)
2	79 (28.9)	67 (24.4)	146 (26.6)
3-5	137 (50.2)	150 (54.5)	287 (52.4)
GELF criteria, n (%)	222 (81.3)	232 (84.4)	454 (82.8)
FL diagnosis confirmed by central pathology, n (%)	256 (93.8)	259 (90.5)	505 (92.2)

Variable	Tafasitamab + Len + R (n=273)	Placebo + Len + R (n=275)	Total (N=548)
Median number of prior lines of therapy (range)	1.0 (1, 7)	1.0 (1, 10)	1.0 (1, 10)
1	147 (53.8)	153 (55.6)	300 (54.7)
2	66 (24.2)	71 (25.8)	137 (25.0)
3	39 (14.3)	30 (10.9)	69 (12.6)
≥4	21 (7.7)	21 (7.6)	42 (7.7)
Time since last antilymphoma therapy, n (%)			
≤2 years	147 (53.8)	157 (57.1)	304 (55.5)
>2 years	126 (46.2)	118 (42.9)	244 (44.5)
POD24, n (%)	85 (31.1)	88 (32.0)	173 (31.6)
Relapse/refractory status to last therapy, n (%)			
Relapsed	148 (54.2)	164 (59.6)	312 (56.9)
Refractory	112 (41.0)	97 (35.2)	209 (38.1)
Undetermined	13 (4.8)	14 (5.1)	27 (4.9)
Refractory to prior anti-CD20 therapy, n (%)	118 (43.2)	115 (41.8)	233 (42.5)

inMIND (NCT04680052) : Tafa-R2 vs placebo-R2

PFS by Investigator Assessment = primary endpoint



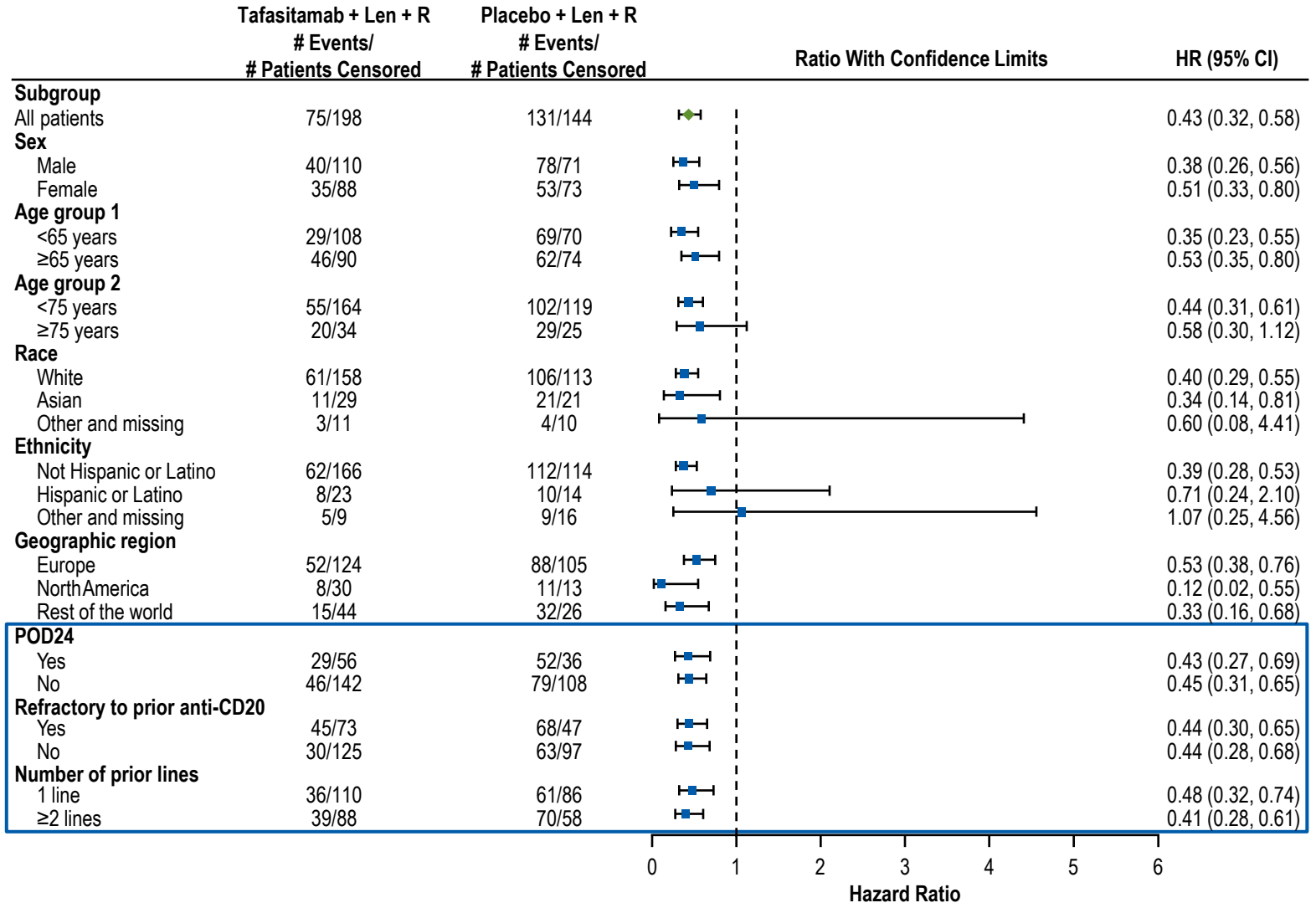
Addition of tafasitamab to lenalidomide and rituximab resulted in significant improvement in PFS, representing a 57% reduction in risk of progression, relapse, or death

No. at Risk																
Tafasitamab + len + R	273	261	250	212	200	164	119	103	71	57	30	22	12	3	2	0
Placebo + len + R	275	265	235	192	173	126	82	70	48	40	26	16	10	2	2	0

Significant improvement in PFS was observed with tafasitamab

Significant PFS benefit was confirmed by independent review committee

Subgroup Analysis of PFS (Prespecified Subgroups)



ITT population. Analysis by investigator assessment.

CI, confidence interval; HR, hazard ratio; ITT, intent-to-treat; len, lenalidomide; PFS, progression-free survival; POD24, progression of disease within 24 months; R, rituximab.

PET-CR and ORR

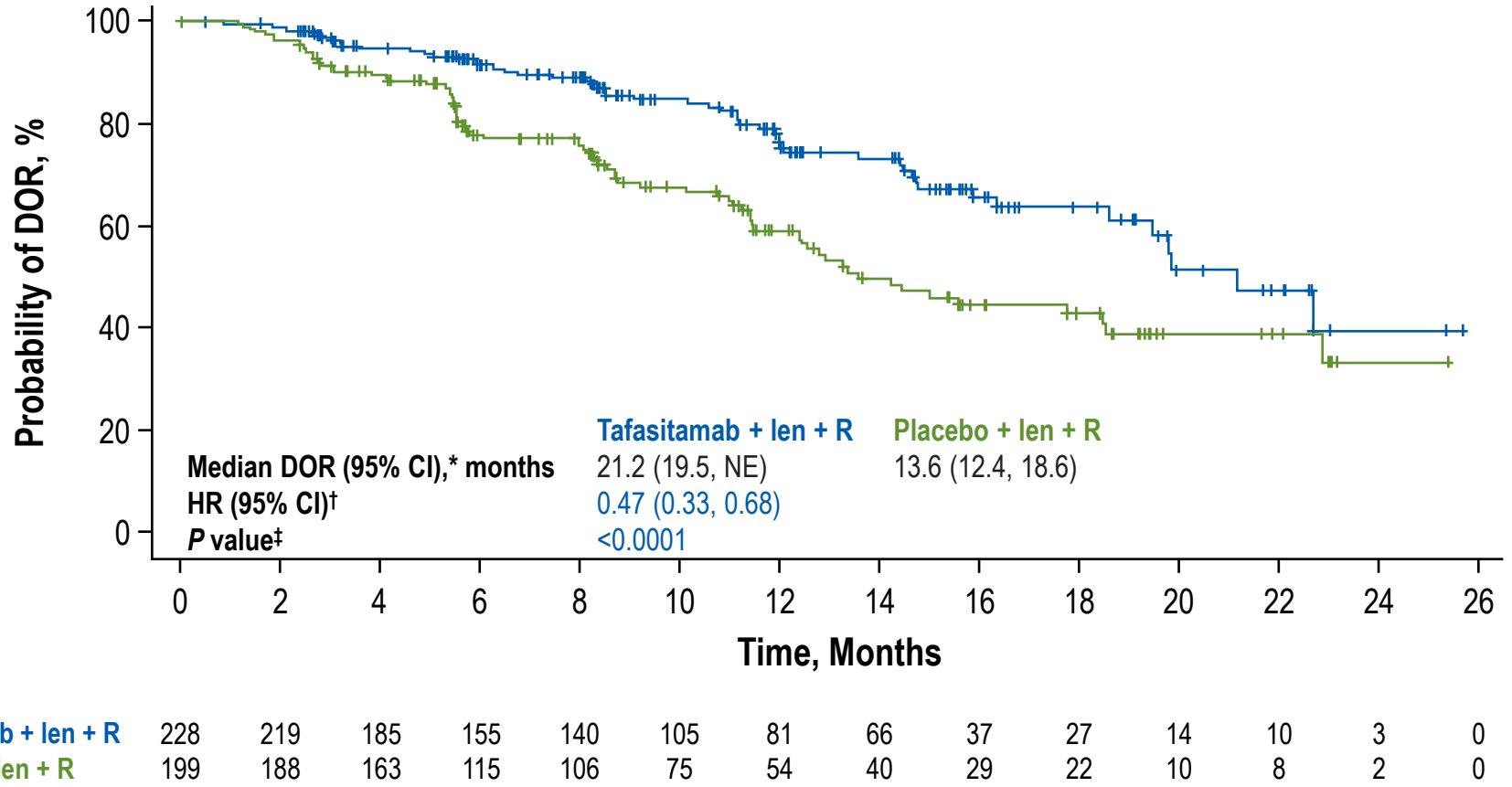
PET-CR (FDG-Avid Population)	Tafasitamab + Len + R	Placebo + Len + R
Patients with FDG-avid disease at baseline	251	254
Patients with postbaseline PET assessments, n (%)*	201/251 (80.1)	205/254 (80.7)
Best metabolic response based on PET, n (%)†		
CMR	124 (49.4)	101 (39.8)
PMR	37 (14.7)	39 (15.4)
NMR/SD	19 (7.6)	12 (4.7)
PMD	19 (7.6)	51 (20.1)
Not done	50 (19.9)	46 (19.3)
PET-CR rate, % (95% CI)	49.4 (43.1, 55.8)	39.8 (33.7, 46.1)
Odds ratio (95% CI)	1.5 (1.04, 2.13)	
Nominal *P* value	0.0286	

ORR (ITT Population)	Tafasitamab + Len + R	Placebo + Len + R
Patients, n	273	275
Best overall response, n (%)‡		
CR	142 (52.0)	112 (40.7)
PR	86 (31.5)	87 (31.6)
SD	28 (10.3)	46 (16.7)
PD	7 (2.6)	20 (7.3)
NE	2 (0.7)	0
Not done	8 (2.9)	10 (3.6)
ORR, % (95% CI)	83.5 (78.6, 87.7)	72.4 (66.7, 77.6)
Odds ratio (95% CI)	2.0 (1.30, 3.02)	
Nominal *P* value	0.0014	

Significant improvement in PET-CR rate and ORR was observed with tafasitamab

Analysis by investigator assessment.
*Calculated based on patients with a positive PET scan at baseline, defined as having a Deauville score of 4 or 5 at baseline. †Two patients (0.8%) in both arms had PET after confirmed PD or new antilymphoma treatment initiation. ‡Per Lugano 2014 classification.
CI, confidence interval; CMR, complete metabolic response; CR, complete response; FDG, fluorodeoxyglucose; ITT, intent-to-treat; len, lenalidomide; NE, not evaluable; NMR, nonmetabolic response; ORR, overall response rate; PD, progressive disease; PET, positron emission tomography; PET-CR, positron emission tomography-complete response; PMD, progressive metabolic disease; PMR, partial metabolic response; PR, partial response; R, rituximab; SD, stable disease.

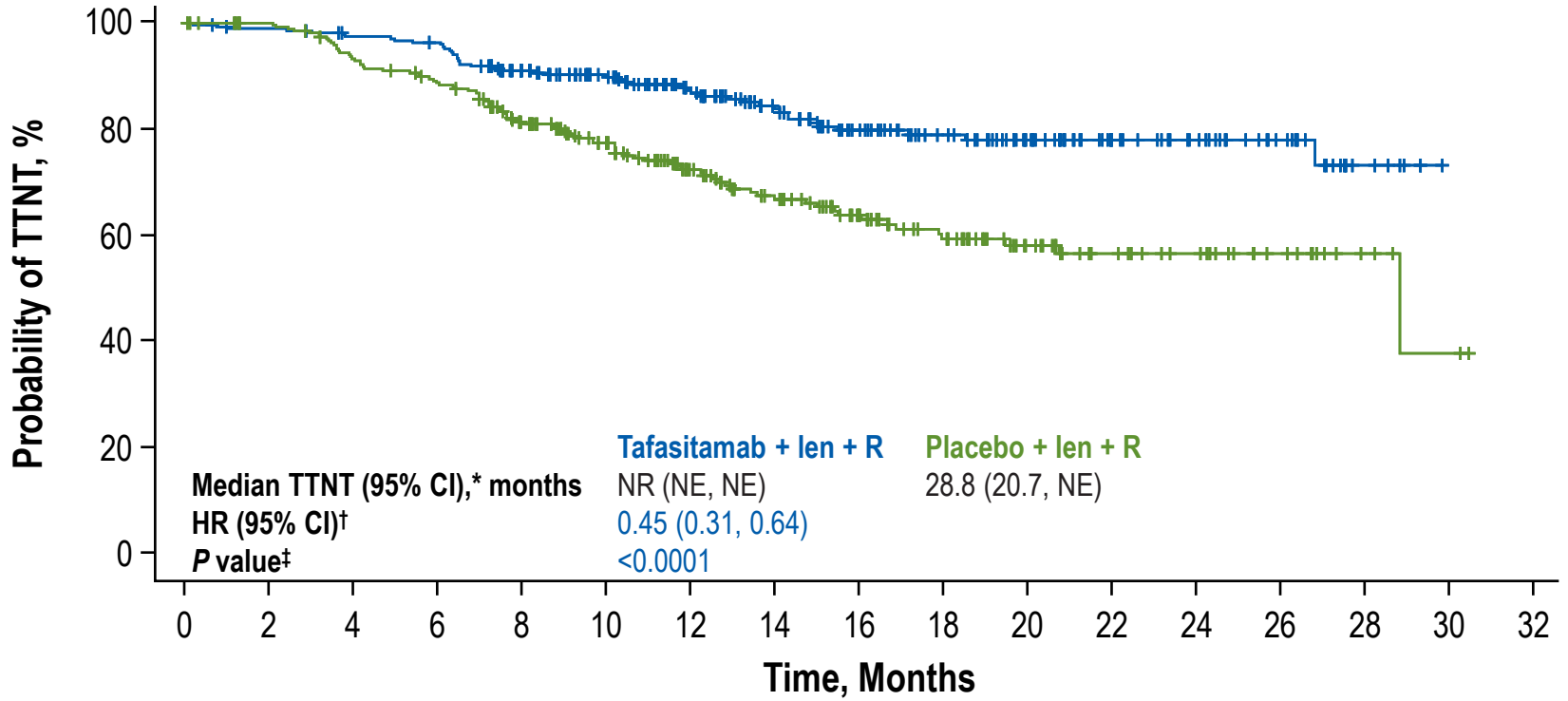
Duration of Response



Significant improvement in DOR was observed with tafasitamab

ITT population. Analysis by investigator assessment.
*Estimated using Kaplan-Meier method. †Estimated using a stratified Cox proportional hazard model. ‡Nominal *P* value; constructed using a Kaplan-Meier distribution function.
CI, confidence interval; DOR, duration of response; HR, hazard ratio; ITT, intent-to-treat; len, lenalidomide; NE, not evaluable; R, rituximab.

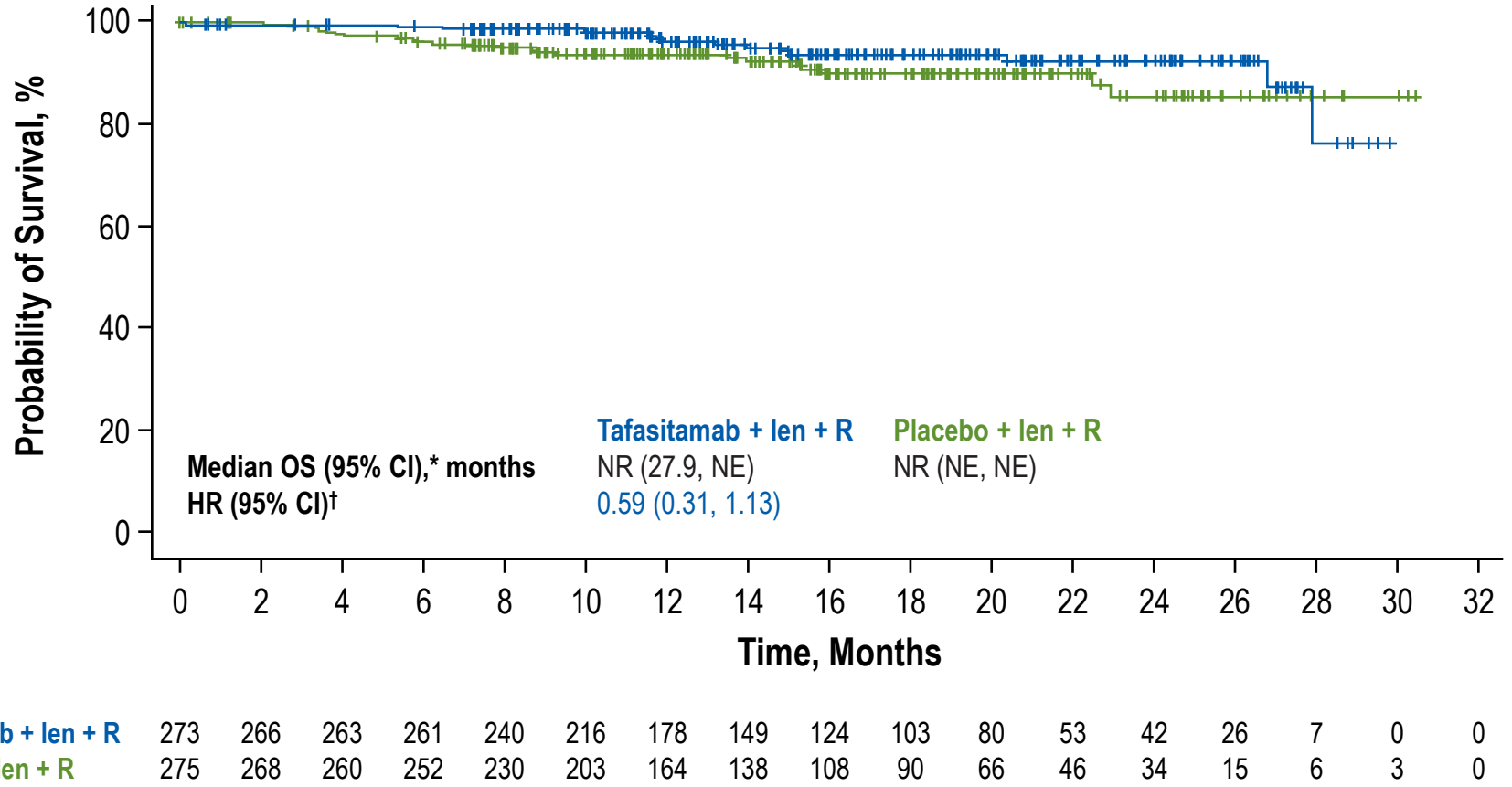
Time to Next Treatment



No. at Risk																
Tafasitamab + len + R	273	268	261	257	224	199	162	132	105	88	67	43	34	22	7	0	0
Placebo + len + R	275	268	248	233	199	166	124	101	78	62	43	30	23	13	5	2	0

ITT population. Analysis by investigator assessment.
*Estimated using Kaplan-Meier method. †Estimated using a stratified Cox proportional hazard model. ‡Nominal *P* value; stratified log-rank test.
CI, confidence interval; HR, hazard ratio; ITT, intent-to-treat; len, lenalidomide; NE, not evaluable; NR, not reached; R, rituximab; TTNT, time to next treatment.

Overall Survival



- OS was tested only for futility at the time of the primary analysis
- After a median follow-up of 15.3 months, the futility threshold was not crossed and a positive trend was observed

ITT population. Analysis by investigator assessment.
*Estimated using Kaplan-Meier method. †Estimated using a stratified Cox proportional hazard model.
CI, confidence interval; HR, hazard ratio; ITT, intent-to-treat; len, lenalidomide; NE, not evaluable; NR, not reached; OS, overall survival; R, rituximab.

Common Grade 3 or 4 TEAEs and Dose Modifications

Grade 3 or 4 TEAEs (≥5% in Any Group)

Preferred Term	Tafasitamab + Len + R (n=274)*	Placebo + Len + R (n=272)†	Total (n=546)
Neutropenia	109 (39.8)	102 (37.5)	211 (38.6)
Pneumonia	23 (8.4)	14 (5.1)	37 (6.8)
Thrombocytopenia	17 (6.2)	20 (7.4)	37 (6.8)
COVID-19	16 (5.8)	6 (2.2)	22 (4.0)
Neutrophil count decreased	16 (5.8)	18 (6.6)	34 (6.2)
COVID-19 pneumonia	13 (4.7)	3 (1.1)	16 (2.9)

- Dose interruptions or discontinuations due to TEAEs were **similar** between tafasitamab and placebo arms, n (%):
  - Dose delay or interruption due to TEAEs: 203 (74%) vs 190 (70%)
  - Discontinued study treatment due to TEAEs: 30 (11%) vs 18 (7%)
- Len discontinuations due to TEAEs were similar between tafasitamab and placebo arms, n (%):
  - 39 (14%) vs 31 (11%)
- Len dose reductions were similar between tafasitamab and placebo arms, n (%):
  - 1 dose reduction: 53 (19%) vs 44 (16%)
  - 2 dose reductions: 23 (8%) vs 14 (5%)
  - ≥3 dose reductions: 9 (3%) vs 9 (3%)

Safety population.
*One patient randomized to the placebo + len + R group is included in the tafasitamab + len + R safety population because the patient erroneously received tafasitamab.
†Three patients randomized to the placebo + len + R group are not included in the safety population because they erroneously received tafasitamab (n=1), or did not receive any study treatment due to confirmation of R hypersensitivity (n=1), or the patient withdrew from the study (n=1).
COVID-19, coronavirus disease 2019; len, lenalidomide; R, rituximab; TEAE, treatment-emergent adverse event.

Chemo-free regimens

- **AUGMENT : R2**
- **inMIND : Tafa-R2**
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- **EPCORE FL : Epco-R2**
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- **SYMPHONY 1 : Taz-R2**
- **SELENE, ROSEWOOD, MAHOGANY : BTKi**

Pivotal trials for CAR-Ts and BsAbs in 3L+ FL

	CAR-Ts			BsAbs		
	Axi-cel	Tisa-cel	Liso-cel	Mosunetuzumab	Epcoritamab	Odronextamab
Main characteristics						
References	(25-27)	(28, 29)	(30)	(46-48)	(49)	(50)
Primary end point	ORR	CRR	ORR	CRR	ORR	ORR
Route	IV	IV	IV	IV	SC	IV
Duration	Single	Single	Single	Fixed	Indefinite	Indefinite
Apheresis, N	127	98	114	—	—	—
Treated, N	124	97	107	90	128	128
Median age, y*	60 (53-67)	57 (49-64)	62 (23-80)	60 (53-67)	65 (39-84)	61 (22-84)
Male, n (%)	73 (59%)	64 (66%)	66 (62%)	55 (61%)	79 (62%)	53%
POD24, n (%)†	68 (56%)	61 (63%)	58 (54%)	47 (52%)	42%	49%
Stage III-IV, n (%)	106 (85%)	83 (86%)	95 (89%)	69 (77%)	85%	85%
High-risk FLIPI (≥3), n (%)	54 (44%)	58 (60%)	61 (57%)	40 (44%)	61%	58%
Prior HCT, %	24%	36%	31%	21%	19%	31%
Prior lines, median	3	4	3	3	3	3
Bridging, n (%)	4 (3%)	44 (45%)	44 (41%)	—	—	—
FU, months	53.7	28.9	17.6	37.4	17.7	22.4

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Efficacy - Pivotal trials for CAR-Ts and BsAbs in 3L+ FL

	CAR-Ts			BsAbs		
	Axi-cel	Tisa-cel	Liso-cel	Mosunetuzumab	Epcoritamab	Odronextamab
Efficacy						
ORR (%)	94%	86%	97%	80%	82%	81%
CRR (%)	79%	68%	94%	60%	63%	73%
PFS, median (mo)	57.3	NR	NR	24	15.4	20.7
DoR, median (mo)	55.5	NR	NR	35.9	NR	22.6
TTNT, median (mo)	62.2	NR	NR	37.3	NR	—
OS, median (mo)	NR	NR	NR	NR	NR	NR

Iacoboni G and Morschhauser F. Blood 2025

Safety - Pivotal trials for CAR-Ts and BsAbs in 3L+ FL

	CAR-Ts			BsAbs		
	Axi-cel	Tisa-cel	Liso-cel	Mosunetuzumab	Epcoritamab	Odronextamab
Safety						
CRS, any (%)	78%	49%	59%	44%	66%	57%‡
CRS G ≥3 (%)	6%	0	1%	2%	2%	2%‡
ICANS, any (%)	56%	4%	15%	6%	6%	2%‡
ICANS G ≥3 (%)	15%	1%	2%	0	0	0

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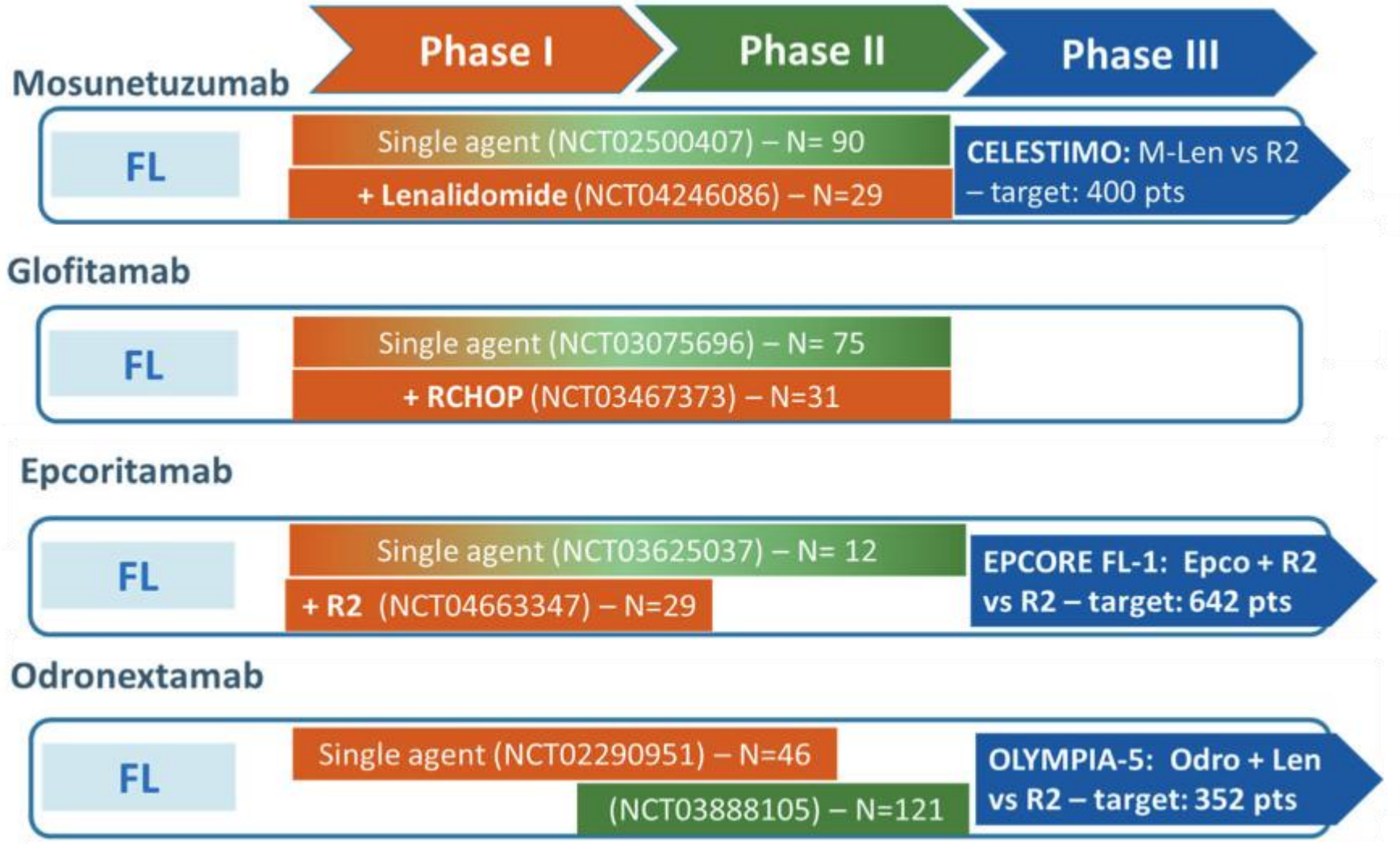
Phase III combined trials with BsAbs in R/R FL



Modified from Abou Dalle et al. Blood Cancer Journal (2024) 14:23

Mosunetuzumab plus lenalidomide (M-Len) in R/R FL with ≥1 prior line (NCT04246086)

Key inclusion criteria

- CD20+ FL Grade 1–3a
- R/R to ≥1 prior chemo-immunotherapy regimen including an aCD20 antibody; prior lenalidomide allowed
- ECOG PS 0–2

Objectives

- Primary: safety and tolerability of M-Len
- Other: efficacy (response, durability of response) and pharmacokinetics

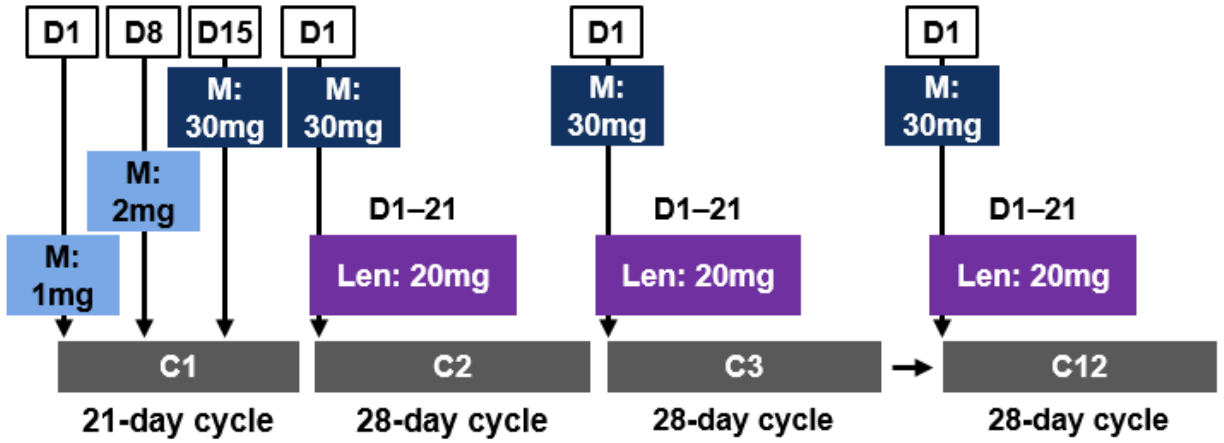
M-Len administration

Mosunetuzumab

- IV administration for 12 cycles (C1: Q3W; C2–12: Q4W)
- C1 step-up dosing (CRS mitigation)
- No mandatory hospitalization

Lenalidomide

- Oral administration for 11 cycles (C2–12)



Franck Morschhauser et al. ASH 2024 NCT04246086. Available at:https://clinicaltrials.gov/ct2/home

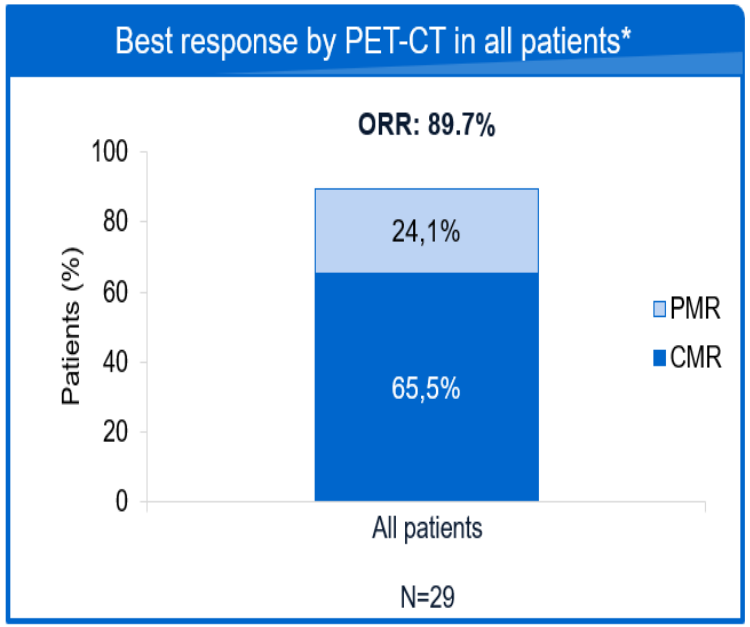
Mosunetuzumab plus lenalidomide (M-Len) in R/R FL with ≥1 prior line (NCT04246086)

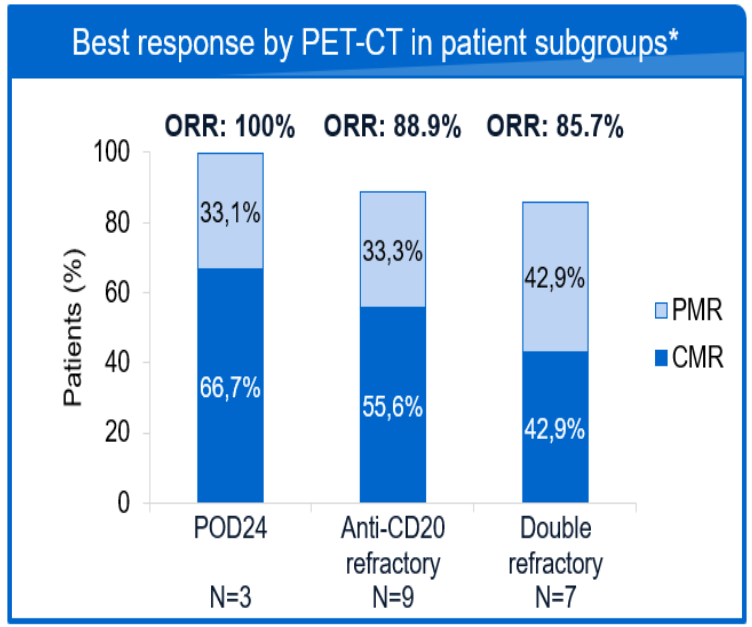
- Median duration of follow-up: 5.4 months (range: 3–12)

Baseline Characteristics

	N=29
Age in years, median (range)	59 (30–79)
Male	13 (44.8%)
Ann Arbor stage at study entry	
I–II	2 (6.8%)
III–IV	27 (93.1%)
FLIPI risk factors at study entry	
0–1	7 (24.1%)
2	8 (27.6%)
3–5	14 (48.3%)
Number of prior lines of therapy, median (range)	1 (1–6)
1 prior line	16 (55.2%)
≥2 prior lines	13 (44.8%)
Refractory to any prior aCD20 therapy	9 (31.0%)
Refractory to any prior aCD20 therapy AND an alkylating agent (double refractory)	7 (24.1%)
POD24	3 (10.3%)

Best response





- Median time to first / best response: 2.5 mo (range: 1.4–5.3) / 2.5 mo (range: 1.4–10.7)

- **Most patients had advanced stage disease**
- **31.0% were refractory to aCD20 therapy**

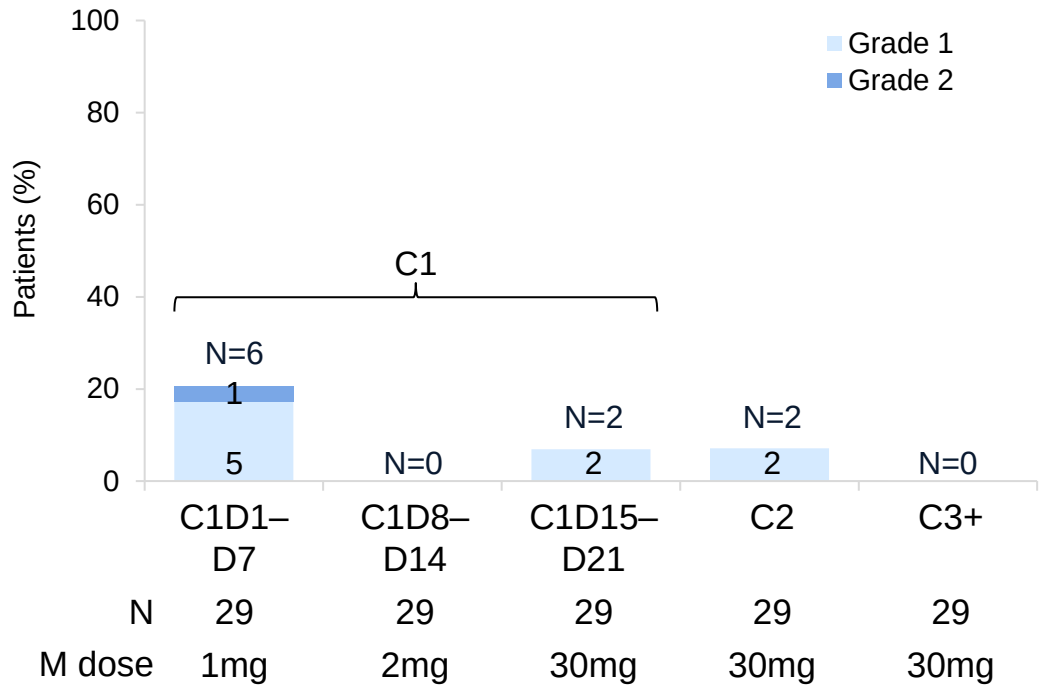
- **High ORR and CMR rate in overall population**
  - **and in patients with high-risk disease**

Franck Morschhauser et al. ASH 2024 NCT04246086. Available at:https://clinicaltrials.gov/ct2/home

Cytokine release syndrome

	N=29
CRS (any Grade)*	8 (27.6%)
Grade 1	7 (24.1%)
Grade 2	1 (3.4%)†
Grade ≥3	0
Serious AE of CRS (any Grade)	4 (13.8%)‡
Median time to first CRS onset, days (range)	1 (1–28)
Median CRS duration, days (range)	3 (2–5)
Corticosteroids for CRS management	0
Tocilizumab for CRS management	0
CRS leading to mosunetuzumab discontinuation	0
CRS resolved	8 (100%)

Patients (%) with CRS by Cycle and Grade



- **CRS was low Grade and confined to C1–2. No increase in rate or severity with addition of lenalidomide.**

*assessed using ASTCT criteria[1]; †patient with WBC of 108k/uL at treatment initiation and circulating FL; patient had fever and hypoxia that required 2L nasal cannula oxygen; ‡Grade 1: 3 patients (10.3%); Grade 2: 1 patient (3.4%)

1. Lee et al. Biol Blood Marrow Transplant 2019;25:625–38

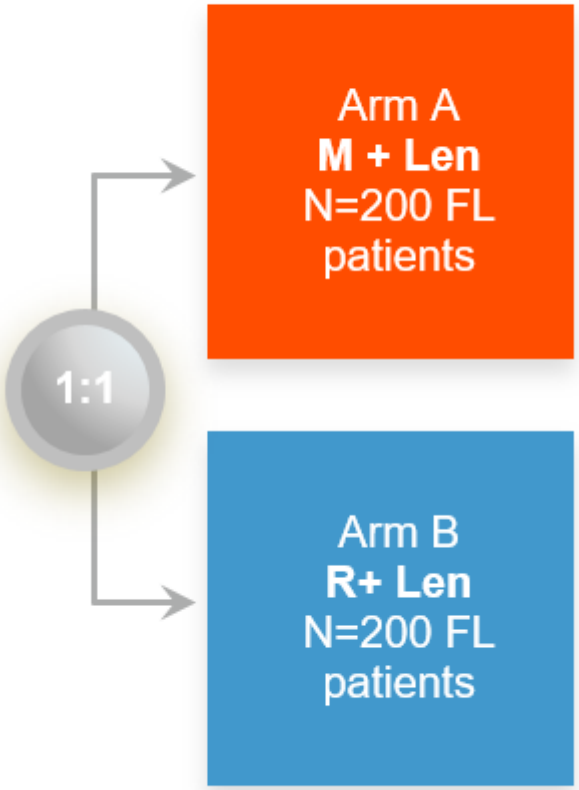
CELESTIMO Study Design

Eligibility

- Histologically confirmed diagnosis of FL (Grade 1, 2 or 3a)
- >=1 prior systemic therapy for FL

Stratification:

- POD24 vs non POD24
- 1 prior therapy vs >1 prior therapy
- CD20 therapy refractory vs not



Endpoints

1° EP: PFS by IRC

2° EP:

- PFS by INV
- ORR, CR
- OS
- DOR
- DOCR
- QoL
- Safety
- Pharmacokinetics
- Biomarkers

Exploratory:

- TTNLT
- TTR
- PFS2
- EFS
- Histologic transformation rate

EPCORE NHL-2 Trial

Fixed-Duration Epcoritamab + R²

Study Design: EPCORE® NHL-2 Arm 2

Key inclusion criteria

- R/R CD20⁺ FL
  - Grade 1–3A
  - Stage II–IV
- ≥1 prior treatment, including an anti-CD20 antibody
- Need for treatment per GELF criteria[1]
- ECOG PS 0–2
- Measurable disease by CT or MRI
- Adequate organ function

Data cutoff: May 15, 2024
Median follow-up: 25.3 months

Concomitant fixed-duration epcoritamab 48 mg + R²
(28-day cycles up to 2 years)

	Agent	C1	C2	C3	C4–5	C6–9	C10–12	C13+
2–step-up-dose regimen[a]	Epcoritamab SC 48 mg							
	Cohort A[b]	QW			Q2W		Q4W	
	Cohort B[b]	QW		Q4W				
R²	Rituximab IV 375 mg/m²	QW	Q4W					
	Lenalidomide PO 20 mg/d	D1–21 of each cycle						

Primary endpoint: ORR per Lugano criteria[c]

Key secondary endpoints: CR rate, DOR, DOCR, PFS, TTNT, OS, MRD analysis,[d] and safety and tolerability

Falchi L et al. ASH 2024

EPCORE NHL-2 Trial

Baseline Characteristics	N=111
Median age, y (range)	65 (30–80)
Male sex at birth, n (%)	56 (50)
Race, n (%)[a]	
White	80 (72)
Asian	2 (2)
Black or African American	2 (2)
Other	2 (2)
Ethnicity, n (%)[b]	
Hispanic or Latino	3 (3)
Not Hispanic or Latino	23 (21)
Ann Arbor stage, n (%)[c]	
III	24 (22)
IV	68 (61)
Histologic grade, n (%)[d]	
1–2	77 (69)
3A	29 (26)
FLIPI, n (%)[e]	
0–2	46 (41)
3–5	65 (59)
Bulky disease (≥7 cm), n (%)	31 (28)

Treatment History	N=111
POD24 (any 1L treatment), n (%)[f]	55 (50)
POD24 (1L CIT), n (%)[g]	42 (38)
Primary refractory, n (%)[h]	39 (35)
Double refractory, n (%)[i]	39 (35)
Median time from diagnosis to first dose, mo (range)	63 (2–331)
Median time from end of last line of therapy to first dose, mo (range)	19 (0.6–198)
Median number of prior lines of therapy (range)	1 (1–7)
1 prior line, n (%)	63 (57)
≥2 prior lines, n (%)	48 (43)
Prior systemic therapies, n (%)[j]	
Anti-CD20	111 (100)
Alkylating agents	103 (93)

Best Response, n (%)[a]	N=111
Overall response	107 (96)
Complete response	97 (87)
Partial response	10 (9)
Progressive disease	2 (2)

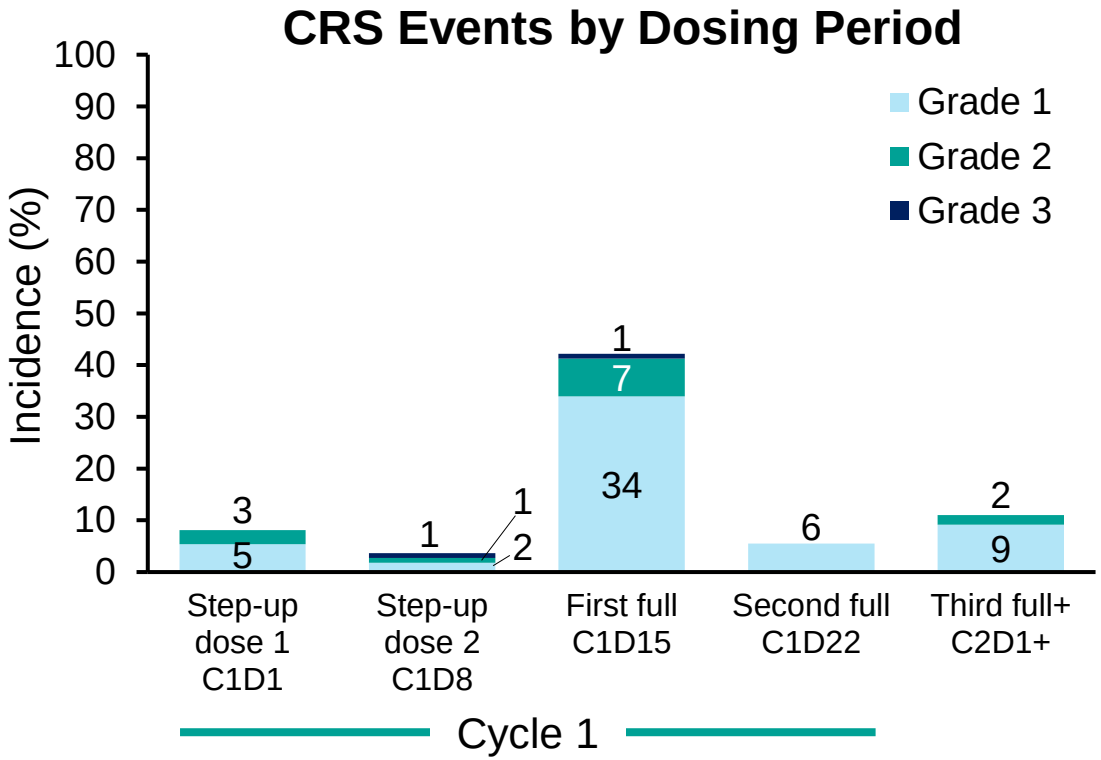
MRD Negativity, n/n (%)	MRD Evaluable
MRD negativity at any time[b]	66/75 (88)
MRD negative and complete response[c]	63/68 (93)
MRD negativity in high-risk subgroups[d]	
POD24 (1L CIT)	26/30 (87)
Primary refractory	25/28 (89)
Double refractory	23/27 (85)

- **ORR was 96% and CR rate was 87% in the overall population**, with a notably higher
  CR rate observed in 2L FL patients (CR rate, 92%)
- MRD-negativity rate was 88%, and MRD negativity correlated with PFS
- Estimated 21-month PFS rates were 80% overall and 86% among MRD-negative patients

Falchi L et al. ASH 2024

Primarily Low-Grade CRS and ICANS With 2 Step-Up Doses; Timing of CRS Was Predictable

	N=111
CRS, n (%)[a]	57 (51)
Grade 1	42 (38)
Grade 2	13 (12)
Grade 3	2 (2)
Median time to onset after first full dose, d (range)	2 (1–9)
CRS resolution, n/n (%)	57/57 (100)
Median time to resolution, d (range)[b]	2 (1–23)
Treated with tocilizumab, n (%)	14 (13)
Leading to epcoritamab discontinuation, n (%)	**0**



- A grade 1 ICANS event occurred; the event resolved in 7 days without treatment and did not lead to treatment discontinuation

[a]Graded by Lee et al 2019 criteria.[1] [b]Median is Kaplan–Meier estimate based on longest CRS duration in patients with CRS. **1.** Lee DW, et al. *Biol Blood Marrow Transplant*. 2019;25:625-38.

Falchi L et al. ASH 2024

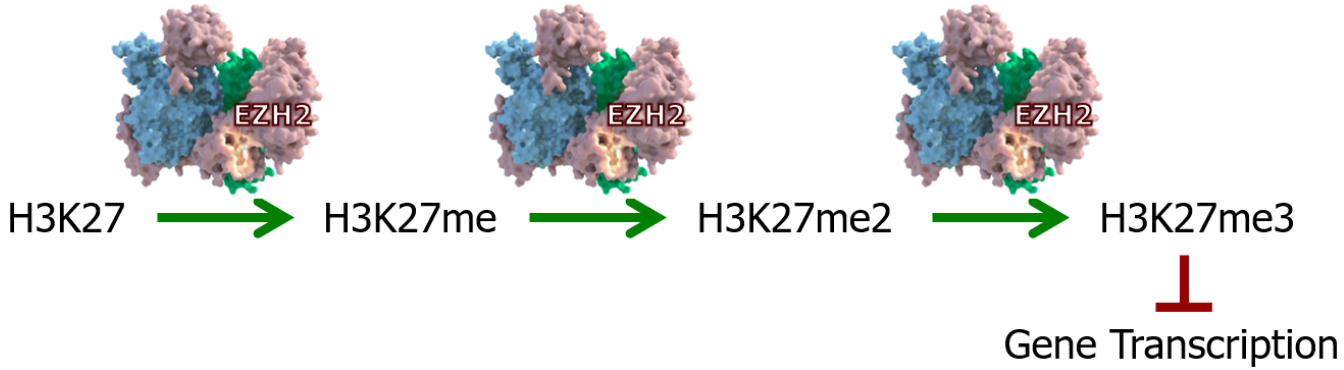
Chemo-free regimens

- **AUGMENT : R2**
- **inMIND : Tafa-R2**
- **CELESTIMO : Mosun-Len**
- **EPCORE FL : Epco-R2**
- **OLYMPIA-5 : Odro-len**
- **SYMPHONY 1 : Taz-R2**
- **SELENE, ROSEWOOD, MAHOGANY : BTKi**

Tazemetostat in FL

Tazemetostat is a first-in-class, selective, oral inhibitor of mutant and wild-type EZH2

- EZH2 an epigenetic regulator
- EZH2 is the catalytic subunit of the multi-protein PRC2 (polycomb repressive complex 2)
- PRC2 is the only protein methyltransferase that can methylate H3K27
  - Catalyzes mono-, di- and tri-methylation of H3K27
  - H3K27me3 is a transcriptionally repressive histone mark
- H3K27 is the only significant substrate for PRC2
- Aberrant trimethylation of H3K27 is oncogenic in a broad spectrum of human cancers, such as B-cell NHL



Activating mutations of EZH2 are present in approximately 20% of patients with follicular lymphoma.

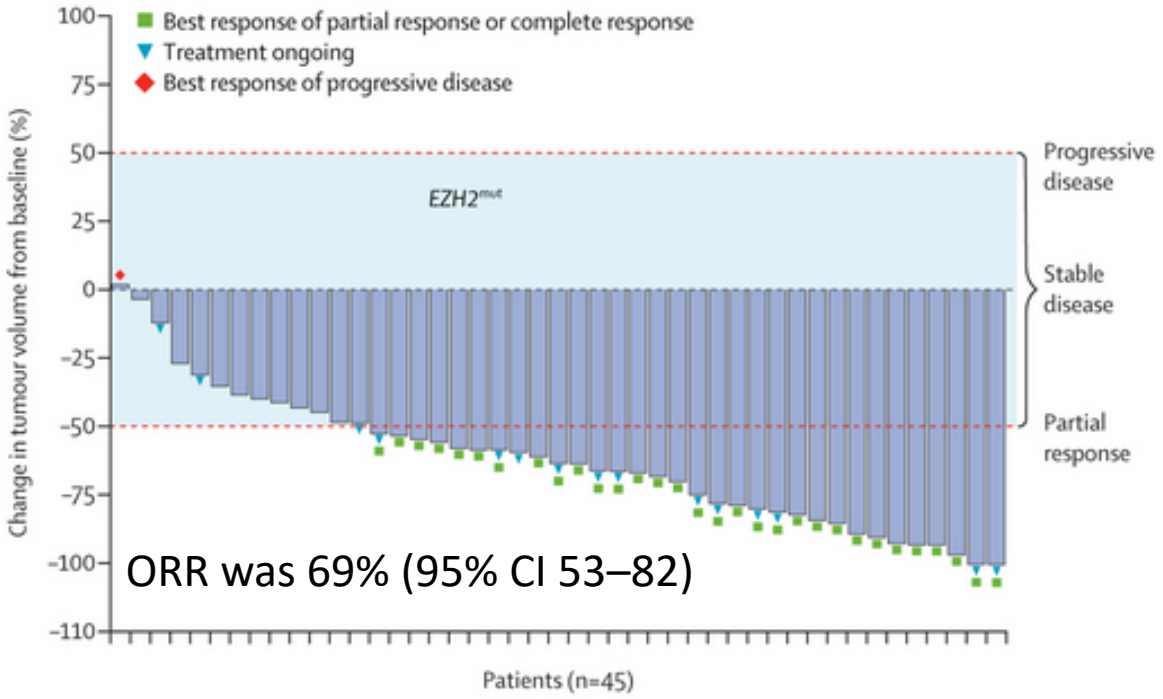
Chase & Cross, Clin. Cancer Res., 2011

Tazemetostat in R/R FL follicular lymphoma

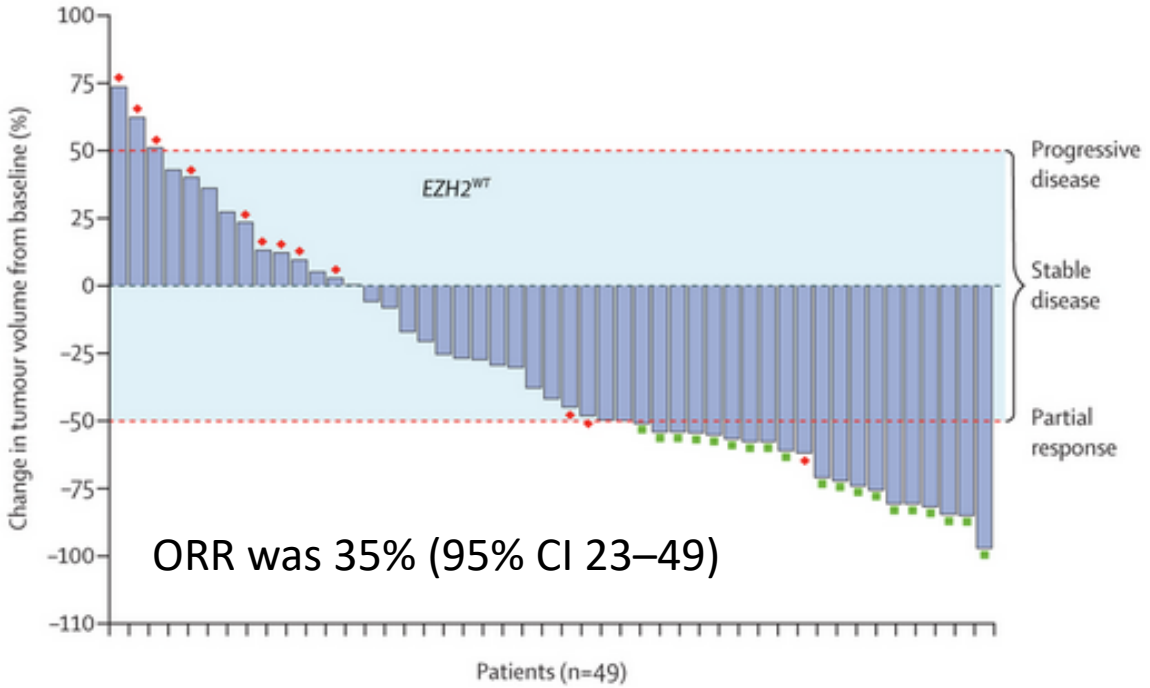
open-label, single-arm, multicentre, phase 2 trial

median follow-up
22·0 months (IQR 12·0-26·7) for the EZH2^{mut} cohort
35·9 months (24·9-40·5) for the EZH2^{WT} cohort

EZH2mut cohort



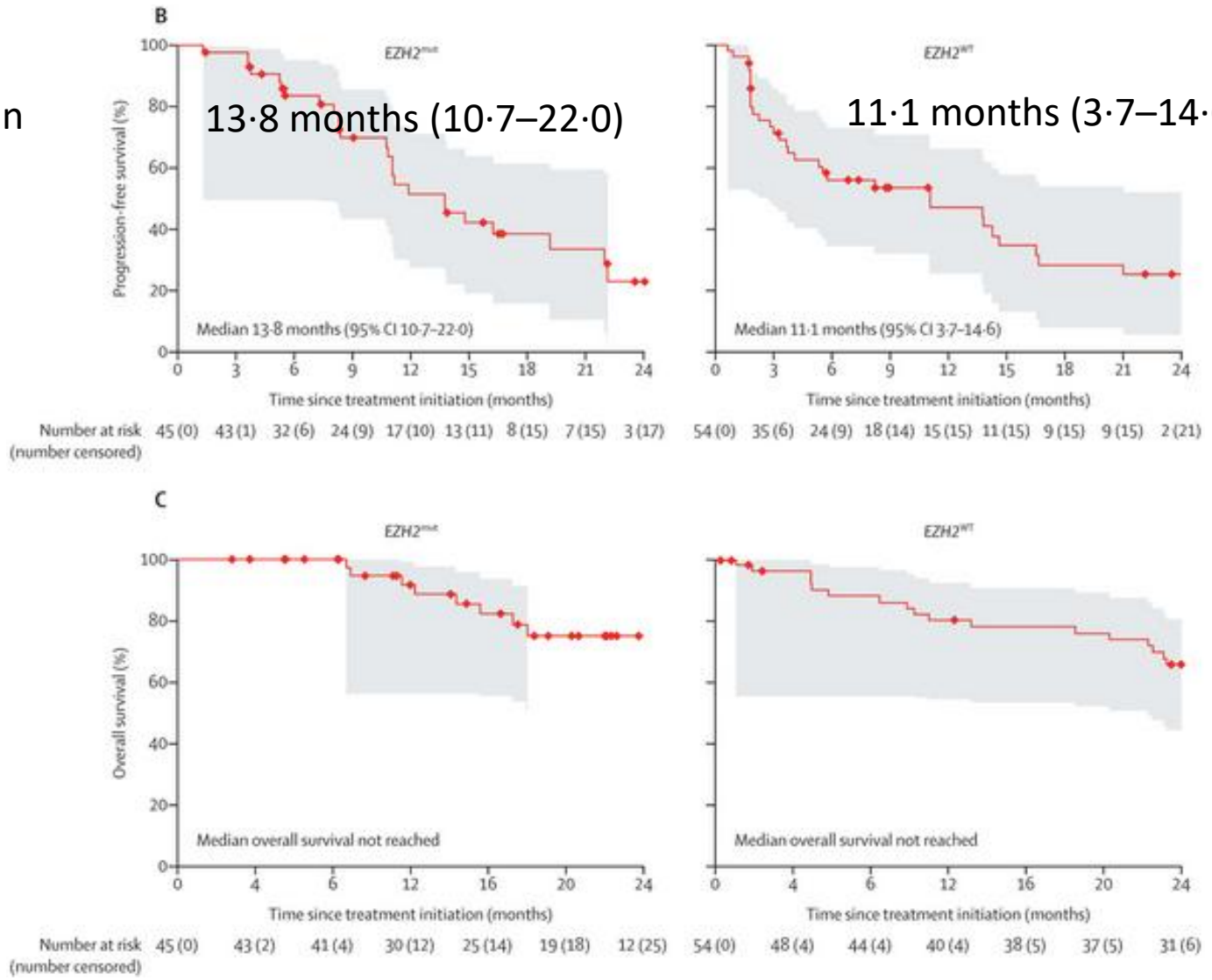
EZH2WT cohort



Morschhauser et al. Lancet Oncol . 2020 Nov;21(11):1433-1442

Tazemetostat in R/R FL follicular lymphoma

median progression free survival



Morschhauser et al. Lancet Oncol . 2020 Nov;21(11):1433-1442

Background and SYMPHONY-1 phase 1b trial design

Dose-escalating 3+3 design

Patients with R/R FL (N=44)

TAZ (12 cycles):
400/600/800 mg PO BID*
Rituximab (5 cycles):
375 mg/m^2 IV†
Lenalidomide (12 cycles):
20/10 mg PO QD‡

RP3D:
800 mg BID
TAZ (24 cycles)§

- **Primary endpoints:** Safety and tolerability, RP3D of TAZ in combination with R[2]
- **Secondary endpoints:** PK parameters
- **Efficacy analysis (ITT):** Best overall response, PFS and DOR (investigator assessment, according to Lugano 2014 response criteria)[1]

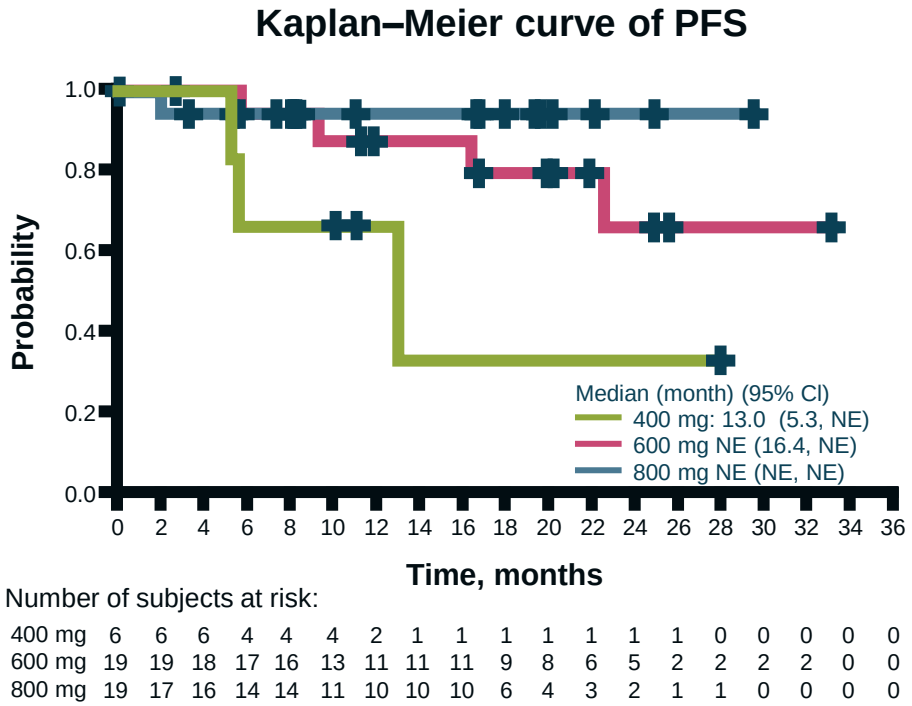
- EZH2 is an important regulator of B cell development; gain of function mutations (MT EZH2) or uncontrolled upregulation of wild type (WT) EZH2 may lead to the development of FL, making EZH2 a therapeutic target in FL[2–4]
- TAZ is a small molecule inhibitor of the epigenetic enzyme EZH2[2–4]

- TAZ is FDA-approved[5] for treatment of adult patients with:
  - R/R FL with MT EZH2 and ≥2 prior therapies
  - R/R FL with no satisfactory alternative treatment options

*28-day cycles for 12 cycles in combination, followed by 24 cycles maintenance open-label TAZ monotherapy; †Days 1, 8, 15, and 22 of cycle 1; then day 1 of cycles 2–5; ‡Depending on creatinine clearance; days 1–21 for 12 cycles; §After initial 12 months of combination therapy, TAZ 800 mg BID continued until disease progression, unacceptable toxicity, or withdrawal of consent.
BID, twice daily; DOR, duration of response; EZH2, enhancer of zeste homolog; FDA, US Food and Drug Administration; FL, follicular lymphoma; ITT, intent-to-trat; IV, intravenous; MT, mutant; PFS, progression-free survival; PK, pharmacokinetic; PO, oral administration; QD, once daily; R^2, lenalidomide and rituximab; RP3D, recommended phase 3 dose; R/R, relapsed/refractory; TAZ, tazemetostat.
1. Cheson BD, et al. J Clin Oncol 2014;32:3059–3068; 2. Huet S, et al. Blood Cancer J 2017;7:e555; 3. Batlevi CL, et al. Blood 2022;140:2296–2298;
4. Morschhauser F, et al. Lancet Oncol 2020;21:1433–1442; 5. 2. TAZVERIK® (tazemetostat). Prescribing Information. Updated June 2020. Available at: accessdata.fda.gov/drugsatfda_docs/label/2020/213400s000lbl.pdf. Last accessed October 2023.

Courtesy Vincent Ribrag

Long-lasting PFS and durable response at TAZ RP3D (800 mg) + R^2



	TAZ dose + R^2			
DOR event rate, % (95% CI)	400 mg (n=6)	600 mg (n=19)	800 mg (n=19)	otal (N=44)
6 months	66.7 (19.5, 90.4)	94.4 (66.6, 99.2	100.0 (100.0, 100.0)	92.2 77.8, 97.4)
12	33.3 (1.4, 75.5)	87.7 (58.8, 96.8	100.0 (100.0, 100.0)	85.1 67.3, 93.6)
18	33.3 (1.4, 75.5)	79.7 (48.7, 93.1	100.0 (100.0, 100.0)	81.0 61.8, 91.2)
24	33.3	66.4	100.0	72.0

- Median PFS and DOR were not reached at 22.5 months
- PFS appeared dose-dependent
- 18-month PFS estimates:
  - 79.5% (ITT; N=44)
  - 94.4% (800 mg cohort; n=19)

Kaplan-Meier estimate for DOR events at each timepoint by dose group (ITT). DOR defined for each subject with response as time from first date of response (complete or partial, whichever is first) to first objectively documented disease progression or death.
CI, confidence interval; DOR, duration of response; ITT, intent-to-treat; NE, not evaluable; PFS, progression-free survival; R^2, lenalidomide and rituximab; TAZ, tazemetostat.

Courtesy Vincent Ribrag

Chemo-free regimens

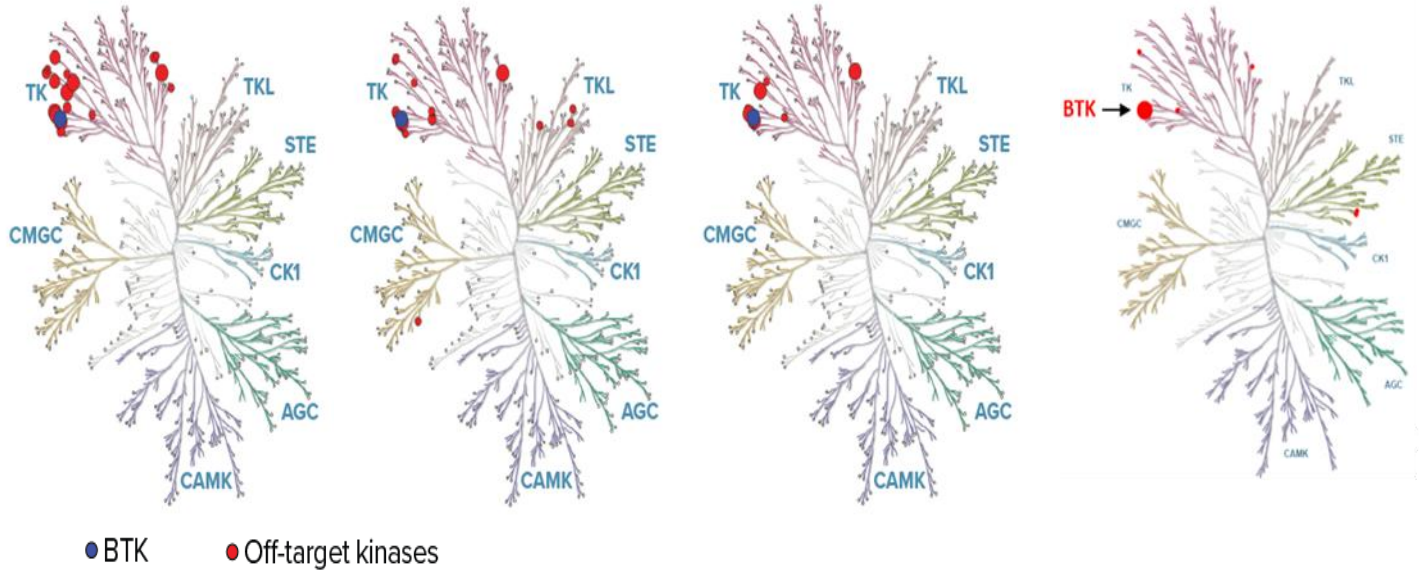
- AUGMENT : R2
- inMIND : Tafa-R2
- CELESTIMO : Mosun-Len
- EPCORE FL : Epco-R2
- OLYMPIA-5 : odronextamab
- SYMPHONY 1 : Taz-R2
- SELENE, ROSEWOOD, MAHOGANY : BTKi

BTK inhibitors

BTKi	Mechanism
Covalent	
First Generation	
Ibrutinib[1]	Irreversible Binding to Cysteine-481
Second Generation	
Acalabrutinib[2]	Irreversible Binding to Cysteine-481
Next Generation	
Zanubrutinib[3]	Irreversible Binding to Cysteine-481
Non-Covalent	
Pirtobrutinib[4]	Reversible Binding to ATP-pocket

Target

Ibrutinib[5] **Acalabrutinib**[5] **Zanubrutinib**[5] **Pirtobrutinib**[6-9]



Assayed by Reaction Biology Corp. at **100X of IC50** (against BTK) concentration with IC50 (BTK)s of 0.71±0.09, 0.32±0.09, and 24±9.2, for zanubrutinib, ibrutinib, and acalabrutinib, respectively.

Please note, the use of different assays used for the Shadman analyses on zanubrutinib, ibrutinib, and acalabrutinib vs the Mato analysis for pirtobrutinib may result in different selectivity outcomes.

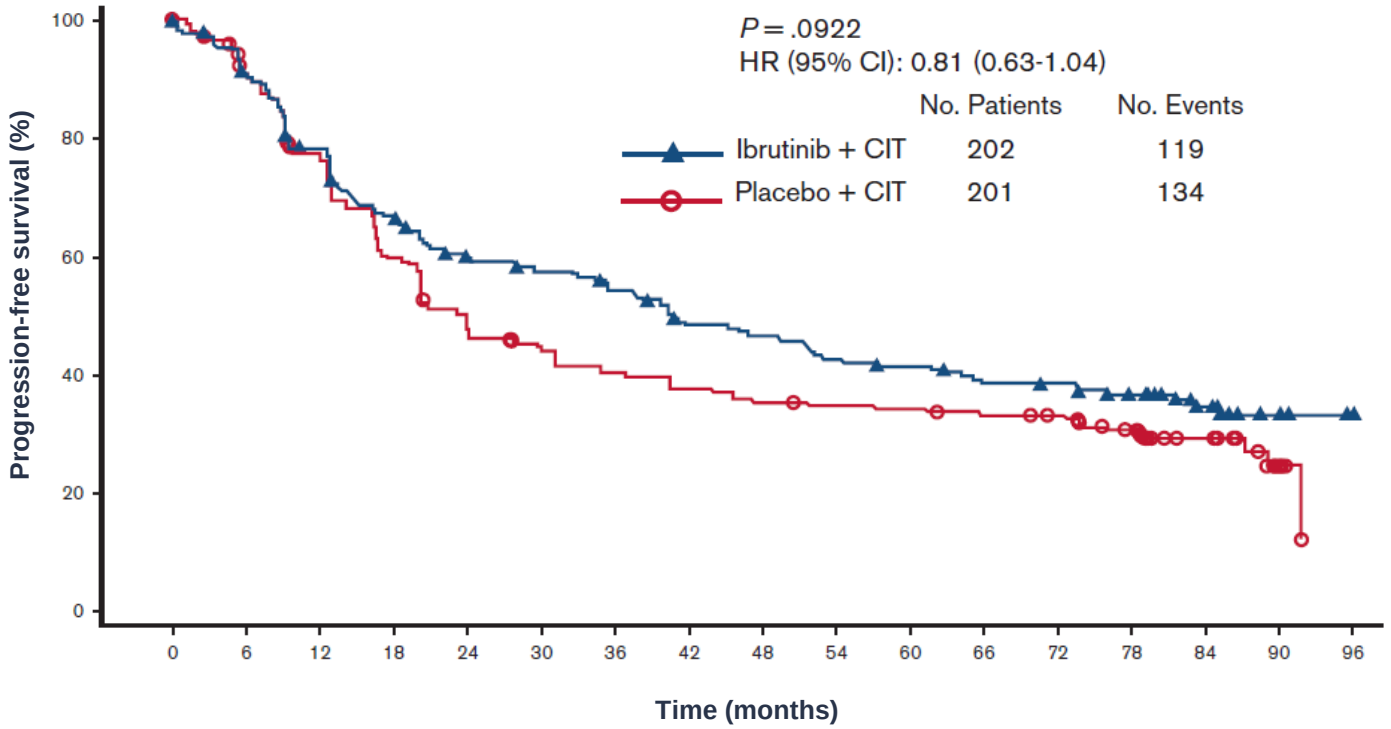
BTK, Bruton tyrosine kinase; IC_{50}, half-maximal inhibitory concentration.

1) Imbruvica SmPC. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/imbruvica; 2) Calquence SmPC. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/calquence; 3) Brukinsa SmPC. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/brukinsa; 4) Jaypirca SmPC. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/jaypirca.
Adapted from 5) Shadman M et al. Lancet Haematol. 2023;10(1):e35-e45; 6) Mato AR et al. Lancet. 2021;397(10277):892-901; 7) Munir T et al. Presented at the BSH; 3-5 April 2022; Manchester, UK (Poster PO55). Available at: https://www.postersessiononline.eu/173580348_eu/congresos/BSH2022/aula/-PO_55_BSH2022.pdf; 8) Brandhuber BJGE and Smith S. Clin Lymphoma Myeloma Leuk. 2018;18:S216; 9) Gomez EB at al. Blood. 2023;142(1):62–72.

Ibrutinib for R/R FL or MZL

SELENE: Phase 3 study of Ibru + CIT vs CIT

Investigator-assessed PFS[1]



Ibrutinib monotherapy:

- Phase 2 DAWN trial[2]: ORR 20.9%, CR 11%
- Phase 2 consortium[3]: ORR 37.5%, CR 12.5%

Summary[1]

- Most patients (86.1%) had FL
- CIT was BR (90.3%) or R-CHOP
- The addition of Ibru to CIT did not significantly improve PFS compared with placebo + CIT
- The safety profile was consistent with known profiles of ibrutinib and CIT

This slide includes data from different clinical trials. These data are meant for demonstration purposes only and are not meant for cross-trial comparison purposes.
BR, bendamustine and rituximab; CIT, chemoimmunotherapy; FL, follicular lymphoma; HR, hazard ratio; Ibru, ibrutinib; MZL, marginal zone lymphoma; PFS, progression-free survival; R-CHOP, rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone; R/R, relapsed/refractory.
Adapted from 1) Nastoupil LJ et al. Blood Adv. 2023;7(22):7141–7150; 2) Gopal AK et al. J Clin Oncol. 2018;36(23):2405-2412; 3) Bartlett NL et al. Blood. 2018;131(2):182-190.

Zanubrutinib Plus Obinutuzumab Versus Obinutuzumab in Patients With R/R Follicular Lymphoma: Updated Analysis of the ROSEWOOD Phase 2 Study

ROSEWOOD Study design[1]

Key eligibility criteria

- Age ≥18 years
- Grade 1-3A R/R FL
- Previous treatment with ≥2 lines of therapy, including an anti-CD20 antibody and an alkylating agent
- Measurable disease
- ECOG PS of 0-2
- Adequate organ function
- No prior BTK inhibitor

127 sites; 17 countries/regions
Randomized November 2017 to June 2021

Arm A
Zanubrutinib[a] + obinutuzumab[b] (N=145)
Until PD or **unacceptable toxicity**

Randomization 2:1
Stratification factors
- Number of prior lines of treatment
- Rituximab-refractory status
- Geographic region

Arm B
Obinutuzumab[b] (N=72)
Option to cross over to combination if PD is centrally confirmed or if there is no response at 12 months

Primary endpoint
- ORR by IRC according to Lugano 2014 classification[2]

Other endpoints
- DOR by IRC[c]
- PFS by IRC[c]
- OS[c]
- TTNT
- Safety (AEs)[c]

[a]Zanubrutinib was given orally at 160 mg twice daily; [b]Obinutuzumab was given intravenously at 1000 mg in both arms on days 1, 8, and 15 of cycle 1, day 1 of cycles 2-6, and then every 8 weeks up to a maximum of 20 doses; [c]Secondary endpoint.
AE, adverse event; BTK, Bruton tyrosine kinase; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; FL, follicular lymphoma; IRC, independent review committee; ORR, objective response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; R/R, relapsed or refractory; TTNT, time to next treatment.
1) Adapted from Zinzani PL et al. Zanubrutinib Plus Obinutuzumab Versus Obinutuzumab in Patients With Relapsed/Refractory Follicular Lymphoma: Updated Analysis of the ROSEWOOD Study. Presented at the 17th International Conference on Malignant Lymphoma; June 13-17, 2023; Lugano, Switzerland; Abstract 81 (Accessed 04 June 2024). Available at: Zinzani_BGB-3111-212_ICML_Presentation_2023.pdf; 2) Cheson BD et al, J Clin Oncol. 2014;32(27):3059-3067.

ROSEWOOD: Study population was heavily pretreated and had refractory disease

Characteristics	Zanu + Obi (n=145)	Obi (n=72)
Age, median (range), years	63.0 (31-84)	65.5 (32-88)
ECOG PS of ≥1, n (%)	59 (40.6)	41 (57.0)
FLIPI score of ≥3, n (%)	77 (53.1)	37 (51.4)
Ann Arbor stage III-IV, n (%)	119 (82.1)	60 (83.3)
Bulky disease (≥7 cm), n (%)	**23 (15.9)**	**12 (16.7)**
High LDH level (>ULN), n (%)	49 (33.8)	29 (40.3)
High tumor burden per GELF criteria, n (%)	**83 (57.2)**	**40 (55.6)**
No. of prior lines of therapy, median (range)	3 (2-11)	3 (2-9)
Refractory to rituximab, n (%)	**78 (53.8)**	**36 (50.0)**
Refractory to most recent line of therapy, n (%)	**47 (32.4)**	**29 (40.3)**
PD ≤24 months after starting first line of therapy, n (%)	**50 (34.5)**	**30 (41.7)**
Prior therapy, n (%)		
Chemoimmunotherapy	143 (98.6)	71 (98.6)
Anthracyclines	118 (81.4)	57 (79.2)
Cyclophosphamide	136 (93.8)	68 (94.4)
Bendamustine	79 (54.5)	40 (55.6)

ECOG PS, Eastern Cooperative Oncology Group performance status; FLIPI, Follicular Lymphoma International Prognostic Index; GELF, Groupe d'Etude des Lymphomes Folliculaires; LDH, lactate dehydrogenase; Obi, obinutuzumab; PD, progressive disease; ULN, upper limit of normal; Zanu, zanubrutinib.
Adapted from Zinzani PL et al. J Clin Oncol. 2023;41(33):5107-5117.

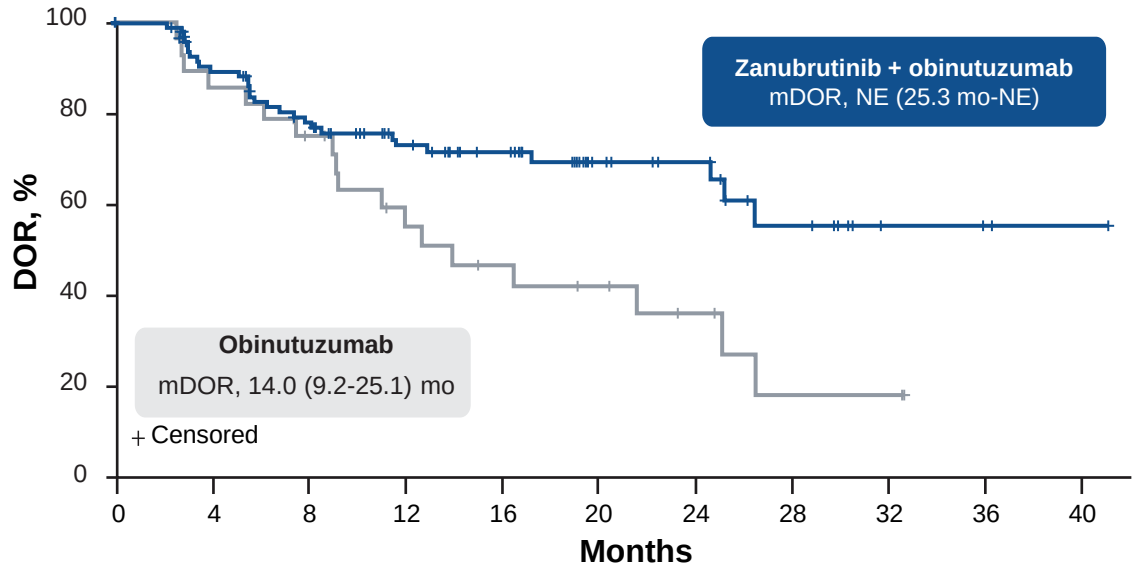
ROSEWOOD: ORR difference by IRC was 22.7% in favor of Zanu-Obi at median study follow-up of 20.2 months

Endpoint	Zanu + Obi (n=145)	Obi (n=72)	2-sided *P* value
ORR by IRC[a] (95% CI), %	**69.0** (60.8-76.4)	**45.8** (34.0-58.0)	.0012
CR	**39.3**	**19.4**	.0035
PR	29.7	26.4	–
DOR by IRC			
Median (95% CI), months	NE (25.3-NE)	14.0 (9.2-25.1)	–
18-month DOR rate (95% CI), %	**69.3** (57.8-78.2)	**41.9** (22.6-60.1)	–
DOCR by IRC			
Median (95% CI), months	NE (26.5-NE)	26.5 (2.7-NE)	–
18-month DOCR rate (95% CI), %	**87.4** (73.8-94.2)	**51.1** (21.0-74.9)	–

[a]ORR difference by IRC was 22.7%; 95% CI, 9.0%–36.5%.
CR, complete response; DOCR, duration of CR; DOR, duration of response; IRC, independent review committee; NE, not estimable; Obi, obinutuzumab; ORR, objective response rate; PR, partial response; Zanu, zanubrutinib.
Adapted from Zinzani PL et al. J Clin Oncol. 2023;41(33):5107-5117.

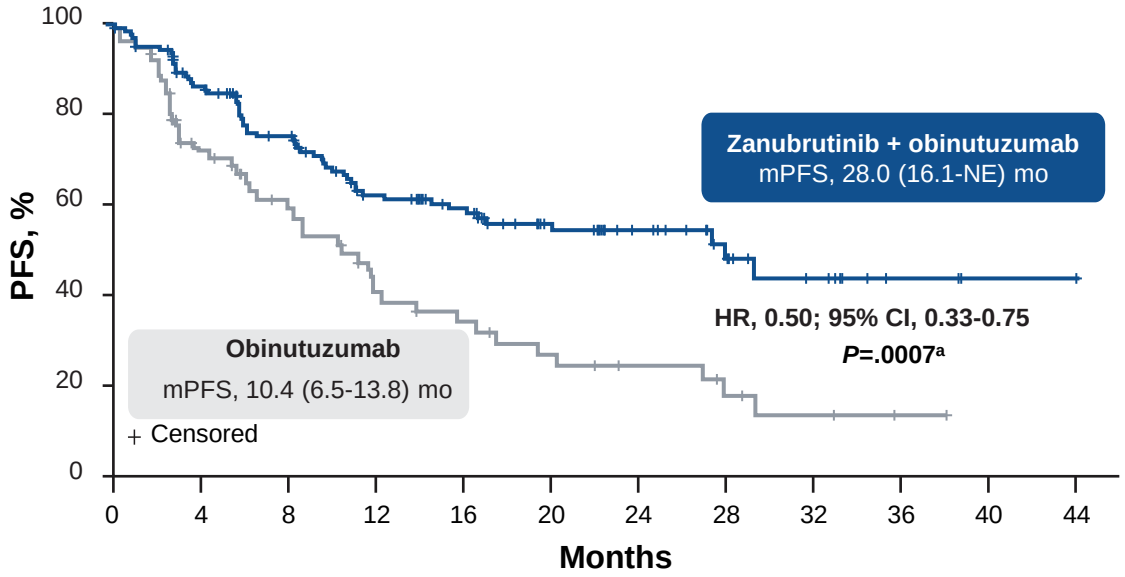
ROSEWOOD: DOR and PFS were longer with Zanu-Obi

DOR by IRC



No. at risk																						
Zanubrutinib + obinutuzumab	100	97	82	73	68	59	51	43	40	33	23	21	19	12	10	7	3	3	2	1	1	0
Obinutuzumab	33	29	24	23	20	16	13	11	10	9	8	6	5	3	2	2	2	0				

PFS by IRC

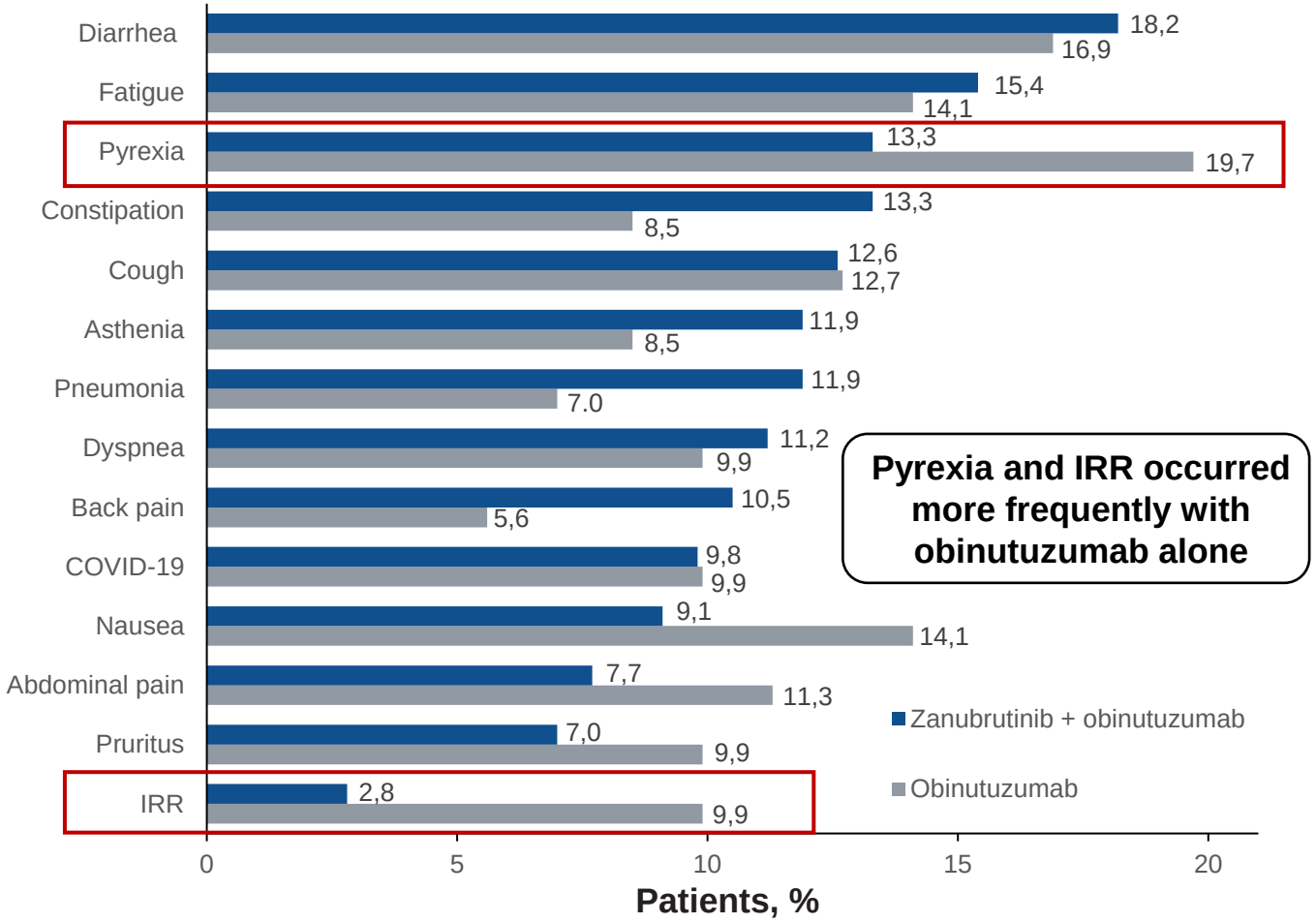


No. at risk																						
Zanubrutinib + obinutuzumab	145	135	116	96	92	79	67	62	56	45	38	35	25	22	15	10	9	5	3	3	1	1	0
Obinutuzumab	72	63	42	34	30	27	19	16	15	12	11	9	8	8	5	3	3	2	1	1	0		

[a]Descriptive 2-sided P value.
DOR, duration of response; HR, hazard ratio; IRC, independent review committee; mDOR, median DOR; mPFS, median progression-free survival; NE, not estimable; Obi, obinutuzumab; zanu, zanubrutinib.
Adapted from Zinzani PL et al. J Clin Oncol. 2023;41(33):5107-5117.

ROSEWOOD: There were no unexpected safety findings with Zanu-Obi

Common nonhematologic TEAEs (any grade)



Grade ≥3 non-hematologic TEAEs

n (%)	Zanu + Obi (n=143)	Obinutuzumab (n=71)
Pneumonia	14 (9.8)	3 (4.2)
COVID-19	8 (5.6)	2 (2.8)
COVID-19 pneumonia	5 (3.5)	2 (2.8)
Diarrhea	4 (2.8)	1 (1.4)
Febrile neutropenia	3 (2.1)	1 (1.4)
Atrial fibrillation	2 (1.4)	0
IRR	1 (0.7)	3 (4.2)
Hypertension	1 (0.7)	1 (1.4)

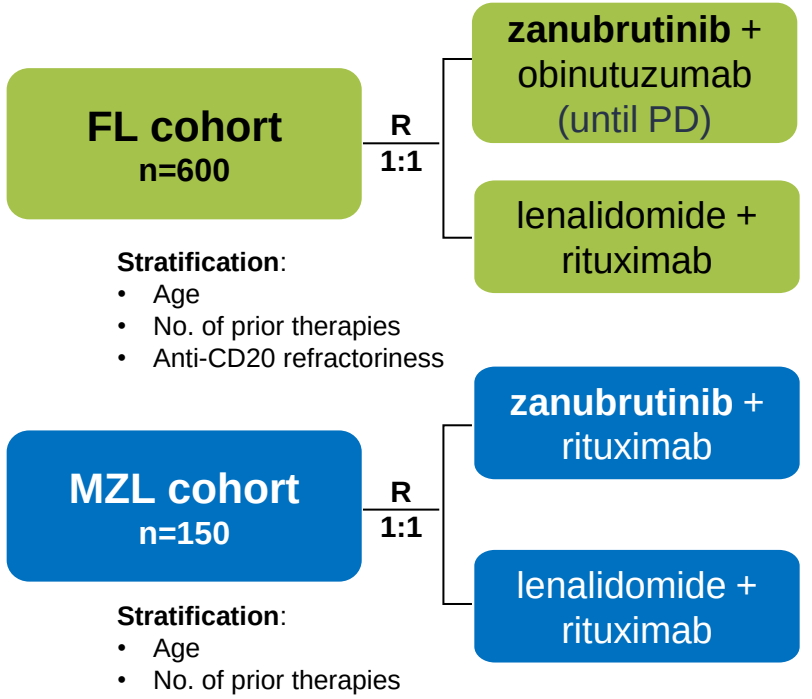
IRR, injection-related reaction; Obi, obinutuzumab; TEAE, treatment-emergent adverse event; Zanu, zanubrutinib.
Adapted from Zinzani PL et al. J Clin Oncol. 2023;41(33):5107-5117.

MAHOGANY: Phase 3 study design

- MAHOGANY (BGB-3111-308; NCT05100862) is a randomized, open-label, multicenter phase 3 trial of **zanubrutinib + anti-CD20 antibody** in R/R FL and with R/R MZL

Key eligibility criteria

- Age ≥18 years
- Histologically confirmed R/R FL (grade 1-3A) or MZL (extranodal, nodal, or splenic)
- **Previous treatment with ≥1 prior line of systemic therapy**, including an anti-CD20–based regimen
- In need of treatment according to modified GELF criteria[1]
- Adequate bone marrow and organ functions
- No prior treatment with BTK inhibitor
- Prior lenalidomide treatment allowed unless no response or short remission (DOR <24 months)
- No clinically significant cardiovascular disease, severe or debilitating pulmonary disease, or history of a severe bleeding disorder



Primary endpoint
PFS

Secondary endpoints
ORR
OS
TTNT
HR-QoL
Safety

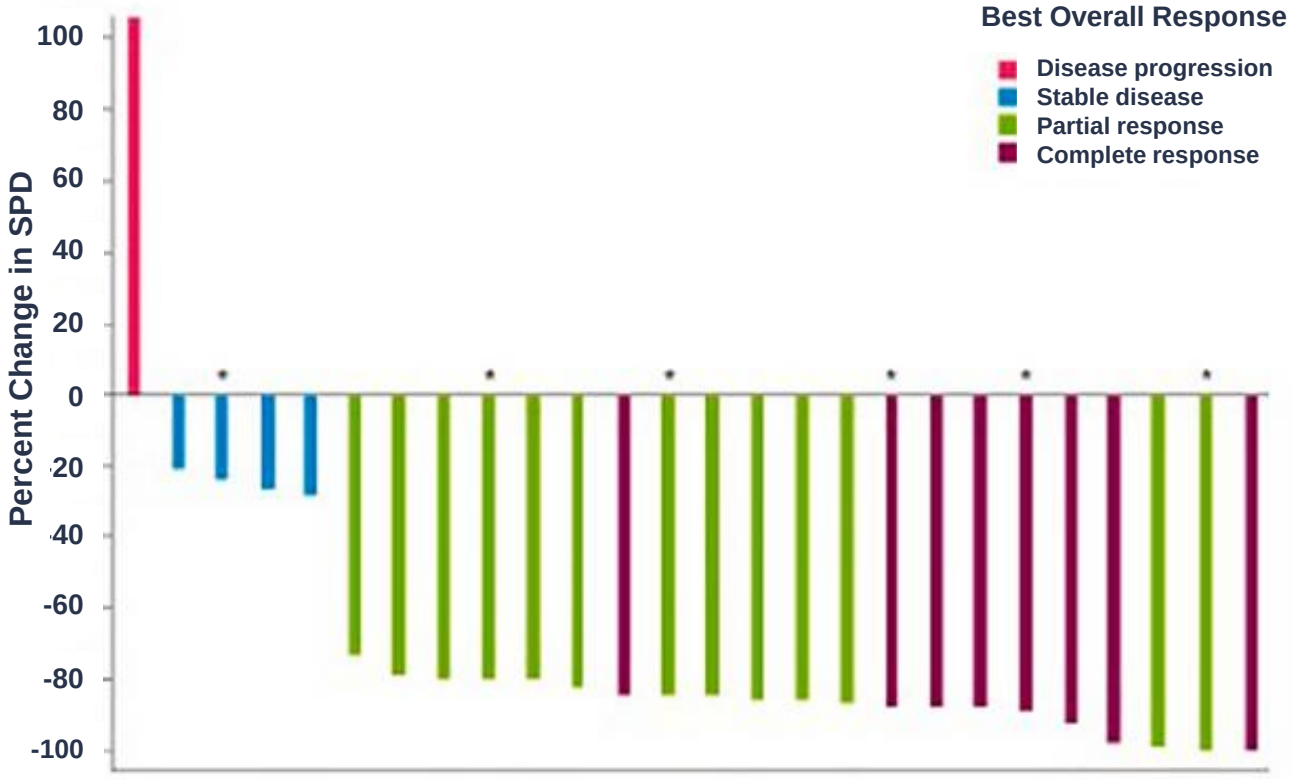
BTK, Bruton tyrosine kinase; DOR, duration of response; FL, follicular lymphoma; GELF, Groupe d'Etude des Lymphomes Folliculaires; HR-QoL; health-related quality of life; MZL, marginal zone lymphoma; ORR, overall response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; R/R, relapsed/refractory; TTNT, time to next treatment.

Adapted from Sehn LH et al. MAHOGANY: A Phase 3 Trial of Zanubrutinib Plus Anti-CD20 Antibodies vs Lenalidomide Plus Rituximab in Patients With Relapsed or Refractory Follicular or Marginal Zone Lymphoma. Presented at 17th International Conference on Malignant Lymphoma, June 13-17, 2023; Lugano, Switzerland; Abstract 994 (Accessed 04 June 2024).
Available at: Sehn_BGB-3111-308_ICML_Presentation_2023.pdf.

Phase 1 study: acalabrutinib and R^2 in patients with relapsed FL

Summary of Safety Profile and Efficacy Results

Best % change from baseline in sum of product diameters in Part 3 (A+R^2 in R/R FL)



Summary:

- The combination of A + rituximab was well tolerated in TN FL and R/R FL
- The addition of lenalidomide 20 mg suggests improved ORR in R/R FL compared with A alone
- Further studies of this regimen in FL are needed

* Indicates patient who received lenalidomide 15 mg. All other patients received lenalidomide 20 mg.

A, acalabrutinib; AE, adverse event; CI, confidence interval; CR, complete response; K-M, Kaplan-Meier; ORR, overall response rate; PD, progressive disease; PR, partial response; R^2, lenalidomide and rituximab; R/R, relapsed/refractory; SD, stable disease; SPD, sum of product diameters; TEAE, treatment-emergent AE; TN, treatment naïve.

Adapted from Strati P et al, Blood. 2022;140(Supplement 1):3606–3608.

Conclusion

- **The therapeutic landscape of FL is rapidly evolving, with many ongoing trials in the R/R and 1L setting**
- **Results are awaited to state their potential to replace CIT and reshape the treatment algorithm in R/R and 1L**
- **BsAbs might be prioritized in earlier lines**
- **Are these T-CELL REDIRECTING THERAPIES going to CURE FL?**

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- Patients and their families
- Research nurses and study coordinators

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