



POST-ORLANDO 2025
Novità dal Meeting della Società Americana di Ematologia

Novità dal Meeting della Società Americana di Ematologia

Torino
Centro Congressi Lingotto
19-21 febbraio 2026

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della Società Americana
di Ematologia

Torino, 19-21 Febbraio 2026

Disclosure Visco

| Company name | Research support | Employee | Consultant | Stockholder | Speakers bureau | Advisory board | Other |
|--------------|------------------|----------|------------|-------------|-----------------|----------------|-------|
| AbbVie | X | | | | X | X | |
| Kite-Gilead | | | | | | X | |
| Janssen | X | | X | | X | X | |
| Gentili | | | | | X | X | |
| Novartis | | | | | | X | |
| Pfizer | | | X | | X | X | |
| Roche | | | | | | X | |
| Incyte | | | | | X | X | |
| Servier | | | | | X | | |
| Astra Zeneca | | | | | X | | |
| BMS | | | | | | X | |
| Kyowa Kirin | | | | | X | | |
| Lilly | | | X | | X | X | |



TOPICS

FIRST LINE

Update of known trials (ECHO)

Triplets becoming mature (BOVEN, TRAVERSE)
TP53 mutations....a problem solved?

R/R SETTING

New drugs and CarT



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ECHO Study Design

ECHO (NCT02972840): multicenter, double-blind, placebo-controlled, phase 3 trial

Untreated MCL (N=598)

- Age ≥ 65 years
- ECOG PS ≤ 2

Stratification

sMIPI score: Low vs intermediate vs high
Geographic region: North America vs Western Europe vs other

R
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1:1

ABR (N=299)

Bendamustine^a
+ Rituximab^b
x 6 cycles

If \geq PR

Maintenance Rituximab
(every 2 cycles x 2 years)

PBR (N=299)

Bendamustine^a
+ Rituximab^b
x 6 cycles

If \geq PR

Maintenance Rituximab
(every 2 cycles x 2 years)

1 cycle = 28 days

Acalabrutinib 100 mg BID, PO until PD or toxicity

Placebo BID, PO until PD or toxicity

Primary endpoint:

- PFS (independent review committee)

Key secondary endpoints:

- ORR (independent review committee)
- OS
- Safety

Crossover to
acalabrutinib after
PD was permitted

Updated Analysis (1 additional year of follow-up)

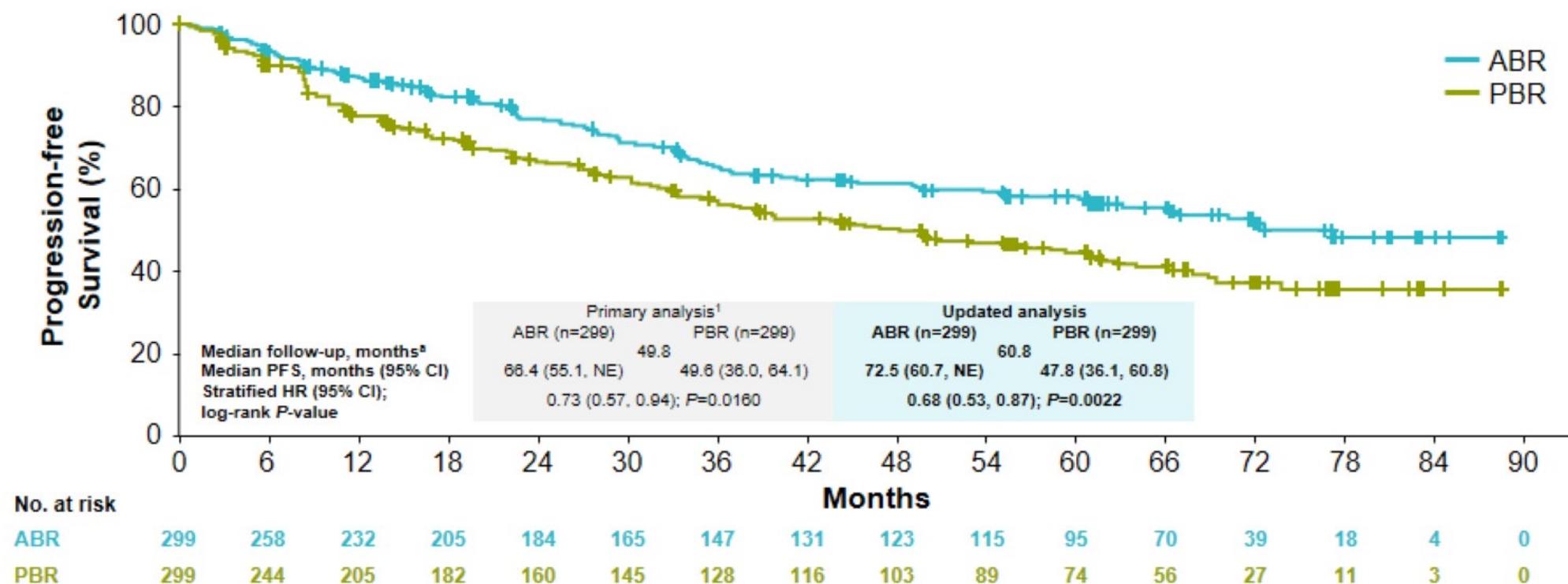
Data cutoff date: February 15, 2025

Median time on study: 51.9 (0.03–93.04) months

^aBendamustine 90 mg/m² on days 1 and 2. ^bRituximab 375 mg/m² on day 1.
 ABR, acalabrutinib plus bendamustine-rituximab; BID, twice daily; ECOG PS, Eastern Cooperative Oncology Group performance status; KM, Kaplan-Meier; MCL, mantle cell lymphoma;
 PBR, placebo plus bendamustine and rituximab; PD, progressive disease; PFS, progression-free survival; PR, partial response; ORR, overall response rate; OS, overall survival;
 PO, orally; sMIPI, simplified MCL International Prognostic Index.



At 60.8 Months of Follow-up, PFS Further Improved With ABR vs PBR



- PFS risk reduction with ABR vs PBR increased from 27% (primary analysis) to 32% (updated analysis)
- Median PFS was longer with ABR vs PBR (6 years vs 4 years)

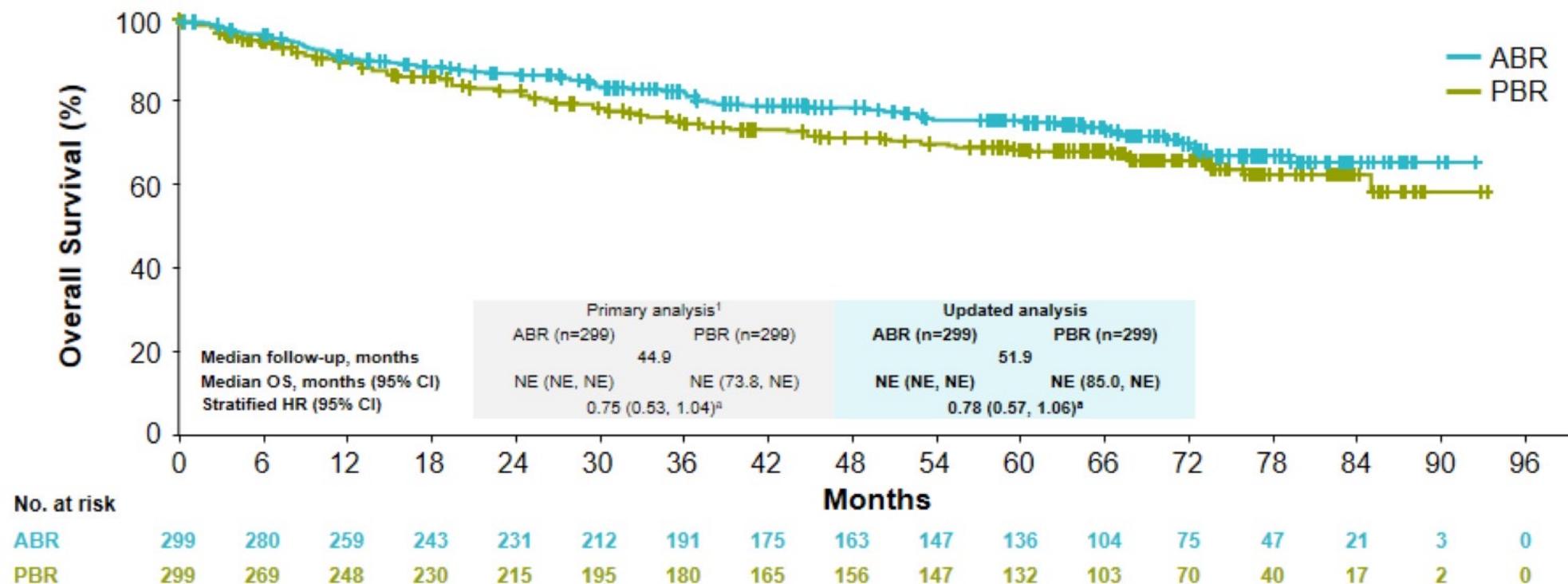
^aMedian follow up for PFS estimated using the reverse K-M method.

ABR, acalabrutinib plus bendamustine-rituximab; CI, confidence interval; HR, hazard ratio; K-M, Kaplan-Meier; NE, not estimable; PBR, placebo plus bendamustine-rituximab; PFS, progression-free survival.

1. Wang M, et al. *J Clin Oncol*. 2025;43:2276-84.



Prespecified OS Analysis Censoring for COVID-19 Deaths Showed Similar Trend as the Primary Analysis



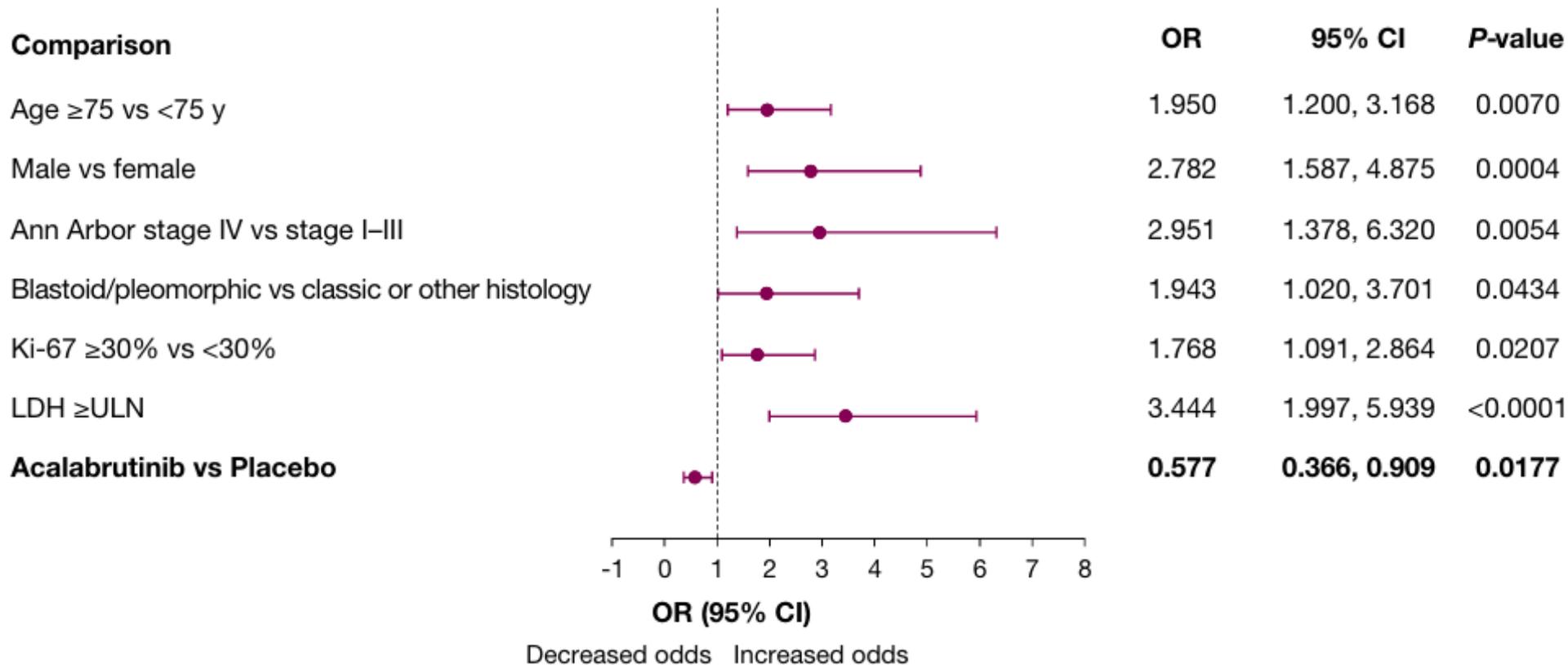
^aThis study was not powered to detect an OS benefit.

ABR, acalabrutinib plus bendamustine-rituximab; CI, confidence interval; HR, hazard ratio; NE, not estimable; OS, overall survival; PBR, placebo plus bendamustine-rituximab.

1. Wang M, et al. *J Clin Oncol*. 2025;43:2278-84.



Factors impacting on POD24 Status



Need for Subsequent Anticancer Therapy Was 3-fold Higher With PBR

Subsequent therapy was required by 11% with ABR vs 33% with PBR

| Number of Patients | ABR (n=299) | PBR (n=299) |
|---|----------------|----------------|
| ≥1 subsequent anticancer therapy | 33 | 100 |
| 2L anticancer therapy^{a,b} | 33 | 100 |
| BTKi | 12 | 79 |
| Chemotherapy | 11 | 13 |
| Non-BTKi targeted therapy ^c | 9 | 6 ^e |
| Others ^d | 1 | 3 ^e |
| 3L anticancer therapy^{a,b} | 10 | 37 |
| BTKi | 3 | 7 |
| Chemotherapy | 4 | 19 |
| Non-BTKi targeted therapy ^c | 3 | 11 |
| 4L+ anticancer therapy^{a,b} | 3 | 14 |
| BTKi | 0 | 5 |
| Chemotherapy | 2 | 7 |
| Non-BTKi targeted therapy ^c | 1 | 7 |

- 57 of 79 patients in the PBR arm who received BTKis in 2L received acalabrutinib on study as crossover

^aA patient receiving multiple subsequent anticancer therapies in the same category is counted only once in the corresponding category.

^bA patient receiving subsequent anticancer therapies in multiple categories is counted once in all categories.

^cTargeted therapy includes all other non-BTKi targeted therapies, including CAR-T (ABR, n=2; PBR, n=5) and T-cell engager therapy (PBR, n=3).

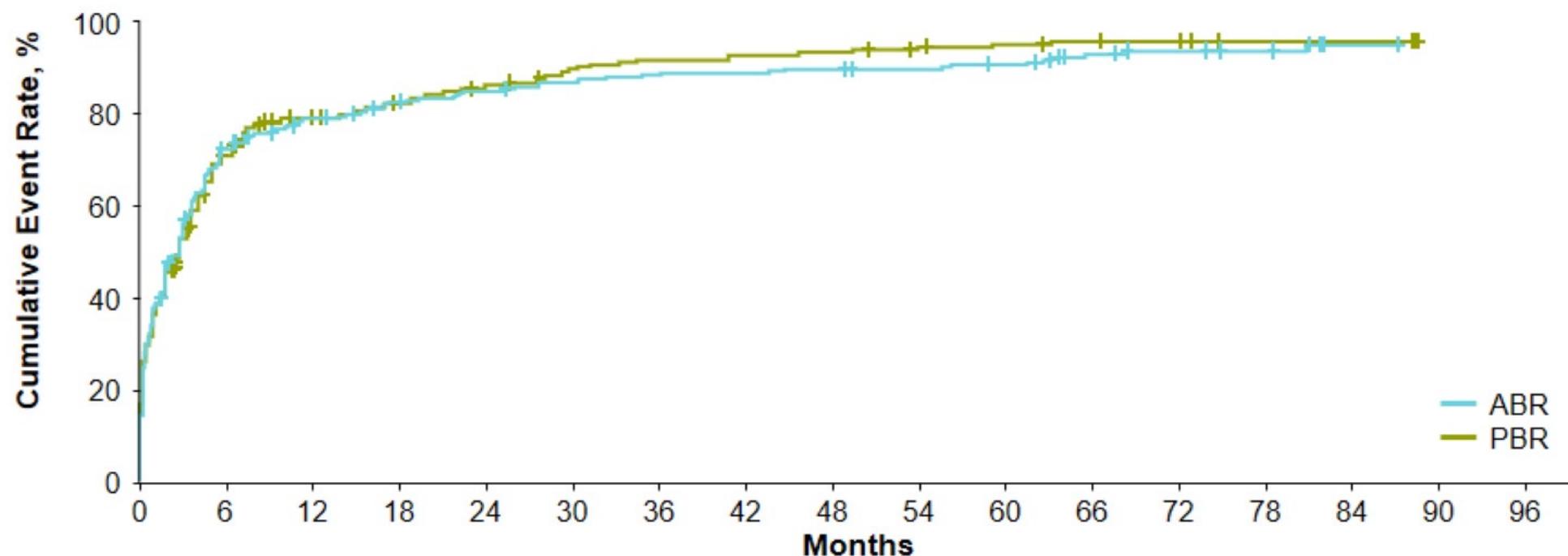
^d"Others" category included radiotherapy and Chinese medicine. "Others" category not included under 3L and 4L+ lines due to 0 applicable patients.

^eOne patient received both targeted therapy (sonrotoclax) and other (radiotherapy) therapy.

2L, second-line; 3L, third-line; 4L+, fourth-line or greater; ABR, acalabrutinib plus bendamustine-rituximab; BTKi, Bruton tyrosine kinase inhibitor; CAR-T, chimeric antigen receptor T-cell therapy; PBR, placebo plus bendamustine-rituximab; SCT, stem cell therapy.



Cumulative Event Rate of Grade ≥ 3 Adverse Events Was Comparable Between Treatment Arms



No. at risk

| | | | | | | | | | | | | | | | | |
|-----|-----|----|----|----|----|----|----|----|----|----|----|----|---|---|---|---|
| ABR | 297 | 80 | 57 | 43 | 36 | 31 | 27 | 26 | 24 | 22 | 19 | 11 | 8 | 6 | 1 | 0 |
| PBR | 297 | 81 | 50 | 39 | 31 | 21 | 17 | 15 | 14 | 11 | 8 | 6 | 5 | 2 | 2 | 0 |





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TP53 mutations....a solved problem?

R/R SETTING

New drugs and CarT

Background

- For older MCL patients, frontline treatments are rapidly evolving with incorporation of targeted therapies.
- Results of the BOVen triplet (*Zanubrutinib, Obinutuzumab, and Venetoclax*) for *TP53*-mutant MCL reported on a small series at ASH2024



**Classical *TP53* mutated:
Stage II bulky noncontiguous;
Stage III, IV**

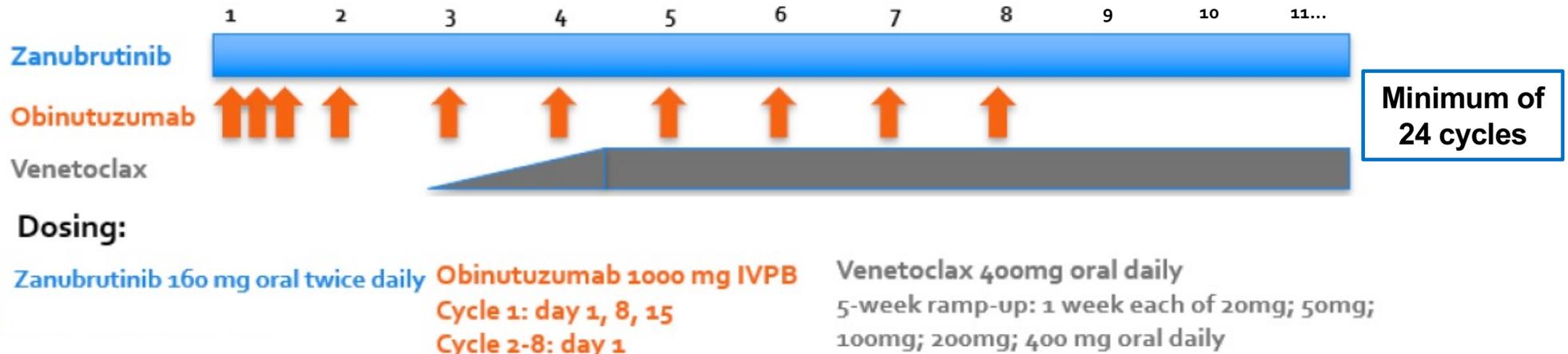


Suitable for all patients

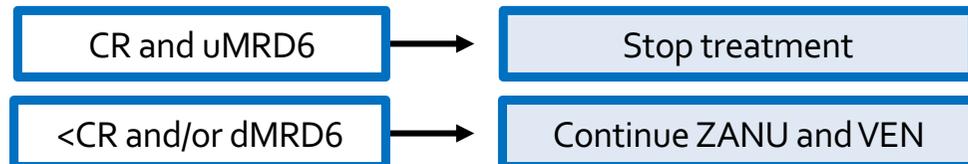
• Zanubrutinib/obinutuzumab/venetoclax

- The results of 2 phase II, multi-center trials, with triplets in the frontline setting (**BOVEN, TRAVERSE**) were reported at ASH2025

Study Design for BOVen



After 24 cycles, MRD-driven approach to limit treatment duration in selected patients:



Key Eligibility Criteria:

- Previously untreated MCL
- ≥ 65 years of age or with comorbidities precluding autologous stem cell transplantation
- ECOG ≤ 2 , adequate organ and hematologic function (ANC >1 , PLT >75 , HGB ≥ 9 (unless due to MCL))

Primary Endpoint:

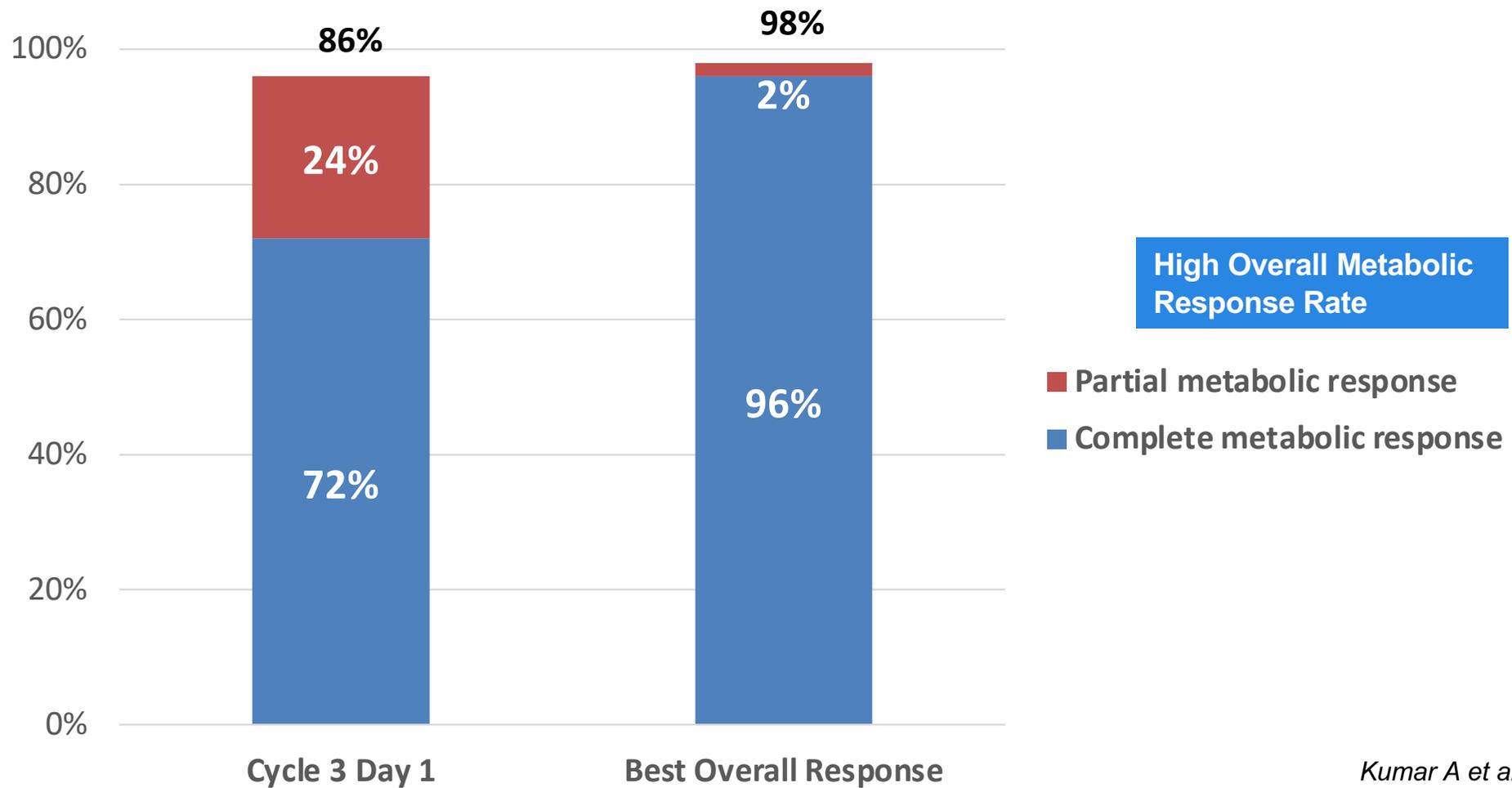
- 3-year progression-free survival
- A promising 3-yr PFS rate $\geq 70\%$ and an unacceptable rate $\leq 50\%$ (historical comparison to Bendamustine-Rituximab)

Baseline Patient Characteristics (n=50)

| Characteristic | N(%) |
|--------------------------------|------------|
| Enrollment Site | |
| Memorial Sloan Kettering | 20 (40%) |
| Massachusetts General Hospital | 27 (54%) |
| Northwestern University | 3 (6%) |
| Age in years | |
| Median (range) | 72 (47-89) |
| ≥75 years of age | 17 (34%) |
| Sex | |
| Male | 32 (64%) |
| MCL Histology | |
| Classical | 35 (73%) |
| Blastoid/Pleomorphic | 7 (15%) |
| Non-nodal leukemic | 6 (13%) |
| Unknown | 2 |
| MIPI Classification | |
| Low | 4 (8%) |
| Intermediate | 11 (22%) |
| High | 35 (70%) |

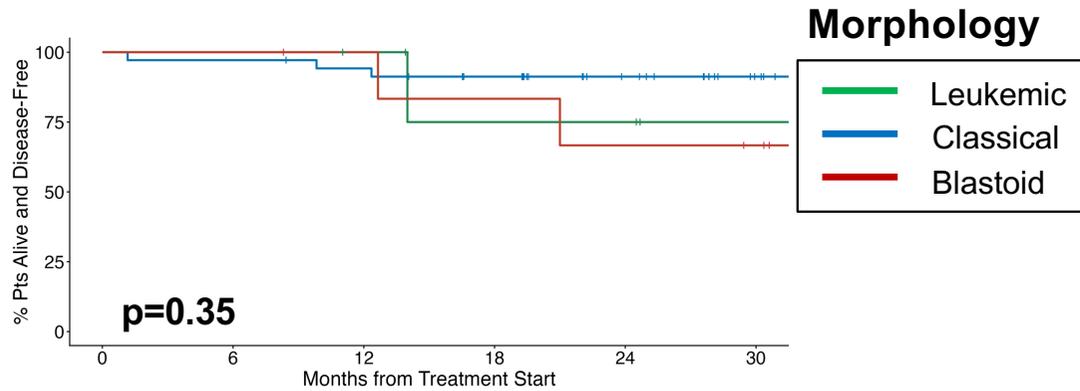
| Characteristic | N(%) |
|---|----------|
| Ki-67 Proliferation Rate | |
| <30% | 24 (49%) |
| ≥30% and <50% | 11 (22%) |
| ≥50% | 14 (29%) |
| Unknown | 1 |
| TP53 mutation by NGS | |
| Yes | 13 (28%) |
| No | 33 (72%) |
| Unknown | 4 |
| 17p deletion by FISH / SNP Array | |
| Yes | 10 (20%) |
| No | 40 (80%) |
| Unknown | |
| TP53 Mutation and 17p deletion | |
| Yes | 7 (14%) |
| No | 39 (78%) |
| Unknown | 4 |

Metabolic Response Rate, n=50



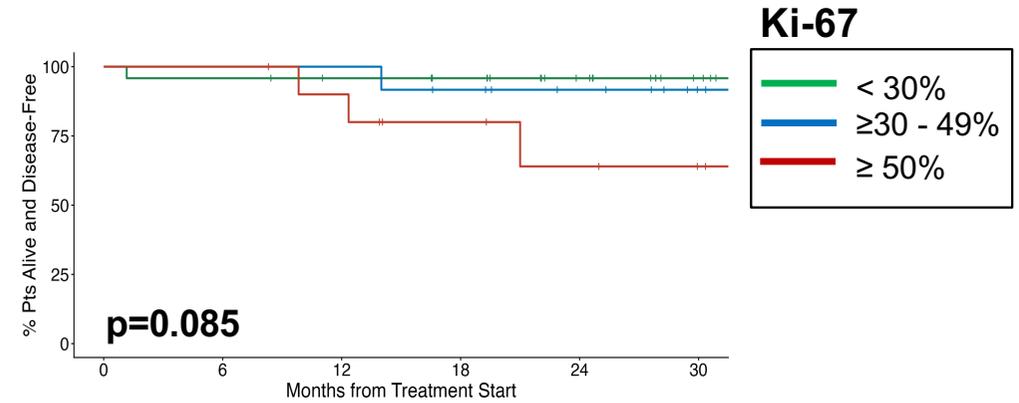
Kumar A et al, ASH 2025

PFS by Baseline Factors



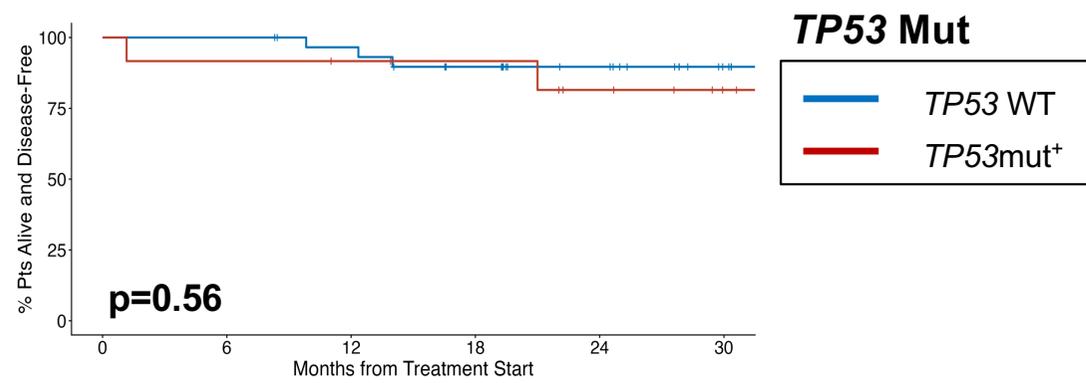
Number at risk: n (%)

| | | | | | |
|----------|---------|---------|---------|---------|--------|
| 6 (100) | 6 (100) | 5 (83) | 3 (50) | 3 (50) | 1 (17) |
| 35 (100) | 34 (97) | 32 (91) | 27 (77) | 16 (46) | 5 (14) |
| 7 (100) | 7 (100) | 6 (86) | 5 (71) | 4 (57) | 3 (43) |



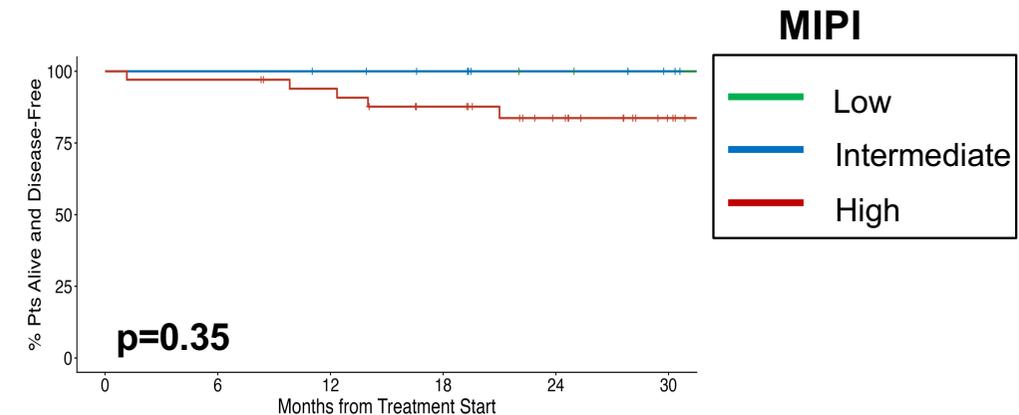
Number at risk: n (%)

| | | | | | |
|----------|----------|----------|---------|---------|--------|
| 24 (100) | 23 (96) | 21 (88) | 19 (79) | 12 (50) | 4 (17) |
| 12 (100) | 12 (100) | 12 (100) | 10 (83) | 7 (58) | 2 (17) |
| 11 (100) | 11 (100) | 9 (82) | 6 (55) | 4 (36) | 2 (18) |



Number at risk: n (%)

| | | | | | |
|----------|----------|---------|---------|---------|--------|
| 31 (100) | 31 (100) | 28 (90) | 22 (71) | 16 (52) | 6 (19) |
| 12 (100) | 11 (92) | 10 (83) | 9 (75) | 6 (50) | 2 (17) |



Number at risk: n (%)

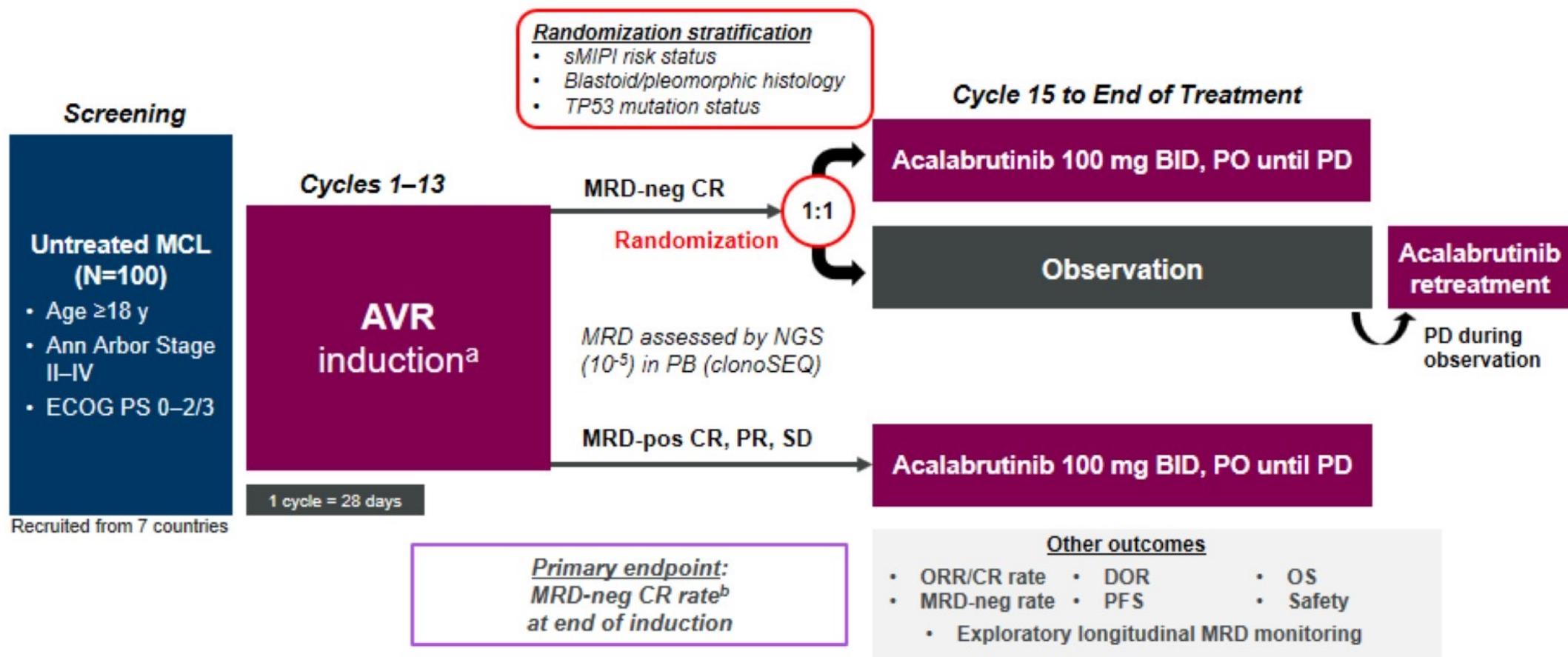
| | | | | | |
|----------|----------|---------|---------|---------|--------|
| 4 (100) | 4 (100) | 4 (100) | 4 (100) | 3 (75) | 1 (25) |
| 10 (100) | 10 (100) | 9 (90) | 7 (70) | 4 (40) | 2 (20) |
| 34 (100) | 33 (97) | 30 (88) | 25 (74) | 17 (50) | 6 (18) |

Acalabrutinib Plus Venetoclax and Rituximab in Patients With Treatment-Naive Mantle Cell Lymphoma: Results From the Phase 2 TrAVeRse Study

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TrAVeRse Study Design: Multicenter, Open-label, Phase 2 Trial



NCT05951959.

^aAVR induction: acalabrutinib 100 mg BID (C1-C13; also given in C14 post-induction), venetoclax (C2-C13 [5-week ramp-up in C2: 20 mg up to 400 mg daily]), rituximab (375 mg/m² day 1 of C1-12).

^bMRD-neg (in PB by NGS [10^{-5} ; clonoSEQ]) while in CR (per Lugano criteria).

AVR, acalabrutinib + venetoclax + rituximab; BID, twice daily; C, cycle; CR, complete response; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; MCL, mantle cell lymphoma; MRD, measurable residual disease; neg, negative; NGS, next-generation sequencing; ORR, overall response rate; OS, overall survival;

PB, peripheral blood; PD, progressive disease; PFS, progression-free survival; PO, orally; pos, positive; PR, partial response; SD, stable disease; sMIPI, simplified Mantle Cell Lymphoma International

Prognostic Index; TM, treatment-naïve.

Demographics and Baseline Characteristics

| Characteristic | AVR (N=108) |
|--|-------------|
| Age, median (range), years | 69 (40–89) |
| Age <65 years, n (%) | 42 (38.9) |
| Male, n (%) | 80 (74.1) |
| White, n (%) | 94 (87.0) |
| Ann Arbor stage IV, n (%) ^a | 99 (91.7) |
| Extranodal involvement, n (%) | 102 (94.4) |
| Bone marrow involvement, n (%) | 90 (83.3) |
| Ki-67 ≥30%, n (%) | 41 (38.0) |
| Blastoid/pleomorphic histology, n (%) ^b | 9 (8.3) |
| <i>p53</i> expression by IHC, n (%) | |
| Positive | 34 (31.5) |
| Negative | 68 (63.0) |
| Missing | 6 (5.6) |
| <i>TP53</i> mutation by NGS, n (%) | |
| Mutated | 17 (15.7) |
| Unmutated | 73 (67.6) |
| Unknown | 18 (16.7) |
| Simplified MIPI, n (%) | |
| Low risk (0–3) | 30 (27.8) |
| Intermediate risk (4–5) | 45 (41.7) |
| High risk (≥6) | 33 (30.6) |

^aAnn Arbor stage II (n=3; 2.8%) and III (n=6; 5.6%).

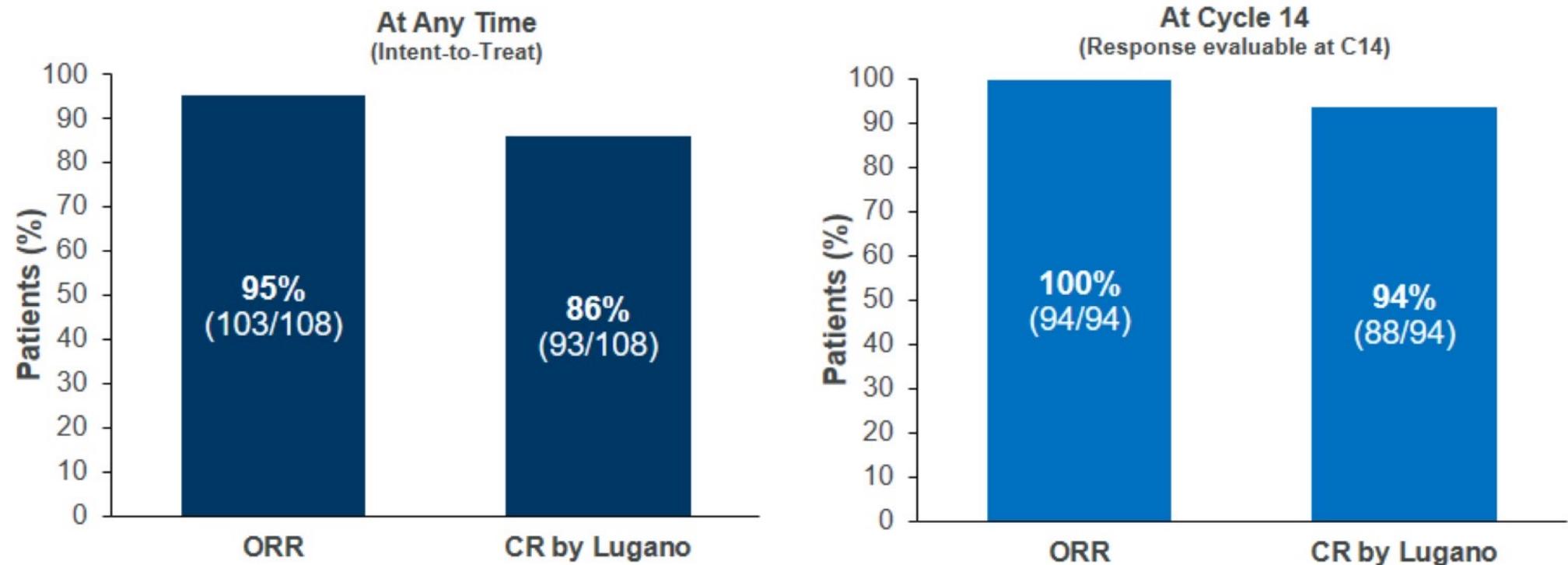
^bOther histology types included classic (n=82; 75.9%), small cell (n=10; 9.3%), and other (n=6; 5.6%); histology type was missing in 1 patient (0.9%).

AVR, acalabrutinib + venetoclax + rituximab; IHC, immunohistochemistry; MIPI, MCL International Prognostic Index; NGS, next-generation sequencing.



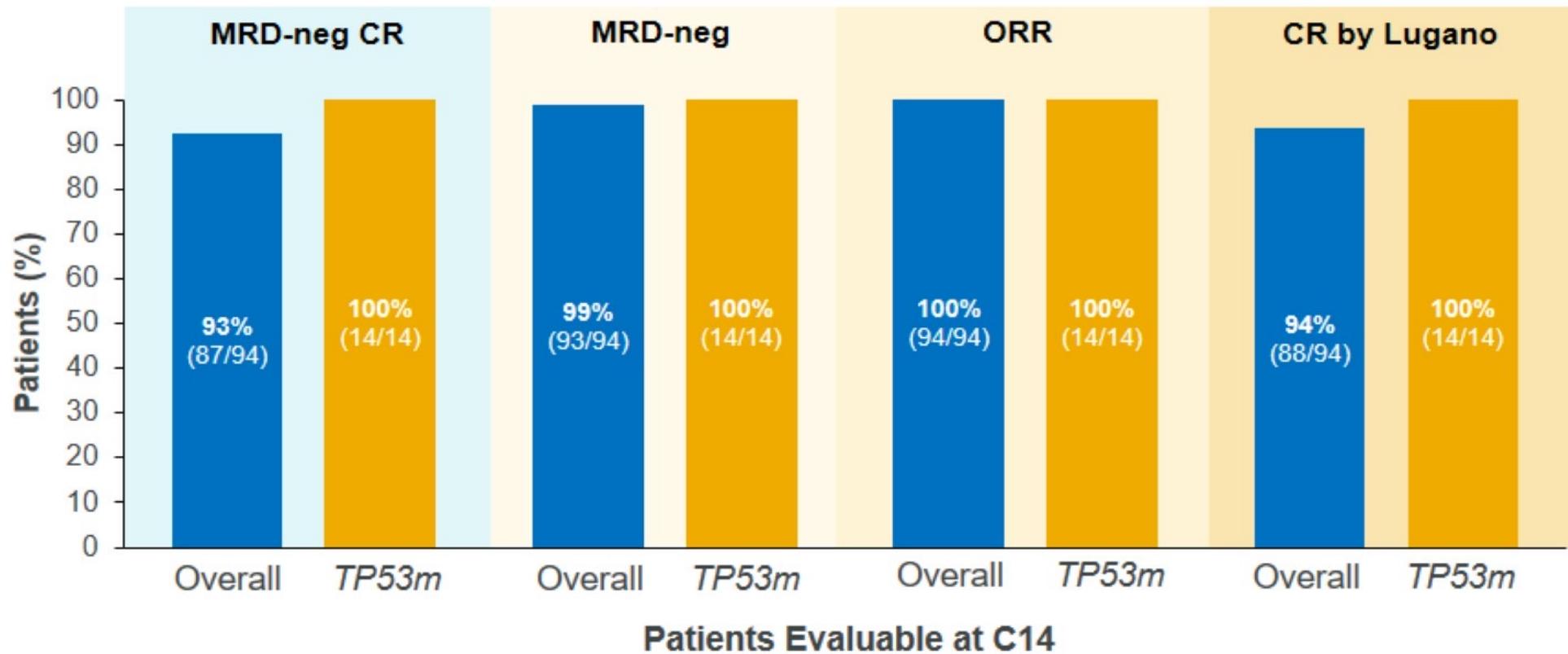
Overall Response and Complete Response

94% had CR by Lugano among patients with response assessment at C14



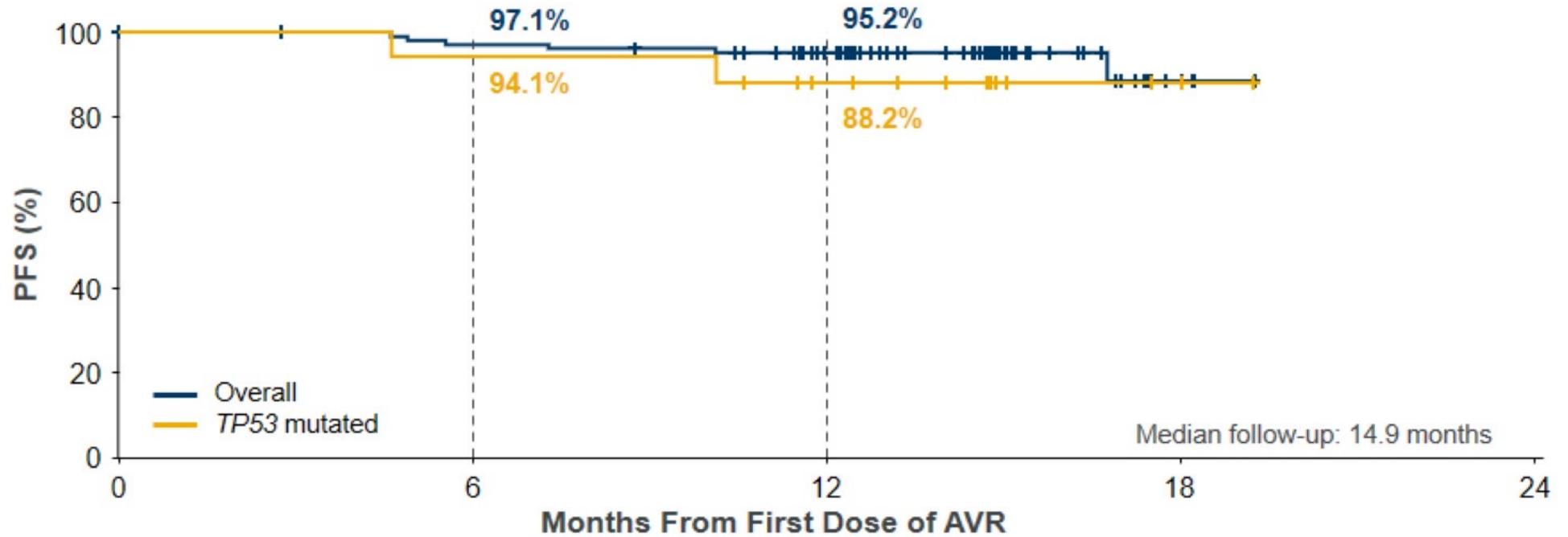
Outcomes at End of Induction in Patients With *TP53* Mutation

*Among evaluable patients who completed induction, those with *TP53m* have comparable benefit*



Progression-free Survival

PFS rates were high, regardless of TP53 mutation status



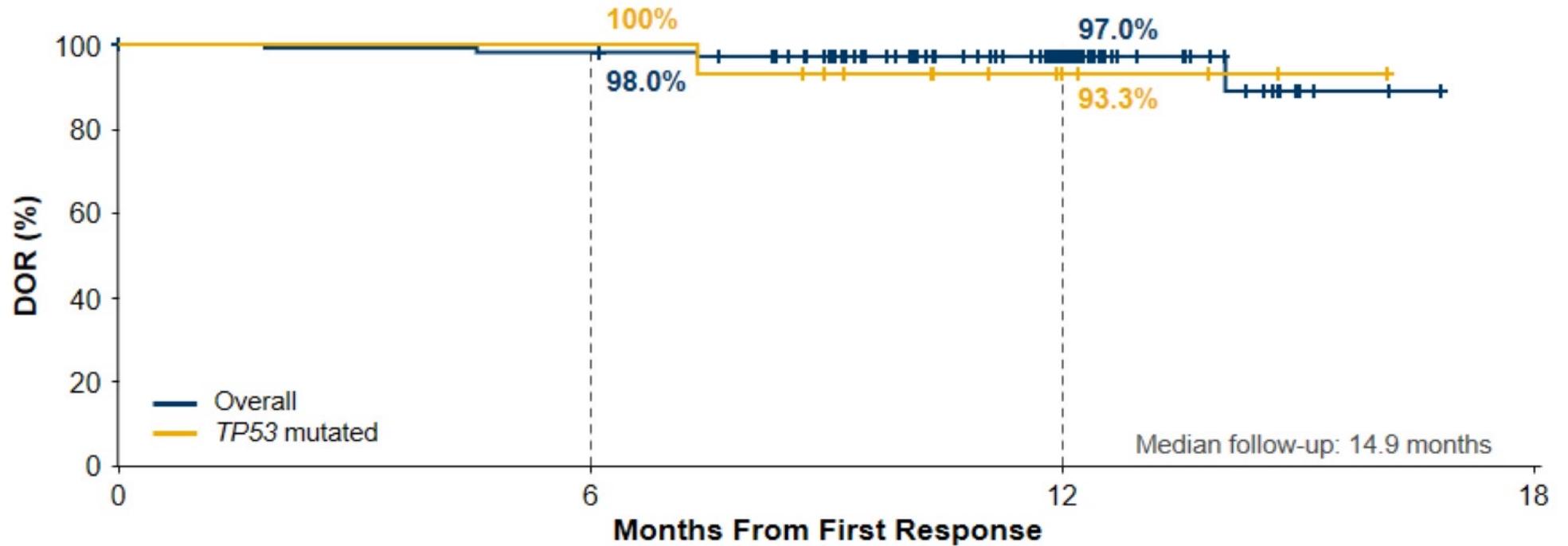
No. at risk

| | 0 | 6 | 12 | 18 | 24 |
|--------------|-----|-----|----|----|----|
| Overall | 108 | 102 | 90 | 3 | 0 |
| TP53 mutated | 17 | 16 | 12 | 2 | 0 |



Duration of Response

Responses were durable, regardless of TP53 mutation status



No. at risk

| | | | | |
|--------------|-----|-----|----|---|
| Overall | 103 | 100 | 46 | 0 |
| TP53 mutated | 15 | 15 | 5 | 0 |





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Triplets becoming mature (BOVEN, TRAVERSE)
TP53 mutations....a solved problem?

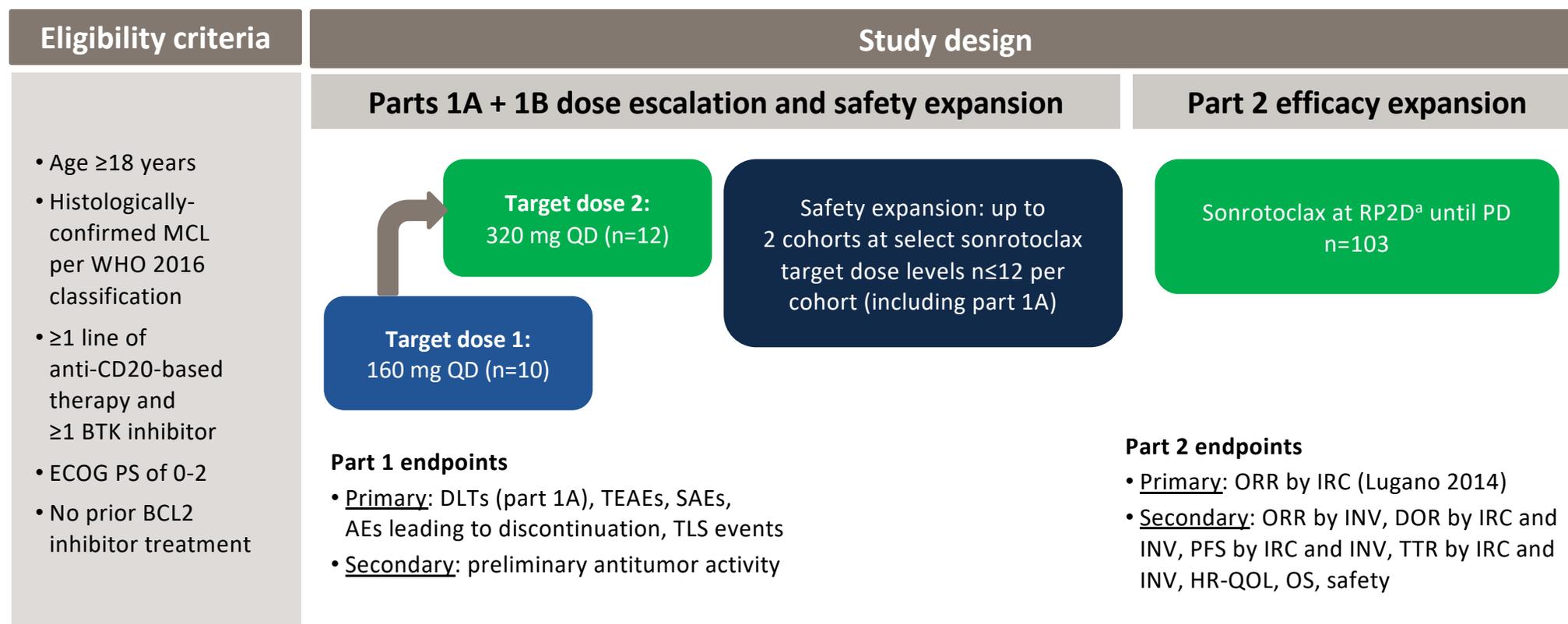
R/R SETTING

New drugs and CarT

Sonrotoclax monotherapy in R/R MCL previously treated with a BTK inhibitor: Early results from a phase 1/2 study

| | Sonrotoclax | Venetoclax | Differences in Design |
|----------------------------------|-----------------------|-----------------------|--|
| Potency (IC₅₀) | 0.014 nM ¹ | 0.20 nM ¹ | 14-fold more potent, which may potentially lead to deeper target inhibition |
| Selectivity (vs BCL-xL) | 2000× ¹ | 325× ¹ | Improved (6-fold) selectivity |
| Half-life in humans | ≈5 hours ² | 26 hours ³ | Short half-life and no accumulation may potentially result in simplified TLS monitoring during sonrotoclax ramp-up |

BGB-11417-201 (NCT05471843) study design



- Sonrotoclax target doses were achieved after a ~4 week ramp-up that did not require hospitalization or 12- or 24-hour post-dose laboratory monitoring

Baseline patient demographics and disease characteristics

| Parameters | Sonrotocla 320 mg (n=115) | Parameters | Sonrotocla 320 mg (n=115) |
|--|---------------------------------|---|---------------------------------|
| Age, median (range), years | 68 (39-85) | Bulky disease status, n (%) | |
| ≥65 years, n (%) | 74 (64.3) | LDi ≥5 cm | 46 (40.0) |
| Male, n (%) | 87 (75.7) | LDi ≥10 cm | 12 (10.4) |
| Race, n (%) | | Bone marrow involvement at baseline, n (%) | 58 (50.4) |
| Asian | 45 (39.1) | Ki67 status, n/N with known status (%) | |
| Black or African American | 3 (2.6) | Positive | 92/98 (93.9) |
| White | 61 (53.0) | ≥30% | 41/98 (41.8) |
| Other/not reported | 6 (5.2) | TP53 mutation, n/N with known status (%) | 27/78 (34.6) |
| Ethnicity, n (%) | | Prior lines of therapy, median (range) | 3 (1-8) |
| Not Hispanic or Latino | 87 (75.7) | ≥3 prior lines, n (%) | 68 (59.1) |
| Hispanic or Latino | 25 (21.7) | Prior BTK inhibitor treatment, n (%) | 115 (100) |
| ECOG performance status, n (%) | | ≥2 prior BTK inhibitors | 22 (19.1) |
| 0 | 34 (29.6) | Prior ASCT, n (%) | 17 (14.8) |
| 1 | 74 (64.3) | Prior CAR-T therapy, n (%) | 3 (2.6) |
| 2 | 7 (6.1) | Reason for ending last line of anticancer therapy, n (%) | |
| Disease stage at study entry, n (%) | | Progressive disease | 79 (68.7) |
| III | 11 (9.6) | Treatment completed | 17 (14.8) |
| IV | 90 (78.3) | Toxicity | 12 (10.4) |
| Disease status to last prior therapy, n (%) | | Other | 7 (6.1) |
| Refractory ^a | 100 (87.0) | | |
| Relapsed ^b | 14 (12.2) | | |
| MIPI, n (%) | | | |
| High | 39 (33.9) | | |
| Intermediate | 41 (35.7) | | |

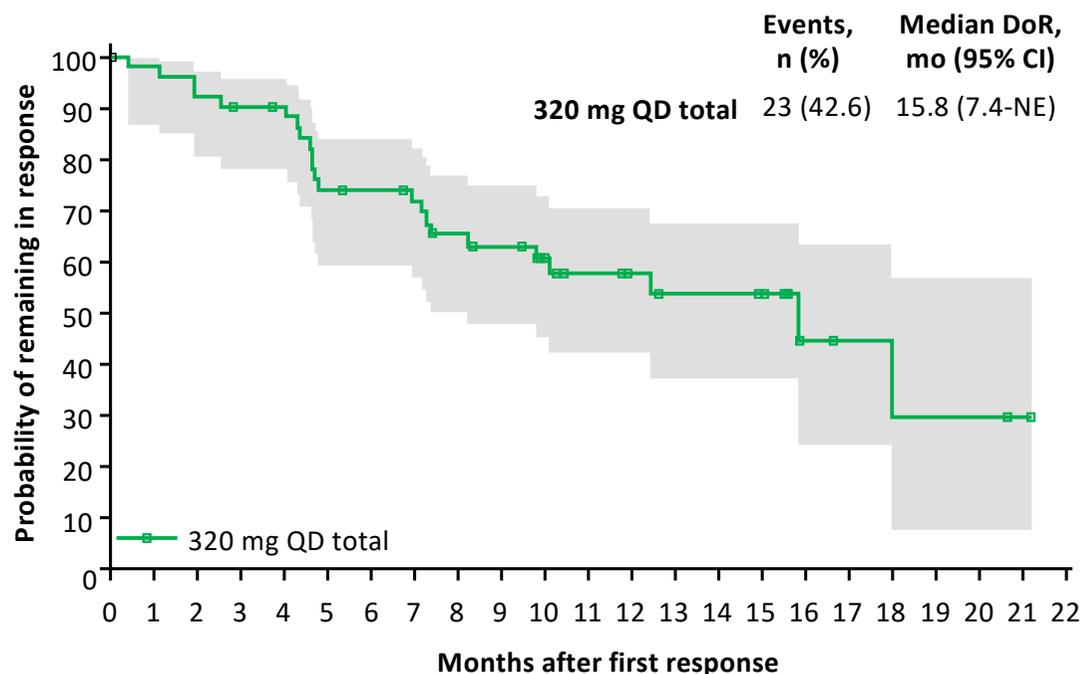
All Grade TEAEs ($\geq 10\%$) and Grade ≥ 3 TEAEs

- Most common grade ≥ 3 TEAEs: hematologic toxicities, infections
- TLS events were reported in 8 patients:
2 had clinical TLS and 6 had laboratory TLS
 - All events resolved without sequelae
 - No events resulted in death or treatment discontinuation

| Patients, n (%) | Sonrotoclax 320 mg (n=115) | |
|--|-------------------------------|----------------|
| | Any grade | Grade ≥ 3 |
| Neutropenia ^a | 41 (35.7) | 22 (19.1) |
| Thrombocytopenia ^b | 28 (24.3) | 11 (9.6) |
| Anemia ^c | 28 (24.3) | 9 (7.8) |
| White blood cell count decreased | 25 (21.7) | 3 (2.6) |
| Hyperuricemia | 22 (19.1) | 0 |
| Hypokalemia | 20 (17.4) | 0 |
| Pneumonia | 18 (15.7) | 12 (10.4) |
| Diarrhea | 16 (13.9) | 5 (4.3) |
| AST increased | 14 (12.2) | 1 (0.9) |
| ALT increased | 12 (10.4) | 0 |
| Constipation | 12 (10.4) | 0 |
| Lymphopenia ^d | 12 (10.4) | 7 (6.1) |
| Select TEAEs by category/AE/SOC | | |
| Infections (SOC) | 45 (39.1) | 19 (16.5) |
| Febrile neutropenia | 2 (1.7) | 2 (1.7) |
| TLS (AE) | 8 (7.0) | 8 (7.0) |

Efficacy for Sonrotoclax at RP2D 320 mg QD

| Part 2: Sonrotoclax 320 mg (n=103) | |
|---|---------------|
| ORR, n (%) | 54 (52.4) |
| 95% CI, % | 42.4-62.4 |
| CR rate, n (%) | 16 (15.5) |
| 95% CI, % | 9.1-24.0 |
| TTR, median (range), months | 1.9 (1.6-6.2) |



No. at risk:

| | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|---|---|---|---|---|---|---|
| 320 mg QD total | 54 | 50 | 47 | 45 | 44 | 36 | 35 | 33 | 29 | 27 | 21 | 17 | 14 | 12 | 12 | 11 | 4 | 3 | 2 | 2 | 2 | 1 | 0 |
|-----------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|---|---|---|---|---|---|---|

News in the Car-T cell field

BREXU-CEL

Long-term RW study found comparable effectiveness and safety outcomes similar to the ZUMA-2 trial. Outcomes were generally consistent irrespective of hepatic, CV, and pulmonary comorbidities, suggesting that age and comorbidity alone should not preclude brexu-cel use in R/R MCL.

Beitinjaneh A et al, ASH 2025

International multicenter study in older pts with R/R MCL. No significant differences in ORR, PFS, or OS were observed between pts aged ≥ 70 and < 70 yrs. Rates of CRS and ICANS were comparable between groups.

Epstein-Peterson et al, ASH 2025

News in the Car-T cell field

GLPG5101

- Fresh, early memory-enriched phenotype CD19 CarT product with robust expansion and long-term persistence
- 7-day vein-to-vein time, 4% drop-out rate, no need for bridging (!)
- No grade ≥ 3 CRS; 100% ORR and 96% CRR despite HR features in 25 patients enrolled in the ATALANTA-1 trial

Kersten MJ et al, ASH 2025

ZAMTO-CEL (LV20.19)

- Lentiviral Anti-CD20/Anti-CD19 CarT product with robust expansion and long-term persistence
- 8-12 days vein-to-vein time, enriched for higher percentages of T_{SCM}/T-naïve cells
- No grade ≥ 3 CRS; ICANS 12%; 100% ORR and 88% CRR despite HR features in 17 patients

Shah J et al, JCO 2025

Take home messages

- BR+Acalabrutinib soon available and standard option for patients not eligible to ASCT (≥ 65 ?)
 - Chemo-free triplets (ZVO and AVR) demonstrated early and sustained response consistently $>90\%$, no additive toxicity observed, limited time Tx?
 - Comparable benefit was seen in *TP53* mutated patients, but numbers still small, and longer follow-up is needed
 - In patients R/R after BTKi failure, sonrotoclax new valid option, while waiting for combinations
-



POST-ORLANDO 2025
Novità dal Meeting della Società Americana di Ematologia

Novità dal Meeting
della Società Americana
di Ematologia

Torino, 19-21 Febbraio 2026



Thanks for your attention



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