

Follicular Lymphoma

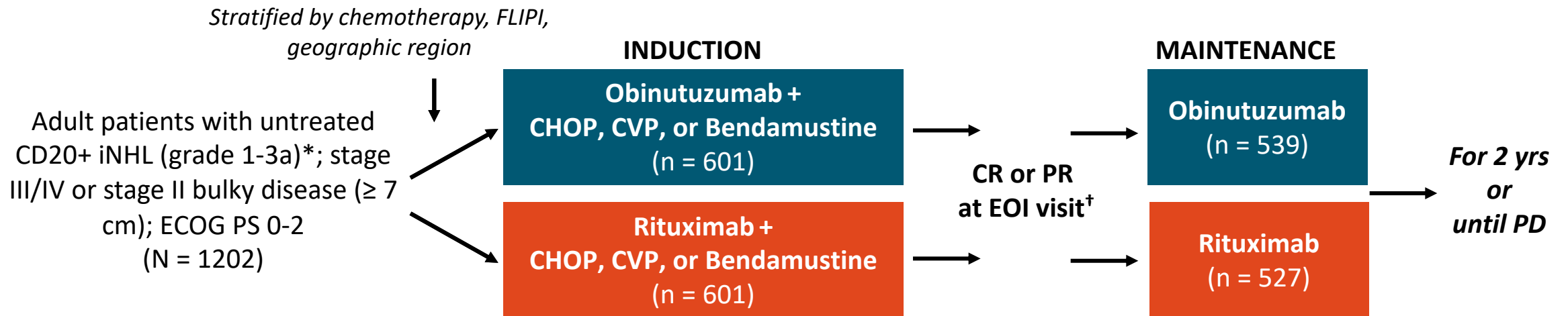
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GALLIUM: Frontline Obinutuzumab-Based vs Rituximab-Based Chemoimmunotherapy

- International randomized, open-label phase III study
 - Obinutuzumab was designed to achieve enhanced therapeutic activity compared with rituximab



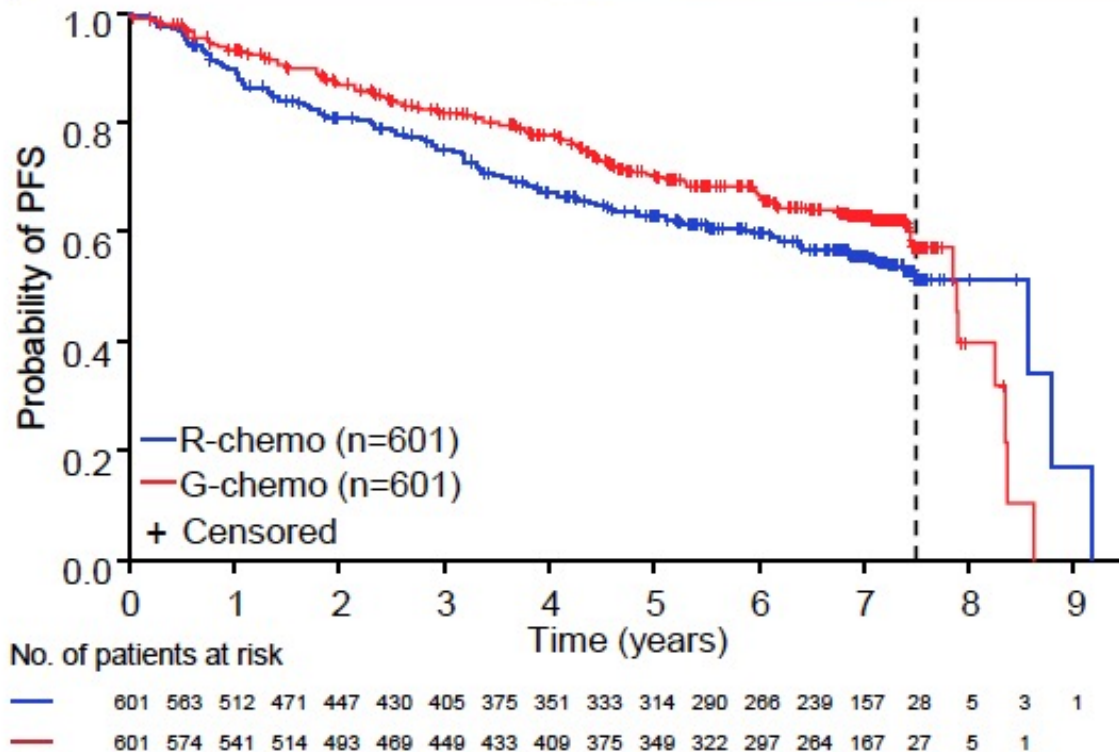
*All data presented for patients with FL, although study also enrolled patients with MZL (randomized separately).

[†]Patients with SD at EOI followed up to 2 yrs for PD.

- Primary endpoint: PFS by investigator in patients with FL
- Secondary endpoints: PFS by IRC, OS, DFS, DoR, TTNT, CR/ORR at EOI (\pm FDG-PET), safety

GALLIUM Final Analysis: PFS Benefit After 8 Years Follow-Up

PFS by INV



KM estimates became unreliable beyond 7.5 years, due to low numbers of patients at risk¹

Median observation time: 7.9 (0.0–9.8) years

INV-assessed PFS

Patients with event, n (%)

G-chemo
(n=601)

R-chemo
(n=601)

7-year PFS, %
(95% CI)

63.4
(59.0–67.4)

55.7
(51.3–59.9)

HR (95% CI)*

0.77 (0.64–0.93)

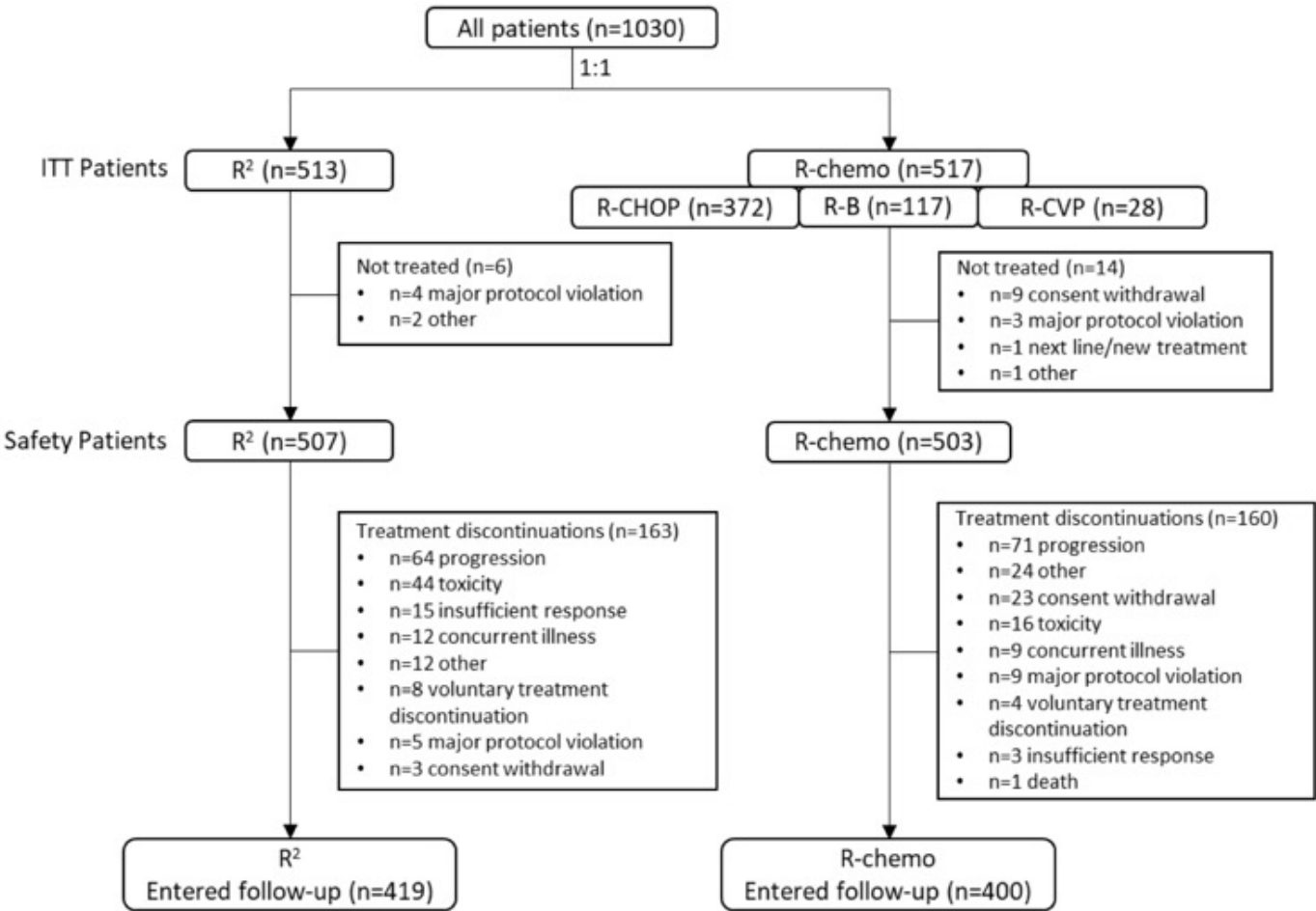
P-value

0.006

R = rituximab; G = obinutuzumab

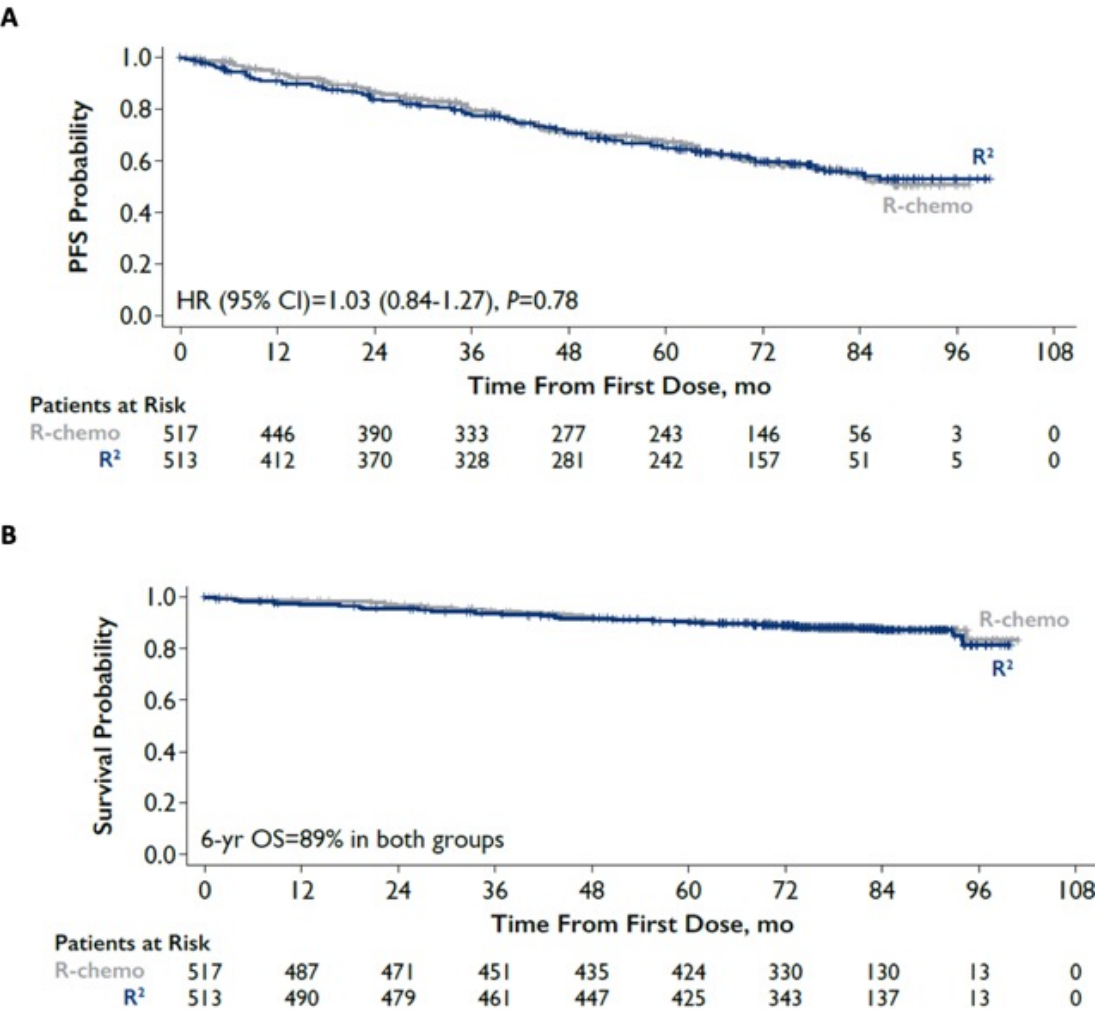
RELEVANCE: R2 vs. R-chemo in frontline FL, 6 year follow-up

Figure 1. Consort Diagram



Morschhauser et al. JCO 2022

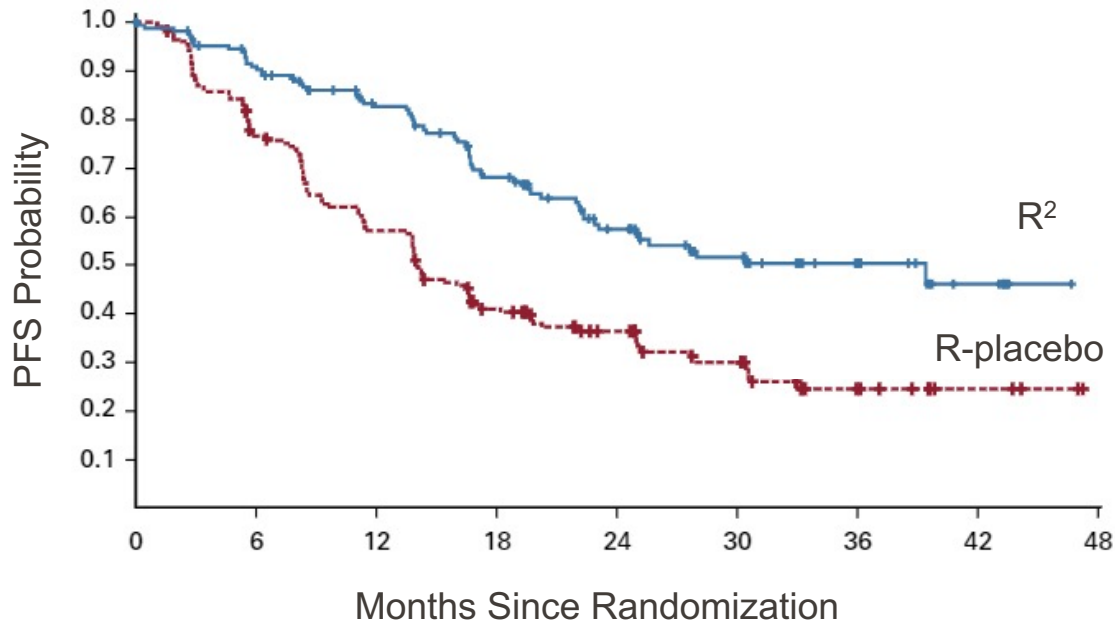
Figure 2. Progression-free Survival by IRC (A) and Overall Survival (B) in the Intention-to-Treat Population



AUGMENT: Rituximab + Lenalidomide vs. Rituximab+ placebo

Efficacy

Progression-Free Survival

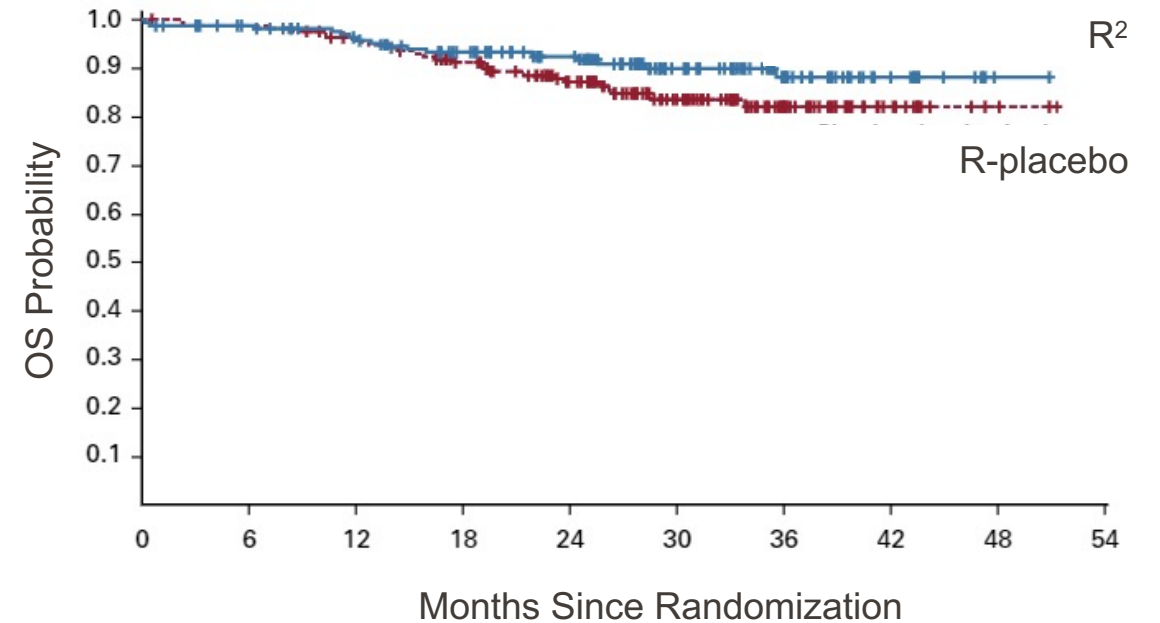


Median PFS by IRC

- R² = 39.4 months
- R-placebo = 14.1 months

HR = 0.46

Overall Survival

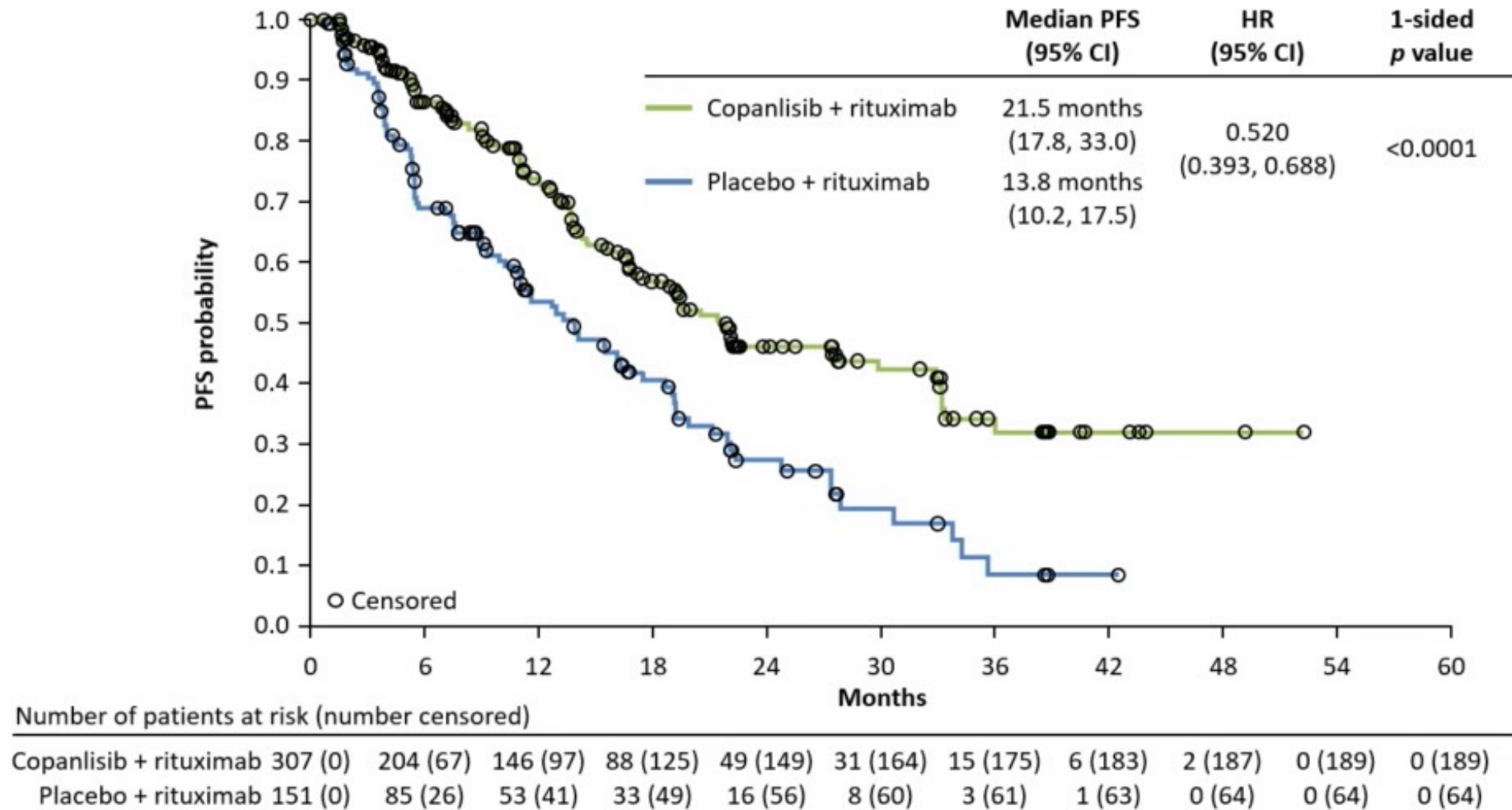


2-year OS

- R² = 93%
- R-placebo = 87%

Median follow-up 28.3 months

CHRONOS-3 in R/R iNHL: PFS



■ Median follow-up
of 19.2 months

PI3K Inhibitors: Emerging Agents

Zandelisib: Phase III COASTAL Study for FL and MZL

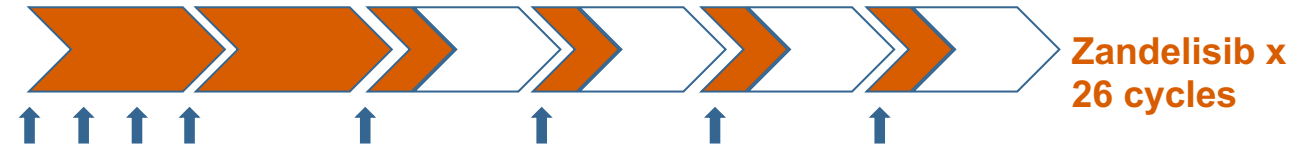
ELIGIBILITY CRITERIA

Major Inclusion Criteria

- Adult male or female subjects
- Histologically confirmed diagnosis of CD20-positive iNHL with histological subtype limited to:
 - FL Grades 1, 2, or 3a
 - MZL (splenic, nodal, or extra-nodal)
- R/R FL or MZL who received ≥ 1 prior line of therapy, which must have included an anti-CD20 antibody in combination with chemotherapy or lenalidomide
- At least one bi-dimensionally measurable lesion > 1.5 cm
- Adequate hematological, renal, and hepatic function
- Eastern Cooperative Oncology Group performance status score 0-1

Major Exclusion Criteria

- Histologically confirmed diagnosis of FL Grade 3b or transformed disease
- Subjects who received both R + bendamustine and R + CHOP (or other anthracycline-containing regimen) as previous lines of therapy, and those who received only single-agent anti-CD20 mAb therapy as a prior line of treatment
- Prior therapy with PI3K inhibitors
- Ongoing or history of drug-induced pneumonitis
- Known lymphomatous involvement of the central nervous system
- Seropositive for or active viral infection with HBV, HCV, or HTLV-1



N = 534 participants

CD20 positive iNHL:

- FL Gr 1, Gr 2, or Gr 3a
 - MZL (splenic, nodal, or extra-nodal)
- ≥ 1 prior lines of therapy*

↑ R 375 mg/m² 4 x weekly in cycle 1,
then Day 1 of Cycles 3-6

➤ **Zandelisib** IDT of 60 mg/day on
Days 1-7 of each 28-day cycle

Rituximab + B (28 D cycles) x 6 or
Rituximab + CHOP (21 D cycles) x 6

Primary endpoints

PFS

Secondary endpoints

ORR, CRR, OS, TTNT, PFS2, PRO, Safety

BGB-3111-212 – ROSEWOOD STUDY



A Phase 2, Multicenter, Open-Label, Randomized Trial for Patients with Relapsed or Refractory Follicular Lymphoma

Eligibility

- Adult patients with histologically confirmed grade 1-3a FL
- Patients with R/R disease, previously treated with ≥ 2 prior systemic treatments including an anti-CD20 antibody and an appropriate alkylator-based combination therapy
- Measurable disease
- ECOG-PS 0-2
- Adequate organ functions
- No prior BTK inhibitor exposure

Stratification factors

- Number of prior lines
- Rituximab refractory status
- Geographic region

ARM A Zanubrutinib plus obinutuzumab N = 140

Until PD/unacceptable toxicity

ARM B Obinutuzumab N = 70

Option to crossover to arm A if PD/SD centrally confirmed at 12 months

Assuming $ORR_A = 0.55$ and $ORR_B = 0.30$, 210 patients will be enrolled in a 2:1 ratio to provide a power of approximately 91% in testing ORR_A versus ORR_B using a normal approximation to binomial distribution with a 2-sided significance level of 0.05 with continuity correction

Primary Endpoint:

ORR assessed by ICR according to Lugano classification

Secondary Endpoints:

- ORR assessed by investigator
- DOR and PFS determined by ICR review and investigator assessment
- Overall survival
- CR and CMR rate assessed by ICR and investigator assessment
- TTR assessed by ICR and investigator assessment
- Patient-reported outcome measured by EORTC QLQ-C30 and EQ-5D-5L questionnaires
- Safety/Tolerability
- Pharmacokinetics parameters (combination arm only)

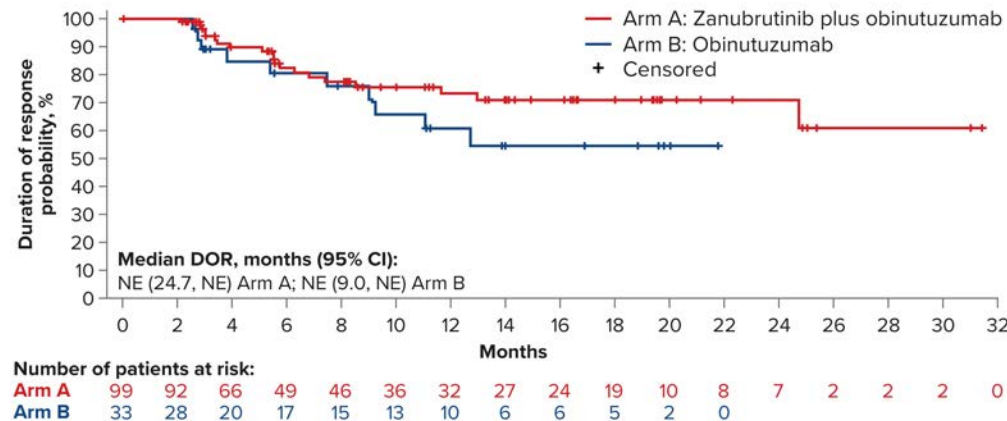
Exploratory Endpoint:

- ORR after crossover to arm A

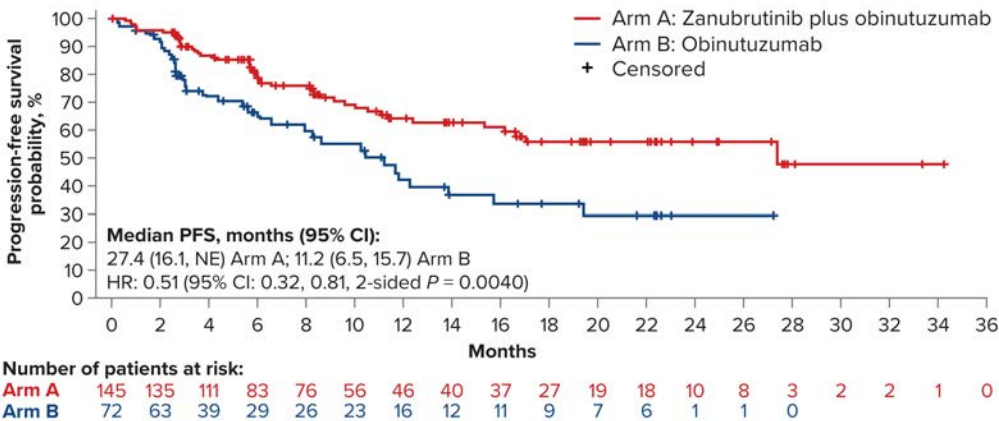
EFFICACY ENDPOINTS: ROSEWOOD STUDY

(ITT ANALYSIS SET)

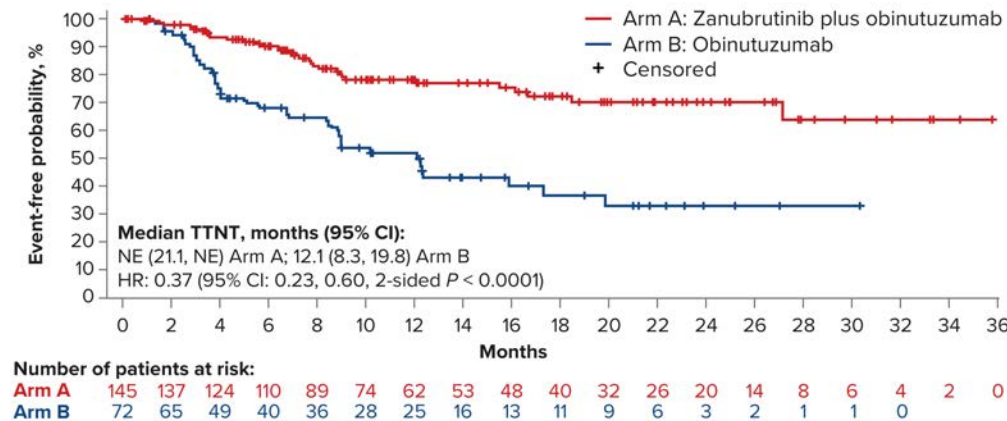
Duration of Response (IRC)



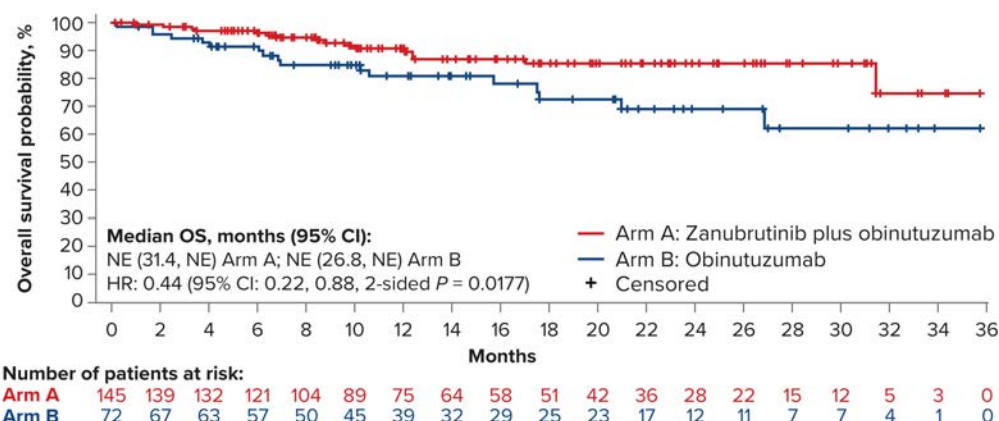
Progression-free survival (IRC)



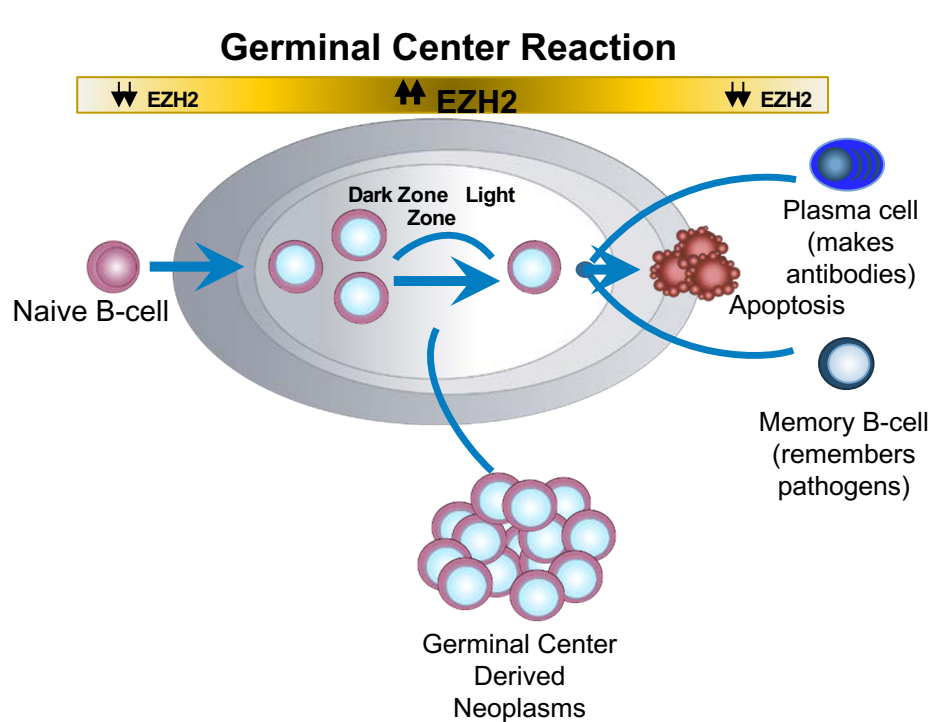
Time to Next Antilymphoma Treatment



Overall survival



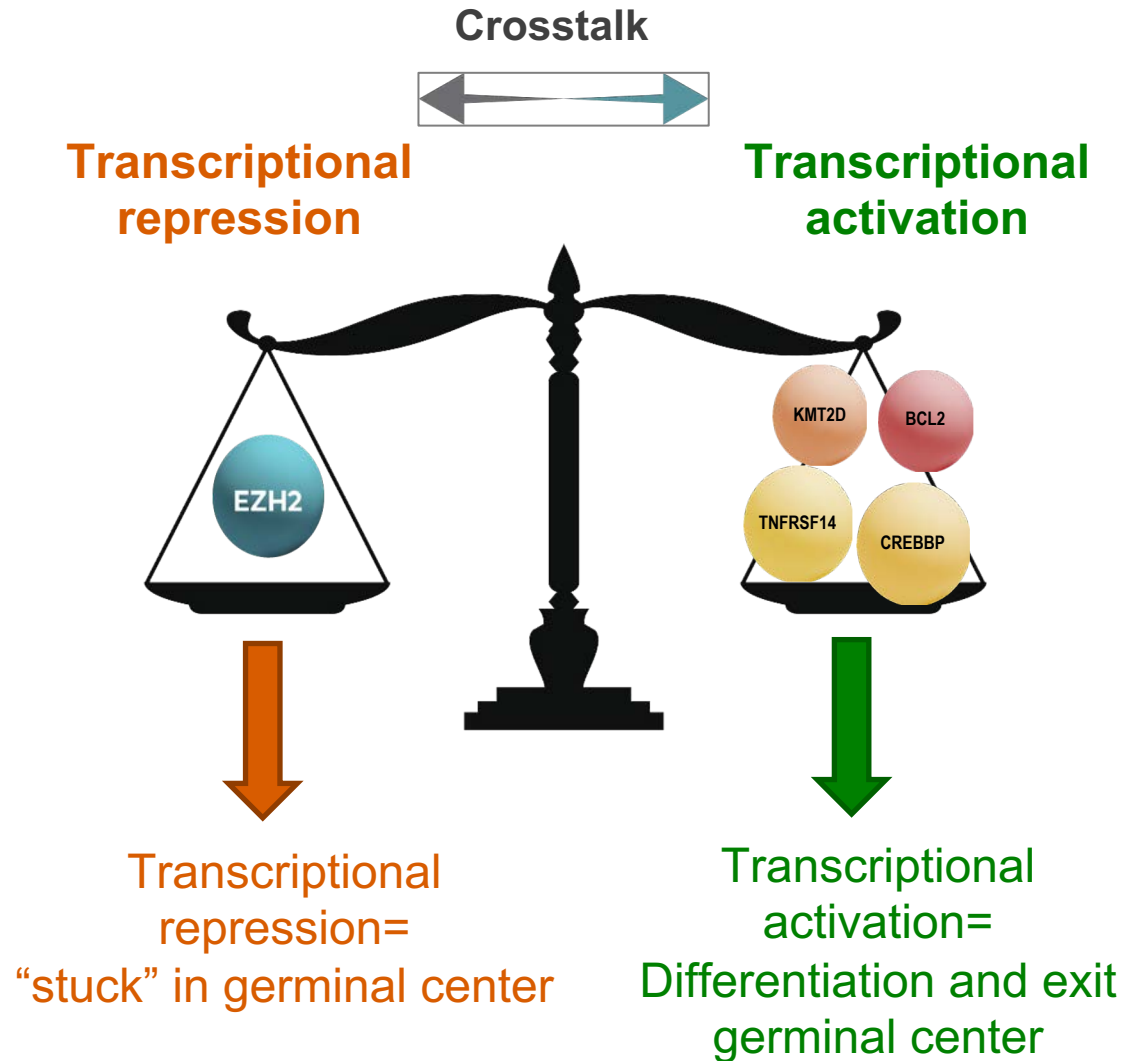
Tazemetostat: Follicular Lymphoma and *EZH2*



EZH2 an epigenetic regulator of gene expression and cell fate decisions¹

EZH2 is required for normal B-cell biology and germinal center formation²

- Oncogenic mutations in *EZH2* suppress exit from germinal state and “lock” B cells in this state thereby transforming into a cancer²



Tazemetostat for R/R FL

Phase 2, Open-Label, Multicenter Study

Response in the MT *EZH2* Cohort

Response in MT <i>EZH2</i> (n=45)	IRC	INV
ORR, n (%) [95% CI ^a]	31 (69) [53, 82]	35 (78) [63, 89]
CR, n (%)	6 (13)	4 (9)
PR, n (%)	25 (56)	31 (69)
SD, n (%)	13 (29)	10 (22)
PD, n (%)	1 (2)	0

- 44 of 45^b (98%) patients with evidence of tumor reduction, by IRC
- mPFS, 13.8 mos (95% CI, 10.7-22.0)

Response in the WT *EZH2* Cohort

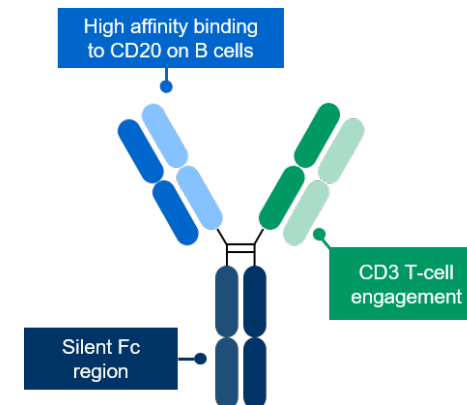
Response in WT <i>EZH2</i> (n=54)	IRC	INV
ORR, n (%) [95% CI ^a]	19 (35) [23, 49]	18 (33) [21, 48]
CR, n (%)	2 (4)	3 (6)
PR, n (%)	17 (31)	15 (28)
SD, n (%)	18 (33)	16 (30)
PD, n (%)	12 (22)	16 (30)
NE/missing/unknown,^b n (%)	5 (9)	4 (7)

- 37 of 49^c (69%) patients with evidence of tumor reduction, by IRC
- mPFS, 11.1 mos (95%CI, 3.7-`14.6)

^aBy Brookmeyer and Crowley method. ^b4 subjects with missing post-baseline values and 1 subject with poor image. ^cBest overall response based on Cheson (2007) criteria for lymphomas.

Mosunetuzumab: CD20xCD3 Bispecific

- Single-arm, pivotal Phase II expansion in patients with R/R FL and ≥ 2 prior therapies

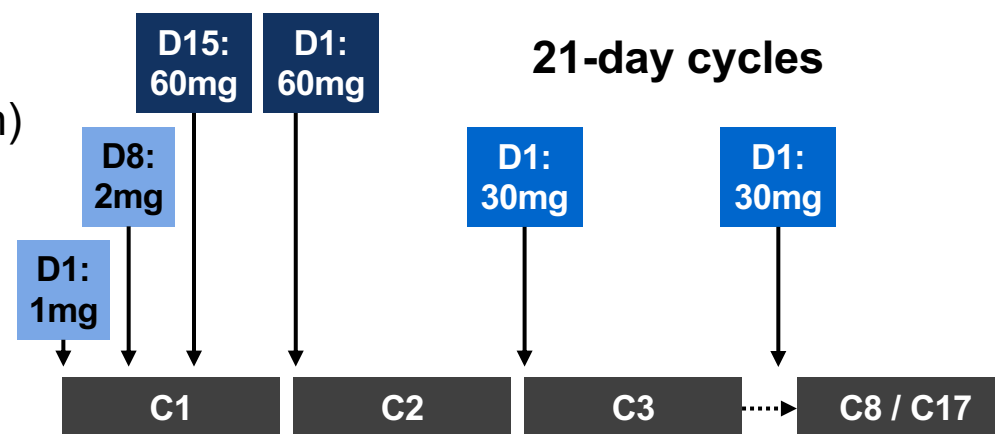


Key inclusion criteria

- FL (Grade 1–3a)
- ECOG PS 0–1
- ≥ 2 prior regimens, including
 - ≥ 1 anti-CD20 Ab
 - ≥ 1 alkylating agent

Mosunetuzumab administration

- Q3W intravenous administration
- C1 step-up dosing (CRS mitigation)
 - Fixed-duration treatment**
 - 8 cycles if CR after C8
 - 17 cycles if PR/SD after C8
- No mandatory hospitalization**



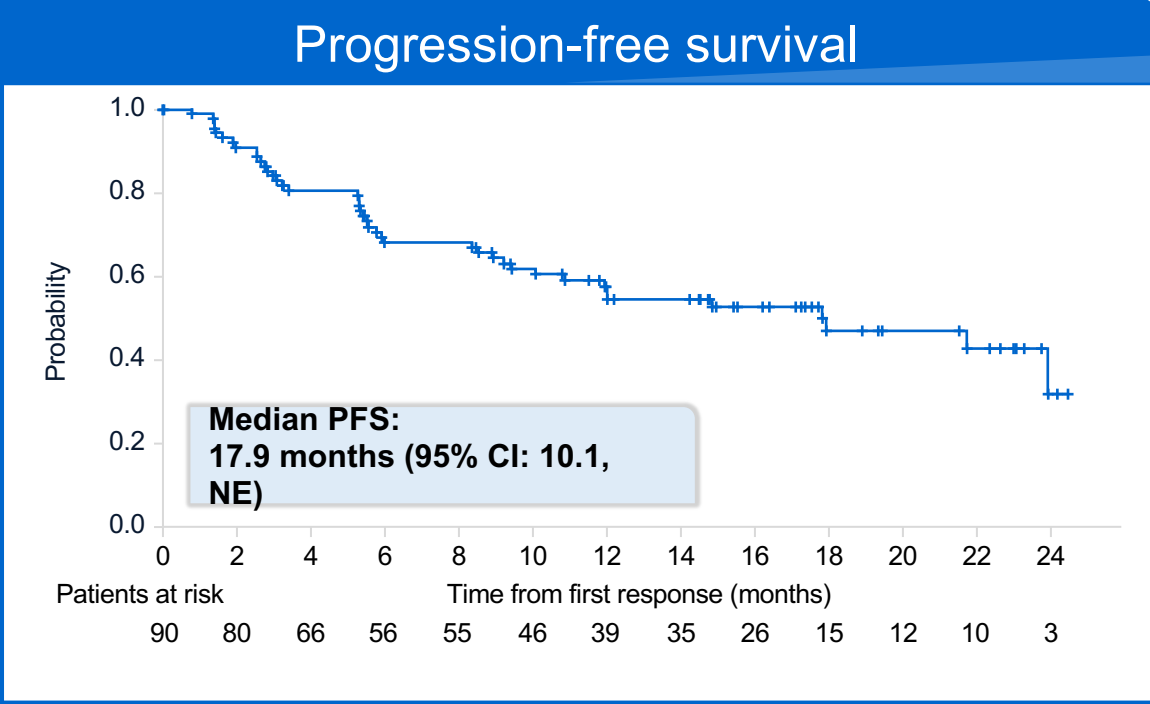
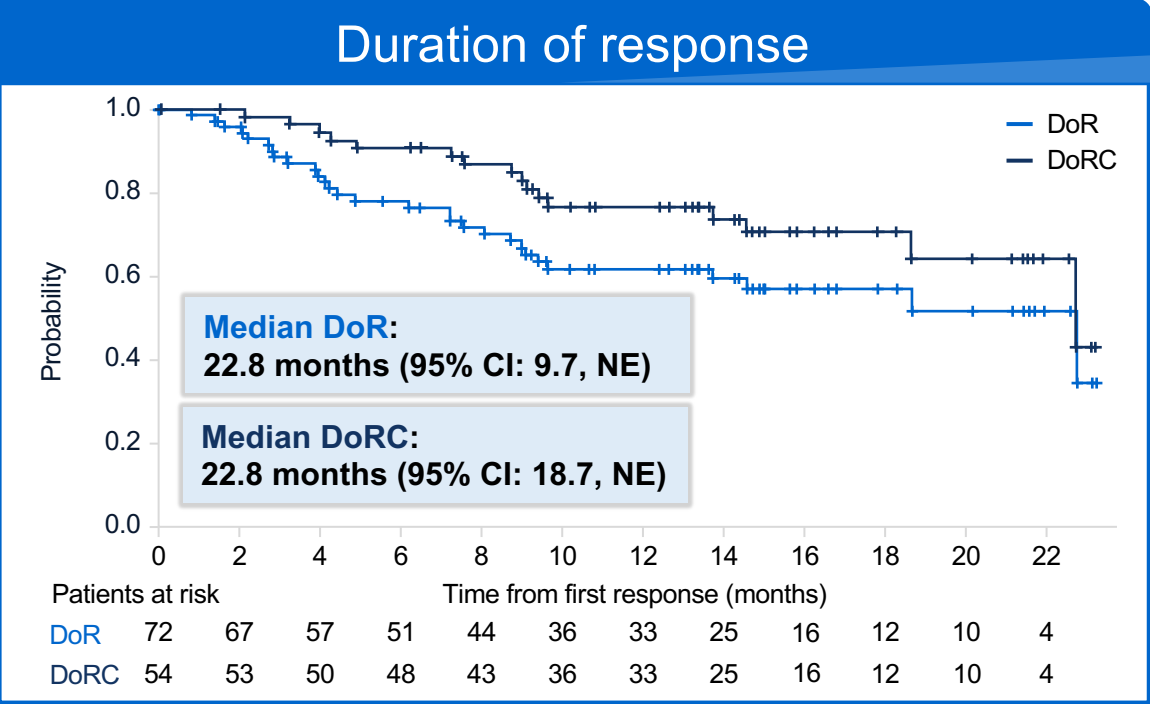
Endpoints

- Primary: CR (best response) rate by IRF* – assessed vs 14% historical control CR rate¹
- Secondary: ORR, DoR, PFS, safety and tolerability

*assessed by CT and PET-CT using Cheson 2007 criteria²; Ab, antibody; CR, complete response; CT, computed tomography; D, Day; DoR, duration of response; IRF, independent review facility; ORR, objective response rate; PET, positron emission tomography; PFS, progression-free survival; PR, partial response; Q3W, once every 3 weeks; SD, stable disease

1. Dreyling et al. J Clin Oncol 2017;35:3898–905
2. Cheson et al. J Clin Oncol 2007;25:579–86

Duration of response and progression-free survival

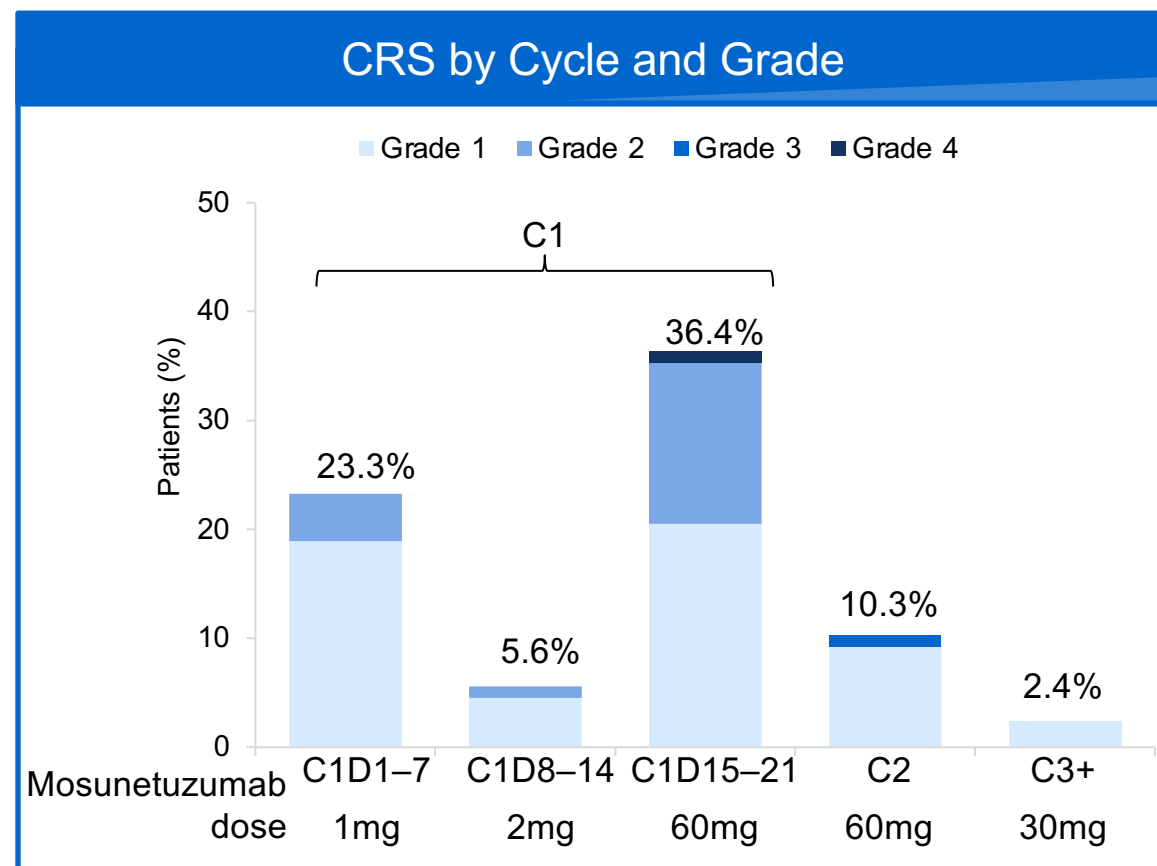


	DoR	DoRC
Median time to first response, mo (range)	1.4 (1.1, 8.9)	3.0 (1.1, 18.9)
12-month event-free rate, % (95% CI)	62% (50%, 74%)	76% (65%, 88%)
18-month event-free rate, % (95% CI)	57% (44%, 70%)	70% (57%, 84%)

DoRC, duration of response in complete responders; DoR, duration of response in responders; mo, month; NE, not estimable

Cytokine release syndrome

N (%)	N=90
CRS (any Grade)*	40 (44.4%)
Grade 1	23 (25.6%)
Grade 2	15 (16.7%)
Grade 3	1 (1.1%)
Grade 4	1 (1.1%)†
Median time to CRS onset, hours (range)	
C1D1	5.2 (1.2–23.7)
C1D15	26.6 (0.1–390.9)
Median CRS duration, days (range)	3 (1–29)
Corticosteroids for CRS management	10 (11.1%)



- CRS was predominately low Grade and in Cycle 1. All events resolved.**

*assessed using ASTCT criteria¹; †patient with leukemic phase FL

MOSUN+LENALIDOMIDE PHASE 1B

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

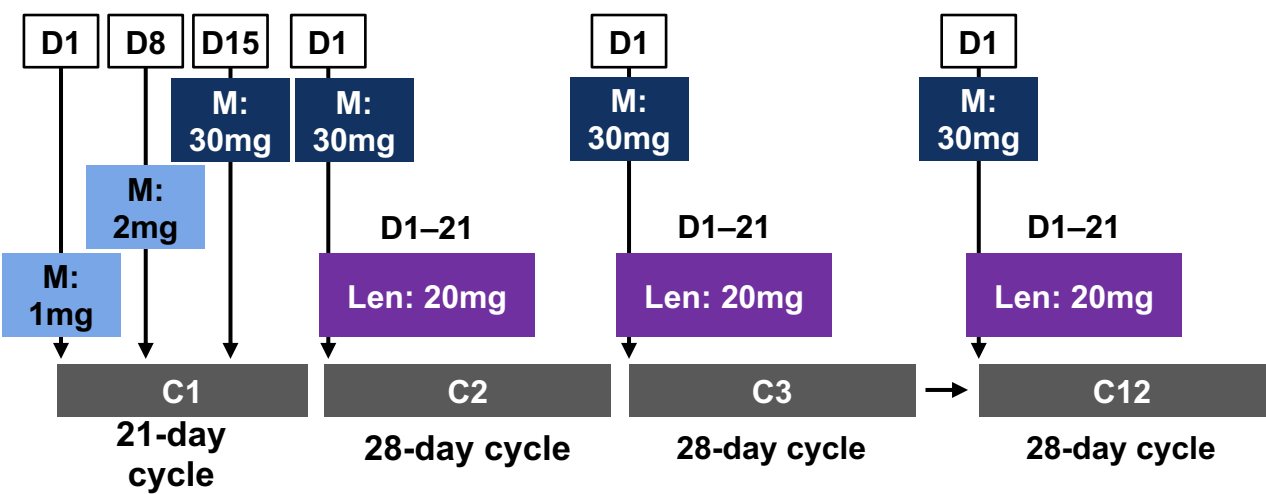
M-Len administration

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)

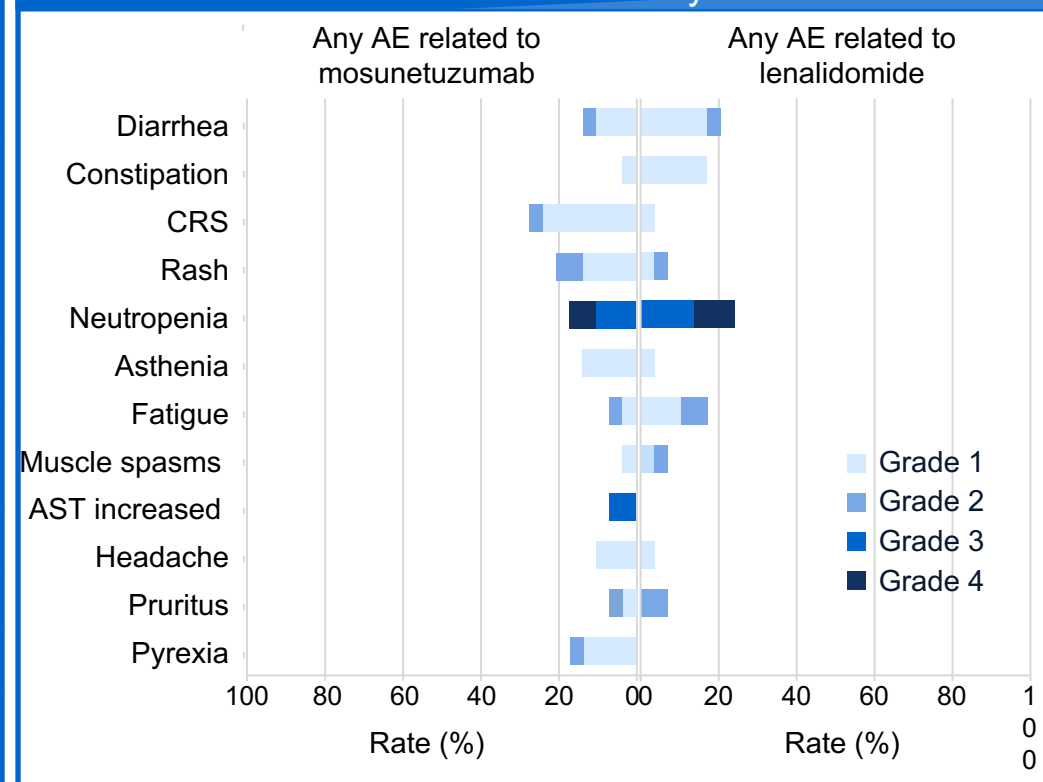


Adverse event summary

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

	N=29
AE	29 (100%)
Related to mosunetuzumab / lenalidomide	27 (93.1%) / 23 (79.3%)
Grade 3–4 AE	13 (44.8%)
Related to mosunetuzumab / lenalidomide	1 (3.4%) / 1 (3.4%)
Serious AE	9 (31.0%)
Related to mosunetuzumab / lenalidomide	6 (20.7%) / 1 (3.4%)
Grade 5 (fatal) AE	0
AE leading to mosunetuzumab / lenalidomide discontinuation	0 / 1 (3.4%)
AE leading to mosunetuzumab dose delay	6 (20.7%)
AE leading to lenalidomide dose reduction	2 (6.9%)
AE leading to lenalidomide temporary dose interruption	6 (20.7%)
AE leading to lenalidomide dose reduction AND temporary dose interruption	4 (13.7%)

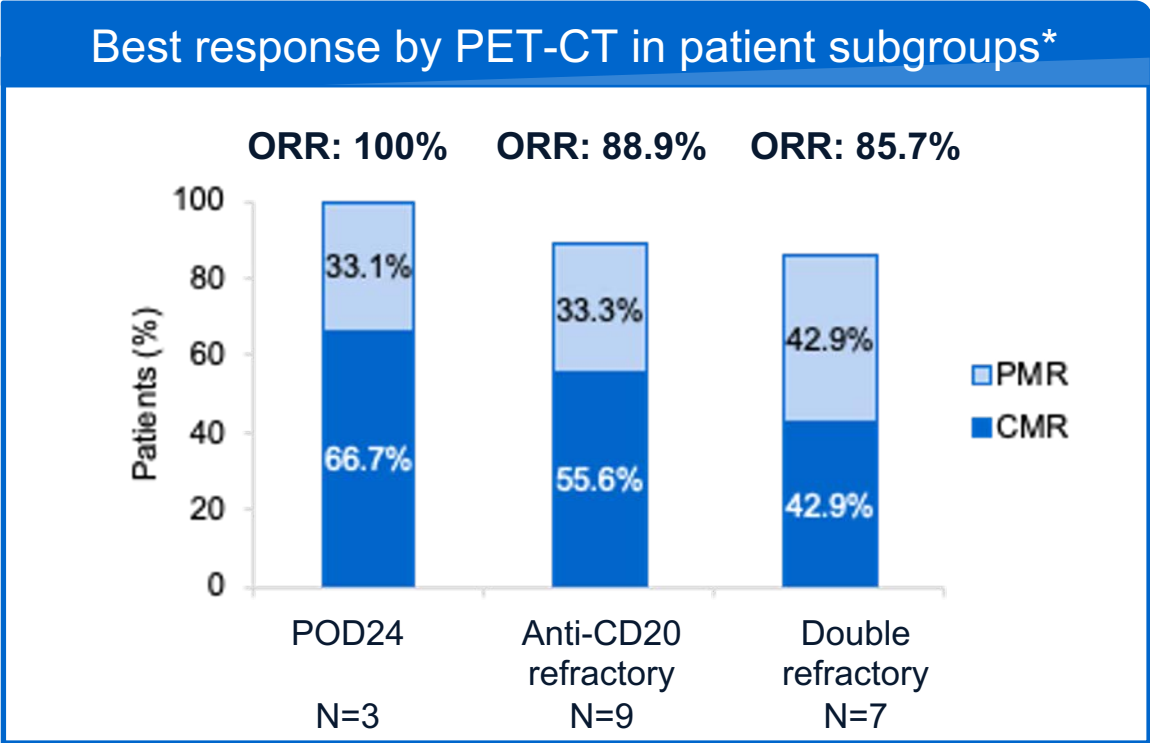
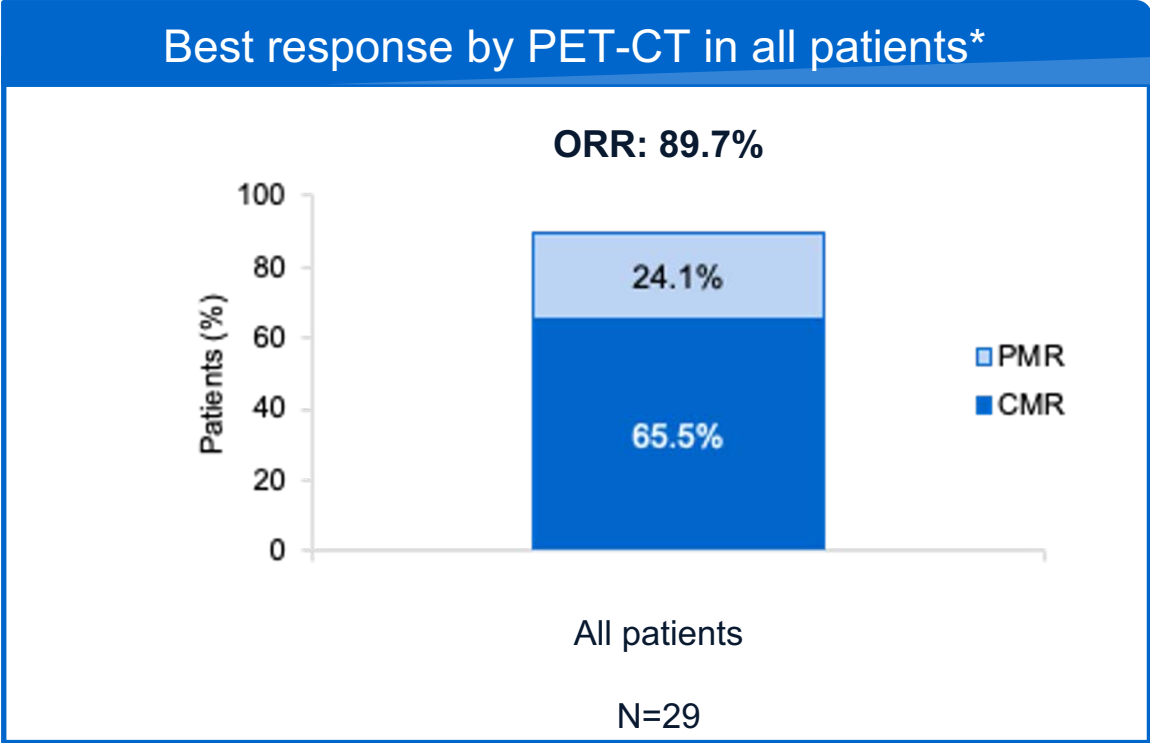
AEs with ≥15% incidence overall and corresponding rates of treatment-related events by Grade



- M-Len had a favorable safety profile. No AEs led to mosunetuzumab discontinuation.**

MOSUN+LEN PHASE 1B EFFICACY

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



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

*assessed by investigators using Lugano 2014 criteria¹; CMR, complete metabolic response; mo, months; ORR, overall response rate; PET-CT, positron emission tomography-computed tomography; PMR, partial metabolic response

1. Cheson et al. J Clin Oncol 2014;32:3059–67

Bispecific Ab Epcoritamab + R2 in R/R FL

Phase I/II EPCORE NHL-2 Trial

N=74

- Adults with R/R CD20+ FL; grade 1-3A
- Stage II-IV
- Treatment needed based on symptoms or disease burden per GELF criteria
- Measurable disease by CT/MRI
- Adequate organ function
- ECOG PS 0-2

Dose Escalation (n = 6)

Cohort 2a
Epcoritamab 24 or 48 mg SC*
 QW for C1-3, Q2W for C4-9,
 Q4W for C10+
 +
 R² for C1-12[†]

Dose Expansion (n = 68)

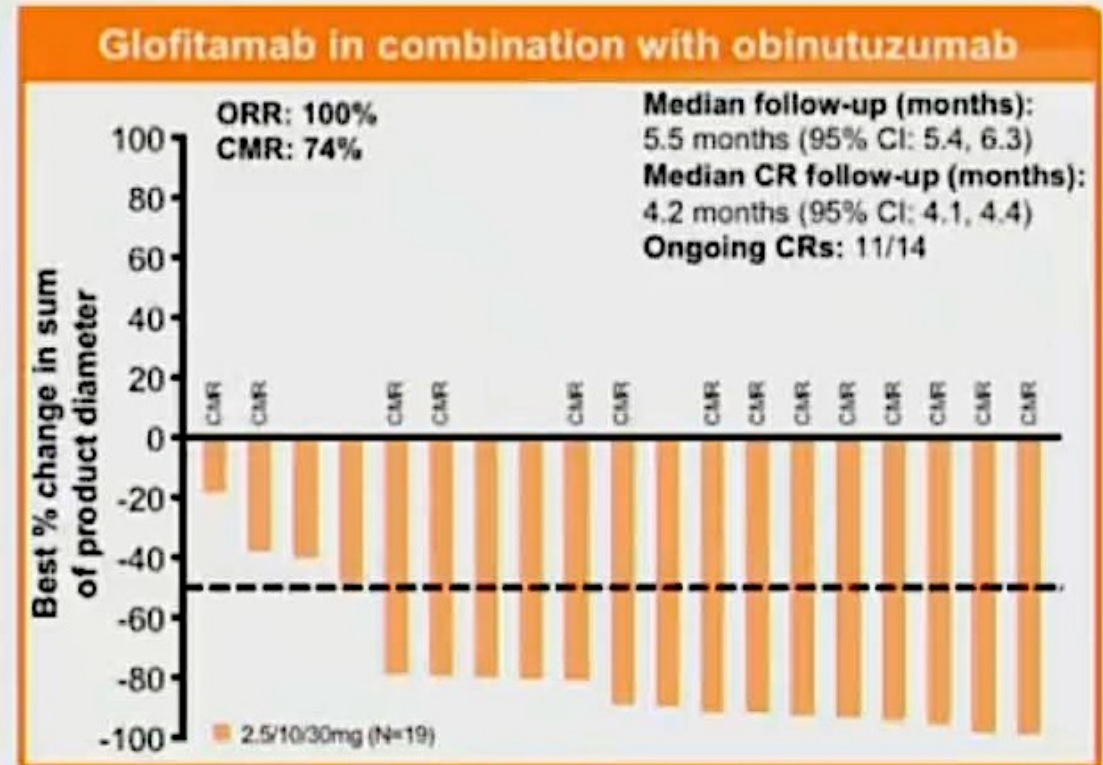
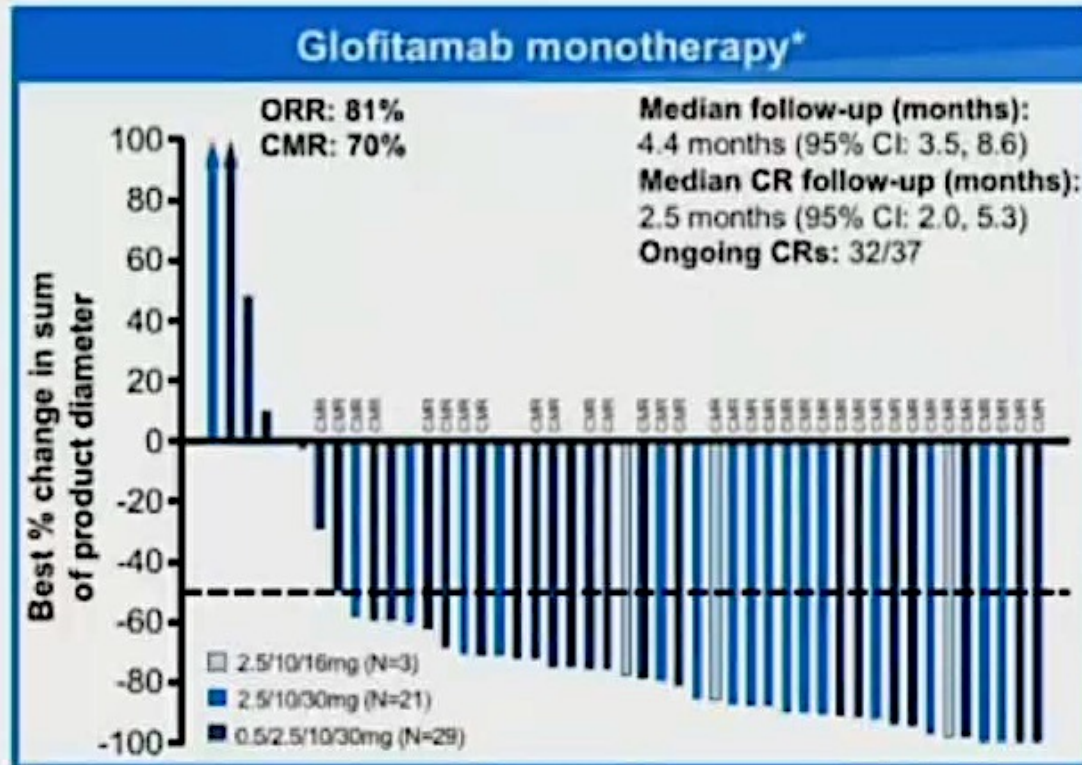
Cohort 2a
Epcoritamab 48 mg SC*
 QW for C1-3, Q2W for C4-9, Q4W for C10+
 +
 R² for C1-12[†]

Cohort 2b
Epcoritamab 48 mg SC*
 QW C1-2, Q4W for C3+
 +
 R² for C1-12[†]

Best Overall Response,* n (%)	Arm 2a		Arm 2b
	At Any Time (n = 28 [†])	At 6 Wk (n = 27)	At 6 Wk (n = 28)
ORR	28 (100)	25 (93)	26 (93)
• CMR	27 (96)	19 (70)	17 (61)
• PMR	1 (4)	6 (22)	9 (32)
SD	0	2 (7)	1 (4)
PD	0	0	1 (4)

- Half of patients experienced CRS, which was predominantly low grade and resolved in all cases
- 1 patient experienced ICANS (grade 2) that resolved

Phase I/II Study of Glofitamab as Monotherapy or in Combination with Obinutuzumab for R/R FL



• Deep responses observed across glofitamab dosing regimens; most complete responses were ongoing

- Myelosuppression was more common with the combination
- CRS rates were high and comparable, and cases were mainly low grade

Conclusions

- Outcomes for the majority of patients with FL are favorable.
- Balancing the goals of therapy with patient specific characteristics generally informs treatment selection given the number of therapies available.
- An unmet need is identifying optimal sequencing of therapy or predictive biomarkers.
- The goal of treatment is to achieve a normal life expectancy without negatively impacting quality of life.

APPENDIX

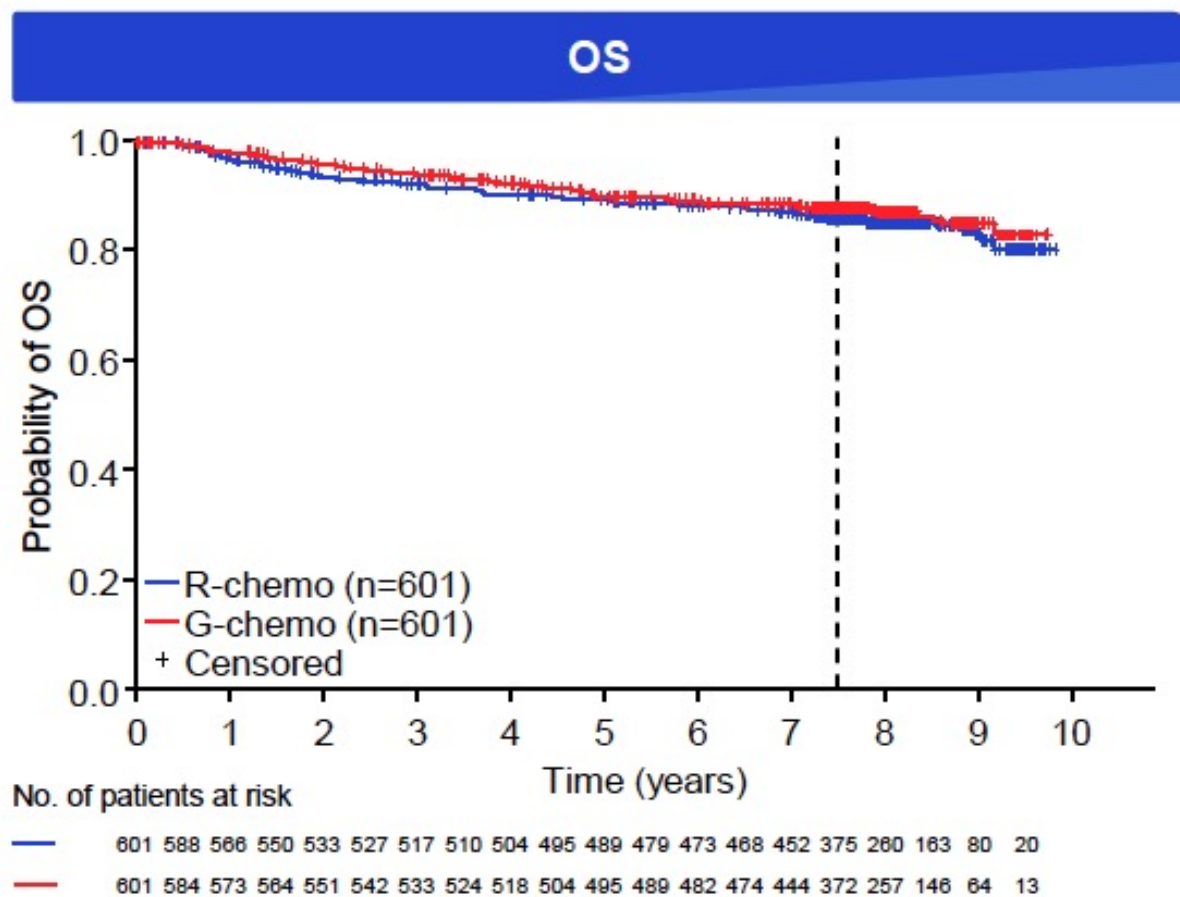
Obinutuzumab plus chemotherapy demonstrates long-term benefit over rituximab plus chemotherapy in patients with previously untreated follicular lymphoma: final analysis of the GALLIUM study

William Townsend,¹ Wolfgang Hiddemann,² Christian Buske,³ Guillaume Cartron,⁴ David Cunningham,⁵ Martin JS Dyer,⁶ John G Gribben,⁷ Elizabeth Phillips,⁸ Martin Dreyling,² John F Seymour,⁹ Andrew Grigg,¹⁰ Judith Trotman,¹¹ Tong-Yu Lin,¹² Xiao-Nan Hong,¹³ Dirk Kingbiel,¹⁴ Tina G Nielsen,¹⁴ Andrea Knapp,¹⁴ Michael Herold,¹⁵ Robert Marcus¹⁶

¹Cancer Research UK and UCL Cancer Trials Centre, University College Hospitals London, London, United Kingdom; ²Ludwig-Maximilians-University Hospital Munich, Munich, Germany; ³Universitätsklinikum Ulm, Ulm, Germany; ⁴CHU Montpellier, Montpellier, France; ⁵Royal Marsden Hospital, Sutton, United Kingdom; ⁶Ernest and Helen Scott Haematological Research Institute, University of Leicester, Leicester, United Kingdom; ⁷Queen Mary, University of London, St Bartholomew's Hospital, London, United Kingdom; ⁸University of Manchester, The Christie Hospital and National Institutes of Health Research Manchester Biomedical Research Centre, Manchester, United Kingdom; ⁹Peter MacCallum Cancer Centre, the Royal Melbourne Hospital, and University of Melbourne, Melbourne, Australia; ¹⁰Austin Hospital, Austin, Australia; ¹¹Concord Repatriation General Hospital, University of Sydney, Concord, Australia; ¹²Sun Yat-Sen University Cancer Centre, State Key Laboratory of Oncology in South China, and Collaborative Innovation Centre for Cancer Medicine, Guangzhou, China; ¹³Fudan University Shanghai Cancer Centre, Shanghai, China; ¹⁴F. Hoffmann-La Roche Ltd, Basel, Switzerland; ¹⁵HELIOS-Klinikum Erfurt, Erfurt, Germany; ¹⁶Kings College Hospital, London, United Kingdom

EHA 2022;Abstract S206.

GALLIUM Final Analysis: Overall Survival



OS	G-chemo (n=601)	R-chemo (n=601)
Patients with event, n (%)	76 (12.6)	86 (14.3)
7-year OS, % (95% CI)	88.5 (85.6–90.9)	87.2 (84.1–89.7)
HR (95% CI)*	0.86 (0.63–1.18)	
P-value	0.36	

- G-chemo: 4% died due to PD, 4% due to AEs[†]
- R-chemo: 6% died due to PD, 5% due to AEs[†]

GALLIUM Final Analysis: Safety Summary

	Induction phase		Maintenance phase		Observation/follow-up phase	
	G-chemo (n=595)	R-chemo (n=597)	G-chemo (n=540)	R-chemo (n=526)	G-chemo (n=577)	R-chemo (n=572)
Any Grade AE,* n (%)	589 (99.0)	585 (98.0)	517 (95.7)	479 (91.1)	254 (44.0)	208 (36.4)
Grade ≥3, n (%)	368 (61.8)	350 (58.6)	216 (40.0)	174 (33.1)	123 (21.3)	90 (15.7)
SAEs, n (%)	168 (28.2)	147 (24.6)	132 (24.4)	114 (21.7)	99 (17.2)	83 (14.5)
Most common AEs of interest, n (%)						
Neutropenia	270 (45.4)	257 (43.0)	114 (21.1)	79 (15.0)	21 (3.6)	12 (2.1)
Grade ≥3	241 (40.5)	223 (37.4)	100 (18.5)	63 (12.0)	20 (3.5)	10 (1.7)
Infections	309 (51.9)	294 (49.2)	382 (70.7)	317 (60.3)	131 (22.7)	105 (18.4)
Grade ≥3	45 (7.6)	45 (7.5)	65 (12.0)	54 (10.3)	50 (8.7)	33 (5.8)
Infusion-related reactions	410 (68.9)	354 (59.3)	45 (8.3)	45 (8.6)	1 (0.2)	1 (0.2)
Grade ≥3	72 (12.1)	43 (7.2)	4 (0.7)	2 (0.4)	0	0

GALLIUM Final Analysis: Fatal AEs and Second Malignancies

Grade 5 AEs	G-chemo				R-chemo			
	+ CHOP (n=194)	+ CVP (n=60)	+ benda (n=338)	Overall (n=595)*	+ CHOP (n=203)	+ CVP (n=56)	+ benda (n=338)	Overall (n=597)
Grade 5 AEs, n (%)	5 (2.6)	1 (1.7)	20 (5.9)	26 (4.4) [†]	5 (2.5)	1 (1.8)	21 (6.2)	27 (4.5) [†]
Events since primary analysis, ¹ n	2	0	0	2	1	0	6	7

Second malignancies (malignant and unspecified tumors)*	G-chemo (n=595)	R-chemo (n=597)
All grades, %	13.1	9.9
Grade ≥3	8.4	6.5

- The difference in rates of second malignancies between arms was predominantly driven by:
 - Non-melanoma skin cancers: G-chemo, 3.9%; R-chemo, 2.8%
 - Hematological malignancies: G-chemo, 1.2%;[†] R-chemo, 0.3%[‡]

Zandelisib with continuous or intermittent dosing as monotherapy or in combination with rituximab in patients with relapsed or refractory B-cell malignancy: a multicentre, first-in-patient, dose-escalation and dose-expansion, phase 1b trial



John M Pagel, Jacob D Soumerai*, Nishitha Reddy, Deepa Jagadeesh, Anastasios Stathis, Adam Asch, Huda Salman, Vaishalee P Kenkre, Alexia Iasonos, Judith Llorin-Sangalang, Joanne Li, Andrew D Zelenetz*

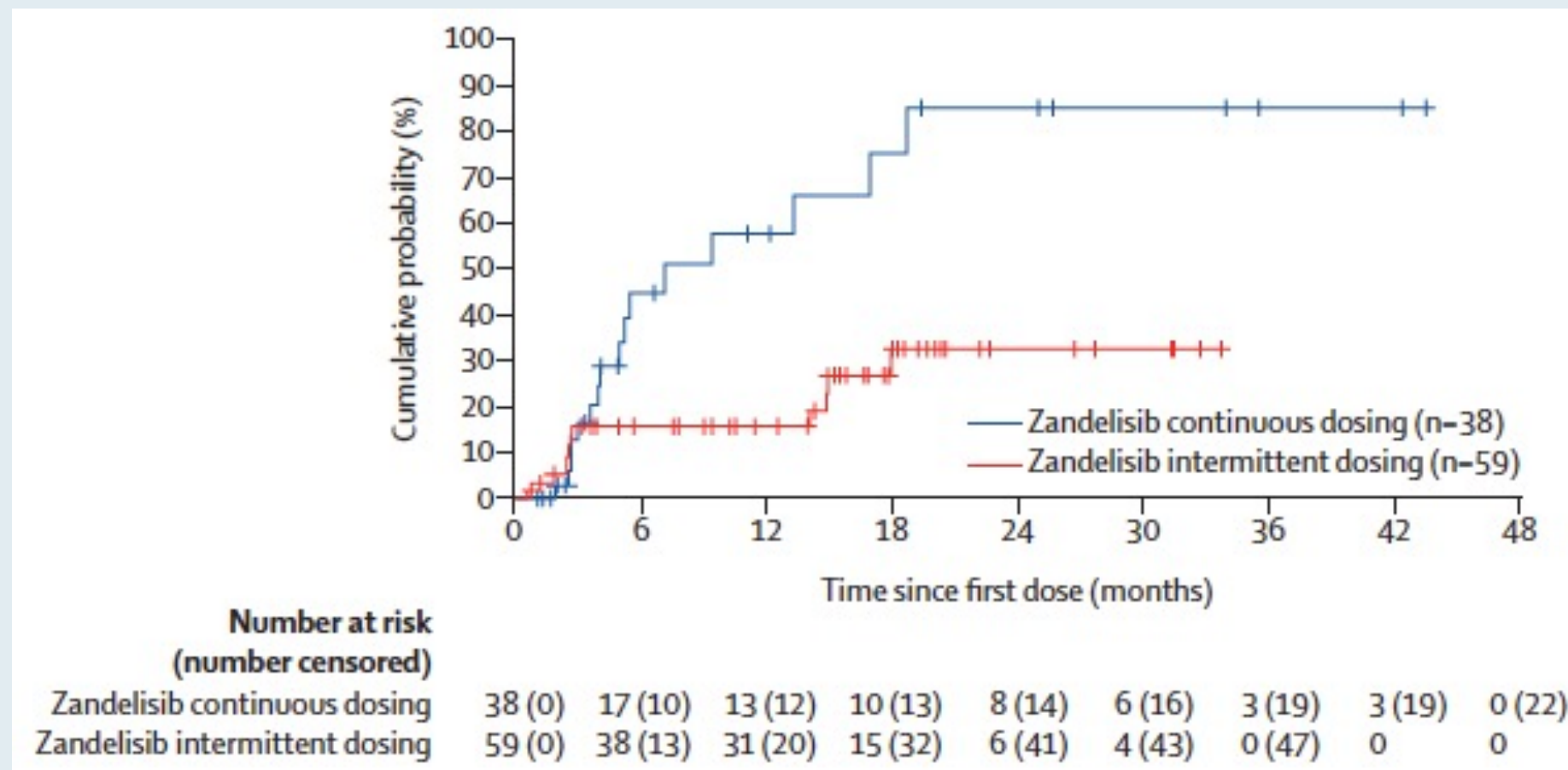
Antitumor Activity of Zandelisib in Patients with Relapsed/Refractory FL

- During the dose-escalation phase, 60 mg of zandelisib was declared as both the minimum biologically effective dose and the recommended Phase II dose for further evaluation

	Evaluable patients	Overall response	Complete response
Follicular lymphoma			
Overall	62	51 (82%; 70–91)	14 (23%; 13–35)
Zandelisib monotherapy	41	32 (78%; 62–89)	9 (22%; 11–38)
Zandelisib plus rituximab	21	19 (90%; 70–99)	5 (24%; 8–47)
Refractory to rituximab*	8	7 (88%; 47–100)	1 (13%; 0–53)
Relapsed to rituximab*	13	12 (92%; 64–99)	4 (31%; 9–61)
Continuous dosing group (zandelisib monotherapy)	25	19 (76%; 55–91)	4 (16%; 4–36)
Intermittent dosing group	37	32 (86%; 71–95)	10 (27%; 14–44)
Zandelisib monotherapy	18	14 (78%; 52–94)	5 (28%; 10–53)
Zandelisib plus rituximab	19	18 (95%; 74–100)	5 (26%; 9–51)

- Intermittent dosing of zandelisib did not result in reduced efficacy compared to continuous dosing

Time to Grade 3 or Worse Adverse Events of Special Interest with Zandelisib by Dosing Group

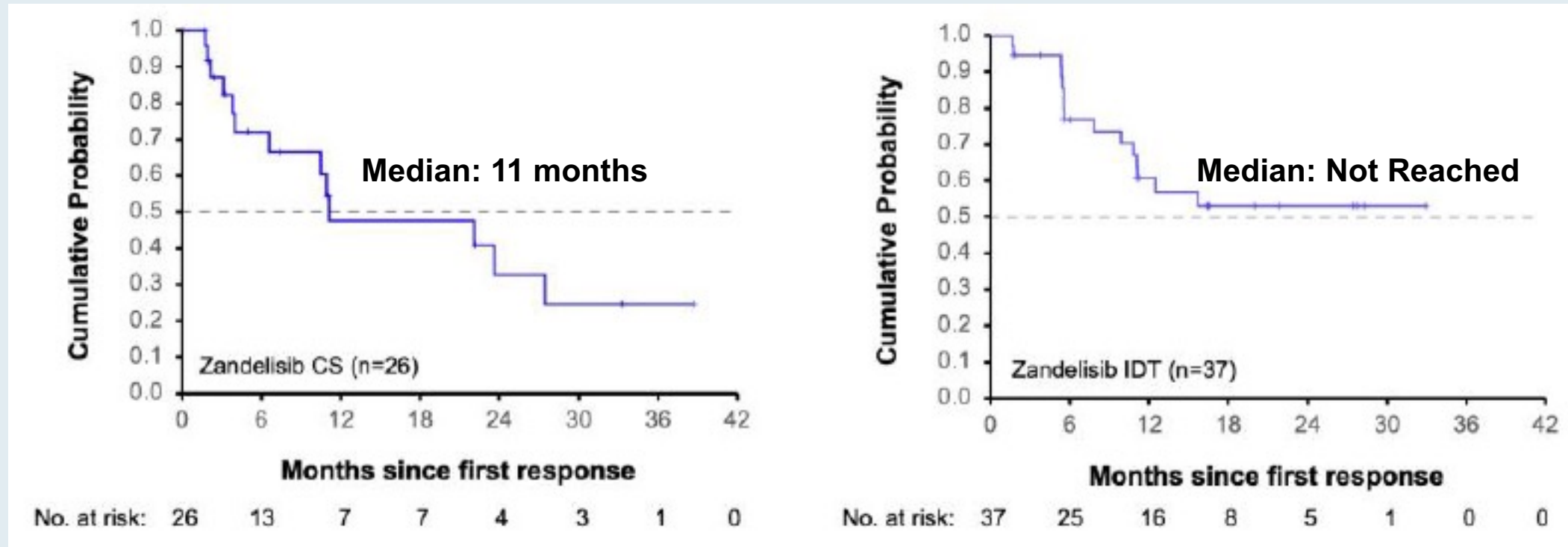


Adverse Events of Special Interest with Zandelisib by Dosing Group

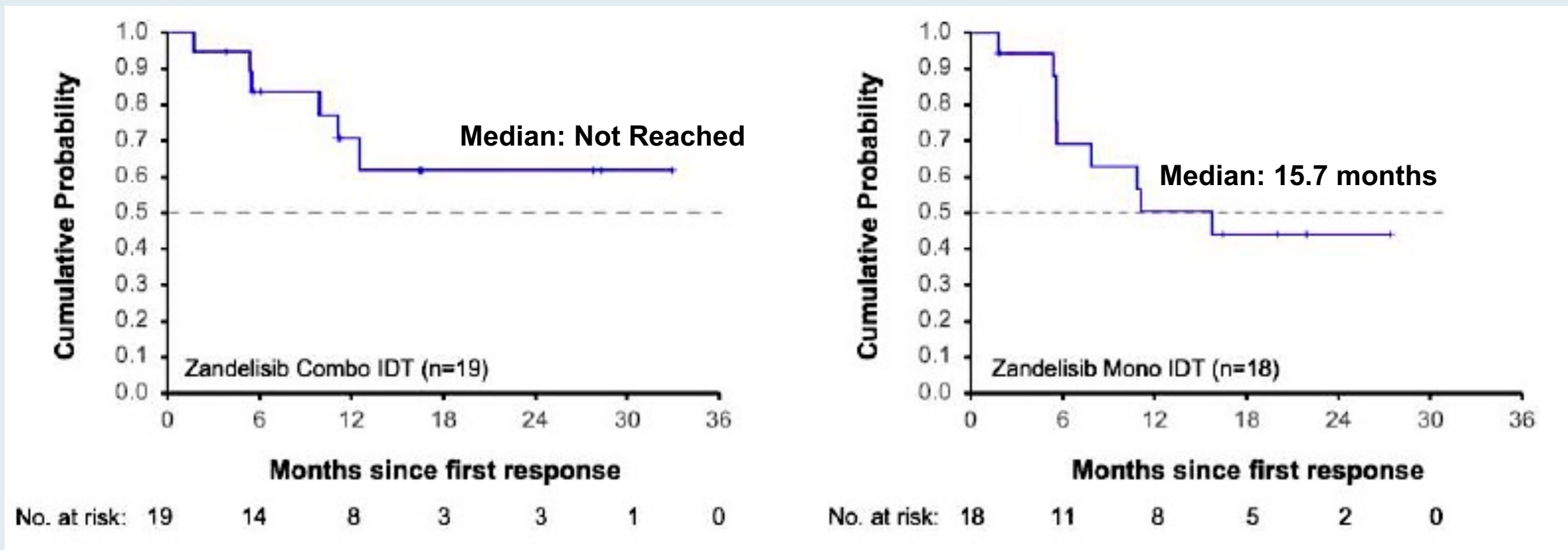
	Continuous dosing group (n=38)			Intermittent dosing group (n=59)*		
	Grade 1-2	Grade 3	Grade 4	Grade 1-2	Grade 3	Grade 4
Diarrhoea or colitis	9 (24%)	9 (24%)	0	22 (37%)	5 (8%)	0
Rash, all types	12 (32%)	2 (5%)	0	14 (24%)	3 (5%)	0
ALT or AST elevation	8 (21%)	2 (5%)	0	13 (22%)	3 (5%)	0
Lung infection or pneumonia	1 (3%)	6 (16%)	0	2 (3%)	1 (2%)	0
Mucositis	6 (16%)	1 (3%)	0	1 (2%)	0	0
Non-infectious pneumonitis	0	0	0	1 (2%)	1 (2%)	0

Zandelisib 60 mg once daily on an intermittent dosing schedule was safe, with low frequency of Grade 3 or worse adverse events

PFS for Patients with FL by Zandelisib Dosing Schedule



PFS by Treatment Arm for Patients with FL Who Received Zandelisib Intermittent Dosing Schedule



Response Rate for Patients with R/R FL and Safety in the Overall Population in a Phase Ib Trial of Zandelisib

Patients with R/R FL				
	Zandelisib 60 mg (n = 6)	Zandelisib 120 mg (n = 10)	Zandelisib 180 mg (n = 5)	Total (N = 21)
Objective response rate	5 (83%)	9 (90%)	4 (80%)	18 (86%)

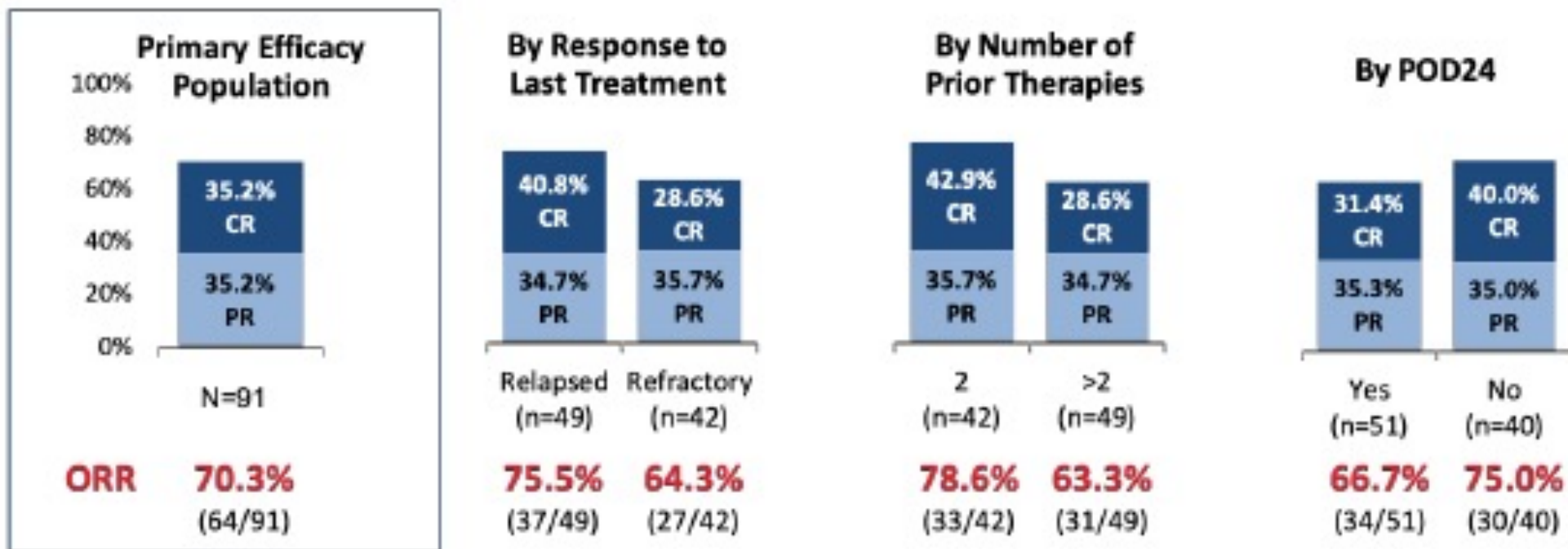
No dose-limiting toxicities were observed, and antitumor activity was similar across the evaluated doses.

Primary Efficacy and Safety Analysis of a Global Phase II Study of Zandelisib Administered by Intermittent Dosing (ID) in Patients with Relapsed or Refractory (R/R) Follicular Lymphoma (FL): The TIDAL Study

Phillips T et al.

SOHO 2022;Abstract 271.

TIDAL: Overall Response Rates with Intermittent Dosing of Zandelisib



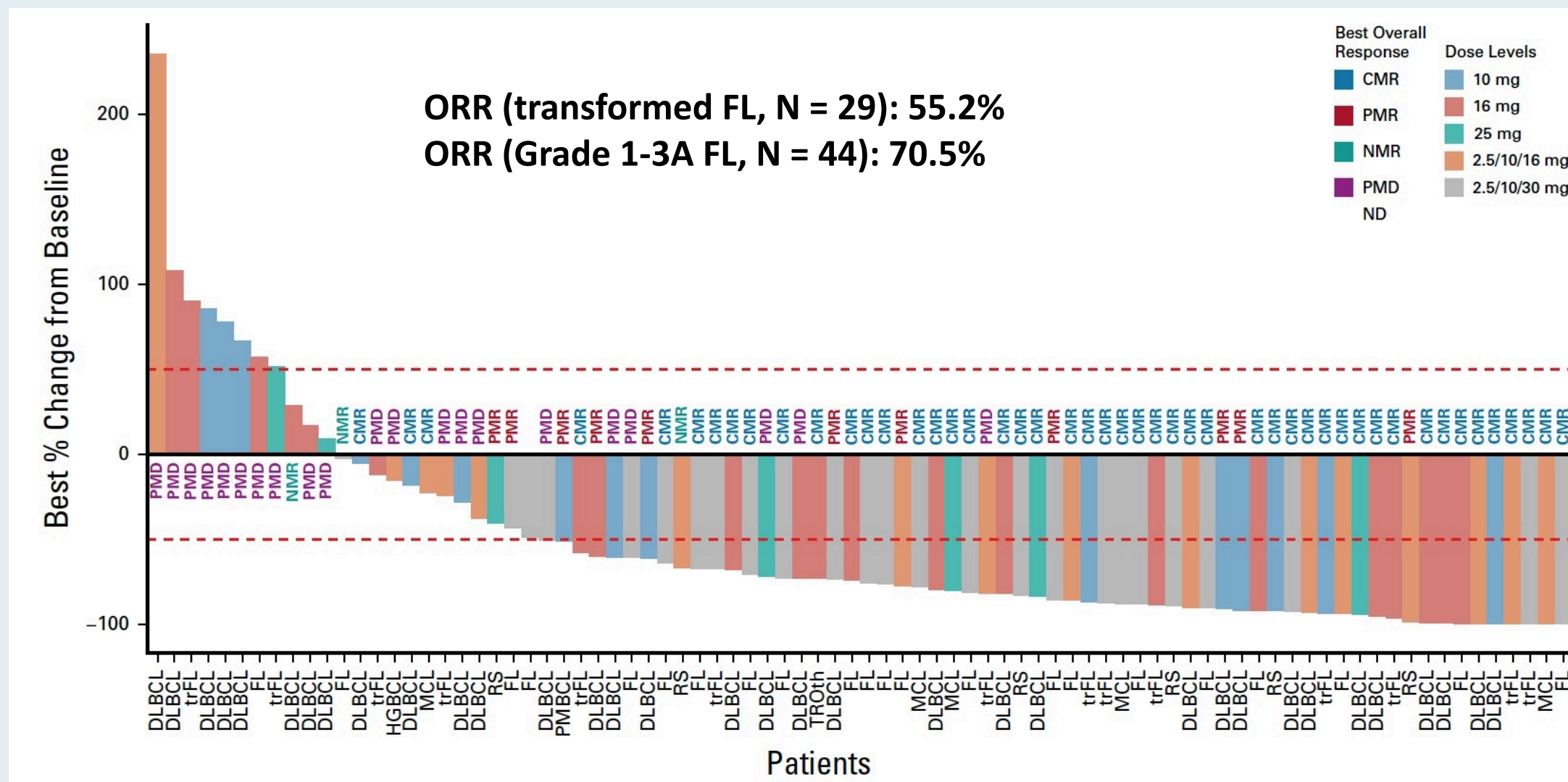
- Disease control (CR+PR+SD) in 77 patients (85%)
- Follow-up is immature to accurately estimate duration of response

Glofitamab, a Novel, Bivalent CD20-Targeting T-Cell–Engaging Bispecific Antibody, Induces Durable Complete Remissions in Relapsed or Refractory B-Cell Lymphoma: A Phase I Trial

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J Clin Oncol 2021;39:1959-70.

Response to Glofitamab in Patients with R/R B-Cell Lymphomas





Glofitamab as Monotherapy and in Combination with Obinutuzumab Induces High Complete Response Rates in Patients with Multiple Relapsed or Refractory (R/R) Follicular Lymphoma (FL)

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