The Implications of Recent Datasets for the Current and Future Management of Non-Hodgkin Lymphoma

A CME/MOC-Accredited Live Webinar

Wednesday, September 17, 2025
5:00 PM – 6:00 PM ET

Faculty

Carla Casulo, MD
Brad S Kahl, MD

Moderator

Neil Love, MD

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Faculty

Carla Casulo, MD
Associate Professor of Medicine
Division of Hematology/Oncology
Assistant Director, Cancer Research Training and Education
University of Rochester
Wilmot Cancer Institute
Rochester, New York

Brad S Kahl, MD
Professor of Medicine
Washington University School of Medicine
Director, Lymphoma Program
Siteman Cancer Center
St Louis, Missouri

MODERATOR
Neil Love, MD
Research To Practice
Miami, Florida

Commercial Support

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Dr Love — Disclosures

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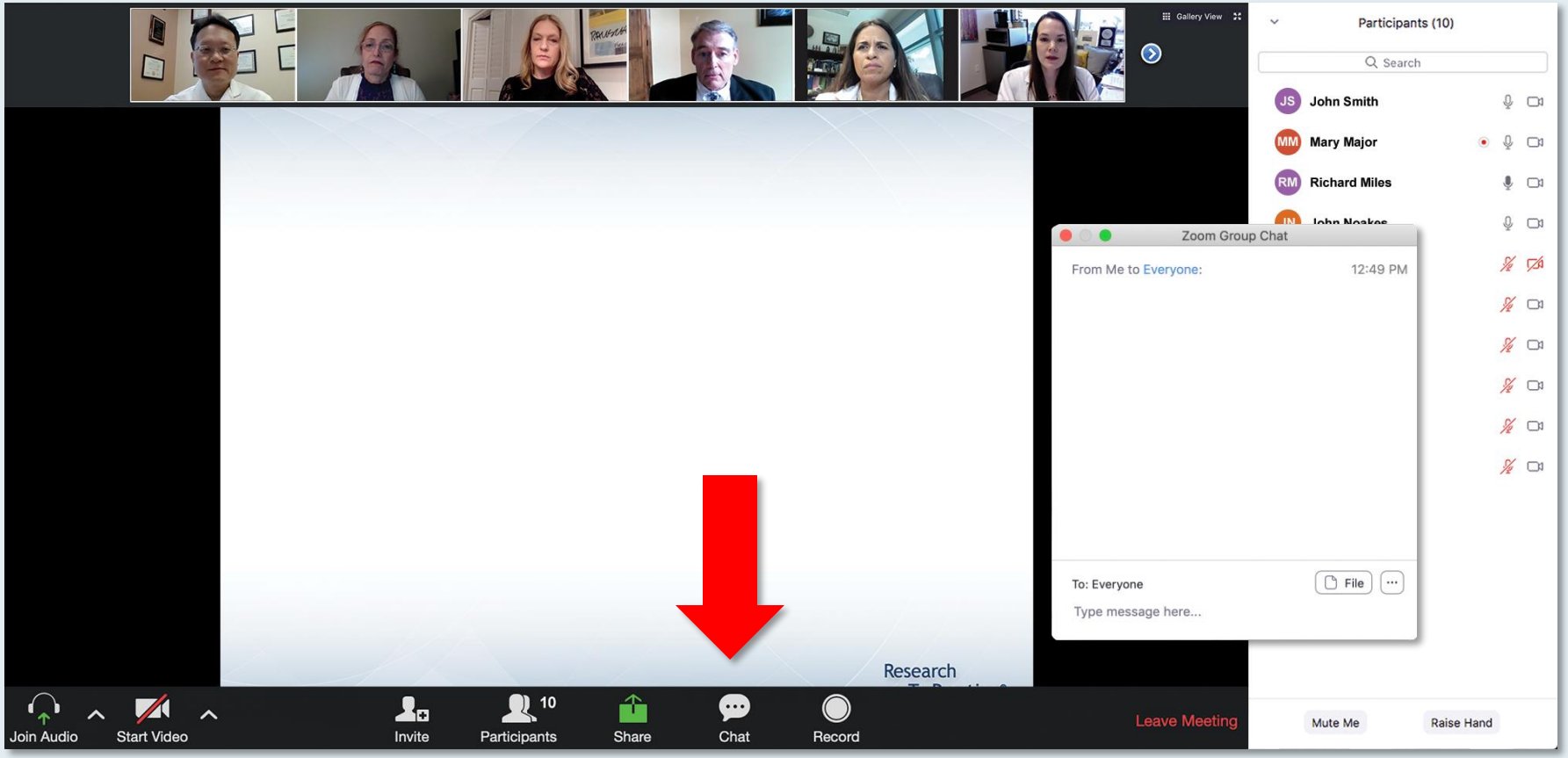

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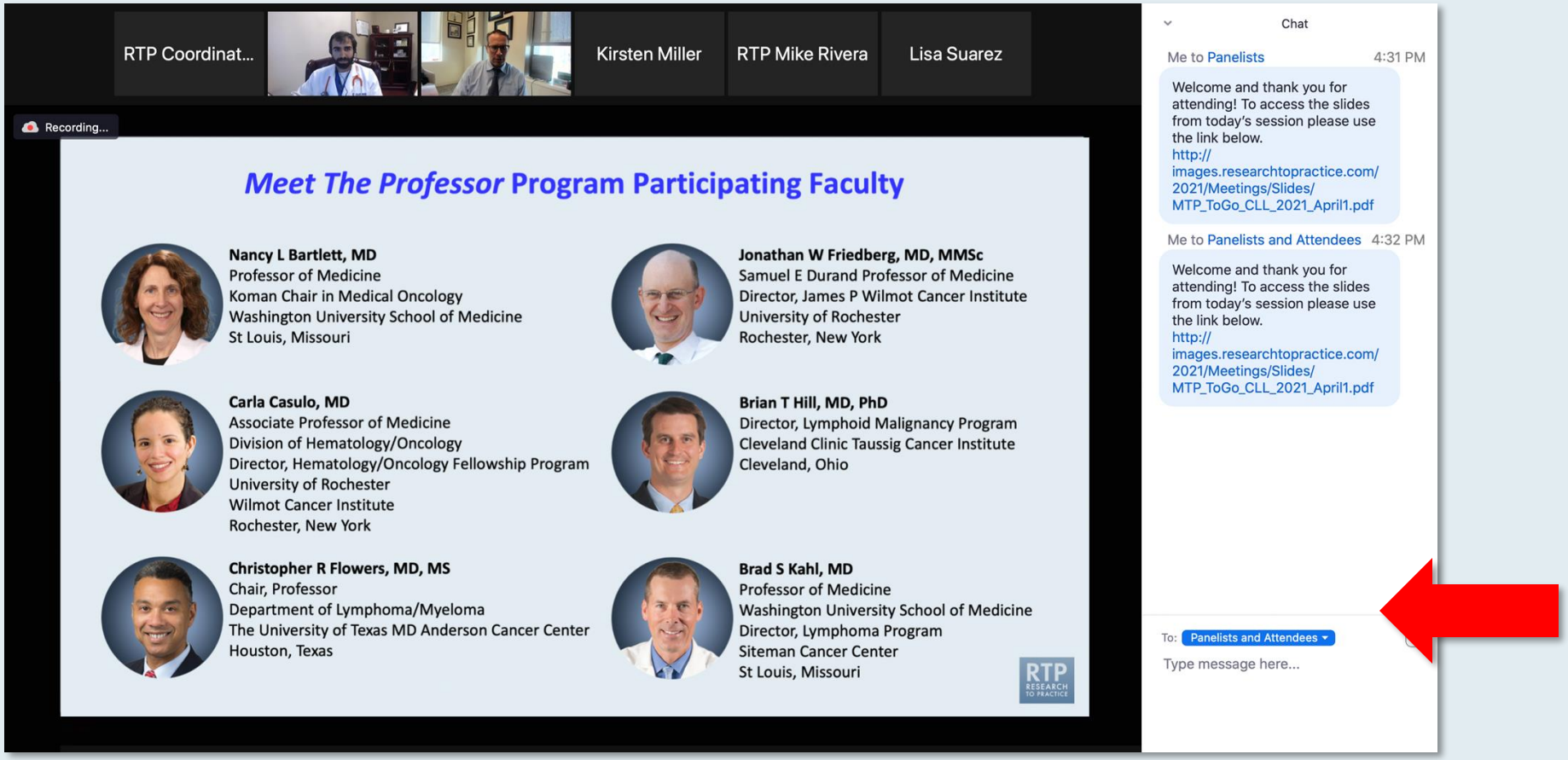

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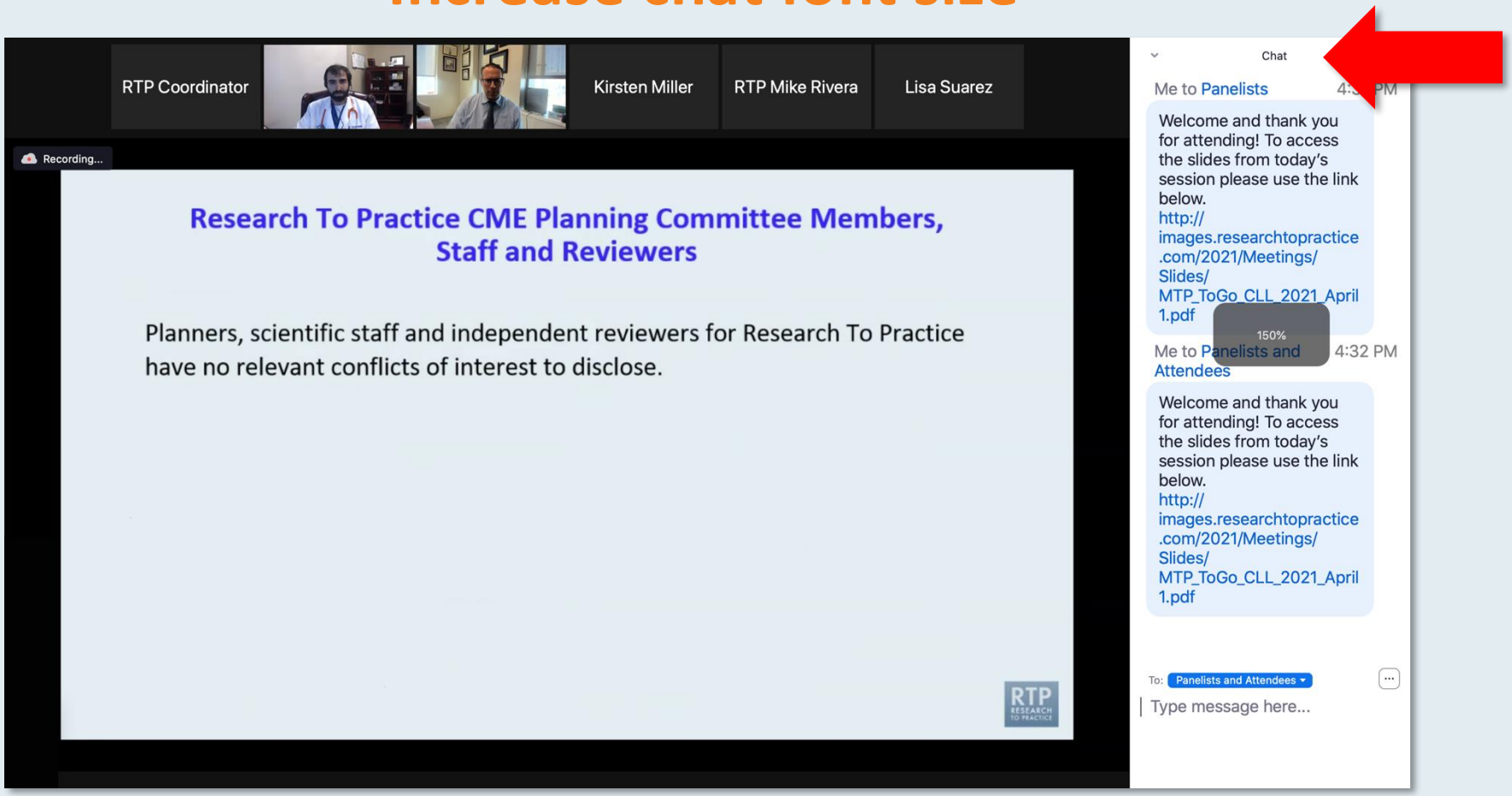

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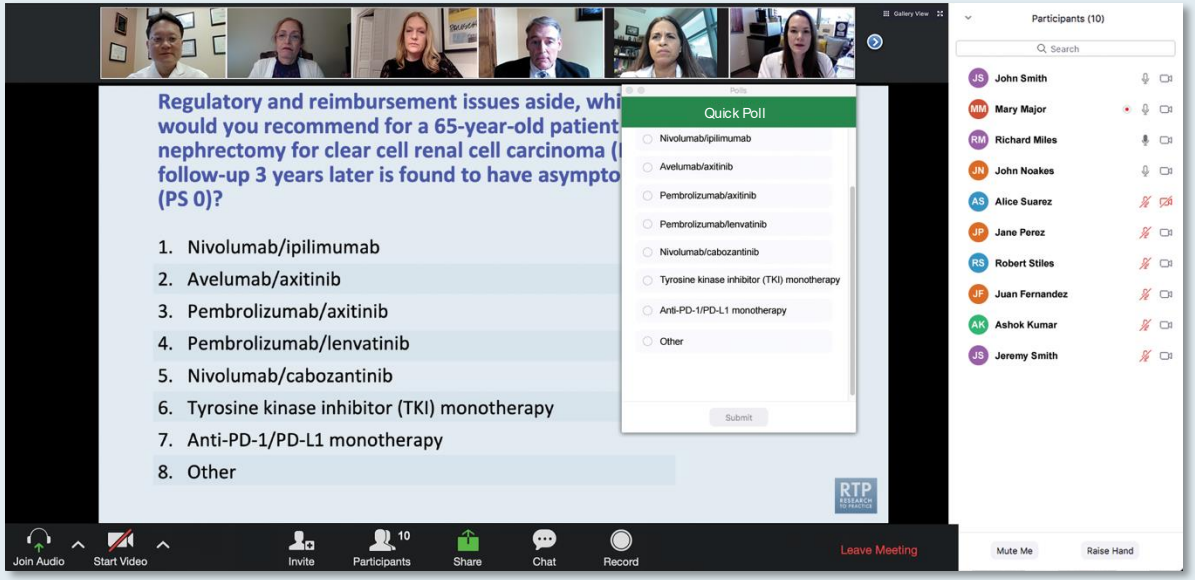

Non-Hodgkin Lymphoma — Year in Review Series on Relevant New Datasets and Advances

DR STEPHEN ANSELL
MAYO CLINIC

DR BRIAN HILL
CLEVELAND CLINIC TAUSSIG CANCER INSTITUTE

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Adam M Brufsky, MD, PhD

Moderator

Neil Love, MD

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Data + Perspectives: Clinical Investigators Explore the Application of Recent Datasets in Current Oncology Care

A Multitumor Symposium in Partnership with Florida Cancer Specialists & Research Institute

Saturday, October 11, 2025
7:15 AM – 12:30 PM ET

The Ritz-Carlton Orlando, Grande Lakes | Orlando, Florida

Faculty

Emmanuel S Antonarakis, MD
Harold J Burstein, MD, PhD
Matthew P Goetz, MD
Christopher Lieu, MD
Matthew Lunning, DO
Heather McArthur, MD, MPH, FASCO
Sonali M Smith, MD
John Strickler, MD

Additional faculty to be announced.

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RTP RESEARCH TO PRACTICE

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RTP RESEARCH TO PRACTICE

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Cancer Q&A: Understanding the Role and Reality of CAR (Chimeric Antigen Receptor) T-Cell Therapy for Non-Hodgkin Lymphoma

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Patients

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Clinicians

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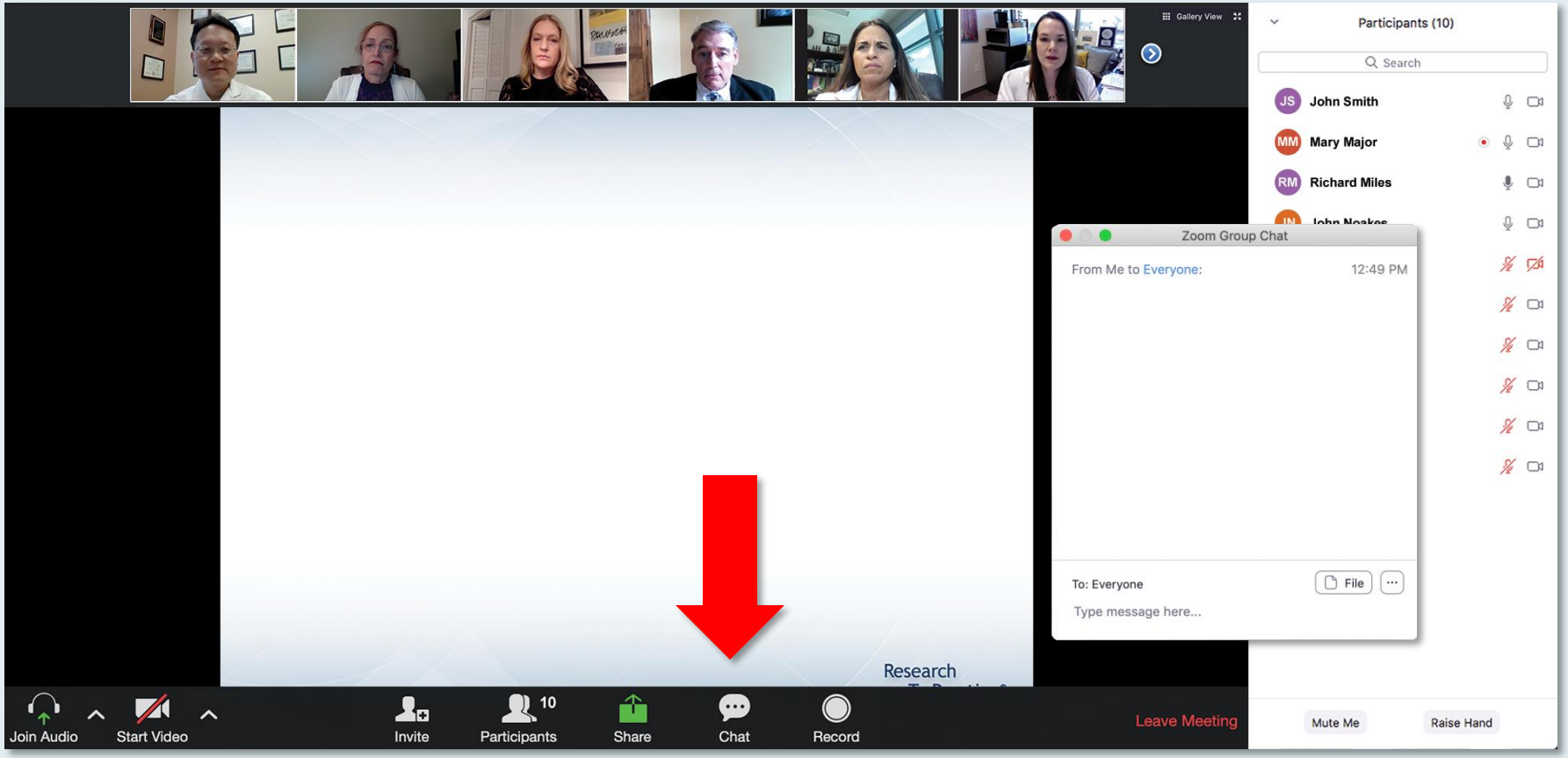

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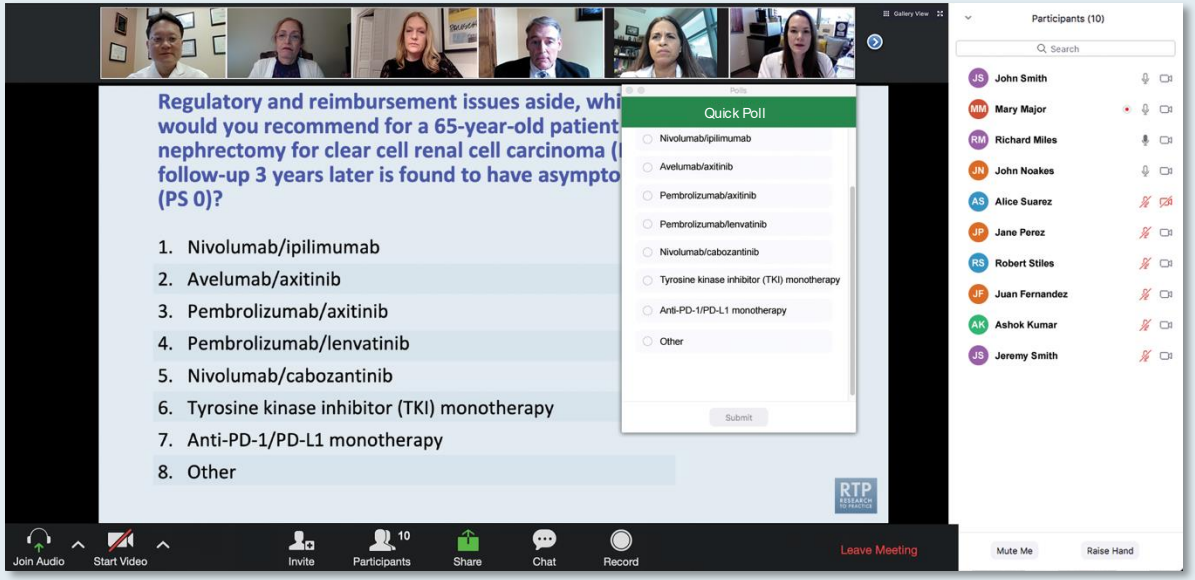

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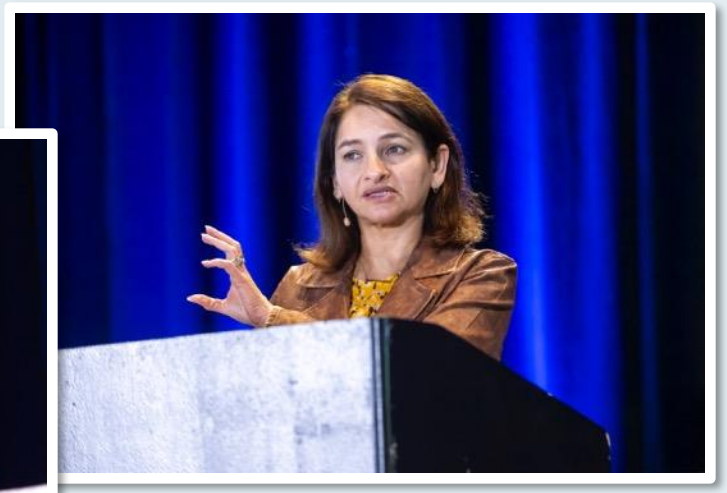
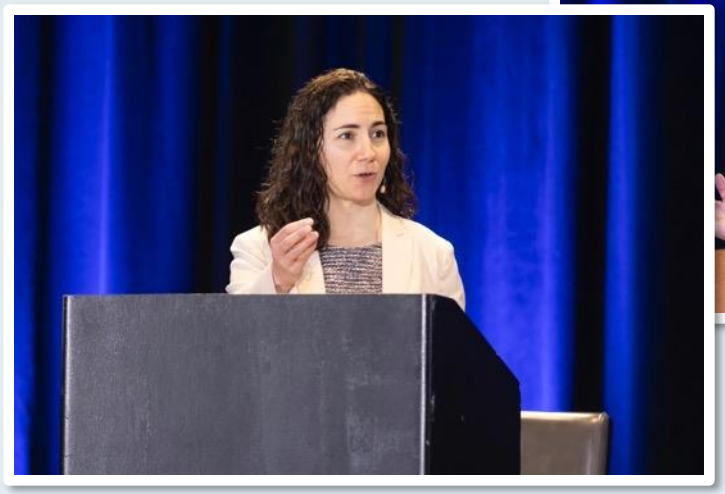
2005 to 2025





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Data + Perspectives: Clinical Investigators Explore the Application of Recent Datasets in Current Oncology Care

Agenda

7:15 AM – 9:15 AM – Breast Cancer

- Localized Hormone Receptor (HR)-Positive Breast Cancer; Initial Therapy for Metastatic Disease
- Therapeutic Options for Relapsed/Refractory HR-Positive Metastatic Breast Cancer
- Management of HER2-Positive Breast Cancer
- Treatment Approaches for Triple-Negative Breast Cancer

9:15 AM – 9:30 AM — Break

9:30 AM – 10:30 AM — Prostate Cancer

- Optimizing the Role of Hormonal Therapy in the Care of Patients with Prostate Cancer
- Other Available and Emerging Therapeutic Approaches

10:30 AM – 11:30 AM — Colorectal Cancer (CRC)

- Current and Future Role of Immune Checkpoint Inhibitors in the Management of CRC
- Other Biomarker-Based Strategies for Patients with CRC

11:30 AM – 12:30 PM — Diffuse Large B-Cell Lymphoma (DLBCL) and Follicular Lymphoma (FL)

- Available and Emerging Novel Therapies for DLBCL and FL
- Role of Chimeric Antigen Receptor T-Cell Therapy and Bispecific Antibodies in Treatment for DLBCL and FL

12:30 PM — Meeting Adjourns

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Faculty Data and Case Presentation – Dr Kahl

- First-line treatment of diffuse large B-cell lymphoma (DLBCL)
- Management of relapsed/refractory DLBCL

Faculty Data and Case Presentation – Dr Casulo

- Follicular lymphoma
- Marginal zone lymphoma
- Mantle cell lymphoma

Key Datasets

Diffuse Large B-Cell Lymphoma — Dr Kahl

- Calabretta E et al. The benefit of **Pola-R-CHP** in DLBclass-defined molecular subsets of newly diagnosed DLBCL in the **POLARIX trial**. ICML 2025;Abstract LBA1.
- Matasar M et al. **Polatuzumab vedotin, rituximab, gemcitabine and oxaliplatin (Pola-R-GemOx)** for relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL): Results from the randomized **phase III POLARGO trial**. EHA 2025;Abstract S101.
- Kerr D et al. Durable efficacy with fixed-duration **epcoritamab + polatuzumab vedotin, rituximab, cyclophosphamide, doxorubicin, and prednisone (Pola-R-CHP)** for 1L diffuse large B-cell lymphoma (**EPCORE NHL-5**). EHA 2025;Abstract S247.
- Crombie JL et al. A multicenter phase II study of **glofitamab plus polatuzumab-R-CHP** for patients with high-risk diffuse large B-cell lymphoma. ICML 2025;Abstract 74.
- Abramson JS et al. **Glofitamab plus gemcitabine and oxaliplatin (Glofit-GemOx)** in patients (pts) with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL): 2-year (yr) follow-up of **STARGLO**. ASCO 2025;Abstract 7015.
- Westin J et al. **Mosunetuzumab plus polatuzumab vedotin** is superior to R-GemOx in transplant-ineligible patients with R/R LBCL: Primary results of the **phase III SUNMO** trial. ICML 2025;Abstract LBA3.

Key Datasets

Diffuse Large B-Cell Lymphoma — Dr Kahl (Continued)

- Alderuccio JP et al. Initial results from **LOTIS-7**: A phase 1b study of **loncastuximab tesirine plus glofitamab** in patients with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL). EHA 2025;Abstract PS1911.
- Carlo-Stella C et al. Updated safety run-in results from **LOTIS-5**: **A phase 3, randomized trial of loncastuximab tesirine with rituximab** versus immunochemotherapy in patients with R/R DLBCL/HGBL. EHA 2025;Abstract PS1957.
- Armand P et al. **WaveLINE-003: Phase 2/3 trial of zilovertamab vedotin plus standard of care** in relapsed/refractory diffuse large B-cell lymphoma. ASCO 2025;Abstract 7005.
- Kim TM et al. Safety and efficacy of **AZD0486, a CD19 x CD3 T-cell engage**r, in relapsed or refractory diffuse large B-cell lymphoma. ASCO 2025;Abstract 7046.
- Le Gouill S et al. **SOUNDTRACK-E**: A phase 1/2, open-label, multicenter study to evaluate the safety and efficacy of **AZD0486 monotherapy or combination therapy** in patients with mature B-cell malignancies. ASCO 2025;Abstract TPS7083.
- Shadman M et al. TITANium: An open-label, global multicenter phase 1/2 study **of AZD5492, a first-in-class subcutaneous CD8-guided tri-specific T-cell engager (TCE),** in patients (pts) with relapsed or refractory (r/r) B-cell malignancies. ASCO 2025;Abstract TPS7091.

Key Datasets

Follicular, Marginal Zone and Mantle Cell Lymphoma — Dr Casulo

- Trneny M et al. **Tafasitamab (tafa) plus lenalidomide (len) and rituximab (R)** for patients with relapsed or refractory **follicular lymphoma** (R/R FL): Results from the **phase 3 INMIND study**. EHA 2025;Abstract S230.
- Thieblemont C et al. 4-year update of **phase 2 ELARA trial**: Clinical outcomes of **tisagenlecleucel** in patients (pts) with high-risk relapsed/refractory **follicular lymphoma** (R/R FL). EHA 2025;Abstract PS2150.
- Ahmed S et al. **Lisocabtagene maraleucel in R/R FL (TRANSCEND FL):** Impact of prior lines of therapy, bendamustine exposure, and disease progression ≤ 24 months of initial systemic therapy. ICL 2025;Abstract 142.
- Heß G et al. Fixed-duration **subcutaneous mosunetuzumab** demonstrates clinically relevant efficacy in patients with relapsed/refractory **follicular lymphoma** with high-risk features: **Pivotal phase II study update**. EHA 2025;Abstract PS1872.
- Vitolo U et al. **Epcoritamab** monotherapy demonstrates deep and durable responses at **3-year follow-up** in patients with relapsed/refractory **follicular lymphoma**. EHA 2025;Abstract PF881.
- Flinn IW et al. Fixed duration **subcutaneous** (SC) **mosunetuzumab** (Mosun) in patients with previously untreated high-tumor burden **follicular lymphoma** (FL): Interim results from the **phase II MorningSun study**. ASCO 2025;Abstract 7014.
- **Phase 3 EPCORE FL-1 clinical trial met dual primary endpoints** in patients with relapsed/refractory (R/R) **follicular lymphoma** (FL) [press release]. August 7, 2025. https://ir.genmab.com/news-releases/news-release-details/genmab-announces-phase-3-epcorer-fl-1-clinical-trial-met-dual.

Key Datasets

Follicular, Marginal Zone and Mantle Cell Lymphoma — Dr Casulo (Continued)

- Palomba ML et al. **Lisocabtagene maraleucel** (liso-cel) in patients (pts) with relapsed or refractory (R/R) **marginal zone lymphoma** (MZL) in the **phase 2 TRANSCEND FL study**. ICML 2025;Abstract 55.
- Burke JM et al. **MorningSun**: Open-label phase II trial of the efficacy and safety of **subcutaneous mosunetuzumab** (mosun SC) as frontline (1L) treatment in symptomatic patients with **marginal zone lymphoma** (MZL). EHA 2025;Abstract S232.
- Dreyling M et al. Efficacy of **rituximab-bendamustine with or without acalabrutinib** in patients with untreated, high-risk **mantle cell lymphoma**: An analysis of the **phase 3 ECHO trial**. EHA 2025;Abstract S233.
- Wang ML et al. Minimal residual disease with **bendamustine-rituximab with or without acalabrutinib** in patients with previously untreated **mantle cell lymphoma**: Results from the **phase 3 ECHO trial**. EHA 2025;Abstract PF882.
- Jain P et al. **Acalabrutinib in combination with rituximab** is highly effective frontline treatment for older patients with **mantle cell lymphoma**. ICML 2025;Abstract 272.

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Overview Discussion

Currently Approved ADCs in Oncology

Solid tumors	Hematologic cancers
Trastuzumab emtansine	Gemtuzumab ozogamicin
Sacituzumab govitecan	Brentuximab vedotin
Datopotamab deruxtecan	Inotuzumab ozogamicin
Trastuzumab deruxtecan	Polatuzumab vedotin
Mirvetuximab soravtansine	Loncastuximab tesirine
Tisotumab vedotin	
Enfortumab vedotin	
Telisotuzumab vedotin	

https://www.fda.gov/drugs/resources-information-approved-drugs/oncology-cancer-hematologic-malignancies-approval-notifications

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Diffuse Large B Cell Lymphoma

Brad Kahl, MD

Professor of Medicine

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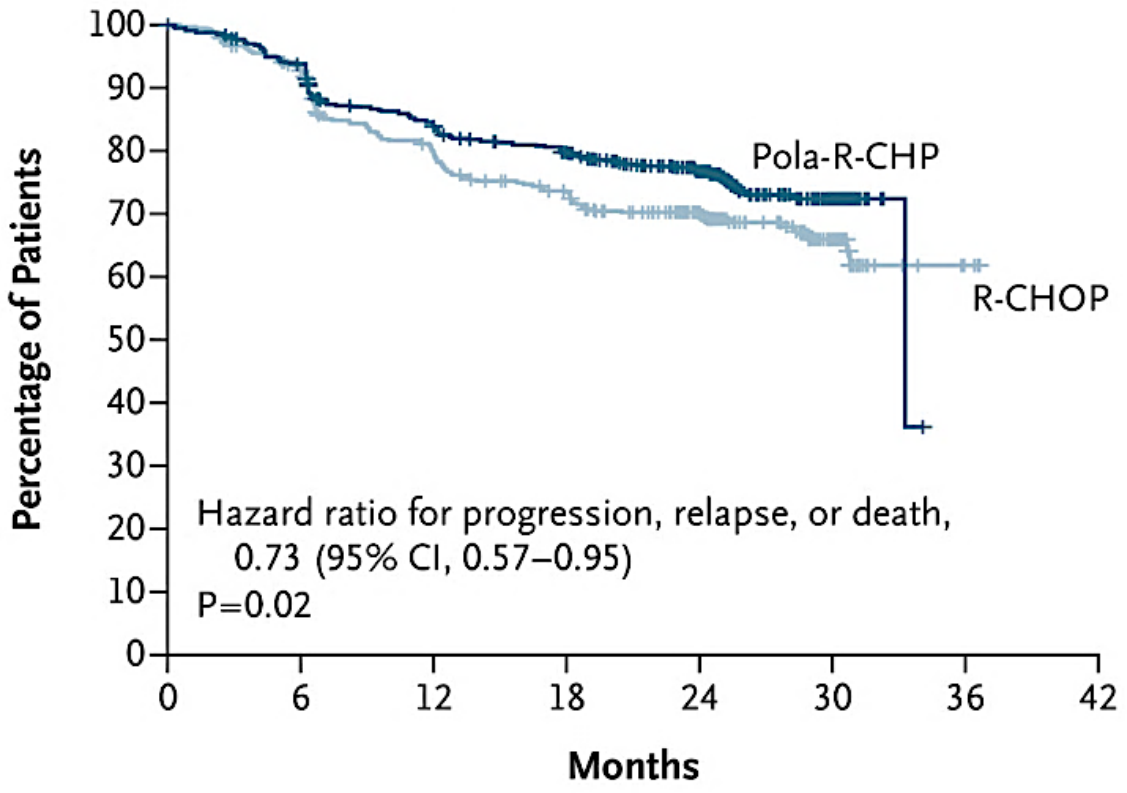
New Data in Frontline DLBCL

- **The benefit of Pola-R-CHP in DLBclass defined molecular subsets of new diagnosed DLBCL.** Calabretta et al, ICML.

- **A multicenter phase II study of glofitamab plus Pola-R-CHP for patients with high-risk DLBCL.** Crombie et al, ICML.

- **Durable efficacy with fixed duration epcoritamab plus Pola-R-CHP for 1L DLBCL (EPCORE NHL-5).** Kerr et al, EHA.

POLARIX Clinical Trial



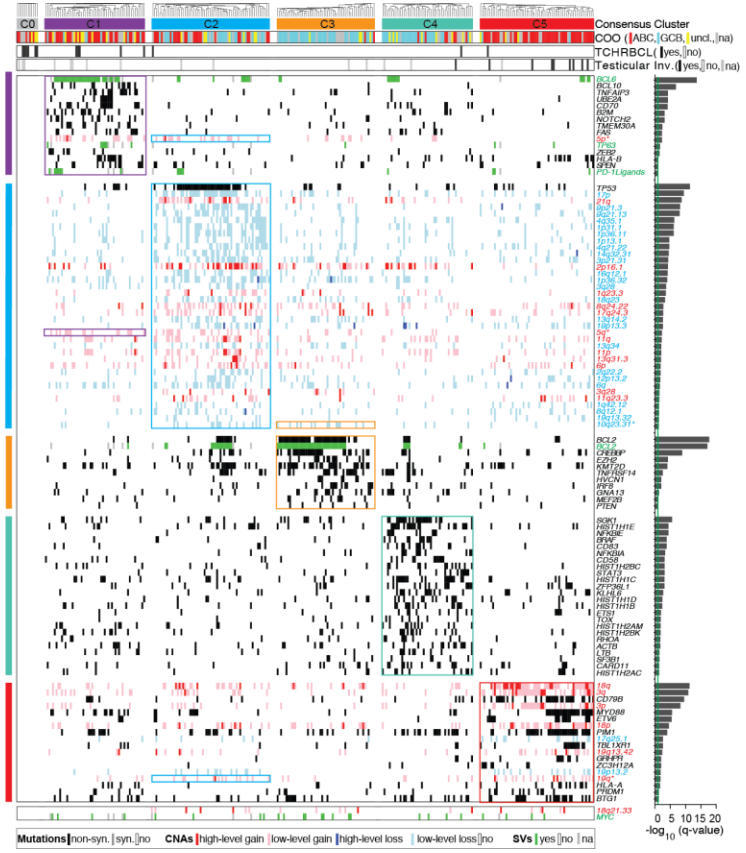
No. at Risk

Pola-R-CHP	440	404	353	327	246	78	NE	NE
R-CHOP	439	389	330	296	220	78	3	NE

- Trial compared efficacy of Pola-R-CHP (polatuzumab [anti-CD79B] vedotin plus rituximab, cyclophosphamide, doxorubicin, and prednisone) versus R-CHOP (R-CHP and vincristine) in newly diagnosed patients with intermediate- to high- risk (IPI 2-5) DLBCL.
- PFS benefit for Pola-R-CHP at 2 years (Pola-R-CHP, **76.7%** [95%CI 72.7-80.8] vs R-CHOP, **70.2%** [95%CI 65.8-74.6])
- PFS benefit persisted at 5 years.
- Exploratory subgroup analysis suggested benefit for Pola-R-CHP in multiple subgroups, including transcriptionally-defined cell-of-origin ABC subtype of DLBCL

Tilly H, Morschhauser F, Sehn LH, et al. N Engl J Med. 2022;386(4):351-363.
Salles G et al., ASH 2024

DLBCL Subsets with Discrete Genetic Features and Outcomes



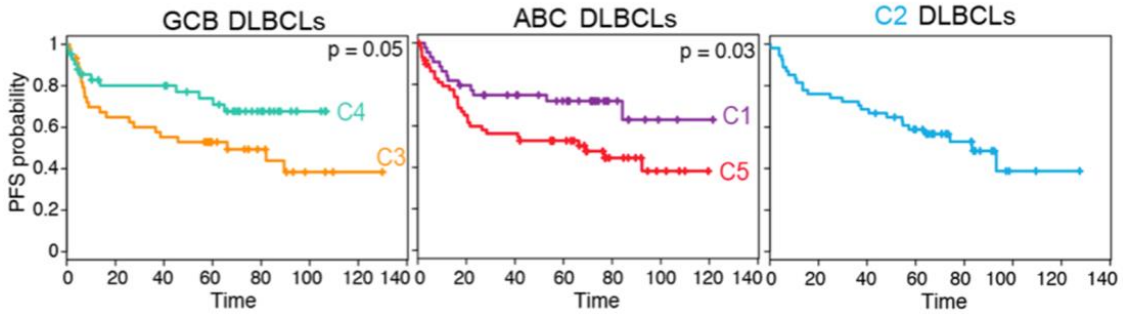
(**C1**) Lower risk subset of ABC-enriched DLBCLs with genetic features of an extrafollicular, possibly marginal zone, origin

(**C2**) ABC/GCB-independent group of tumors with biallelic inactivation of *TP53*, 9p21.3/*CDKN2A* copy loss and associated genomic instability

(**C3**) Higher risk GCB DLBCLs with *BCL2* SVs, inactivating mutations and/or copy loss of *PTEN,* mutations of additional BCR/PI3K signaling modifiers and epigenetic enzymes

(**C4**) Lower risk group of GCB-enriched DLBCLs with distinct alterations in JAK/STAT and BRAF pathway components and multiple histones

(**C5**) Higher risk ABC DLBCLs with near-uniform *BCL2* copy gain, frequent activating *MYD88*^{L265P} and *CD79B* mutations and extranodal tropism

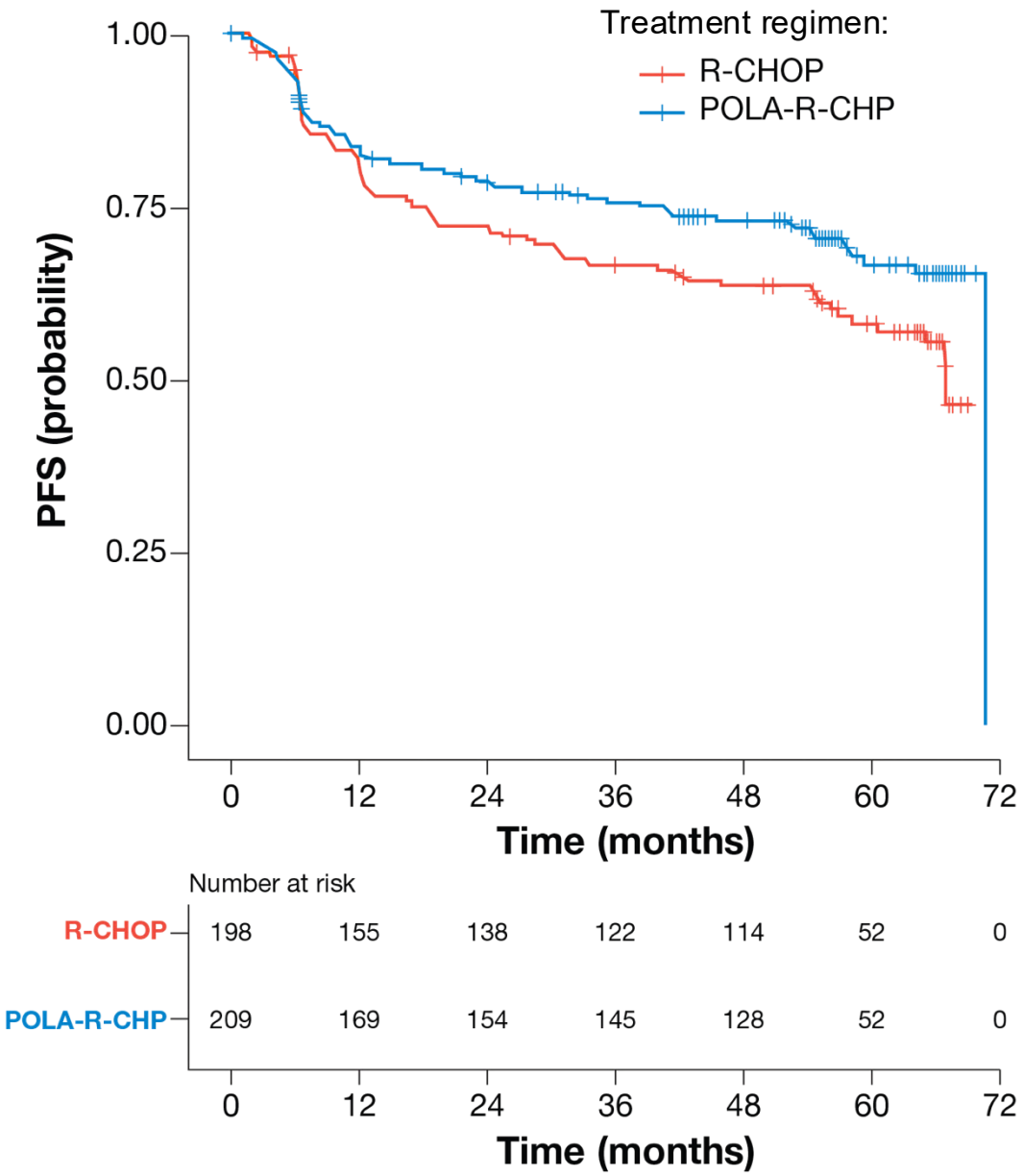


- All types of alterations (mutations, CNAs, SVs) needed to capture structure
- Additional genetic heterogeneity beyond previously defined transcriptional subtypes (ABC, GCB)

Chapuy, Stewart, Dunford, et al Nat Med 2018; 24:679-69

18th ICML

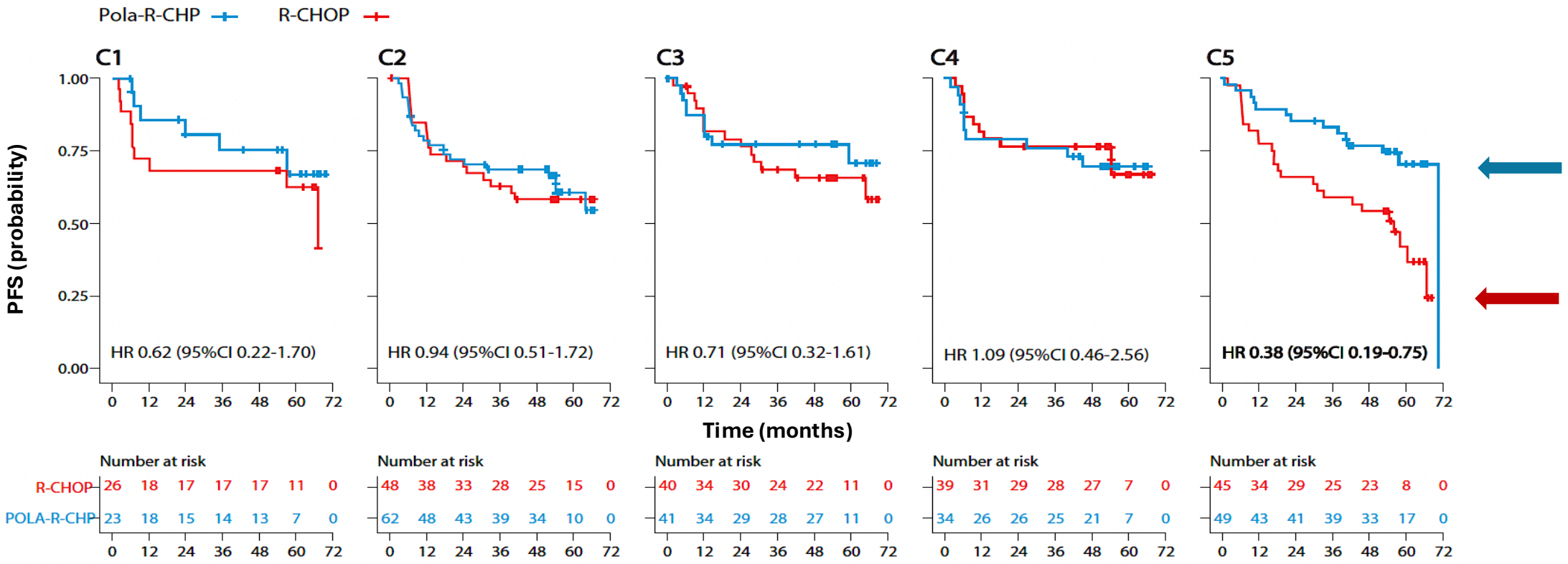
Study Population



- N=407 patients
- 5-year PFS estimates:
  - Pola-R-CHP: 66.7% (95% CI 59.7-74.5)
  - R-CHOP: 58.1% (95% CI 51.0-66.3)
- Treatment arms balanced for clinical prognostic factors

Calabretta E et al. ICML 2025;Abstract LBA1.

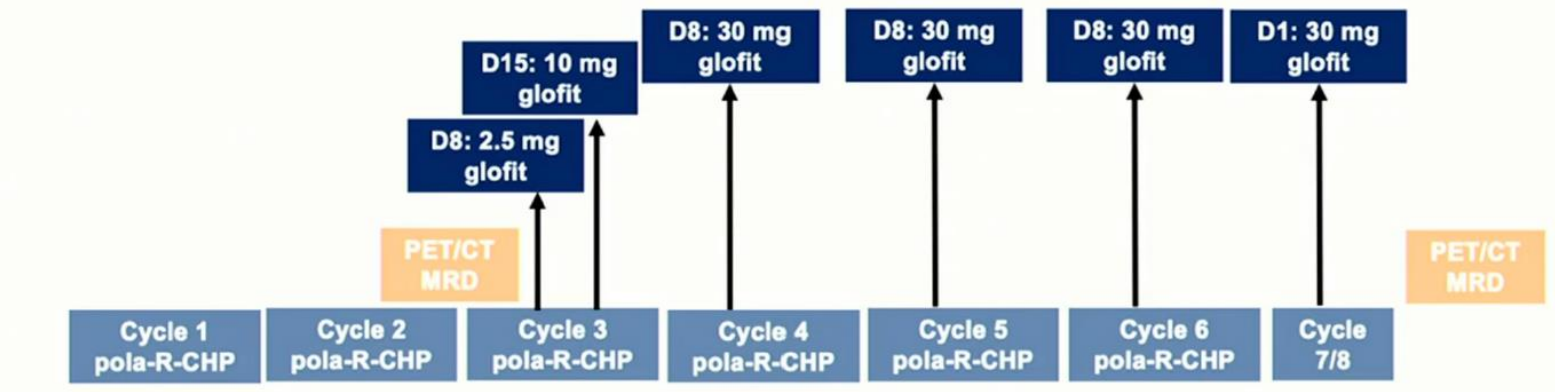
Benefit of Pola-R-CHP in Patients with Cluster 5 DLBCLs

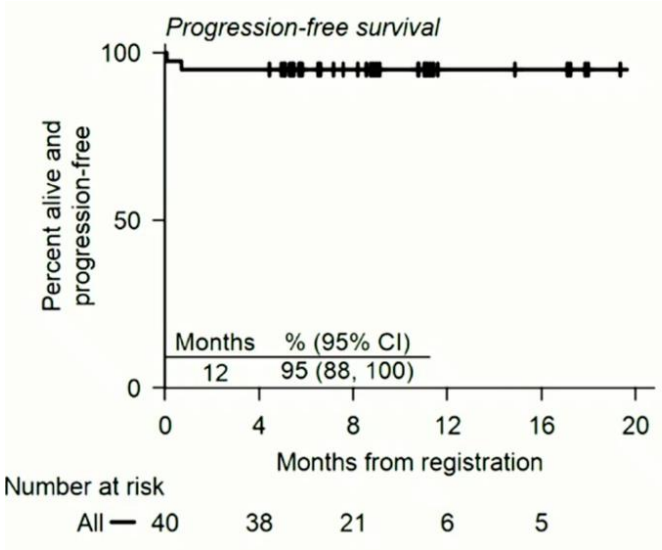


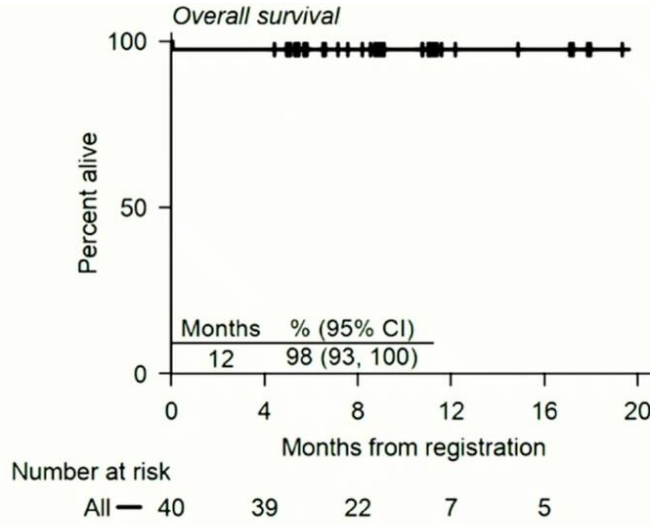
- Patients with C5 DLBCLs – 5-yr PFS higher in Pola-R-CHP versus R-CHOP treatment arm
  - Pola-R-CHP **70.4%** (95%CI 57.6-86.1)
  - R-CHOP **42.0%** (95% CI 28.0-63.0)
- Hazard ratio (HR) for Pola-R-CHP vs R-CHOP **0.38** (95% CI 0.19-0.75, **p=0.005**) in patients with C5 DLBCLs
- Pola-containing regimen abrogated the predicted poor outcome in C5 tumors.
- In contrast, 5-yr PFSs and HRs comparable for patients with C1-C4 DLBCLs in the two treatment arms

Calabretta E et al. ICML 2025;Abstract LBA1.

Glofitamab + Pola-R-CHP







- Grade 1 CRS in 4 patients (10%)
  - 1 patient after 2.5 mg dose, improved with dexamethasone
  - 3 patients with fever after C6D8 (steroid premedications omitted)

- No treatment-related deaths occurred during the study
- One grade 5 AE due to disease related respiratory failure prior to glofitamab treatment
- Febrile neutropenia in 5 patients
- Two cases of COVID-19 (grade 1 and grade 3)

Crombie et al. ICML 2025

Epco-Pola-R-CHP in 1L DLBCL

- Eligibility
  - DLBCL NOS | HGBCL | FL G3B
  - IPI 2 – 5
- Treatment
  - 6 cycles Pola-R-CHP
  - 8 cycles of Epco (with dose ramp-up)
  - G-CSF support
- Endpoints
  - ORR/CRR, time to response, safety

EHA. Abstract 247. Kerr et al.

Epco-Pola-R-CHP in 1L DLBCL

- Median follow up 16 months
- ORR 100% (97% CR)
- Median time to response 2.7 months

- Hematologic toxicity was common
  - 65% neutropenia
- 51% CRS (G1-G2, no grade 3)
  - No ICANS

EHA. Abstract 247. Kerr et al.

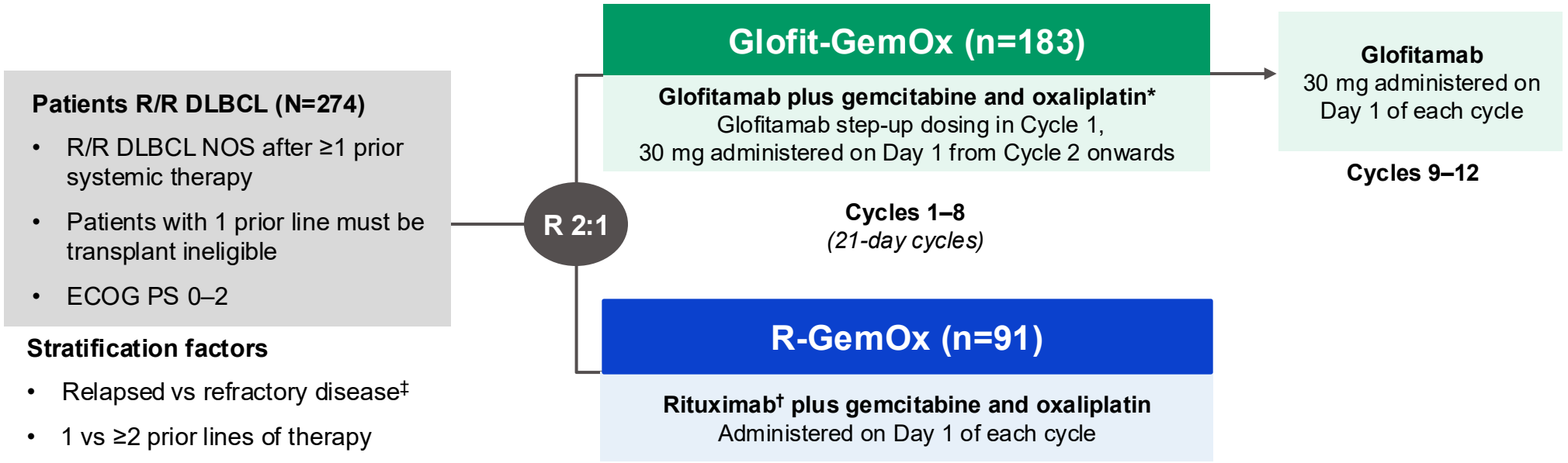
New combinations vs. R-GemOx in R/R DLBCL

- **Glofit-GemOx in patient with R/R DLBCL: 2 year follow up of STARGLO**. Abramson et al, ASCO.

- **Pola-R-GemOx for R/R DLBCL: Results from the phase III POLARGO Trial.** Matasar et al, EHA.

- **Mosunetuzumab plus Polatuzumab Vedotin is superior to R-GemOx in transplant ineligible patients with R/R DLBCL: Results from the phase III SUNMO trial.** Westin et al, ICML.

STARGLO: a randomized, global, Phase III trial



Primary endpoint:	Key secondary endpoints:	Safety endpoints:	Additional analyses:
OS	PFS, CR rate, DoCR (all IRC-assessed)	incidence, nature, and severity of AEs	landmark analysis at 1 year of patients in CR at EOT, subgroup analyses in 2L patients, ctDNA analyses, and immune recovery

*Gemcitabine 1000 mg/m^2 and oxaliplatin 100 mg/m^2. In C1, Gpt administered on D1, GemOx on D2, followed by Glofit 2.5 mg on D8 and Glofit 10 mg on D15; in C2–8, Glofit 30 mg and GemOx are administered on D1. †Rituximab 375 mg/m^2. ‡Relapsed disease: recurrence following a response that lasted ≥6 months after completion of the last line of therapy; refractory disease: disease that did not respond to, or that progressed <6 months after completion of the last line of therapy.

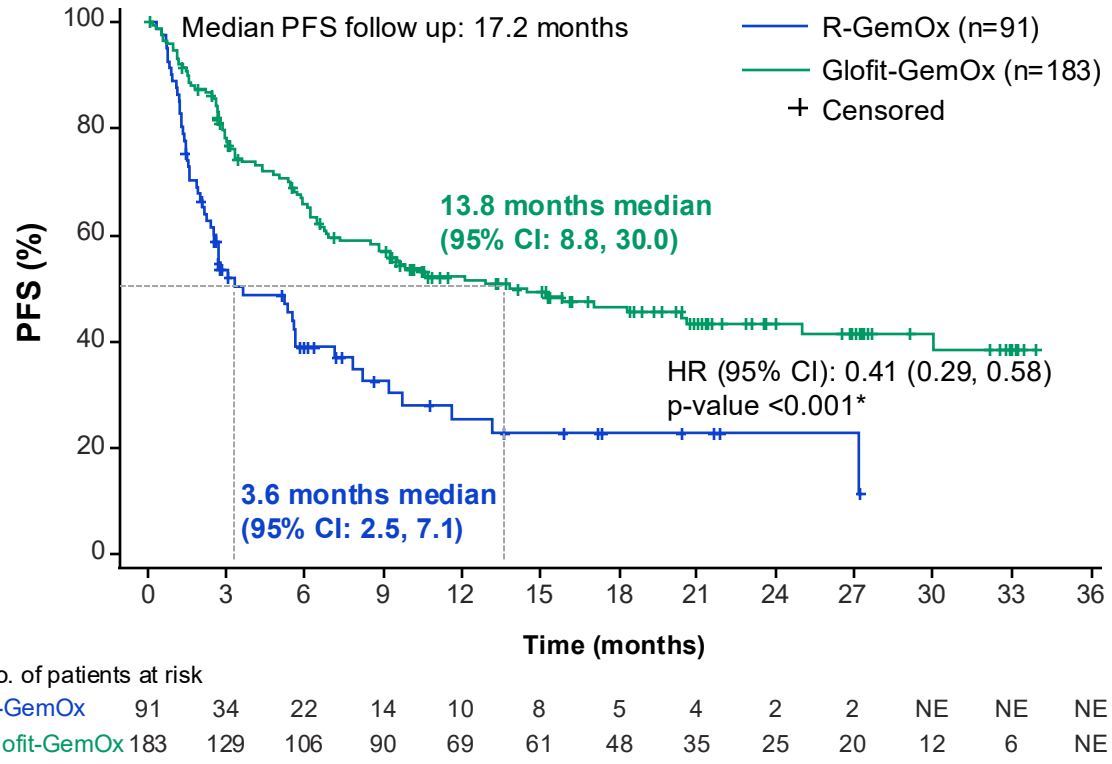
2L, second-line; AEs, adverse events; C, cycle; ctDNA, circulating tumor DNA; D, day; DoCR, duration of complete response; ECOG PS, Eastern Cooperative Oncology Group performance status; EOT, end of treatment; Gpt, obinutuzumab pre-treatment; IRC, independent review committee; R 2:1, patients randomized in a 2:1 ratio.

NCT04408638. Available at: https:www.clinicaltrials.gov.

Abramson JS et al. ASCO 2025;Abstract 7015.

Sustained PFS benefit with Glofit-GemOx

Progression-free survival with extended follow up



Outcome	R-GemOx (n=91)	Glofit-GemOx (n=183)
PFS, median (95% CI); months	**3.6** (2.5, 7.1)	**13.8** (8.8, 30.0)
18-month PFS, % (95% CI)	**23.0** (11.5, 34.4)	**46.5** (38.5, 54.5)
ORR, % (95% CI)	**40.7** (30.5, 51.5)	**68.3** (61.0, 75.0)
CR rate, % (95% CI)	**25.3** (16.8, 35.5)	**58.5** (51.0, 65.7)
DoCR, median (95% CI); months	24.2 (6.9, NE)	NE (27.2, NE)
Ongoing CR, % (n)	**17.6** (16)	**42.1** (77)

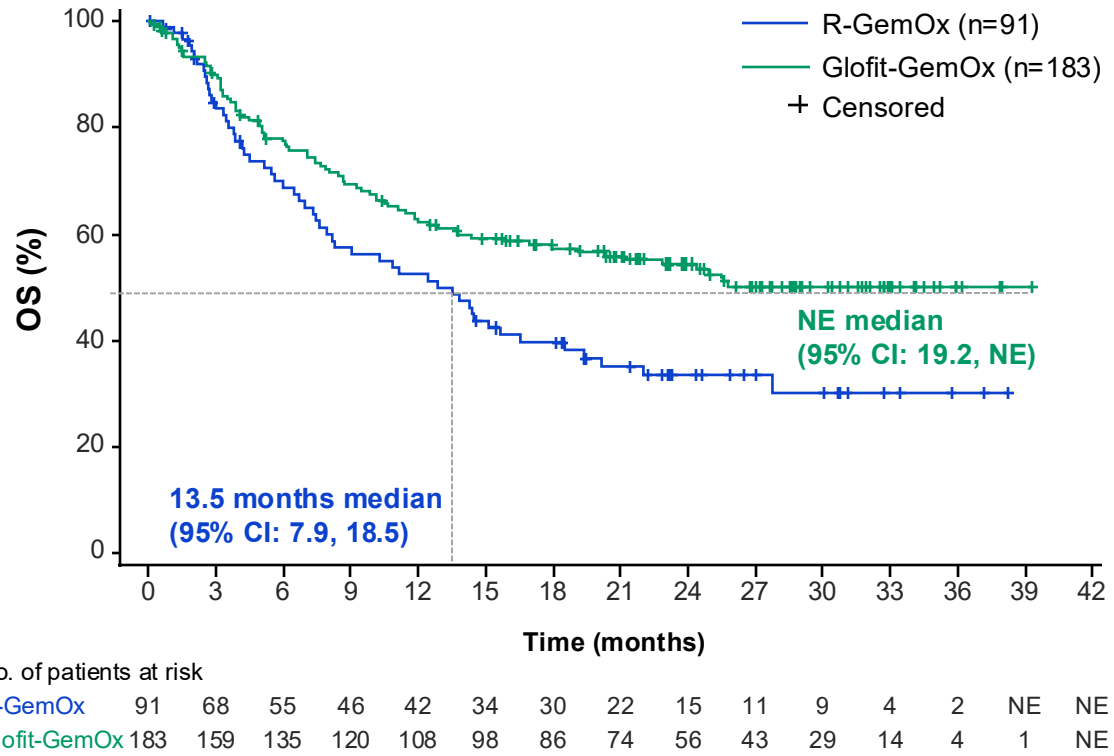
Patients treated with Glofit-GemOx showed a sustained PFS benefit versus R-GemOx after 2 years of follow up

CCOD: June 17, 2024. Median follow up for CR: 17.7 months. Outcomes were IRC-assessed. *p-value is descriptive.
ORR, overall response rate.

Abramson JS et al. ASCO 2025;Abstract 7015.

Sustained OS benefit with Glofit-GemOx

Overall survival with ~2 years of follow up



Outcome	R-GemOx (n=91)	Glofit-GemOx (n=183)
2-year follow up analysis (median follow up: 24.7 months)		
OS, median (95% CI); months	13.5 (7.9, 18.5)	NE (19.2, NE)
HR (95% CI)	**0.60** (0.42, 0.85)	
p-value*	0.003	
24-month OS, % (95% CI)	**33.6** (22.9, 44.2)	**54.4** (46.8, 62.0)

- 26.9% of Glofit-GemOx-treated patients and 57.1% of R-GemOx-treated patients had received ≥1 NALT

Clinically meaningful OS benefit for Glofit-GemOx versus R-GemOx remains after 2 years of follow up

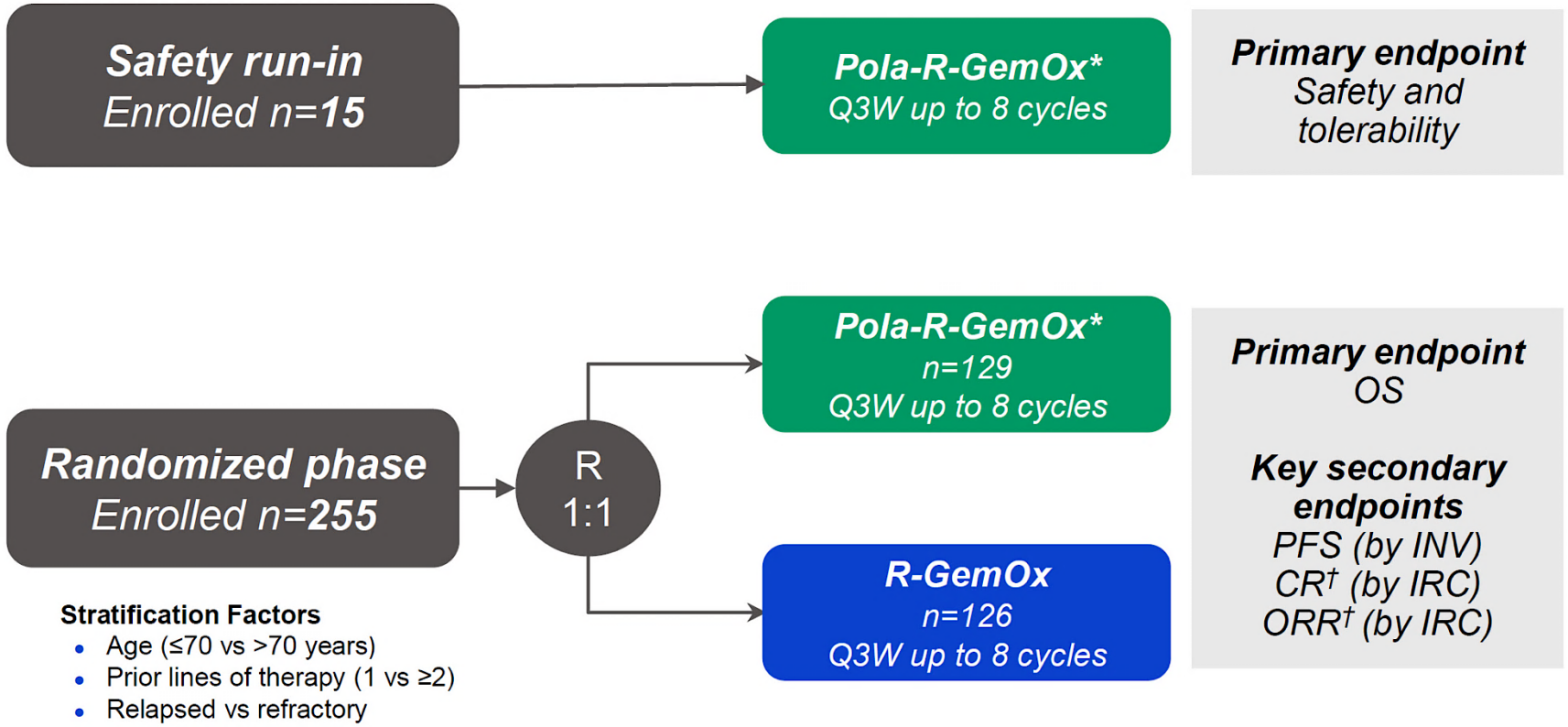
CCOD: June 17, 2024. *p-value is descriptive.
CI, confidence interval; HR, hazard ratio; NALT, new anti-lymphoma treatment; NE, not evaluable.

Abramson JS et al. ASCO 2025;Abstract 7015.

PolaRGO

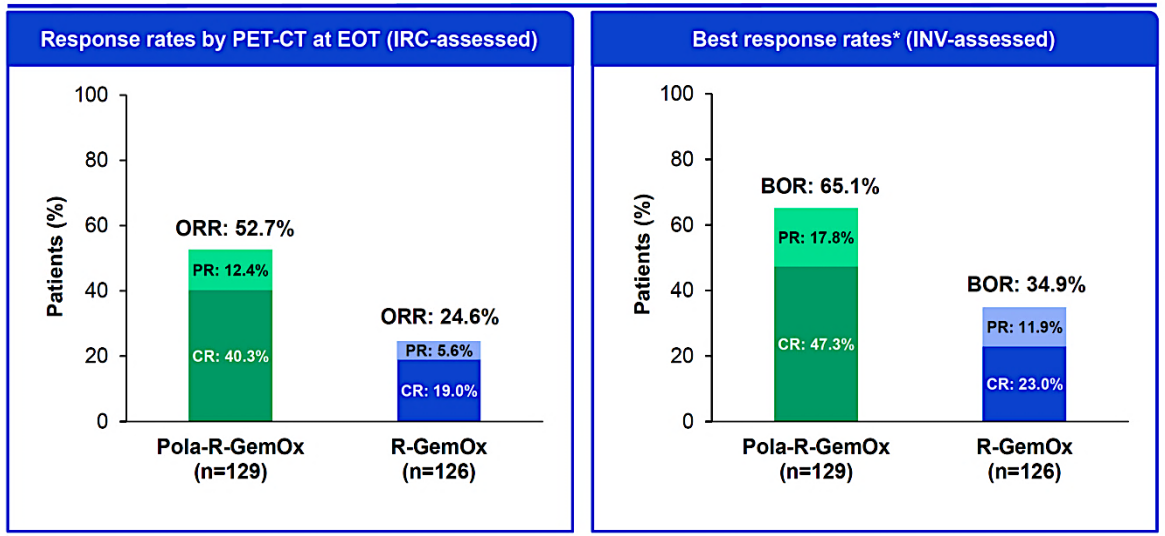
Key eligibility criteria

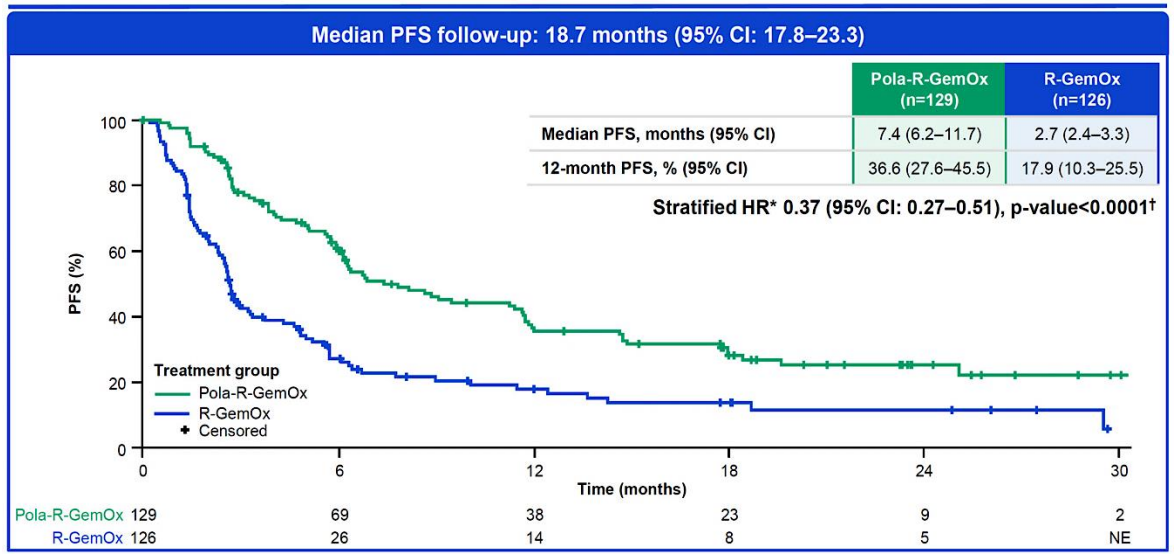
- DLBCL, NOS or history of transformation of indolent disease to DLBCL
- R/R disease after ≥1 prior line of treatment
- Ineligible for transplant

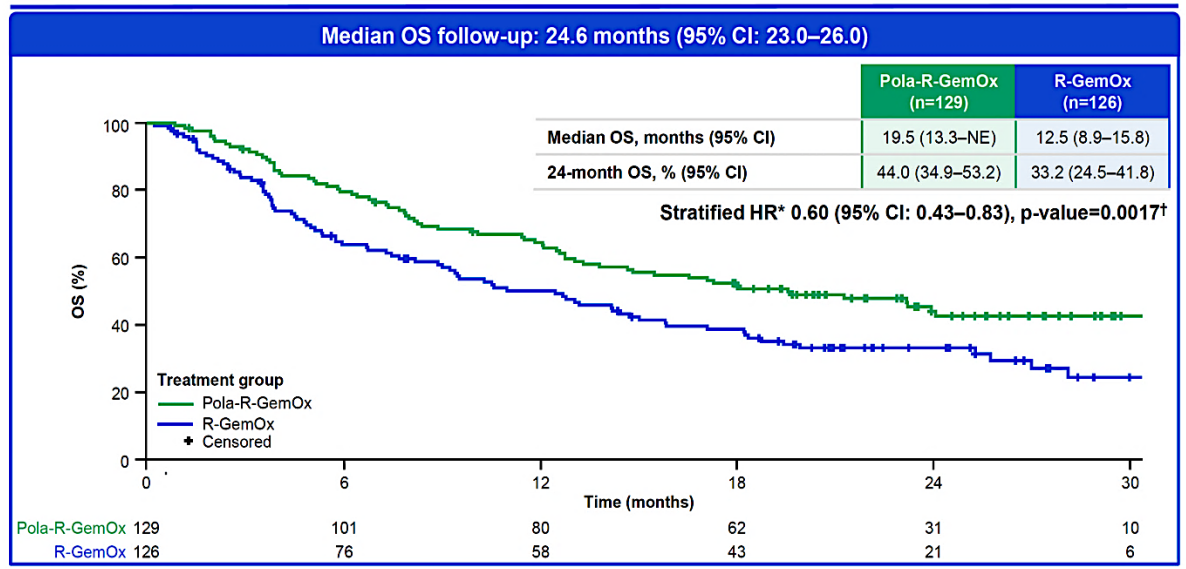


Matasar et al, EHA. Abstract S101.

PolaRGO







Matasar et al, EHA. Abstract S101.

SUNMO Study design

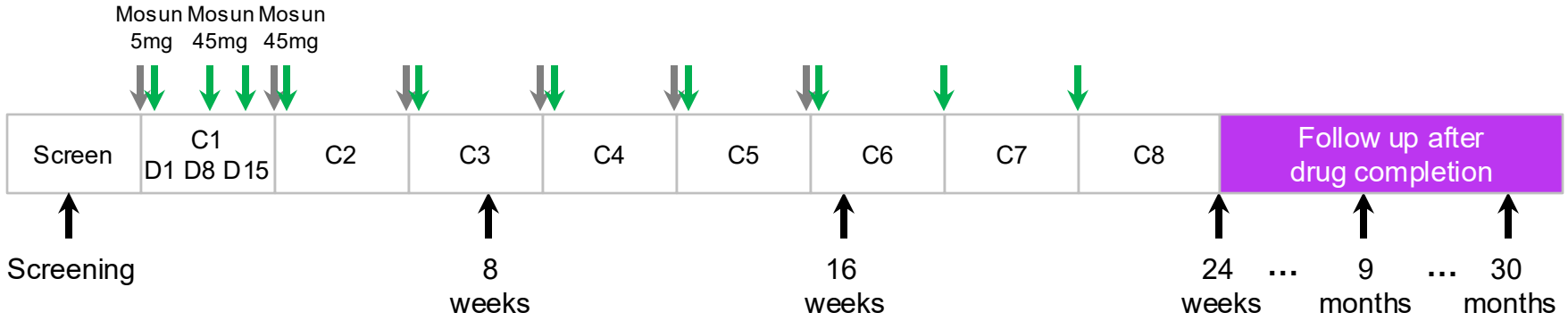
Key eligibility

R/R LBCL with ≥1 prior therapy and ASCT-ineligible:

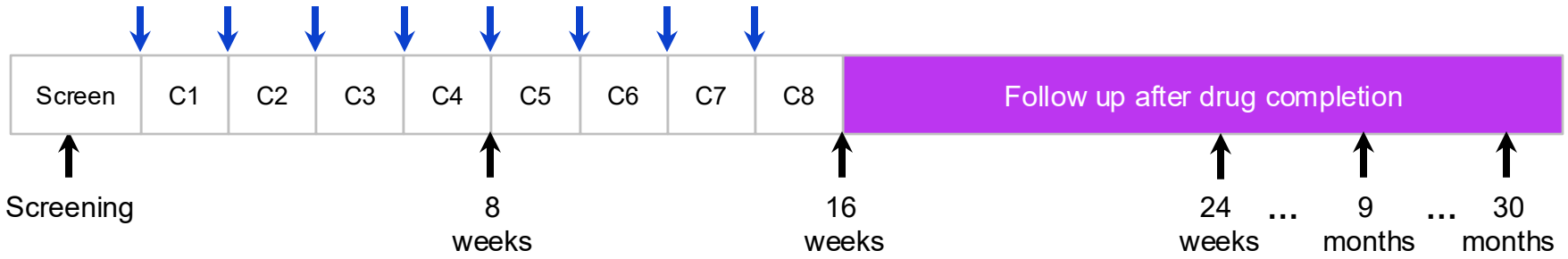
- DLBCL NOS
- Transformed FL
- HGBCL
- Grade 3B FL

2:1

Outpatient Mosun SC (8 cycles) + Pola IV (6 cycles) (21-day cycles)

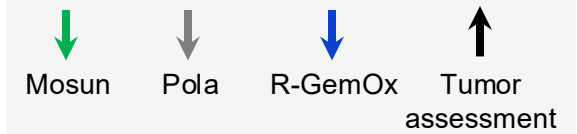


R-GemOx IV (8 x 14–21-day cycles*)



Stratification factors

- 1 vs ≥2 prior lines of systemic therapy
- Relapsed vs refractory disease

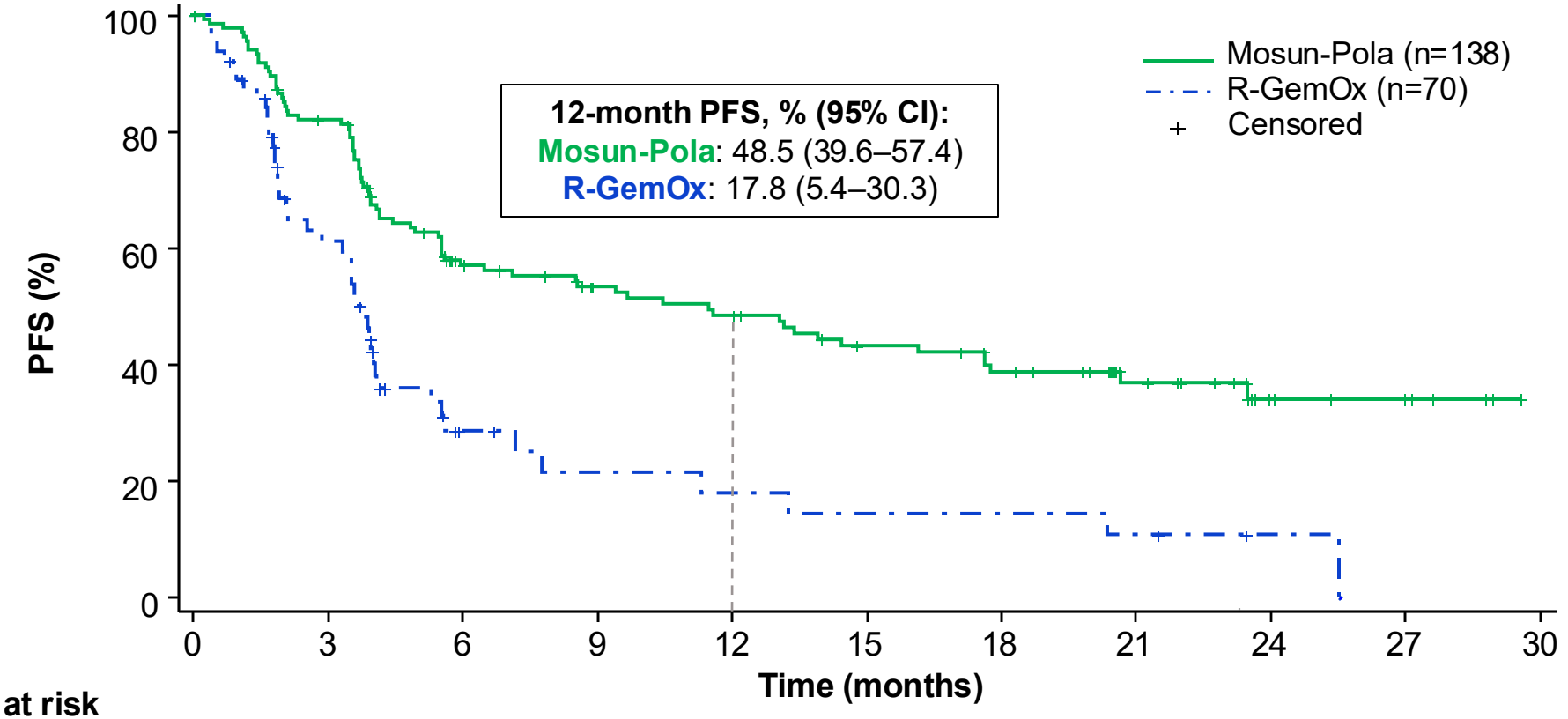


*14-day cycles unless delayed to 21-day cycles if needed in case of hematologic toxicity.
C, cycle; D, day; DLBCL, diffuse large B-cell lymphoma; FL, follicular lymphoma; HGBCL, high-grade B-cell lymphoma; IV, intravenous; NOS, not otherwise specified; SC, subcutaneous.

Presented as LBA3 by Westin et al, ICML 2025

Mosun-Pola significantly prolonged progression-free survival versus R-GemOx

Primary endpoint: Progression-free survival by IRC



n at risk

Mosun-Pola	138	108	65	54	49	40	34	20	8	5	NE
R-GemOx	70	33	9	6	5	4	4	3	1	NE	NE

Mosun-Pola demonstrates a 59% risk reduction for progression or death compared with R-GemOx

Clinical cut-off date: 17 February, 2025. PFS is censored at earliest of NALT or two or more missing tumor assessments, whichever occurred first.
CI, confidence interval; HR, hazard ratio; NALT, new anti-lymphoma therapy; NE, non estimable

Presented as LBA3 by Westin et al, ICML 2025

Three new combinations vs. R-GemOx

	ORR	CR	12 month PFS
R-GemOx	**40%**	**25%**	**18%**
Pola-R-GemOx	**65%**	**47%**	**36%**
Glofit-GemOx	**68%**	**58%**	**50%**
Mosun-Pola	**70%**	**51%**	**48%**

What is "preferred" regimen going forward?

- I have been favorably impressed with single agent Glofitamab in R/R DLBCL (CR rate 40%) but not available until 3rd line.
- I can see myself starting patients on Glofit-GemOx (2nd line frail) and dropping GemOx after 2 cycles and continuing with single agent Glofitamab.
- I could see Mosun-Pola getting good community uptake (less CRS with Mosun).

New ADC Data in R/R DLBCL

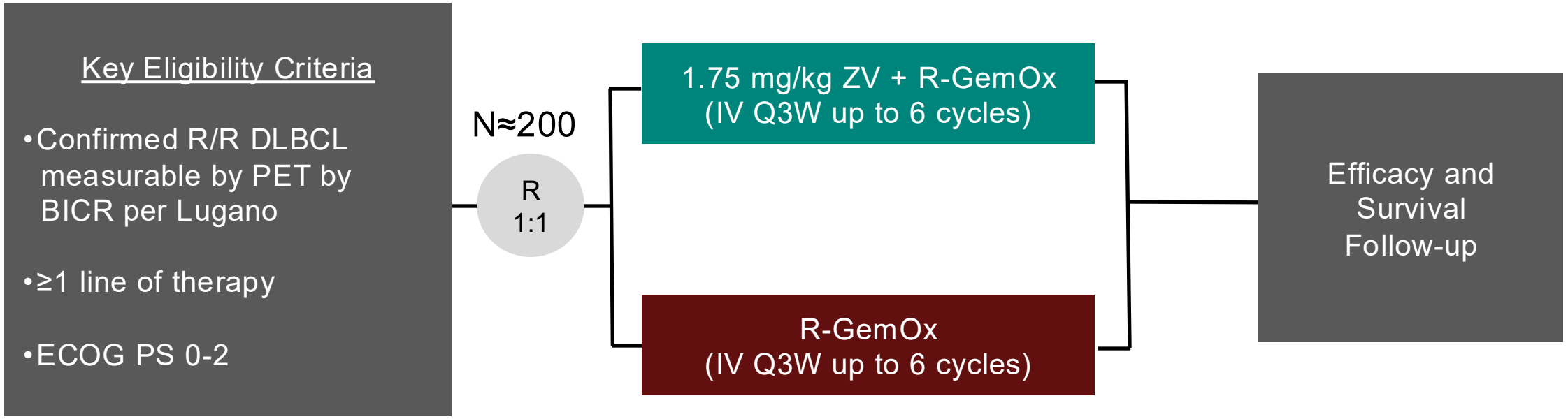
- **WaveLINE-003: Phase 2/3 trial of zilovertamab vedotin plus standard of care in R/R DLBCL.** Armand et al, ASCO.

- **Updated safety run in results from Lotis-5: A phase III trial of Lonca-T plus rituximab vs. immunochemotherapy in patients with R/R DLBCL.** Carlo-Stella et al, EHA.

- **Initial Results from LOTIS-7: A phase 1B study of Lonca-T plus Glofitamab in patients with R/R DLBCL.** Alderuccio et al, EHA.

waveLINE-003 Phase 3 Study Design (NCT05139017)

Zilovertamab vedotin in combination with R-GemOx versus R-GemOx in R/R DLBCL

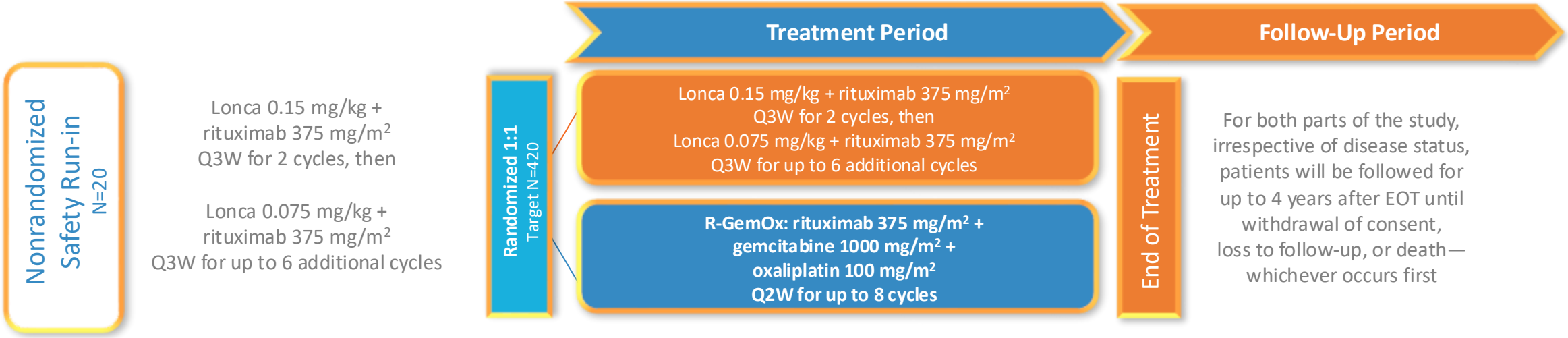


Endpoints:
- Primary: Progression-free survival per Lugano criteria by BICR, and overall survival
- Secondary: Objective response and duration of response per Lugano criteria by BICR

Armand P et al. ASCO 2025;Abstract 7005.

LOTIS-5 Trial Design

Phase 3 trial of Lonca in combination with rituximab[1,2]



PRIMARY ENDPOINTS

- PFS[a] by independent central review

SECONDARY ENDPOINTS

- OS, ORR, CRR, DOR
- Frequency and severity of AEs and laboratory parameters
- PK parameters, for Lonca total Ab, PBD-conjugated Ab, and free SG3199
- ADA titers to Lonca
- Changes in PROs from baseline

KEY INCLUSION/EXCLUSION CRITERIA

- Adults with a pathologic diagnosis of R/R DLBCL (including DLBCL transformed from indolent lymphoma) or HGBCL, with *MYC* and *BCL2* and/or *BCL6* rearrangements
- R/R disease following ≥1 multi-agent systemic treatment regimen
- Measurable disease (2014 Lugano classification)
- Not a candidate for SCT based on performance status, advanced age, and/or significant medical comorbidities (as considered by the investigator)
- If patient had received previous CD19 directed therapy, biopsy proven CD19 expression required
- ECOG performance status of 0-2
- Excludes previous treatment with Lonca or R-GemOx

[a]Defined as time between randomization and the first documentation of recurrence or progression, or death from any cause.

Abbreviations: Ab, antibody; ADA, antidrug antibody; CRR, complete response rate; DOR, duration of response; ECOG, Eastern Cooperative Oncology Group; EOT, end of treatment; PK, pharmacokinetics; ORR, overall response rate; OS, overall survival; PBD, pyrrolobenzodiazepine; PRO, patient reported outcome; Q2W, every 2 weeks; Q3W, every 3 weeks; SCT, stem cell transplant; R-GemOx, rituximab + gemcitabine + oxaliplatin.

1. Carlo-Stella C, et al. Updated Safety Run-in Results From LOTIS-5: A Phase 3, Randomized Trial of Loncastuximab Tesirine With Rituximab Versus Immunochemotherapy in Patients With R/R DLBCL/HGBL. Poster presented at the European Hematology Association 30th Annual Congress (EHA 2025). June 12-15, 2025. Milan, Italy.
2. ADCT Therapeutics SA. Study to evaluate loncastuximab tesirine with rituximab versus immunochemotherapy in participants with relapsed or refractory diffuse large B-cell lymphoma (LOTIS 5). ClinicalTrials.gov registration number: NCT04384484. Updated May 30, 2025. Accessed June 2, 2025. https://clinicaltrials.gov/ct2/show/NCT04384484.

LOTIS-5 Safety Run-in: Efficacy Results[1,a]

- The ORR by central review was 80% (16/20)
- A total of 50% (10/20) and 30% (6/20) patients attained CR and PR, respectively
- The median DOR was 8.0 months (95% CI, 3.2-NE)
- The median PFS was 8.3 months (95% CI, 4.5-NE)
- No new safety signals were identified
- Trial has progressed to randomization

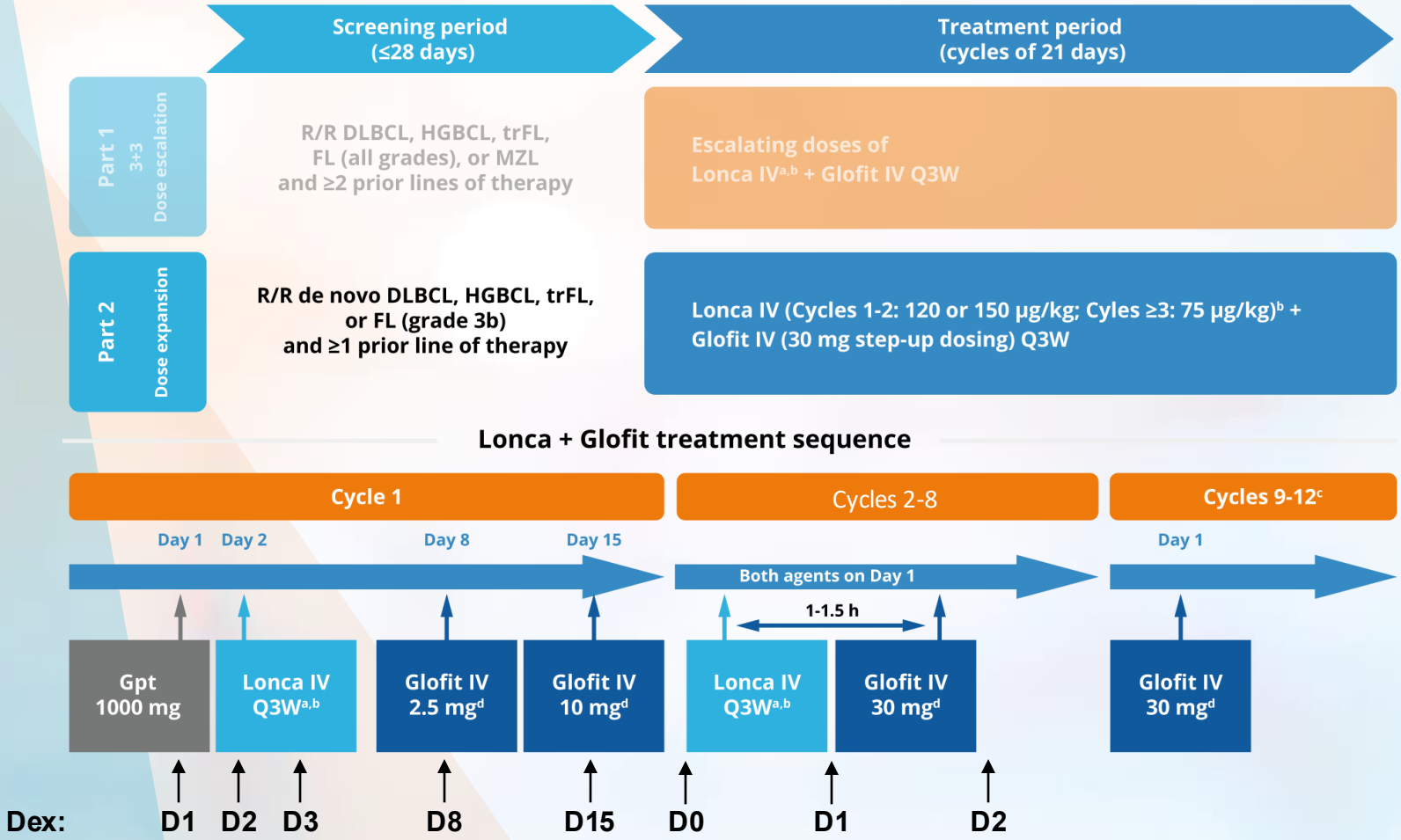
Efficacy outcomes in safety run-in population (N=20)	
ORR (95% CI), %	80.0 (56.3, 94.3)
CR rate (95% CI), %	50.0 (27.2-72.8)
Median DOR (95% CI), months	8.0 (3.2-NE)
Median PFS (95% CI), months	8.3 (4.5, NE)
Efficacy outcomes in responders (n=16)	
Median DOR (95% CI), months	8.0 (3.19-NE)
Events (%), n	5 (31.3)
Efficacy outcomes in complete responders (n=10)	
Median DOR (95% CI), months	NE (3.19-NE)
Events (%), n	3 (30.0)
MRD results in patients with ctDNA measurements (n=8)	
CR and MRD negative (%), n	4 (50.0)
MRD negative at end of treatment (%), n	4 (50.0)

[a]October 4, 2024, data cutoff.

Abbreviations: CR, complete response; ctDNA, circulating tumor DNA; DOR, duration of response; EOT, end of therapy; MRD, minimal residual disease; NE, not estimable; ORR, overall response rate; PFS, progression-free survival; PR, partial response; SCT, stem cell transplant.

1. Carlo-Stella C, et al. Updated Safety Run-in Results From LOTIS-5: A Phase 3, Randomized Trial of Loncastuximab Tesirine With Rituximab Versus Immunochemotherapy in Patients With R/R DLBCL/HGBL. Poster presented at the European Hematology Association 30th Annual Congress (EHA 2025). June 12-15, 2025. Milan, Italy.

LOTIS-7 STUDY DESIGN & PATIENT POPULATION



Study population

- Patients with 3L+ R/R B-NHL (part 1) and 2L+ R/R LBCL (part 2)
- ECOG PS score of 0-2
- Prior autologous SCT (>100 days) or CAR-T therapy (>100 days) is allowed
- Measurable disease (per 2014 Lugano Classification)
- Excludes patients with clinically significant third-space fluid accumulation

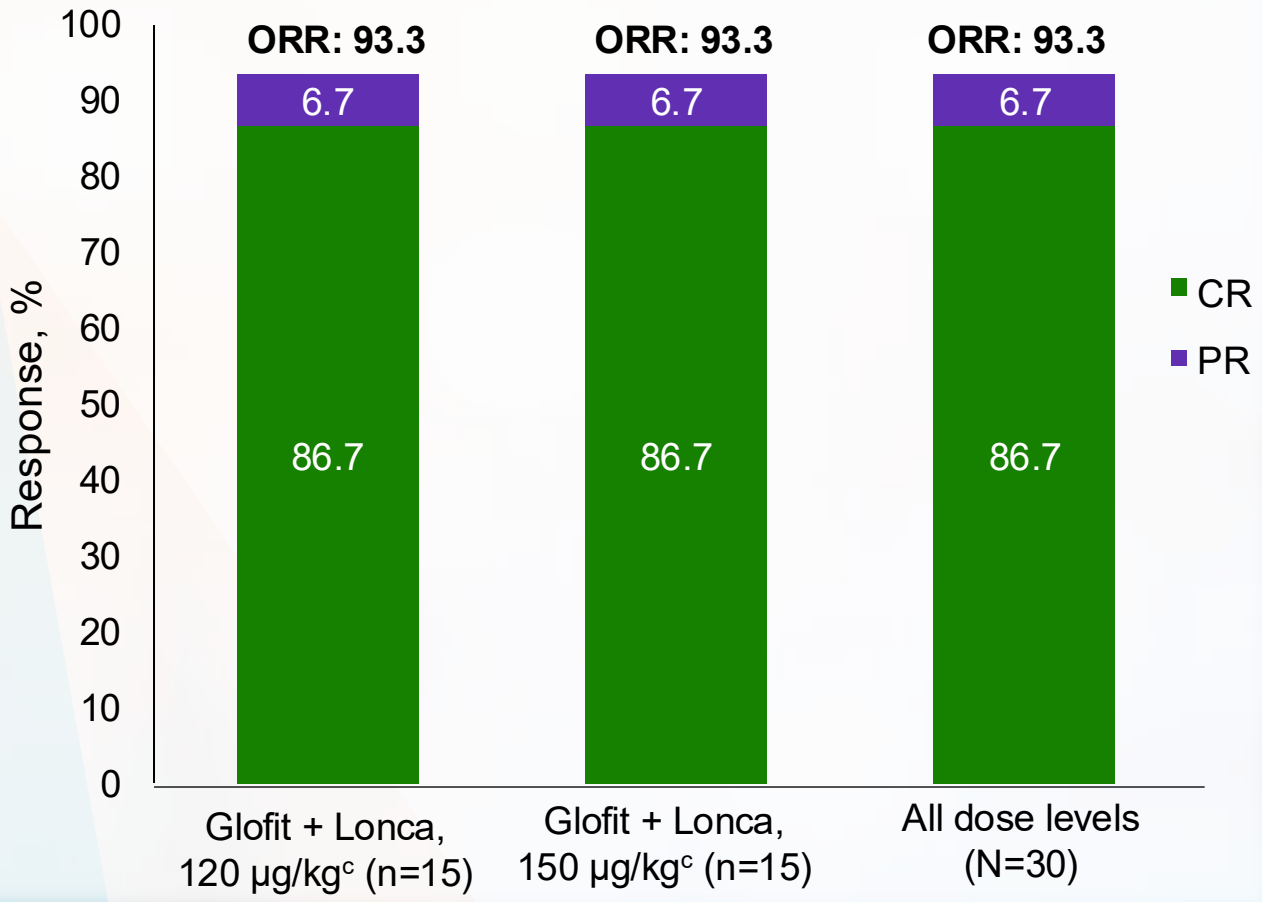
Endpoints

- **Primary**: safety and tolerability; MTD and/or RDE
- **Secondary**: ORR, DOR, CR rate, PFS, RFS, and OS; PK and immunogenicity
- **Exploratory**: Glofit concentration in circulation; biomarker and PK correlations with clinical outcomes

BEST OVERALL RESPONSE & DURATION OF RESPONSE

EFFICACY EVALUABLE POPULATION (N=30)[a]

Best overall response[b]



Duration of response

Characteristic, n (%)	Glofit + Lonca, 120 µg/kg[c] (n=15)	Glofit + Lonca, 150 µg/kg[c] (n=15)	All dose levels (N=30)
DOR[d] Median	(n=14) NE	(n=14) NE	(n=28) NE
Time to first response (CR or PR) Median, days	(n=14) 42.0	(n=14) 42.0	(n=28) 42.0
Time to first CR Median, days	(n=13) 80.0	(n=13) 42.0	(n=26) 70.5

Data cutoff: April 14, 2025.

CR, complete response; DOR, duration of response; Glofit, glofitamab; Lonca, loncastuximab tesirine; NE, not estimable; ORR, overall response rate; PR, partial response.

[a]The efficacy evaluable population (N=30) included all patients who received ≥1 dose of the study drug with a valid baseline and ≥ 1 valid postbaseline disease assessment. Patients who did not have a postbaseline assessment owing to early clinical progression or death were also included. [b]Percentages do not add up to total due to rounding. [c]When the starting dose of Lonca is 120 µg/kg or 150 µg/kg, the dose will be reduced to 75 µg/kg for Cycles ≥3. [d]In the efficacy evaluable population, the DOR and probability of maintaining an event-free response were evaluated in responders (n=28), including all patients who had a best response of CR or PR.

Alderuccio JP et al. EHA 2025;Abstract PS1911.

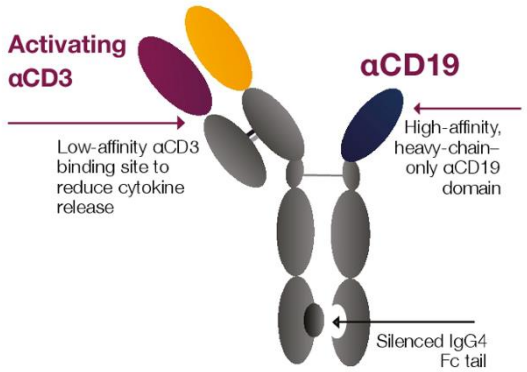
Novel Agents

- **Safety and efficacy of AZD0486, a CD19XCD3 T-cell engager in R/R DLBCL.** Kim et al, ASCO.
  - ORR 46%. CR 33%.

- **A phase 1/2 study to evaluate the safety and efficacy of AZD0486 monotherapy or combination therapy in patients with mature B cell malignancies.** Eyre et al, ASCO.
  - Substudy 1 CLL. Substudy 2 MCL. Substudy 3 with R-CHOP in DLBCL.

- **TITANium: An open label phase 1/2 study of AZD5492, a first in class SQ CD8 guided tri-specific T cell engager in patients with R/R B cell malignancies.** Shadman et al, ASCO.
  - CD20/CD8/TCR

AZD0486: CD19xCD3 T-cell engager – Phase 1 Study



Overall Study Design

Fixed-dose escalation
0.03 mg to 2.4 mg Q2W
n=4

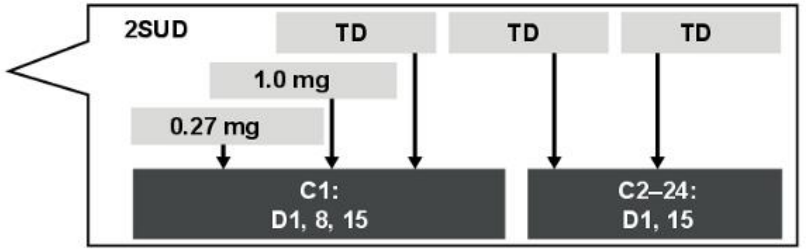
Single step-up (1SUD)
C1D1: 0.27 mg or 1.0 mg
C1D15 then Q2W: TD (0.8–10 mg)
n=12

Double step-up (2SUD)
C1D1: 0.27 mg, C1D8: 1 mg
C1D15 then Q2W: TD (2.4–25 mg)
n=72

TD 2.4 mg → TD 7.2 mg → TD 15 mg → TD 25 mg

2SUD Treatment Schedule

- AZD0486 is administered intravenously
- 2SUD on C1D1, C1D8 with TD on C1D15, then on D1, D15 each 28-day cycle up to 2 years
  - Cycle 1 doses were inpatient
- Patients with CR on 2 consecutive scans may receive AZD0486 every 4 weeks after C6



Kim TM et al. ASCO 2025;Abstract 7046.

AZD0486: CD19xCD3 T-cell engager – Phase 1 Study

Table 2. Response Rates by Target Dose (≥7.2 mg)

	Overall (N=58)			CAR-T Naive (n=31)			CAR-T Exposed (n=27)		
	n	ORR	CR rate	n	ORR	CR rate	n	ORR	CR rate
7.2 mg	24	46%	33%	9	67%	44%	15	33%	27%
15 mg	26	62%	39%	16	75%	38%	10	40%	40%
25 mg	8	75%	63%	6	83%	67%	2	50%	50%

- Of the 21 patients with CR and evaluable for MRD in the TD ≥7.2 mg cohorts, 20 (95%) achieved undetectable MRD in plasma (**Figure 2**)
- In patients who received ≥7.2 mg, median DOR was not reached; 12-mo DOR estimate was 77% (95% CI 53, 90) (**Figure 3**); 12-mo DOCR estimate was 87% (95% CI 58, 97)

Kim TM et al. ASCO 2025;Abstract 7046.

AZD0486: CD19xCD3 T-cell engager – Phase 1 Study

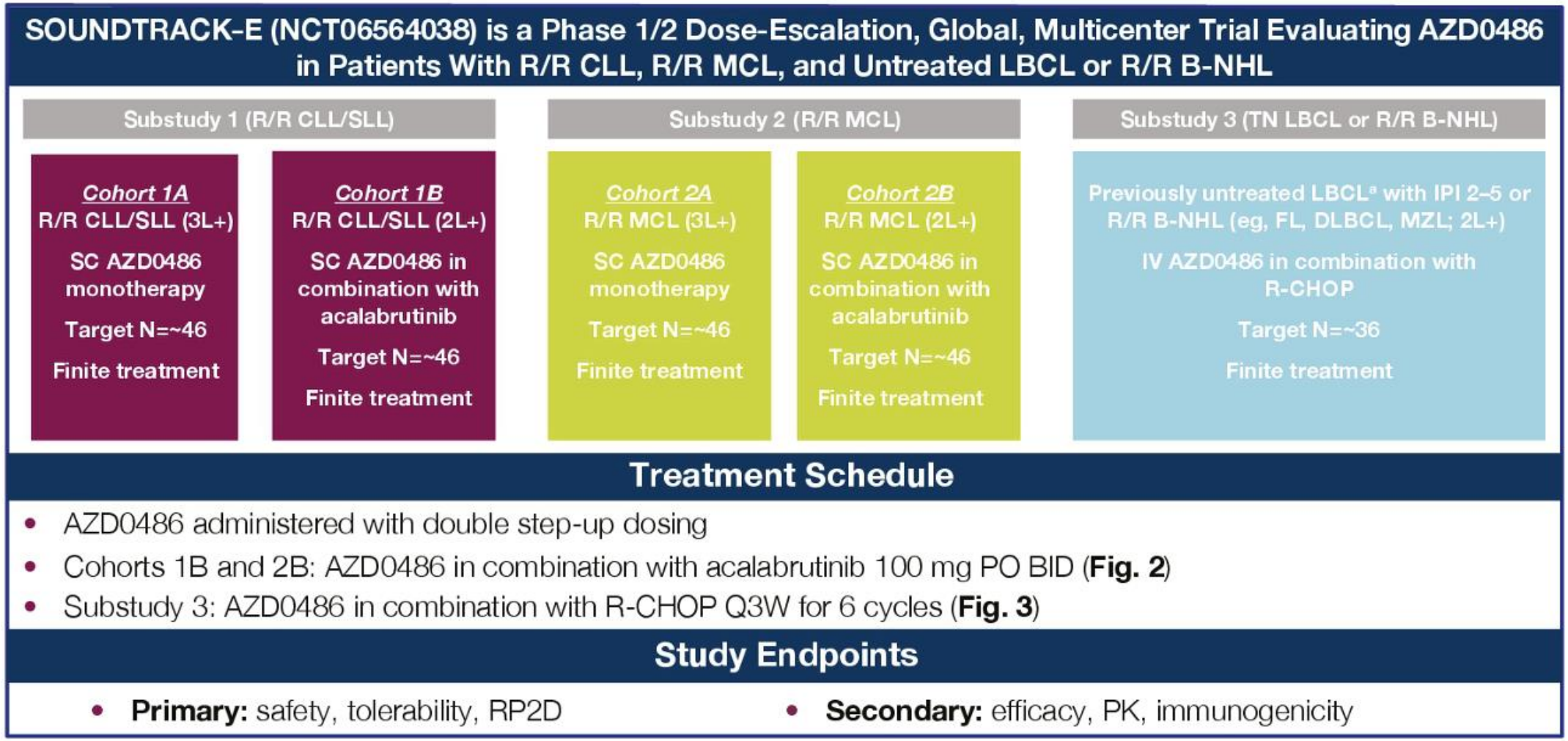
Most common AEs (≥15%)	Any grade	Grade 3	Grade 4
CRS	42 (49)	0	0
Infections and infestations[b]	39 (45)	10 (12)	1 (1)
Neutropenia	29 (34)	9 (10)	15 (17)
Constipation	21 (24)	0	0
Anemia	20 (23)	14 (16)	0
Fatigue	20 (23)	3 (3)	0
ICANS	17 (20)	5 (6)	0
Hypogammaglobulinemia	16 (19)	0	0
Nausea	16 (19)	1 (1)	0
Diarrhea	14 (16)	0	0
Pyrexia	13 (15)	0	0

Table 4. CRS and ICANS Events

AZD0486 2SUD cohort (n=70), n (%)	Grade 1	Grade 2	Grade 3	Grade ≥4	Total
CRS	30 (43)	4 (6)	0	0	34 (49)
ICANS	4 (6)	6 (9)	4 (6)	0	14 (20)

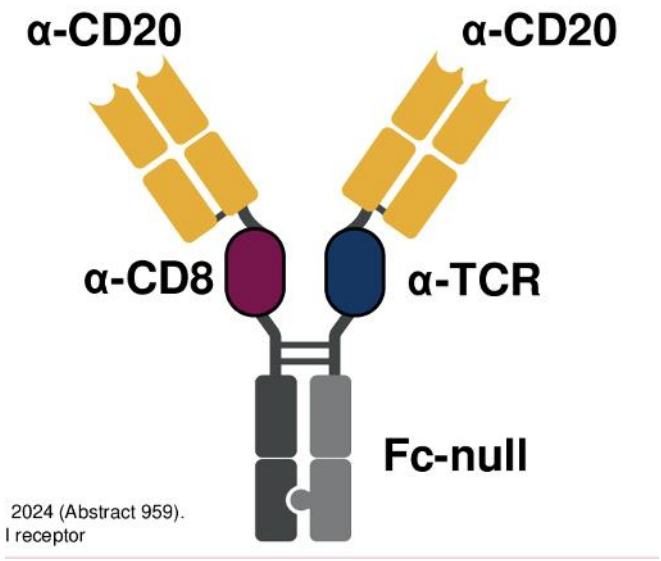
Kim TM et al. ASCO 2025;Abstract 7046.

AZD0486: SOUNDTRACK-E Study Design

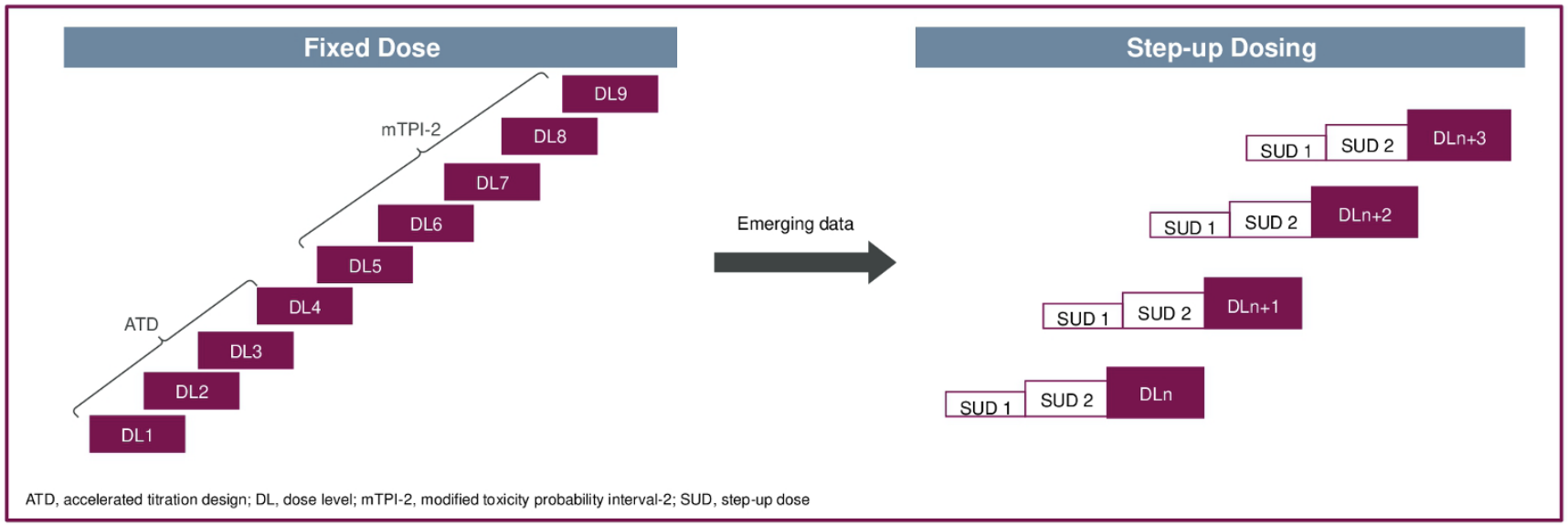


Eyre TA et al. ASCO 2025;Abstract TPS7083.

AZD5492: CD8-guided Tri-specific T-cell engager



2024 (Abstract 959).
l receptor



ATD, accelerated titration design; DL, dose level; mTPI-2, modified toxicity probability interval-2; SUD, step-up dose

Study design and treatment

- Part A is a phase 1 dose escalation study of subcutaneous AZD5492 monotherapy and will consist of two independent dose-escalation groups (A1 and A2):
  - A1 will enroll patients with mantle cell lymphoma (MCL) or chronic lymphocytic leukemia (CLL)/small lymphocytic leukemia (SLL).
  - A2 will enroll patients with large B-cell lymphoma (LBCL) or follicular lymphoma (FL).
- An accelerated titration design will be implemented at lower dose levels which will switch to a modified toxicity probability interval-2 design based on emerging data.
- Both fixed and step-up dose escalation strategies will be explored during Part A1 and A2. Each part will proceed with dose escalation independently (**Figure 3**).
- Patients will receive AZD5492 until treatment completion, unacceptable toxicity, or fulfillment of other discontinuation criteria.

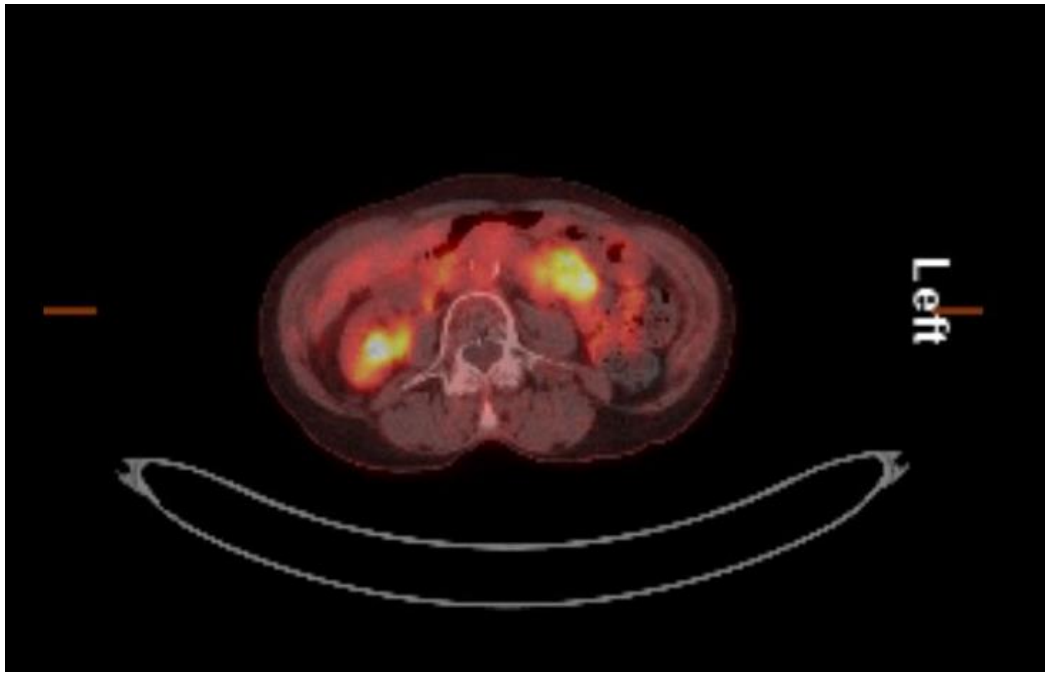
Shadman M et al. ASCO 2025;Abstract TPS7091.

A patient case

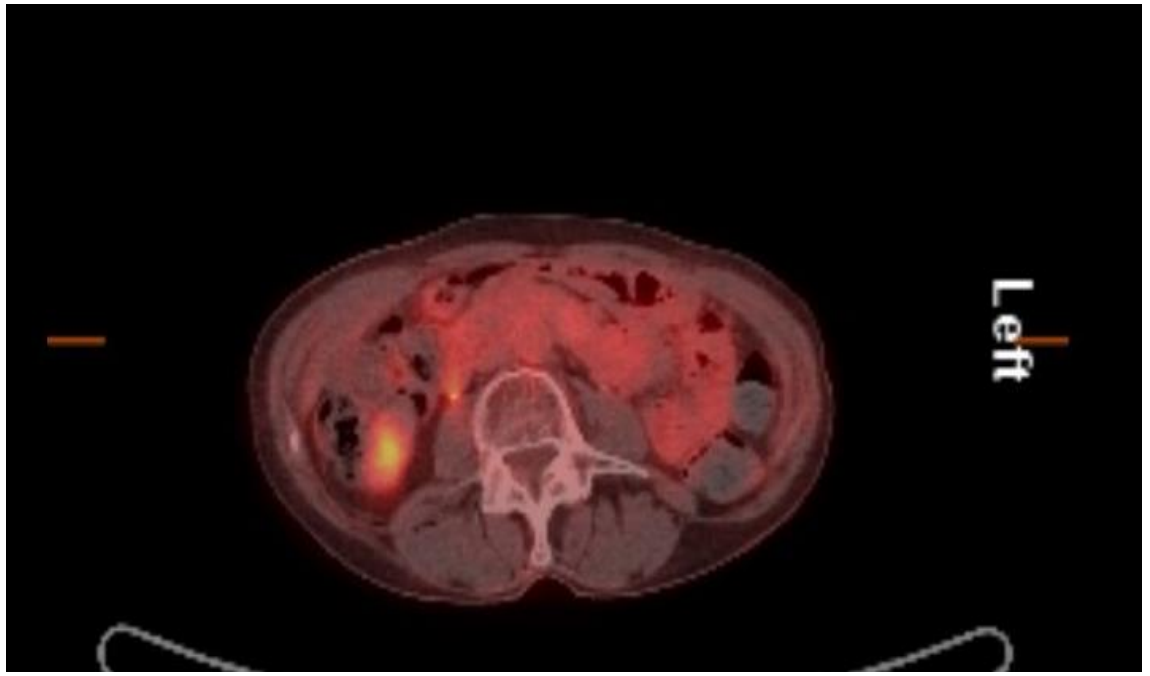
- **May 2012.** 70 yo woman diagnosed with DLBCL. GCB subtype. Stage 3. IPI score 4. Treatment with **R-CHOP x 6**. Achieves CR.
- **April 2018.** New RP mass. Bx show DLBCL. Now age 76. Receive **R-GemOx** for 8 cycles. Achieves PR after cycle 4 but has PD by cycle 8.
- **Nov 2018.** Referred to see me. I recommended **Axi-Cel** CART therapy. No bridging therapy required. Day 30 PET shows CR.
- **June 2019.** New mesenteric mass detected by surveillance imaging. Biopsy shows DLBCL. She receives **Lonca-T** (on a clinical trial) x 8 cycles. Achieves CR. Therapy stopped due to 3rd spacing.
- **Feb 2021.** New mesenteric mass detected by surveillance imaging. Biopsy shows DLBCL. Offered **glofitamab** (on a clinical trial) x 12 cycles.

Pre and Post Glofitamab PET images

FEB 2021 PET SCAN



AUGUST 2021 PET SCAN



Patient Update

- Therapy complicated by hypogammaglobulinemia - on IVIg since 2021
- MAI/MAC infection requiring Azithromycin/Rifampin/Ethambutol 2021 - 2022
- Chronic neutropenia requiring filgrastim 3X/week 2022 – 2023

- RTC August 2025. Now age 82. Patient remains in CR. On IVIg every 6 weeks. Looks fabulous. She and daughter treat themselves to a nice lunch every trip to St. Louis.

Agenda

Faculty Data and Case Presentation – Dr Kahl

- First-line treatment of diffuse large B-cell lymphoma (DLBCL)
- Management of relapsed/refractory DLBCL

Faculty Data and Case Presentation – Dr Casulo

- Follicular lymphoma
- Marginal zone lymphoma
- Mantle cell lymphoma

Overview Discussion

Selection of first-line treatment for

- Low-risk FL
- Standard-risk FL
- Mantle cell lymphoma

The Implications of Recent Data Sets for Current and Future Management of Non-Hodgkin Lymphoma (NHL): Insights from ASCO/EHA/ICML, Highlighting Follicular, Marginal, and Mantle Cell Lymphoma

Carla Casulo, MD
Wilmot Cancer Institute, University of Rochester

September 17th, 2025

Relapsed Follicular Lymphoma with POD24

Case 1:

- 59 year old man with no PMH diagnosed with grade 2-3a FL treated with R-CHOP x 6 cycles; with CR
- 14 months later, develops fatigue, abdominal pain, inguinal fullness
- Laboratory values show hemoglobin 8.9 g/dL, LDH normal
- PET shows large mesenteric mass with bilateral pelvic lymphadenopathy, SUV max 6.4
- Biopsy reveals classical FL, no signs of transformation

What are new options for 2nd line FL?

inMIND: Phase 3, Double-Blind, Placebo-Controlled, International, Multicenter Randomized Study

Key Inclusion Criteria

- Age ≥18 years
- FL grades 1-3A (or MZL)*
- ≥1 prior line of therapy, including an anti-CD20 mAb
- ECOG PS 0-2
- No prior treatment with Len in combination with R

Screening ≤28 days

Randomization 1:1

Tafasitamab Arm (Experimental Arm)

- Tafasitamab 12 mg/kg iv, 12 cycles (cycles 1-3: qw; cycles 4-12: q2w)
- Len 20 mg/day (days 1-21) po for 12 cycles
- R 375 mg/m^2 iv for 5 cycles (cycle 1: qw; cycles 2-5: q4w)

Placebo Arm (Control Arm)

- Placebo iv for 12 cycles (cycles 1-3: qw; cycles 4-12: q2w)
- Len 20 mg/day (days 1-21) po for 12 cycles
- R 375 mg/m^2 iv for 5 cycles (cycle 1: qw; cycles 2-5: q4w)

End of treatment

5-year follow-up

Stratification Factors (Patients With FL)

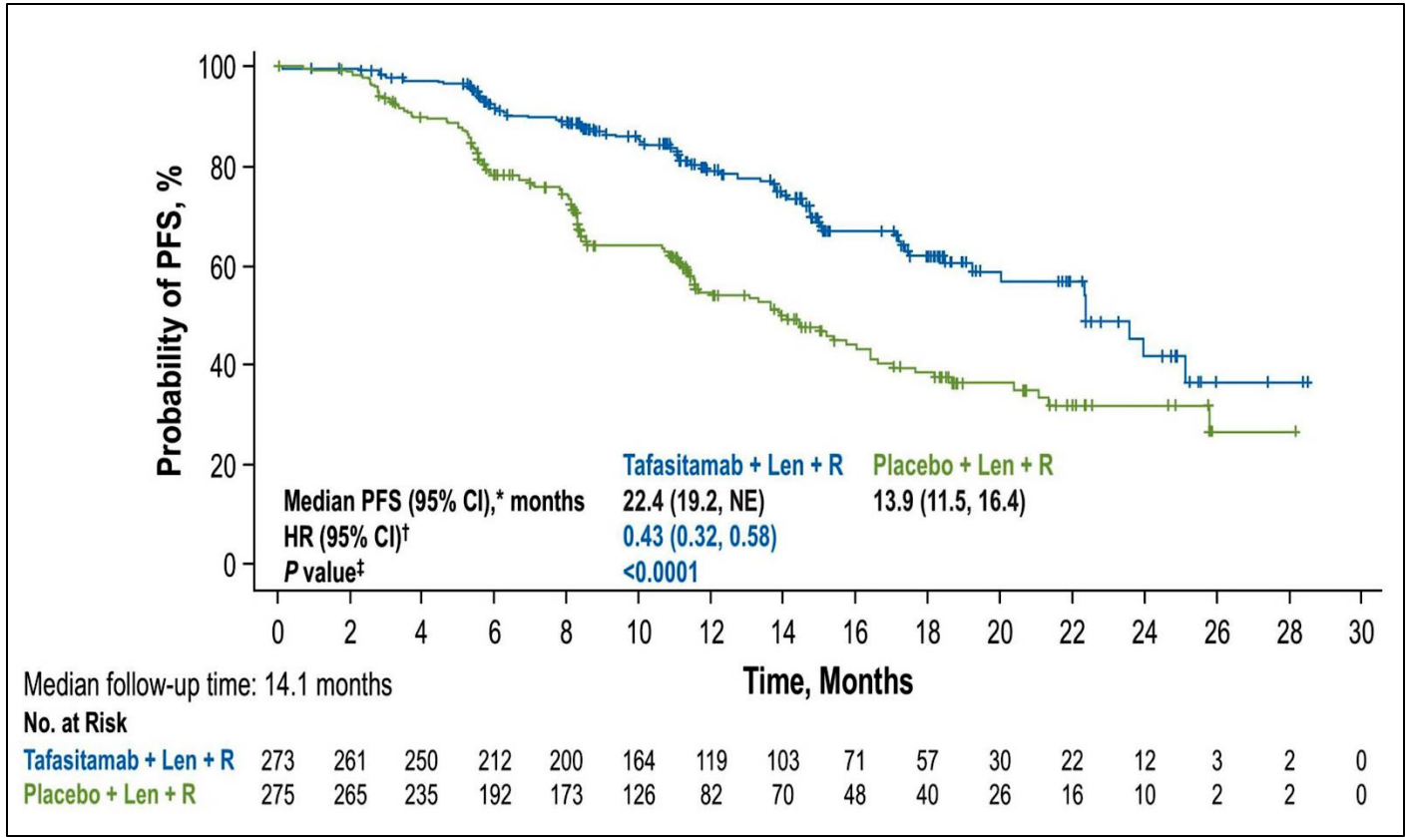
- POD24
- Refractoriness to prior anti-CD20 mAb therapy
- Number of prior lines of therapy (1 or ≥2)

Study Endpoints in FL Population (Investigator Assessed Unless Specified)

- **Primary study endpoint:** PFS
- **Key secondary:** PET-CR rate in the FDG-avid population, OS
- **Select other secondary:** PFS by IRC, ORR, DOR, safety, QoL, MRD
- **Exploratory:** TTNT, B-cell recovery, Ig levels, CD19 expression

Patient Characteristics, Safety, Efficacy

548 total patients, 273 Tafa/R^2, 275 Placebo R^2



Median PFS	Tafa/R^2	Placebo/R^2
	22.4 months	13.9 months

Benefit with Tafa/R^2 confirmed by IRC, observed regardless of POD24 status, refractoriness to prior anti-CD20, number of prior lines

Similar Rates of Treatment Related Adverse Events (TRAE)

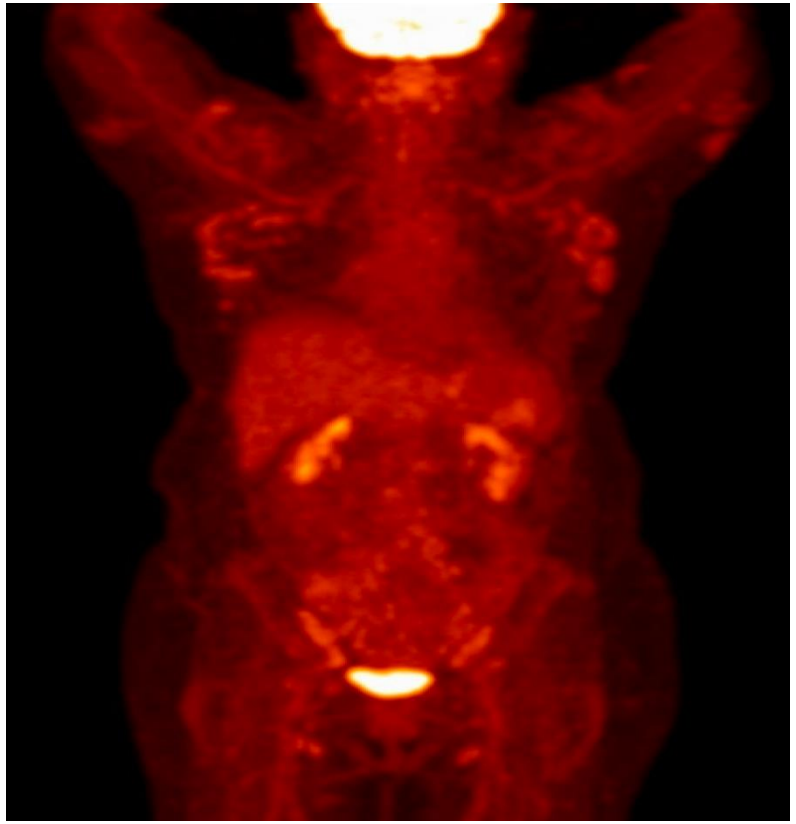
- Neutropenia most common grade 3/4 AE
- Discontinuation in 11% and 7% from AE
- Deaths in 6% Tafa/R^2, 9% placebo arm
- 5 (2%) vs 17 (6%) from progression
- 6 (2%) in each arm from fatal AEs

EHA 2025; Abstract S230. Trneny M et al.

Relapsed Follicular Lymphoma

Case 2:

- 64 year old woman with past medical history of ER/PR/HER-2 negative breast cancer s/p ACT chemotherapy at age 58 with CR and in remission
- Diagnosed with advanced stage high tumor grade 1 FL treated with BR x 6 cycles; with CR
- 5 years after BR, develops axillary lymphadenopathy and fatigue
- Biopsy reveals classical FL



- PET shows bilateral prominent axillary, subpectoral nodes with SUV max 6.8
- Increase in size and metabolic activity of right external iliac lymph node, concerning for disease progression

Relapsed Follicular Lymphoma

Case 2 continued:

- 64 year old woman with advanced stage high tumor grade 1 FL treated with BR x 6 cycles; with CR
- Past medical history of ER/PR/HER-2 negative breast cancer s/p ACT chemotherapy at age 58 with CR and in remission
- 5 years after BR, develops axillary lymphadenopathy and fatigue
- Biopsy reveals classical FL

➢ Treated with R^2, complete response

➢ 1 year later, develops recurrent classic FL involving bulky disease in lymph nodes (>7 cm), pleural

What are updated options for 3rd line FL?

Bispecific Antibody Update at EHA 2025

Mosunetuzumab

- Phase 2 dose expansion cohort
- 94 patients enrolled
- 47% double refractory, 44% POD24 from start of first-line treatment
- 30% elevated LDH
- 23% with bulky disease (>7cm)

PS1872

Fixed-duration subcutaneous mosunetuzumab▼ demonstrates clinically relevant efficacy in patients with relapsed/refractory follicular lymphoma with high-risk features: Pivotal Phase II study update

Georg Hess,[1*] Laurie H. Sehn,[2] L. Elizabeth Budde,[3] Sarit Assouline,[4] Pratyush Giri,[5] John Kuruvilla,[6] Stephen J. Schuster,[7] Sung-Soo Yoon,[8] Keith Fay,[9] Martin Dreyling,[10] Norma C. Gutierrez,[11] Eva Cybulski,[12] Fidelis Sabalvaro,[12] Elicia Penuel,[12] Samuel Tracy,[12] Denison Kuruvilla,[12] Joseph Chen,[12] Volker Wiebking,[12] Michael C. Wei,[12] Nancy L. Bartlett[13]

Efficacy Outcomes in Overall and High-Risk Population

	Overall population N=94	Ann Arbor stage III/V n=82	Double refractory n=44	POD24 n=41	Elevated LDH n=28	Bulky disease (>7cm) n=22
ORR, n (%) [95% CI]	72 (76.6) [66.7–84.7]	63 (76.8) [66.2–85.4]	31 (70.5) [55.0–83.2]	30 (73.2) [57.0–86.0]	17 (60.7) [40.6–78.5]	16 (72.7) [49.8–89.3]
CR, n (%) [95% CI]	58 (61.7) [51.1–71.5]	50 (61.0) [49.6–71.6]	22 (50.0) [35.0–65.0]	23 (56.1) [39.7–72.0]	12 (42.9) [24.5–62.8]	13 (59.1) [36.4–79.3]
18-month DOCR, % (95% CI)	69.7 (57.1–82.3)	71.9 (58.9–84.9)	69.1 (48.3–90.0)	66.4 (43.4–89.4)	90.9 (73.9–100.0)	67.1 (40.7–93.6)
Median DOCR, months (95% CI)	34.6 (20.7–NE)	22.6 (20.7–NE)	20.8 (15.5–NE)	22.6 (15.5–NE)	NR (NE–NE)	18.8 (8.5–NE)
18-month PFS, % (95% CI)	56.8 (46.4–67.2)	56.7 (45.5–67.9)	50.1 (34.5–65.8)	53.8 (38.0–69.6)	50.8 (30.8–70.8)	51.0 (29.2–72.8)
Median PFS, % (95% CI)	23.7 (14.6-NE)	23.7 (11.3–35.9)	18.5 (5.8–24.0)	24.0 (8.3–35.9)	NR (3.25–NE)	20.3 (5.7–NE)

EHA 2025; Abstract PS1872. Hess G et al.

Safety

n (%)	N=94
Infections and infestations, any grade	51 (54.3)
Serious infections	16 (17.0)
Serious infections (≥1% incidence), any grade	
Viral infections	9 (9.6)
COVID-19*	6 (6.4)
Herpes zoster	1 (1.1)
Unspecified pathogen	6 (6.4)
Device-related	2 (2.1)
Sepsis	2 (2.1)
Pneumonia	1 (1.1)
Sinusitis bacterial	1 (1.1)
Opportunistic infections	1 (1.1)
Cytomegalovirus infection reactivation	2 (2.1)
Candida sepsis	1 (1.1)

*Includes preferred terms COVID-19 and COVID-19 pneumonia.

- Infections occurred in > 50% of patients, mostly viral
- Grade 5 events (3%) were COVID related

EHA 2025; Abstract PS1872. Hess G et al.

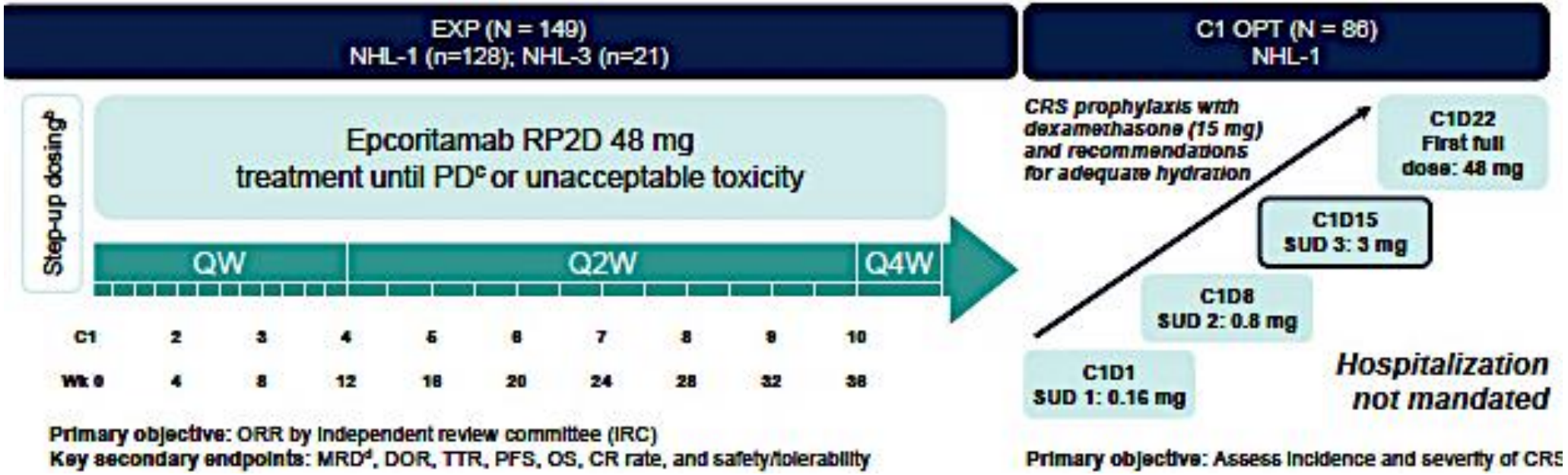
Epcoritamab

- 3-year follow up from 2 pooled cohorts (N=149) and C1 optimization group (N=86)
- Exploratory outcomes in patients stopping early in CR

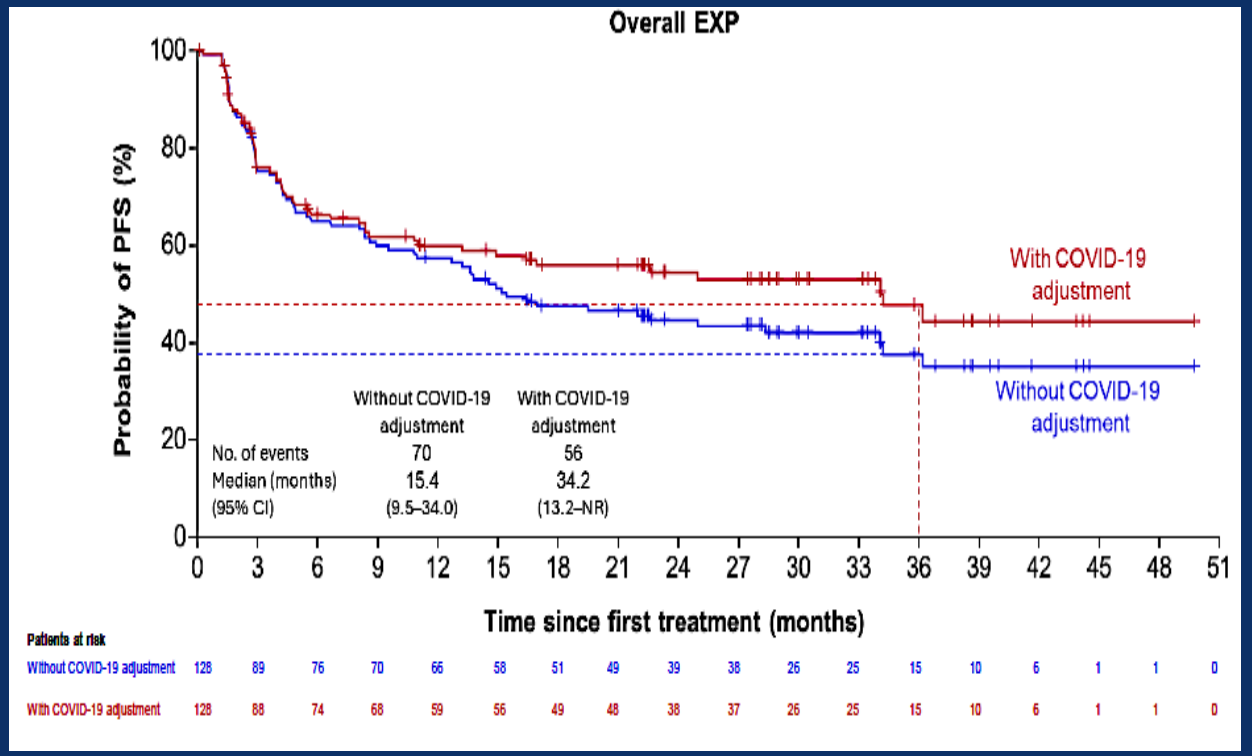
PF881

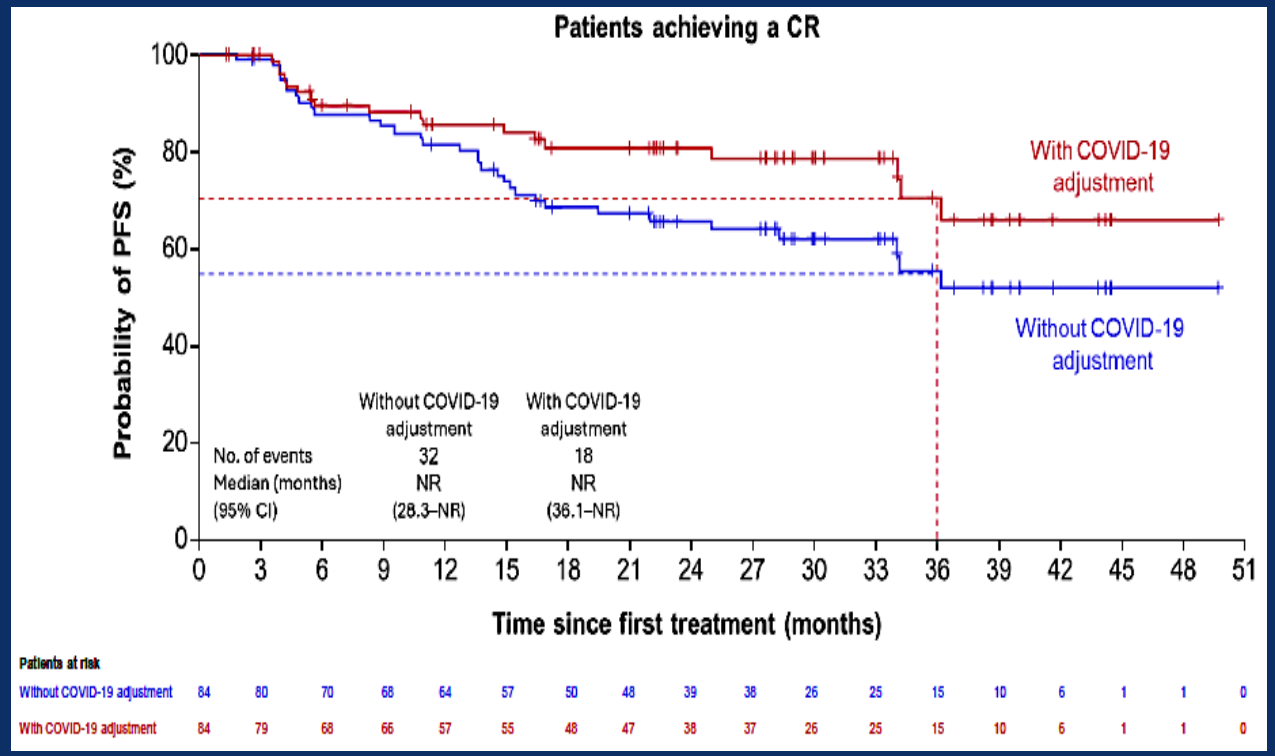
Epcoritamab Monotherapy Demonstrates Deep and Durable Responses at 3-year Follow-up in Patients With Relapsed/Refractory Follicular Lymphoma

Umberto Vitolo,[1] Wojciech Jurczak,[2] Pieternella J. Lugtenburg,[3] Emmanuel Gyan,[4] Julio C. Chavez,[5] Anna Sureda,[6] Jacob Haaber Christensen,[7] Hervé Tilly,[8] Raúl Córdoba,[9] David J. Lewis,[10] Martin Hutchings,[11] Michael Roost Clausen,[12] Juan-Manuel Sancho,[13] Tara Cochrane,[14] Sirpa Leppä,[15] Martine E. D. Chamuleau,[16] Catherine Thieblemont,[17] Koji Izutsu,[18] Noriko Fukuhara,[19] Paolo F. Caimi,[20] Yasmin H. Karimi,[21] Charalambos Andreadis,[22] Julie M. Vose,[23] Elena Favaro,[24] Poliana Patah,[25] Milan Geybels,[26] Isil Altintas,[27] Christopher Morehouse,[24] Kim M. Linton[28]



Updated Outcomes with Epcoritamab





- 35 patients discontinued treatment in CR without PD/death: 16 from AE, 9 patient decision
- 94% (33/35) had sustained CR on subsequent scan
- Median time in CR after treatment discontinuation: 13 months (2 patients had PD)

NCI Cancer Center
A Cancer Center Designated by the National Cancer Institute

EHA 2025; Abstract PF881; Vitolo U et al.

UR MEDICINE | WILMOT CANCER INSTITUTE

Updates to EPCORE FL-1 Study

Phase 3 EPCORE® FL-1 Clinical Trial Meets Dual Primary Endpoints in Patients with Relapsed/Refractory Follicular Lymphoma

https://ir.genmab.com/news-releases/news-release-details/genmab-announces-phase-3-epcorer-fl-1-clinical-trial-met-dual

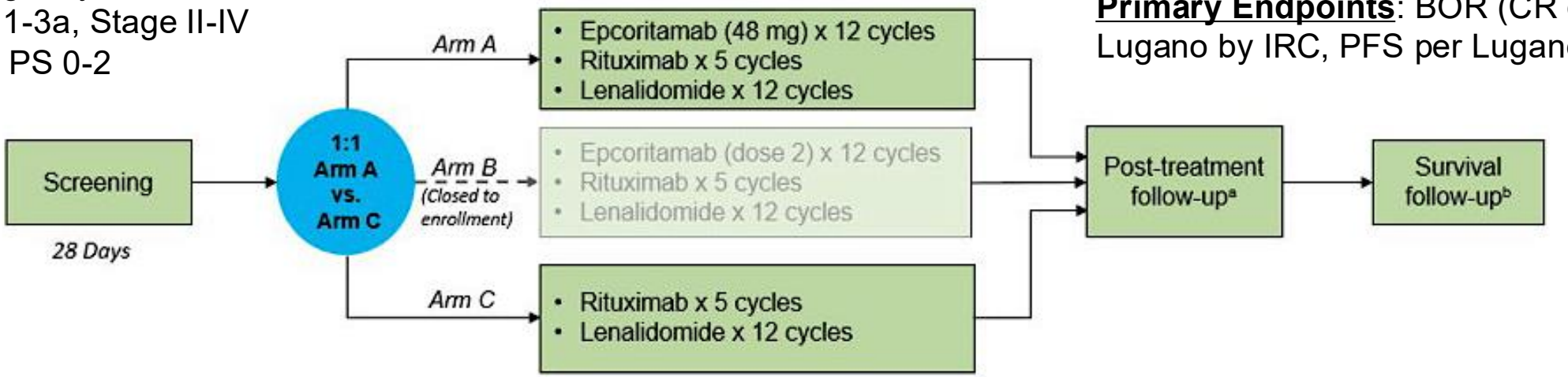
A Phase 3, Open-Label Study to Evaluate Safety and Efficacy of Epcoritamab in Combination With Rituximab and Lenalidomide (R^2) Compared to R^2 in Subjects With Relapsed or Refractory Follicular Lymphoma (EPCORE FL-1)

NCT05409066

Key Inclusion Criteria

- 2L+ FL ≥1 prior treatment including an anti-CD20 mAb in combination with chemotherapy (not refractory to lenalidomide; no lenalidomide within 12 months)
- Histologically confirmed CD20+
- Grade 1-3a, Stage II-IV
- ECOG PS 0-2

Primary Endpoints: BOR (CR or PR) per Lugano by IRC, PFS per Lugano by IRC



After initial step-up dosing during cycle 1, epcoritamab will be administered weekly in cycles 2-3, then Q4W in cycles 4-12.

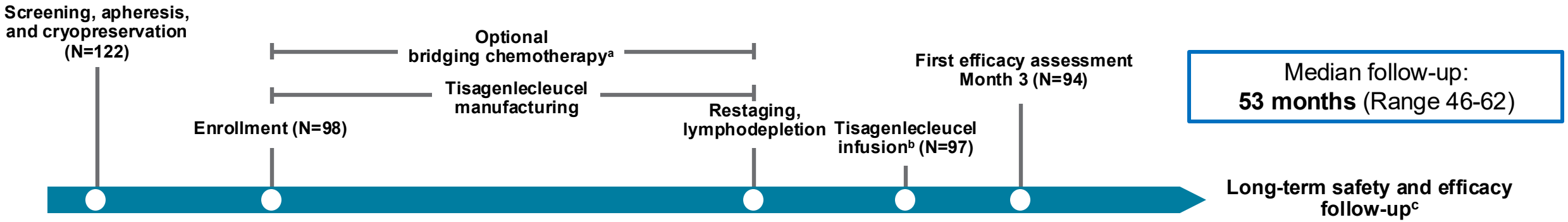
[a]Patients who complete treatment or discontinue treatment for reasons other than disease progression will proceed to post-treatment follow-up.
[b]Patients who have confirmed disease progression, initiate another line of treatment for FL, or refuse post-treatment follow-up visits will proceed to survival follow-up.
Q4W, every 4 weeks.

Phase 2 ELARA Trial 4-year Update: Clinical Outcomes of Tisagenlecleucel in Patients With High-Risk Relapsed/Refractory Follicular Lymphoma

Catherine Thieblemont, MD[1]; Martin Dreyling, MD[2]; Michael J. Dickinson, MBBS, D Med Sci, FRACP, FRCPA[3]; Joaquin Martinez-Lopez, MD, PhD[4]; Arne Kolstad, MD, PhD[5]; Jason Butler, MBBS[6]; Monalisa Ghosh, MD[7]; Leslie L. Popplewell, MD, FACP, MPH[8]; Julio C. Chavez, MD[9]; Emmanuel Bachy, MD, PhD[10]; Koji Kato, MD, PhD[11]; Hideo Harigae, MD, PhD[12]; Marie José Kersten, MD, PhD[13]; Charalambos Andreadis, MD, MS[14]; Peter A. Riedell, MD[15]; P. Joy Ho, MBBS, FRACP, FRCPA[16]; Jose Antonio Pérez Simon, MD, PhD[17]; Andy Chen, MD, PhD[18]; Loretta J. Nastoupil, MD[19]; Bastian von Tresckow, MD[20, 21]; Andrés José María Ferreri, MD[22]; Takanori Teshima, MD, PhD[23]; Piers E.M. Patten, MBChB, FRCP, FRCPath, PhD[24]; Joseph P. McGuirk, DO[25]; Fritz Offner, MD, PhD[26]; Andreas Viardot, MD, PhD[27]; Pier Luigi Zinzani, MD, PhD[28, 29]; Ram Malladi, MD, PhD[30]; Aiesha Zia, MSc[31]; Rakesh Awasthi, PhD[32]; Davide Germano, PhD[33]; Roberto Javier Ramos, MD[32]; Pei Hsu, MD[31]; Stephen J. Schuster, MD[34]; Nathan H. Fowler, MD[35]

EHA 2025;Abstract PS2150

ELARA Study Design

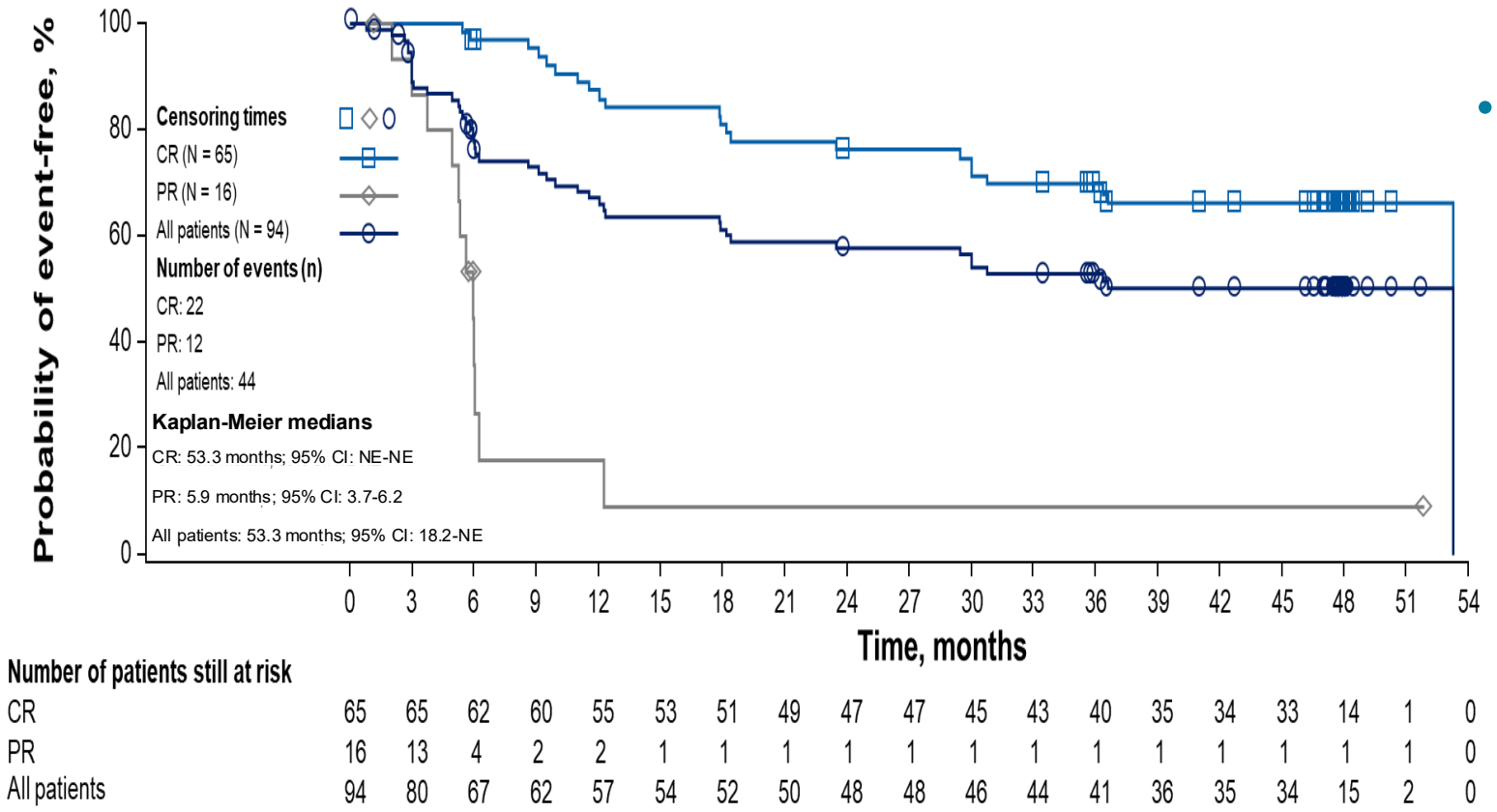


Median follow-up:
53 months (Range 46-62)

Key eligibility criteria	Study treatment	End points
• ≥18 years of age • FL grade 1, 2, or 3A • Relapsed/refractory disease[d] • No evidence of histological transformation/FL3B • No prior anti-CD19 therapy or allogeneic HSCT	Tisagenlecleucel dose range (single IV infusion) was $0.6\text{-}6\times10^8$ CAR-positive viable T cells	**Primary:** CRR by IRC **Secondary:** ORR, DOR, PFS, OS, safety, cellular kinetics

- Bridging therapy was allowed and was followed by disease re-evaluation before tisagenlecleucel infusion
- Cellular kinetics were determined by measurement of transgene levels by qPCR
- MRD levels were determined via clonoSEQ® next-generation sequencing assay performed at Adaptive Biotechnologies (Seattle, WA, USA)

Durable and High Responses Reported



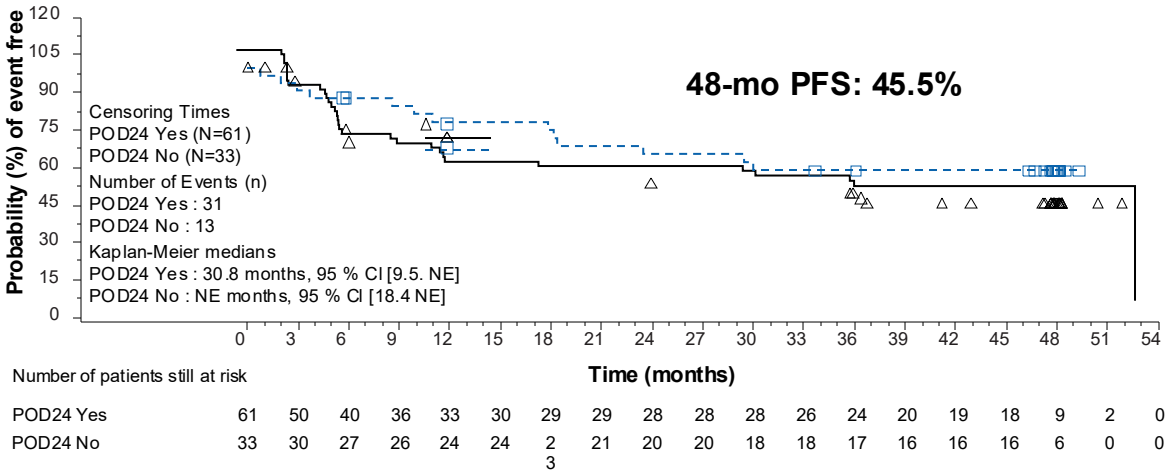
- Key patient subgroups at high risk (N = 94):
  - Disease refractory to ≥2 prior regimens: 72%
  - Bulky disease (>7 cm or at least 3 lesions >3 cm): 66%
  - POD24 from first anti-CD20 mAb-containing therapy: 65%
  - High FLIPI (≥3): 61%
  - High tumor burden (TMTV >510 mL[1,2]): 21%

	48-mo PFS, %
In all patients	50.2
In patients with BOR of CR	66.1

- High response rate reported anytime post-infusion (CR: 69.1%)

Durable and High Responses Reported in Patients With High-risk Disease Characteristics

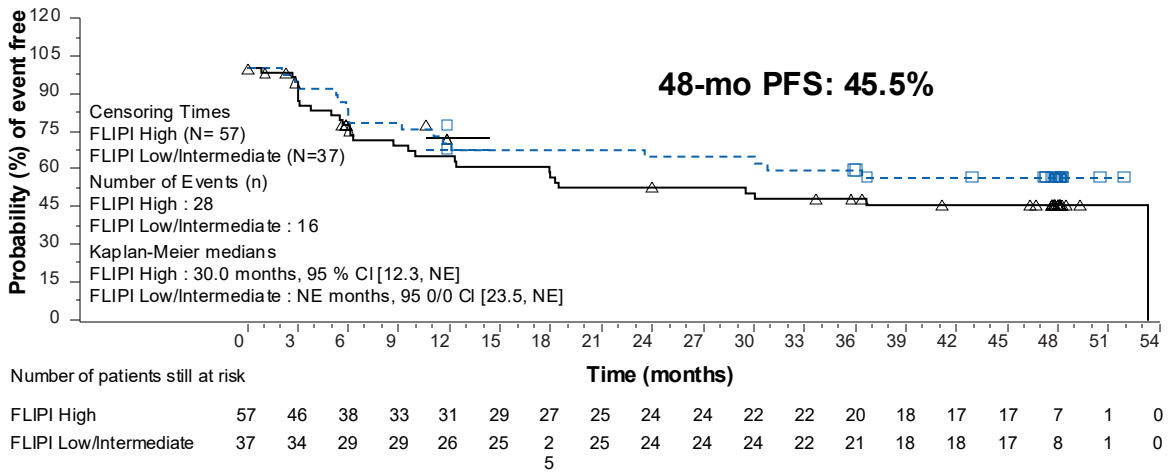
POD24



Number of patients still at risk

POD24 Yes	61	50	40	36	33	30	29	29	28	28	28	26	24	20	19	18	9	2	0
POD24 No	33	30	27	26	24	24	23	21	20	20	18	18	17	16	16	16	6	0	0

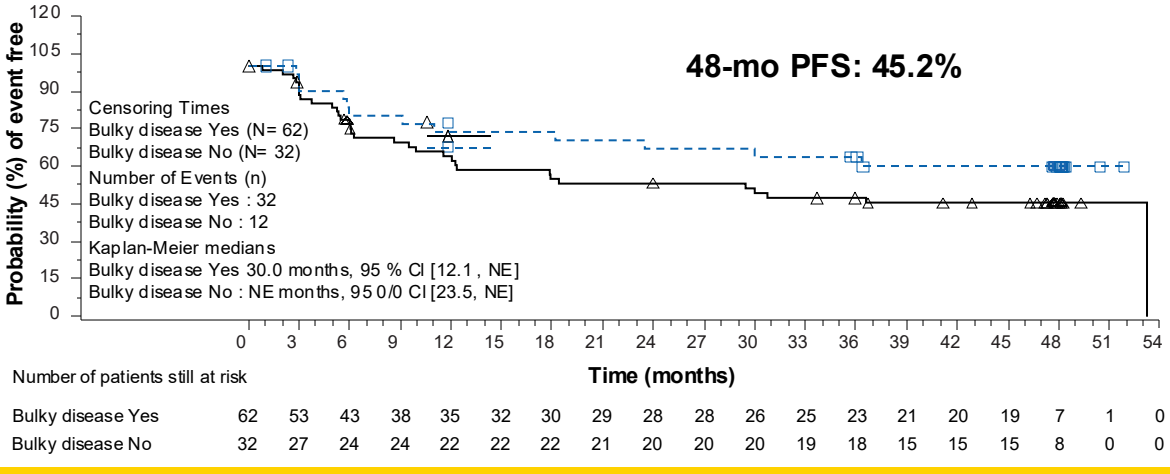
High FLIPI



Number of patients still at risk

FLIPI High	57	46	38	33	31	29	27	25	24	24	22	22	20	18	17	17	7	1	0
FLIPI Low/Intermediate	37	34	29	29	26	25	25	25	24	24	24	22	21	18	18	17	8	1	0

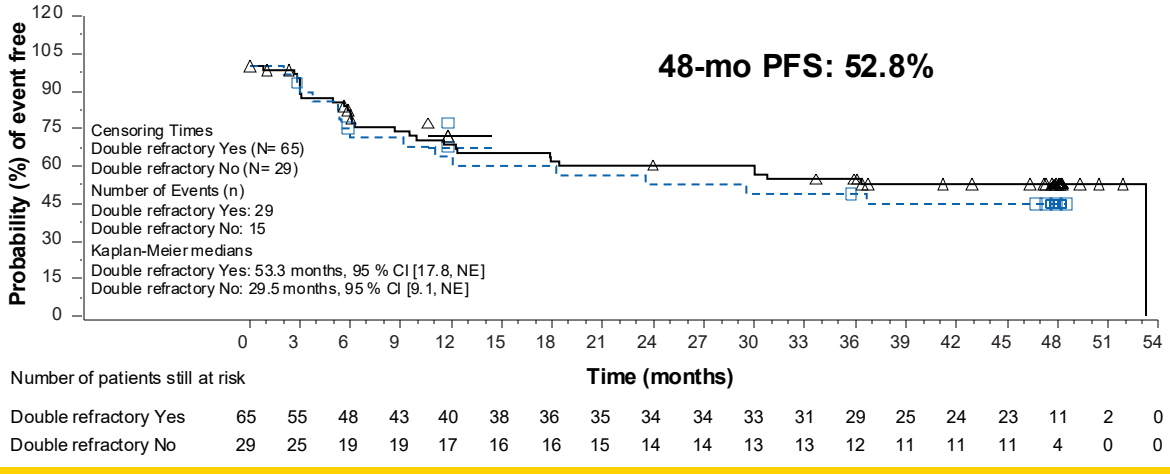
Bulky disease



Number of patients still at risk

Bulky disease Yes	62	53	43	38	35	32	30	29	28	28	26	25	23	21	20	19	7	1	0
Bulky disease No	32	27	24	24	22	22	22	21	20	20	20	19	18	15	15	15	8	0	0

Double refractory



Number of patients still at risk

Double refractory Yes	65	55	48	43	40	38	36	35	34	34	33	31	29	25	24	23	11	2	0
Double refractory No	29	25	19	19	17	16	16	15	14	14	13	13	12	11	11	11	4	0	0

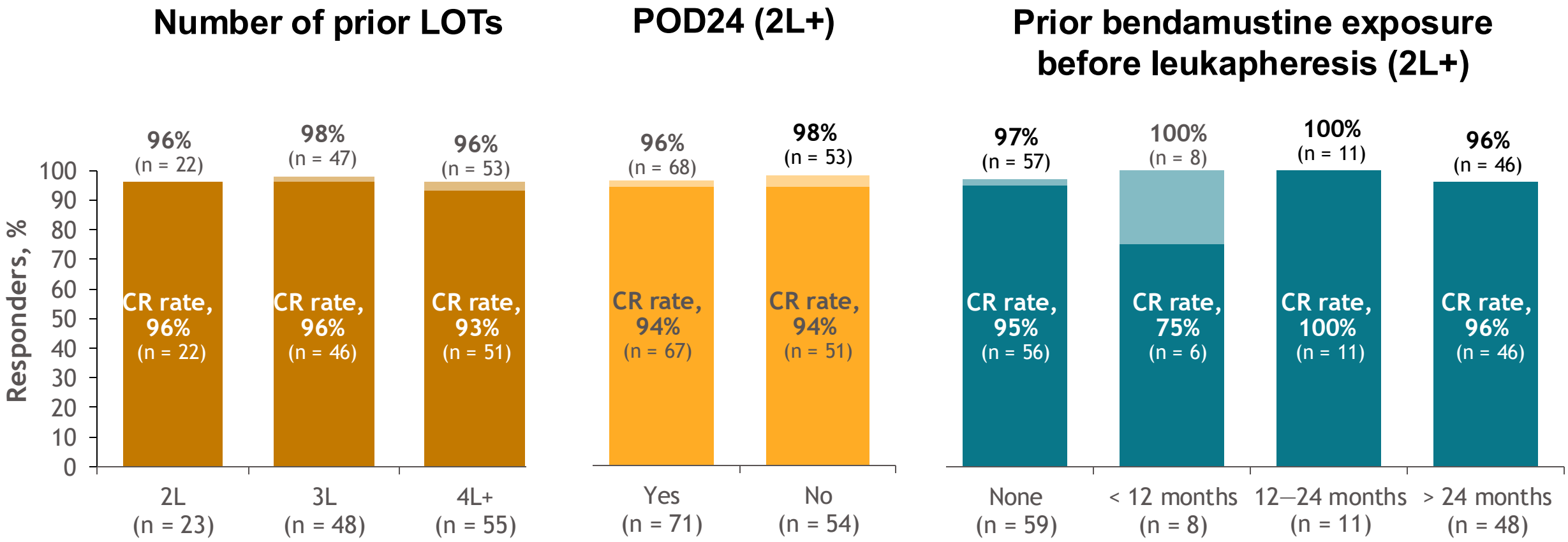
What is the Impact of Prior Bendamustine Exposure and POD24 on Treatment Efficacy?

Lisocabtagene maraleucel in relapsed or refractory follicular lymphoma (TRANSCEND FL): impact of prior lines of therapy, bendamustine exposure, and disease progression ≤ 24 months of initial systemic therapy

Sairah Ahmed,[1] Juan Luis Reguera Ortega,[2] Franck Morschhauser,[3] Guillaume Cartron,[4] Aaron P. Rapoport,[5] Koji Izutsu,[6] Hervé Ghesquieres,[7] M. Lia Palomba,[8] Hideki Goto,[9] John Kuruvilla,[10] Jeremy S. Abramson,[11] Peter Borchmann,[12] Ulrich Jäger,[13] Manali Kamdar,[14] Merav Bar,[15] Maria Strocchia,[16] Martina Raggi,[16] Rina Nishii,[17] Alejandro Martín García-Sancho[18]

- Post hoc analyses of efficacy and safety outcomes in patients with R/R FL from TRANSCEND FL by number of prior LOTs, POD24 status from first-line therapy with anti-CD20 antibody/alkylator, and prior bendamustine exposure before leukapheresis

ORR and CR Rates Across Subgroups



- ORR was 96%—100% across all subgroups

Ahmed S, et al. ICML 2025 [Abstract #142]

Time-to-event Outcomes Generally High Across Subgroups

	Number of prior LOTs			POD24 (2L+)[a]		Prior bendamustine exposure before leukapheresis (2L+)				Total 2L+ population (N = 126)
	2L (n = 23)	3L (n = 48)	4L+ (n = 55)	Yes (n = 71)	No (n = 54)	None (n = 59)	< 12 mo (n = 8)	12—24 mo (n = 11)	> 24 mo (n = 48)	
Median DOR, months[b]	NR	NR	30.9	30.9	NR	NR	NR	NR	NR	NR
24-month DOR rate, %	86	76	73	70	87	77	50	72	82	77
Median (95% CI) PFS, months[b]	NR	NR	31.8	31.8	NR	31.8	NR	NR	NR	NR
24-month PFS rate, %	83	75	71	67	85	74	50	72	79	74
24-month OS rate, %	96	89	87	86	94	93	71	91	88	90
Free of next treatment at 24-month rate, %	91	85	76	78	89	85	58	91	81	82

- A trend toward better outcomes was observed with liso-cel in earlier versus later (4L+) LOTs
- 24-month rates generally better for patients without POD24 but clinically meaningful in patients with POD24
- Outcomes consistently high for all prior bendamustine subgroups except for the < 12-month subgroup where trend for lower 24-month rates observed; interpretation with caution **due to small sample size (n = 8)**

First line Follicular Lymphoma

Case 3:

- Patient is a 71 year old man with a history of prostate cancer s/p prostatectomy and nephrolithiasis
- He develops cervical lymphadenopathy, undergoes excisional biopsy showing classical follicular lymphoma
- He feels well and is minimally symptomatic except for mild back pain
- PET shows advanced stage high tumor burden disease with retroperitoneal lymphadenopathy complicated by ureteral compression and hydronephrosis
- Laboratory tests show mild renal insufficiency (creatinine 1.76 mg/dL)

What are new studies in 1st line FL?

MorningSun study design: HTB FL cohort

Key inclusion criteria

- Previously untreated FL
- HTB by GELF criteria
- ECOG performance status 0–2

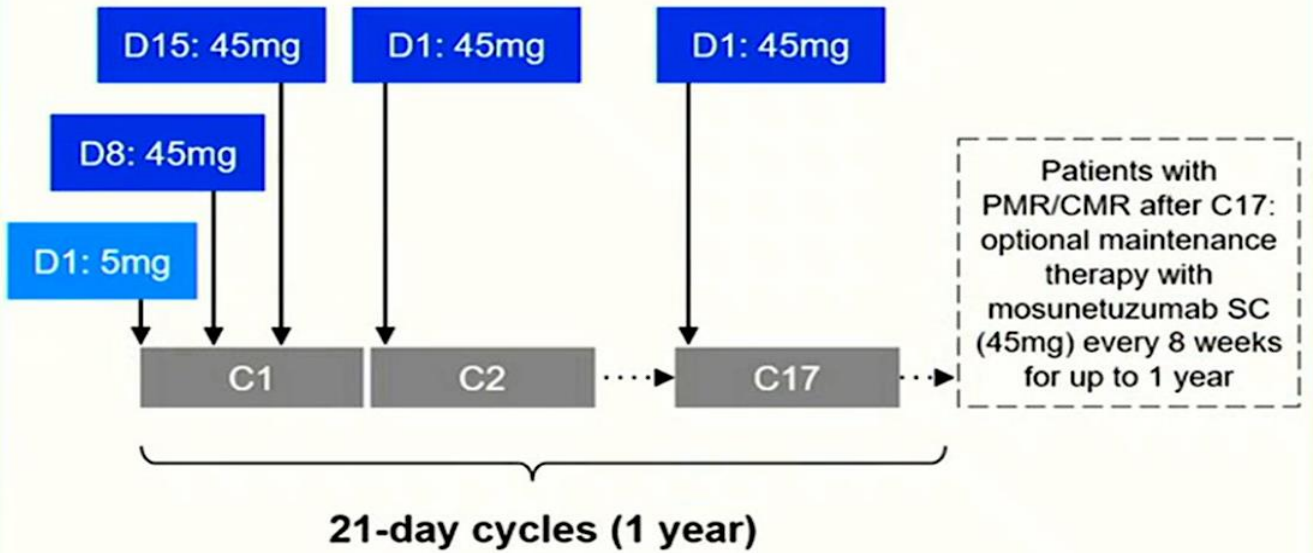
CRS mitigation

- Mosunetuzumab SC step-up dosing in C1
- Corticosteroid prophylaxis* was mandatory in C1–2 and optional thereafter
- Hospitalization was not mandatory

Endpoints

- Primary: PFS rate at 24 months
- Key secondary: ORR, time to response, safety

Mosunetuzumab SC administration



*Dexamethasone (20mg) or methylprednisolone (80mg); premedication with oral acetaminophen or paracetamol and/or diphenhydramine could also be administered prior to administration of mosunetuzumab.
C, cycle; CMR, complete metabolic response; CRS, cytokine release syndrome; D, day; ECOG, Eastern Cooperative Oncology Group; GELF, Groupe d'Études des Lymphomes Folliculaires; ORR, objective response rate; PFS, progression-free survival; PMR, partial metabolic response.

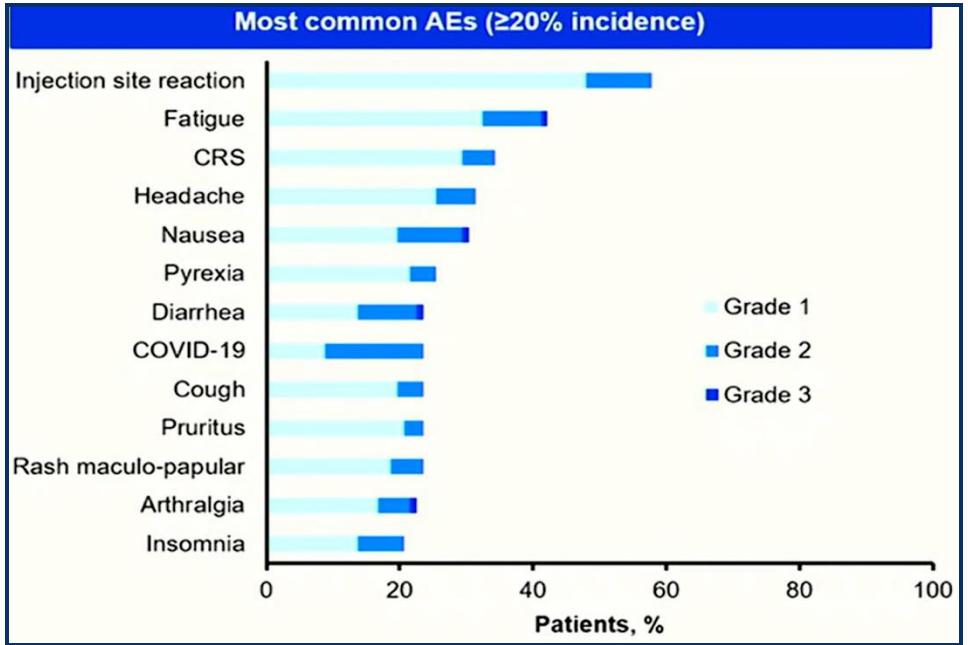
Flinn et al. ASCO 2025;Abstract 7014.

Baseline characteristics and patient disposition

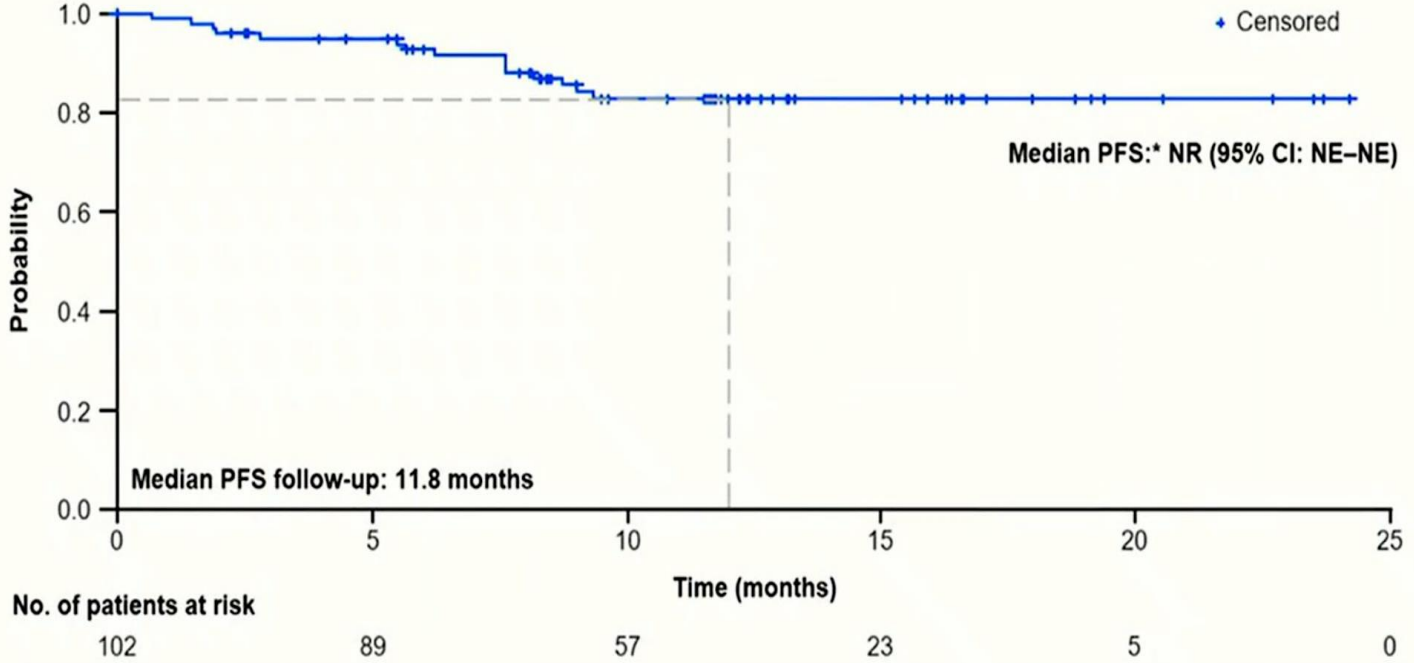
n (%) unless stated	N=102
Median age, years (range)	64.5 (24–86)
Female	53 (52.0)
Race	
White	81 (79.4)
Asian	5 (4.9)
American Indian or Alaska Native	3 (2.9)
Black or African American	2 (2.0)
Not reported	8 (7.8)
Unknown	3 (2.9)
B-symptoms	23 (22.5)
Elevated LDH	
Yes	25 (24.5)
No	77 (75.5)
ECOG performance status	
0/1	101 (99.0)
2	1 (1.0)

n (%) unless stated	N=102
Follicular lymphoma grade	
Grade 1–2	79 (77.5)
Grade 3A	20 (19.6)
Missing	3 (2.9)
Ann Arbor stage	
II	9 (8.8)
III	38 (37.3)
IV	55 (53.9)
Extranodal involvement	39 (38.2)
Bulky disease	
Yes	40 (39.2)
No	54 (52.9)
Unknown	8 (7.8)
FLIPI score	
0/1	22 (21.6)
2	34 (33.3)
3–5	46 (45.1)

Safety and Efficacy



n (%)	N=102
Any grade AE	**102 (100)**
Grade 3/4 AE	**41 (40.2)**
Most common Grade 3/4 AE (≥10%)	
Neutropenia/neutrophil count decreased	14 (13.7)
Grade 5 AEs	**4 (3.9)**
COVID-19 pneumonia	2 (2.0)
Cardiogenic shock	1 (1.0)
Death (unexplained)	1 (1.0)
Serious AE	**30 (29.4)**
Select AE of interest	
ICANS	1 (1.0)
Grade 4	1 (1.0)
Most common infections (≥10%)	
COVID-19/COVID-19 pneumonia	27 (26.5)
Sinusitis	14 (13.7)
Urinary tract infection	13 (12.7)
Pneumonia	12 (11.8)
AE leading to mosunetuzumab discontinuation	8 (7.8)*



	N=102
12-month PFS rate, % (95% CI)	82.8 (73.0–89.3)
Patients with progressive disease/relapse, n (%)	10 (9.8)
Patients who died, n (%)	5 (4.9)

Flinn et al. ASCO 2025;Abstract 7014.

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Summary of Updates in FL

Follicular Lymphoma

- Front line: Mosunetuzumab in 1st line FL

- Relapsed:
  - inMIND study
  - Tisa-cel in high risk FL
  - Liso-cel in Benda-exposed cohorts and POD24
  - Subcutaneous Mosun
  - Epcor update
  - EPCORE-FL1 update

First Line Marginal Zone Lymphoma

- 52 year old man with history of hypertension underwent an MRI of the spine to evaluate back pain and fatigue
    - Found to have retroperitoneal lymphadenopathy, 2.8 - 4.2 cm
- CT chest, abdomen and pelvis showed mesenteric lymphadenopathy along aortic bifurcation, inguinal region
- Lymph node biopsy showed marginal zone lymphoma, laboratory tests showed Hgb 10.7, otherwise normal
- Bone marrow biopsy shows low level lymphoma involvement

What are new studies in 1st line MZL?

MorningSun: Open-label Phase II trial of the efficacy and safety of subcutaneous mosunetuzumab (Mosun SC) as frontline (1L) treatment in symptomatic patients with marginal zone lymphoma (MZL)

John M. Burke,[1] Aung M. Tun,[2] Jose Villasboas,[3] L. Elizabeth Budde,[4] Mitul Gandhi,[5] Tara Graff,[6] Prachi Jani,[7] Juliana M. L. Biondo,[7] Mei Wu,[7] Rona Farighi,[7] Yong Mun,[7] Tony Lin,[7] Javier Munoz,[8] Ian Flinn[9]

[1]Rocky Mountain Cancer Centers, Aurora, CO, USA; [2]University of Kansas Cancer Center, Kansas City, KS, USA; [3]Mayo Clinic, Rochester, MN, USA; [4]City of Hope National Medical Center, Duarte, CA, USA; [5]Virginia Cancer Specialists, Gainesville, VA, USA; [6]Mission Cancer and Blood, Des Moines, IA, USA; [7]Genentech, Inc., South San Francisco, CA, USA; [8]Mayo Clinic, Phoenix, AZ, USA; [9]Tennessee Oncology/OneOncology, Nashville, TN, USA.

NCI Cancer Center
A Cancer Center Designated by the National Cancer Institute

EHA 2025;Abstract S232

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MorningSun study design: 1L MZL cohort

Key inclusion criteria

- Symptomatic MZL (splenic, nodal, and extranodal, including gastric/MALT)
- Previously untreated, with an indication to start systemic therapy
- ECOG performance status 0–2

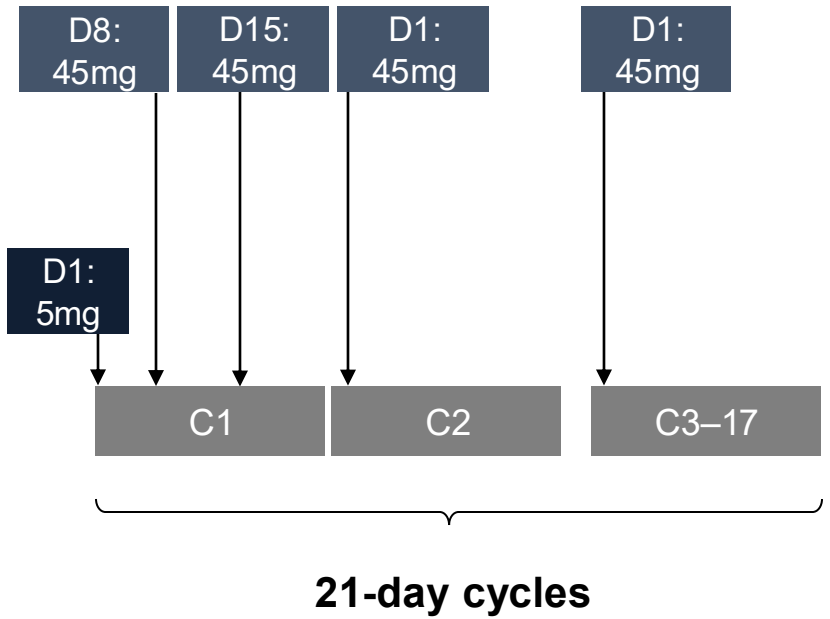
CRS mitigation

- Mosunetuzumab SC step-up dosing in C1
- Corticosteroid prophylaxis* was mandatory in C1–2 and optional thereafter
- Hospitalization was not mandatory

Endpoints

- Primary: INV-assessed ORR by Lugano criteria
- Key secondary: PFS, DOR, DOCR, time to response, safety

Mosunetuzumab SC administration

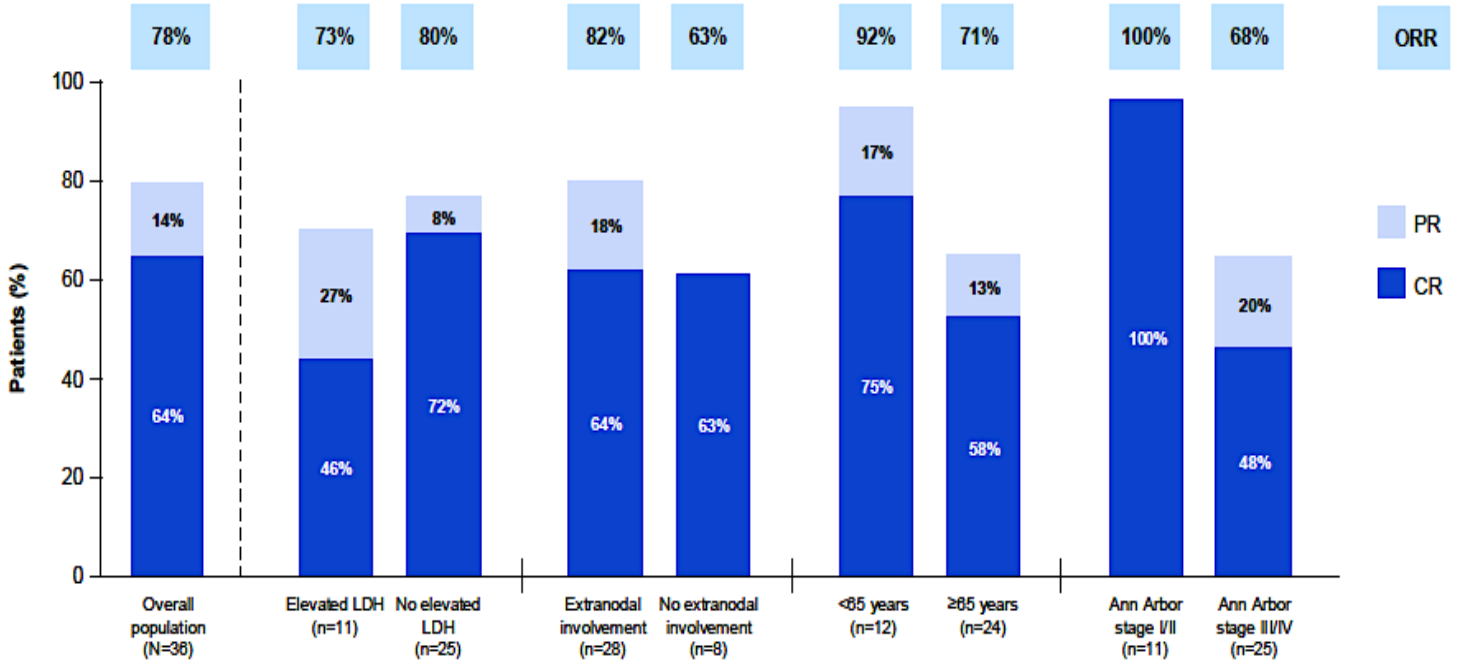


Patients were treated for up to 17 cycles unless disease progression or unacceptable toxicity occurred

Population and Outcomes

n (%), unless stated	N=36
Median age, years (range)	69 (36–81)
Female	24 (66.7)
Race*	
White	32 (88.9)
Black or African American	1 (2.8)
Extranodal involvement	28 (77.8)
Bulky disease	7 (19.4)
ECOG performance status	
0	20 (55.6)
1	13 (36.1)
2	3 (8.3)

Efficacy: Best response rates

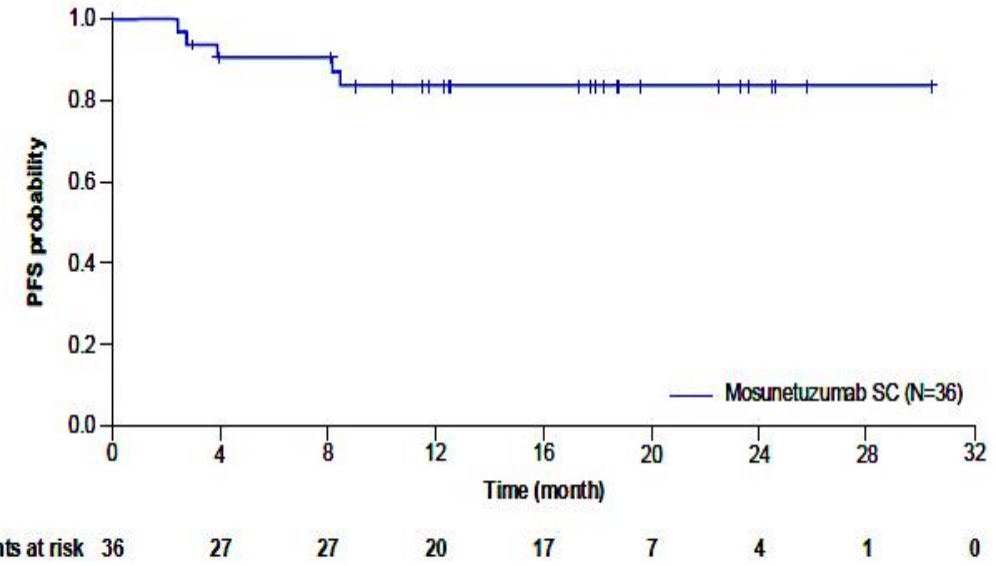


CR rates across high-risk subgroups were consistent with the overall population

Safety and Efficacy

n (%)	N=36
Any grade AE	36 (100)
Grade 3/4 AEs	23 (63.9)
Most common Grade 3/4 AEs (≥10%)	
Neutropenia/neutrophil count decreased	10 (27.8)
Anemia	4 (11.1)
Grade 5 AEs	0
Select AEs of interest	
ICANS	0
Serious AEs*	14 (38.9)
AE leading to mosunetuzumab discontinuation†	6 (16.7)

Progression Free Survival



	N=36
Median PFS, months (95% CI)	NR (NE–NE)
6-month event-free rate, % (95% CI)	90.5 (73.4–96.8)
12-month event-free rate, % (95% CI)	83.6 (64.8–92.8)

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EHA 2025; Abstract S232; Burke J et al.

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Relapsed Marginal Zone Lymphoma

- 52 year old man with history of hypertension underwent an MRI of the spine to evaluate back pain and fatigue
    - Found to have retroperitoneal lymphadenopathy, 2.8 - 4.2 cm
- CT chest, abdomen and pelvis showed mesenteric lymphadenopathy along aortic bifurcation, inguinal region
- Lymph node biopsy showed marginal zone lymphoma, laboratory tests showed Hgb 10.7, otherwise normal
- Bone marrow biopsy shows low level lymphoma involvement

➢ Patient is treated with BR x 6 cycles with PR → observation

➢ 3 years later develops recurrent MZL with axillary, mesenteric, and inguinal lymphadenopathy, treated with BTKi → 18 months later progression

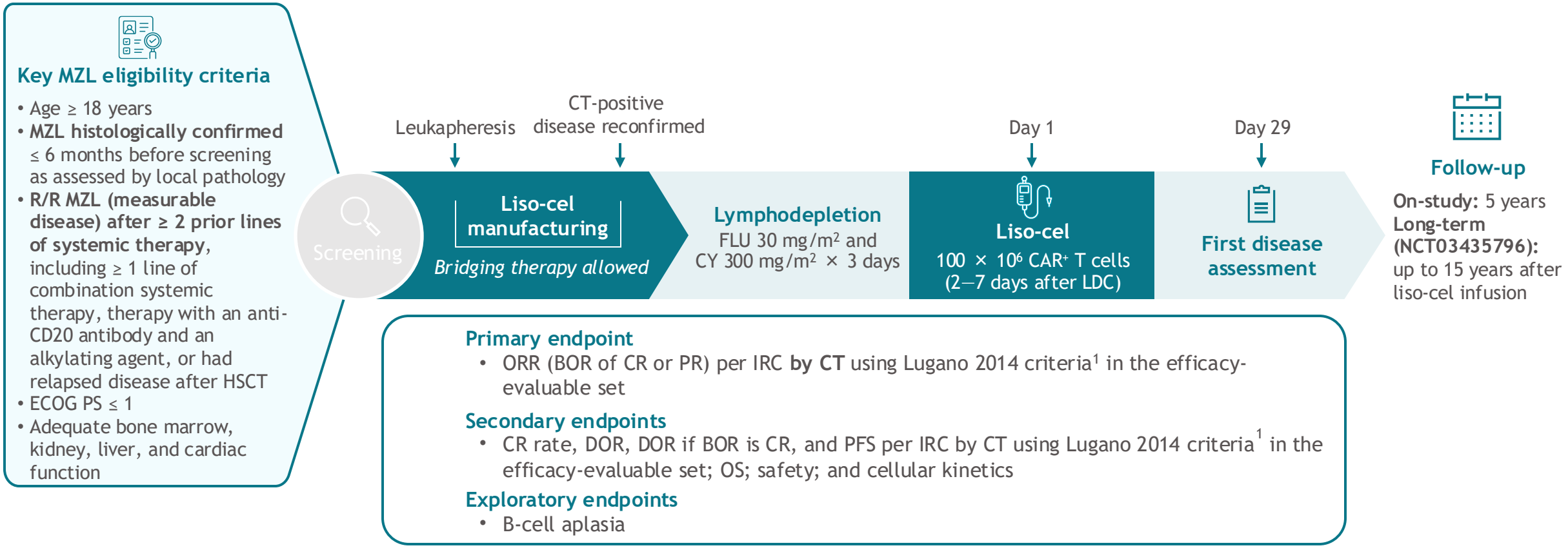
What are new studies in relapsed MZL?

Lisocabtagene maraleucel in patients with relapsed or refractory marginal zone lymphoma in the phase 2 TRANSCEND FL study

M. Lia Palomba,[1] Stephen J. Schuster,[2] Reem Karmali,[3] Alan P. Skarbnik,[4] Jeremy S. Abramson,[5] Kirit Ardeshna,[6] Peter Borchmann,[7] Brian T. Hill,[8] Alejandro Martin Garcia-Sancho,[9] Antonio Pinto,[10] Aaron P. Rapoport,[11] Guillaume Cartron,[12] Isabelle Fleury,[13] Koji Izutsu,[14] Manali Kamdar,[15] Stephan Mielke,[16] Anna Maria Barbui,[17] Juan Luis Reguera Ortega,[18] Loretta J. Nastoupil,[19] Sairah Ahmed,[20] Merav Bar,[21] Lizbeth Diaz,[22] Victoria Diab,[23] Min Vedal,[22] Silvia Colicino,[22] Ariel Avilion,[21] Rina Nishii,[23] Franck Morschhauser[24]

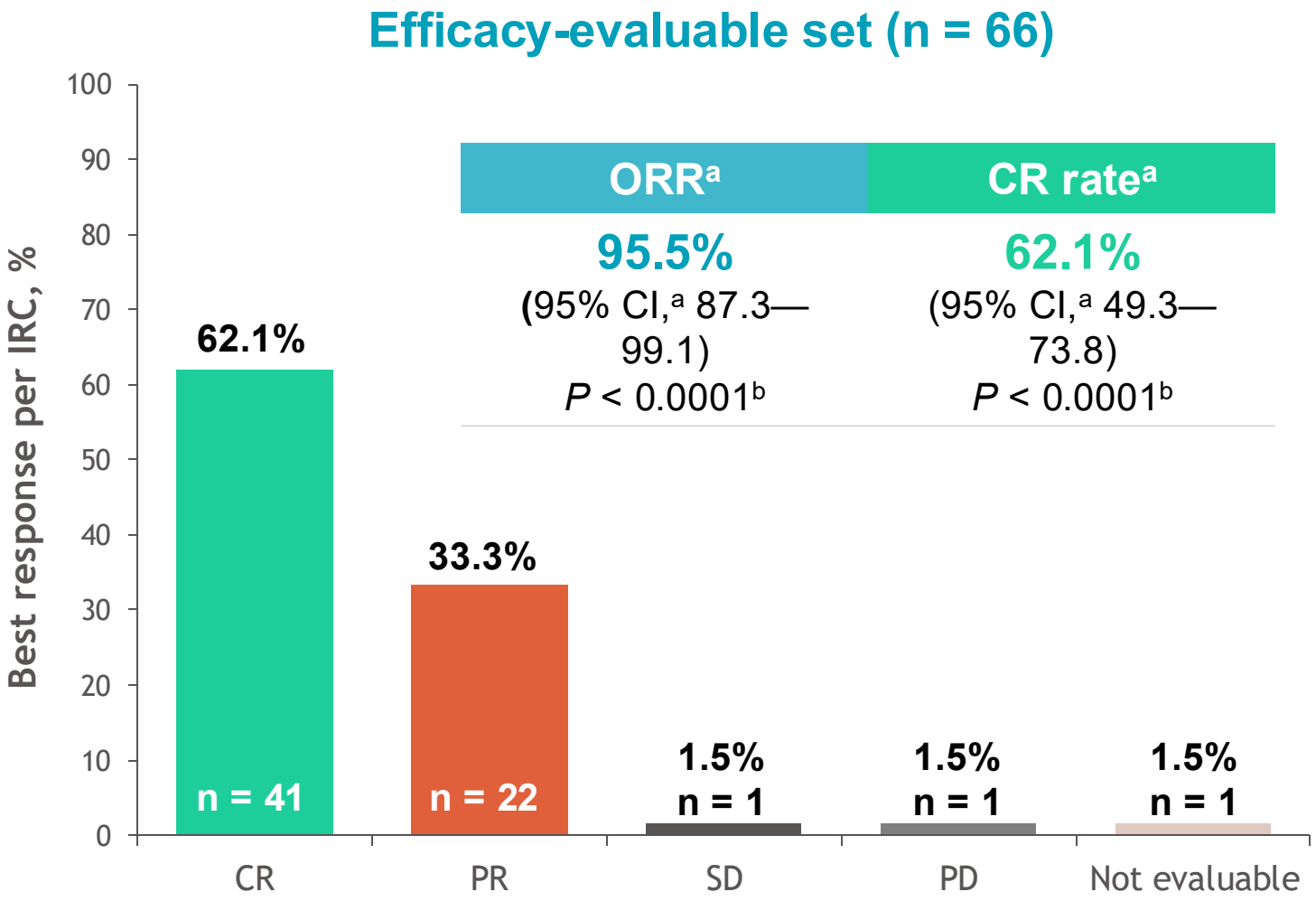
ICML 2025, Presentation 055

TRANSCEND FL study design: MZL cohort



- Study endpoints of ORR and CR rate were tested hierarchically in the following order at 1-sided α = 0.025 significance: ORR (H_0: ORR ≤ 50%) and then CR rate (H_0: CR rate ≤ 5%)

ORR and CR rate per **CT assessed by IRC**



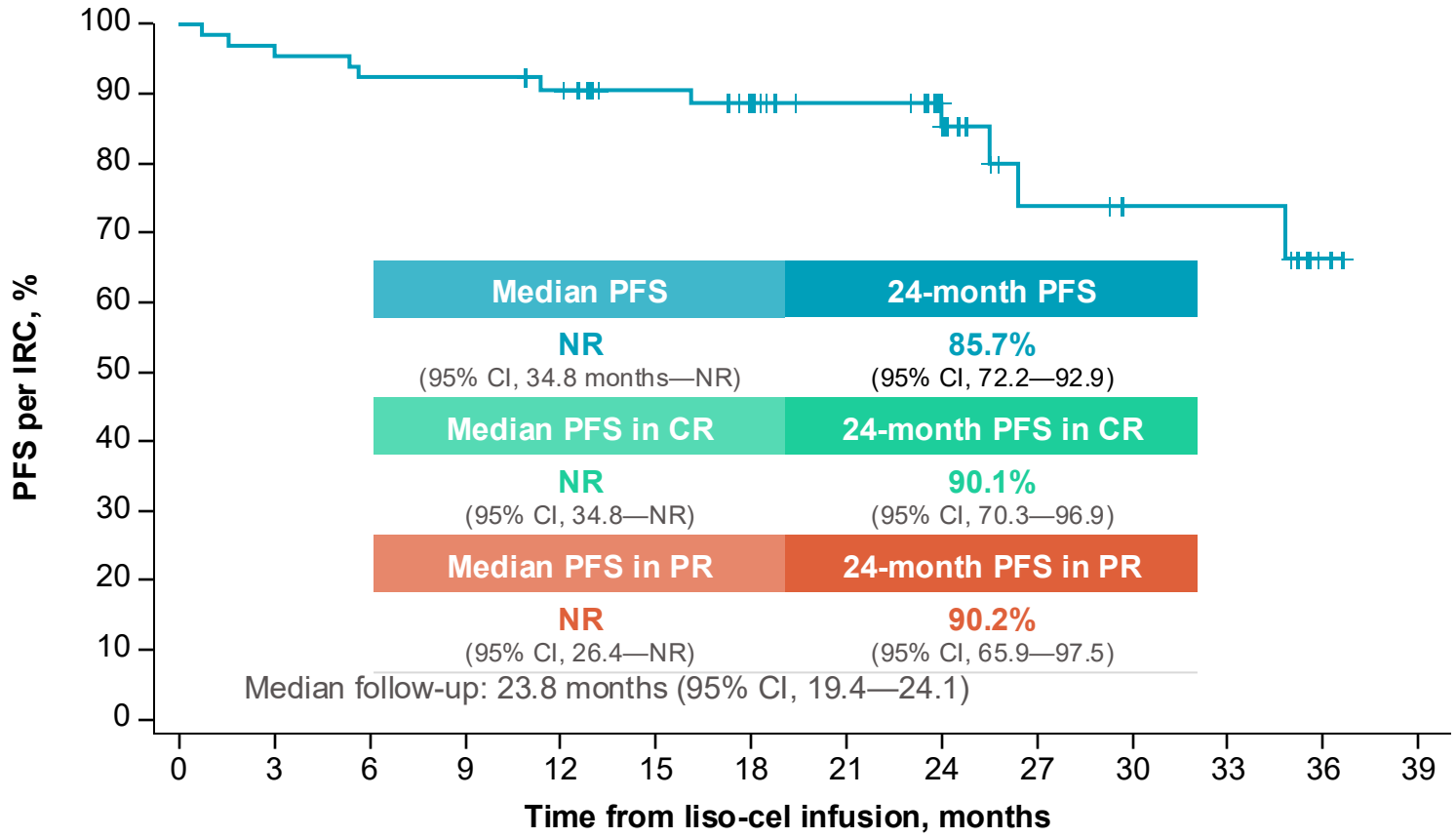
	Liso-cel—treated set (n = 67)
Median (range) age, y	62 (37—81)
< 65 y	37 (55)
≥ 65 y to < 75 y	20 (30)
≥ 75 y	10 (15)
Male, n (%)	39 (58)
MZL subtype, n (%)	
Nodal	32 (48)
Splenic	18 (27)
Extranodal/Mucosa-associated lymphoid tissue	17 (25)

- The primary endpoint of ORR and secondary endpoint of CR rate per CT assessed by IRC were met
- **Among patients with PET-positive disease at baseline (n = 56), ORR was 98.2%[c] and CR rate was 91.1%[c]**

Palomba ML, et al. ICML 2025 [Abstract #055]

Progression Free Survival

Median (95% CI):
NR (34.8 months—NR)



No. at risk														
3L+ MZL	66	63	61	61	59	51	45	37	23	12	10	10	3	0

Summary of Updates in MZL

Marginal Zone Lymphoma

- Front line: Mosunetuzumab in 1st line MZL
- Relapsed: Liso-cel in relapsed MZL

First Line Mantle Cell Lymphoma

- 65 year old man with no past history develops tonsillar enlargement and pharyngitis
- Receives treatment with several antibiotics, no improvement
- Undergoes a tonsillar biopsy showing mantle cell lymphoma. Ki-67 index is 40%, MIPI is intermediate risk
- NGS testing shows no mutations in TP53
- PET shows widespread lymphadenopathy, and bilateral tonsillar enlargement and uptake. Bone marrow biopsy shows involvement of mantle cell lymphoma
- Patient begins treatment with Acalabrutinib, Bendamustine and Rituximab

What are new updates in 1st line MCL?

ECHO Study Design

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

Primary endpoint:
- PFS (independent review committee)

Key secondary endpoints:
- OS
- ORR (independent review committee)

Safety

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

Enrollment: April 2017 to March 2023
Sites: 195 globally

RANDOMIZE 1:1

Bendamustine[a] Rituximab[b] x 6 cycles → if ≥PR → Maintenance Rituximab (every 2 cycles x 2 years)

Acalabrutinib 100 mg BID, PO until PD or toxicity

Bendamustine[a] Rituximab[b] x 6 cycles → if ≥PR → Maintenance Rituximab (every 2 cycles x 2 years)

Placebo BID, PO until PD or toxicity

Crossover to acalabrutinib after PD was permitted

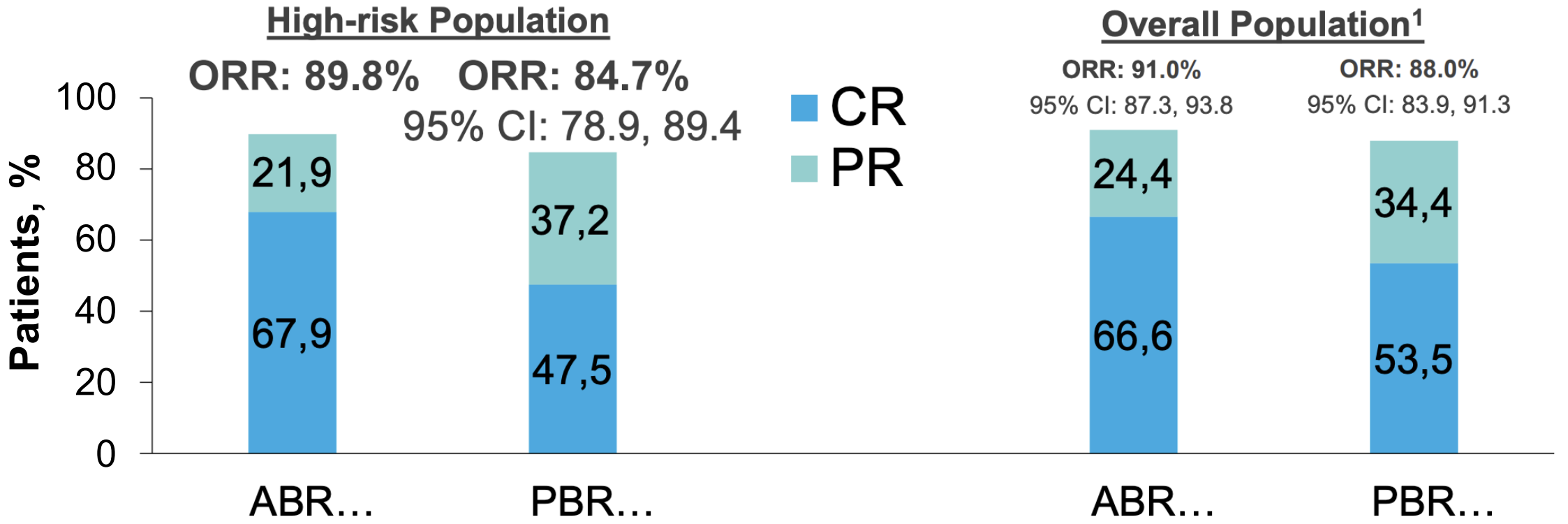
1 cycle = 28 days

Data cutoff date: February 15, 2024
Median time on study: 44.9 months

[a]Bendamustine 90 mg/m^2 on days 1 and 2
[b]Rituximab 375 mg/m^2 on day 1

High-risk disease defined as any of the following:
- **High-risk MIPI (6–11)**
- ***TP53* mutation**
- **Ki-67 index ≥30%**
- **Blastoid/pleomorphic histology**

Best Response of CR Significantly Higher With ABR in Patients With High-risk MCL

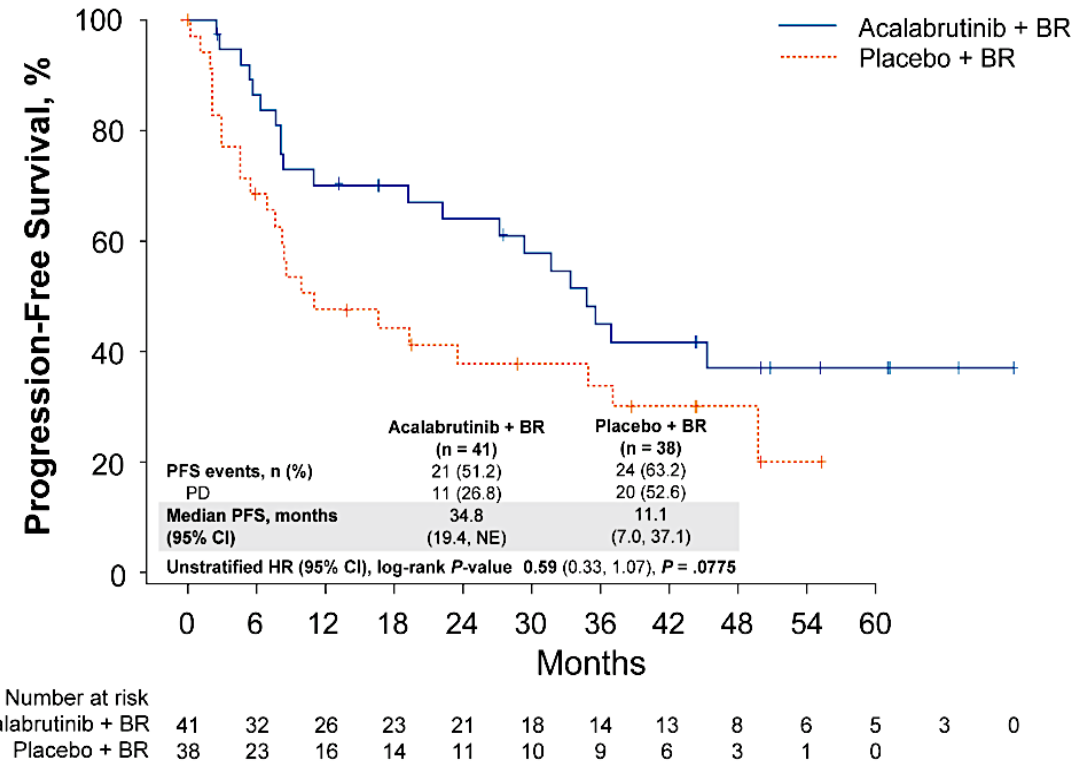


	ORR	CR
Difference (ABR vs PBR)	5.1%	20.4%
95% CI	-1.7, 12.1	10.4, 30.0
P-value	.1382	**<.0001**

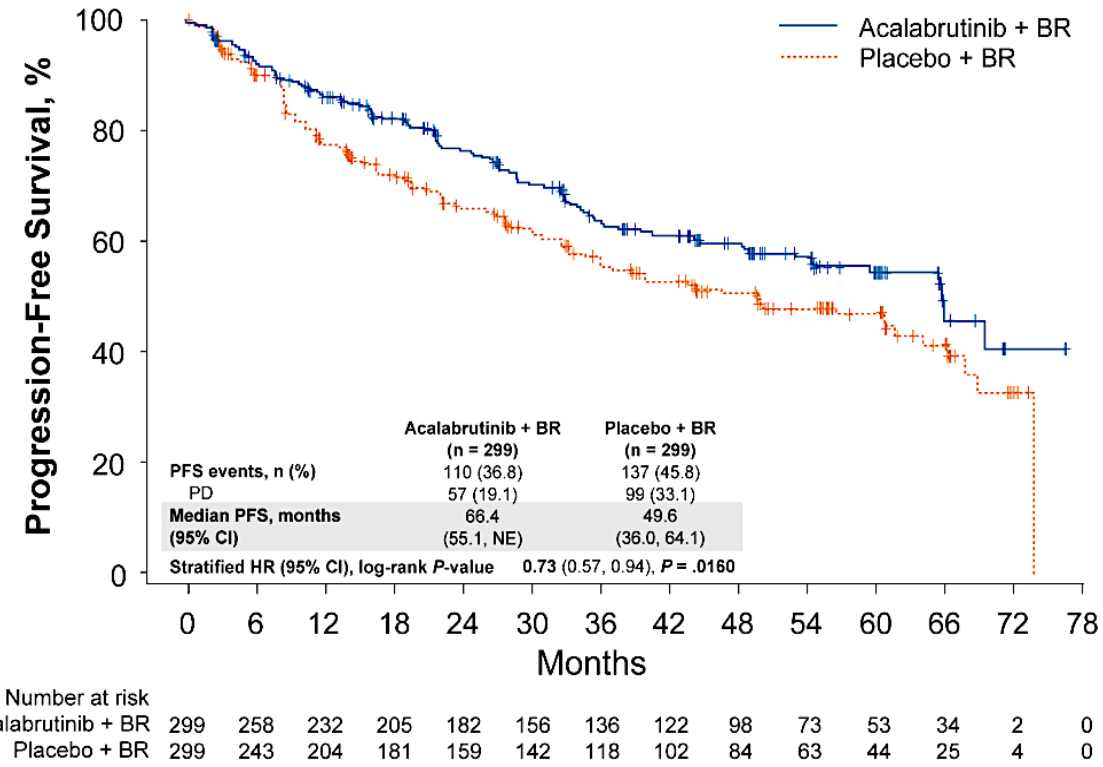
	ORR
Difference (ABR vs PBR)	3.0%
95% CI	-2.0, 8.1
P-value	.2196

PFS in Patients With Blastoid/Pleomorphic Histology

PFS in Patients With Blastoid/Pleomorphic Histology

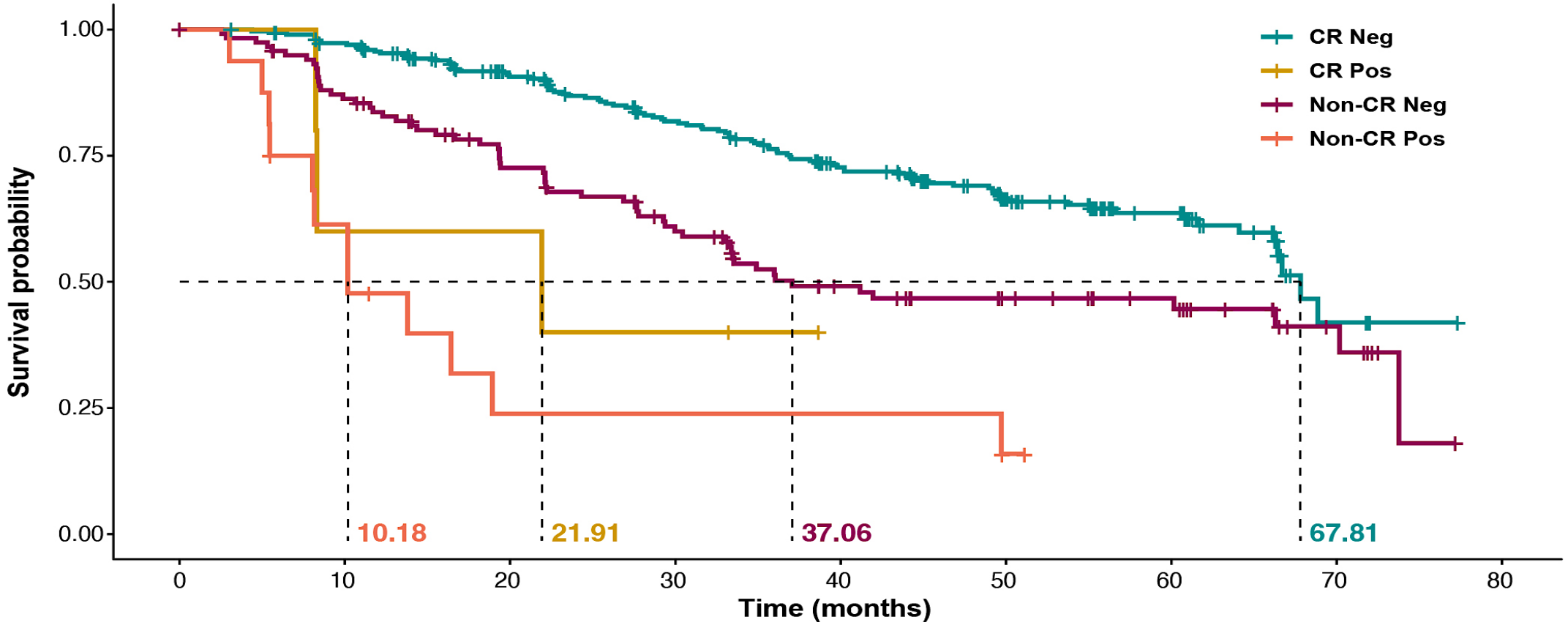


PFS in Full Analysis Population[1]



- Sample size in this subgroup was small; the difference in median PFS was ~24 months

Figure. Kaplan-Meier Plot of Progression-free Survival by Best Clinical Response and Minimal Residual Disease Status (<10^{-5} by NGS) in Peripheral Blood at Any Time



Number at risk:

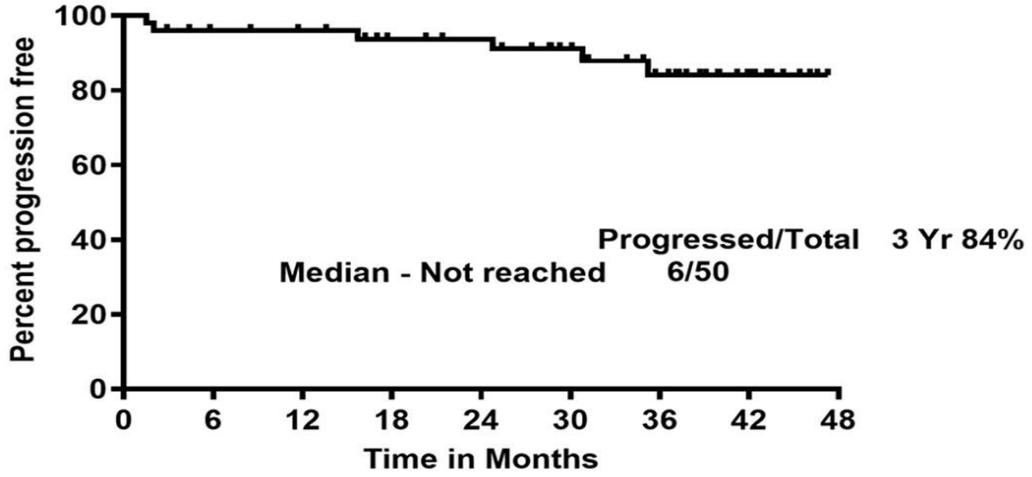
CR Neg	303	289	244	209	174	109	69	9	0
CR Pos	5	3	3	2	0	0	0	0	0
Non-CR Neg	122	100	77	60	41	30	22	8	0
Non-CR Pos	16	9	3	3	3	1	0	0	0

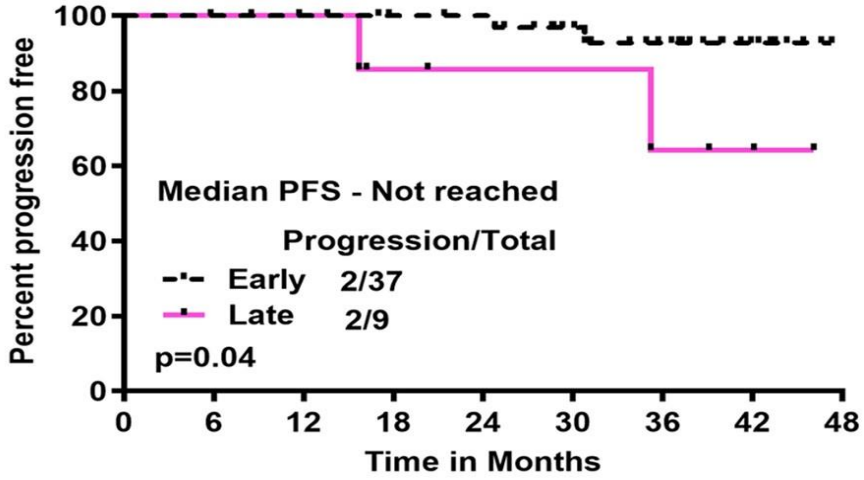
CR, complete response; NGS, next-generation sequencing.

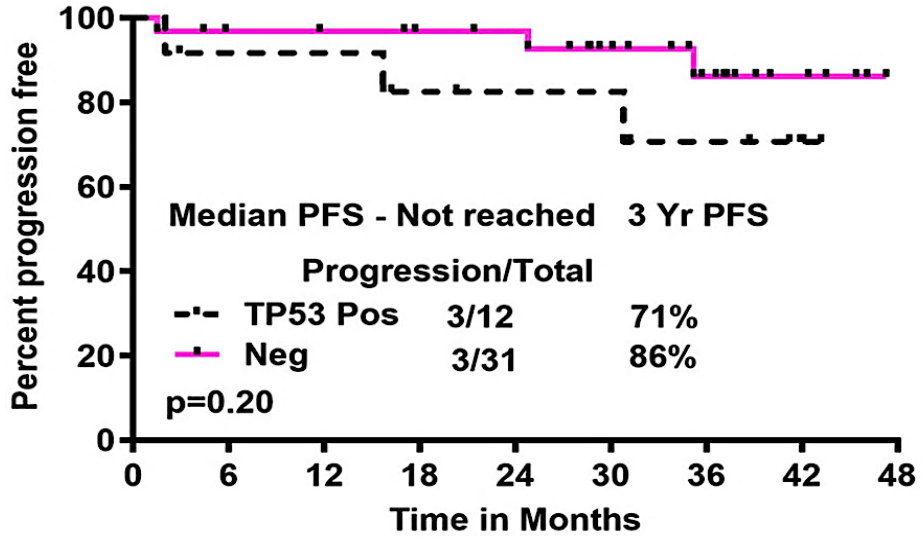
Acalabrutinib in Combination with Rituximab is Highly Effective Frontline Treatment for Older Patients with Mantle Cell Lymphoma

- Single institution trial, 50 patients
- Acalabrutinib 100 mg orally twice daily and rituximab weekly for four weeks, then monthly for 12 months, and every two months up to 24 months. Acalabrutinib was continued beyond 24 months
- Primary endpoint: ORR
- ClonoSEQ-based MRD assessment and multiomic analysis were conducted on serial blood, plasma, and tissue samples

Outcomes


Percent progression free
100
80
60
40
20
0
0 6 12 18 24 30 36 42 48
Time in Months
Progressed/Total 3 Yr 84%
Median - Not reached 6/50


Percent progression free
100
80
60
40
20
0
0 6 12 18 24 30 36 42 48
Time in Months
Median PFS - Not reached
Progression/Total
Early 2/37
Late 2/9
p=0.04


Percent progression free
100
80
60
40
20
0
0 6 12 18 24 30 36 42 48
Time in Months
Median PFS - Not reached 3 Yr PFS
Progression/Total
TP53 Pos 3/12 71%
Neg 3/31 86%
p=0.20

Summary of Updates in MCL

Mantle Cell Lymphoma

- Frontline:
  - ECHO trial updates and MRD data
  - Acalabrutinib and rituximab in frontline older MCL

Current and Future Integration of Antibody-Drug Conjugates into the Management of Metastatic Breast Cancer

A CME/MOC-Accredited Live Webinar

Tuesday, September 30, 2025
5:00 PM – 6:00 PM ET

Faculty

Aditya Bardia, MD, MPH
Adam M Brufsky, MD, PhD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Thank you for joining us!

Please take a moment to complete the survey currently up on Zoom. Your feedback is very important to us. The survey will remain open for 5 minutes after the meeting ends.

Information on how to obtain CME and ABIM MOC credit is provided in the Zoom chat room. Attendees will also receive an email in 1 to 3 business days with these instructions.

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