Kompetenznetz Maligne Lymphome

Lymphom Kompetenz KOMPAKT

KML KONGRESSE

Expert:innen berichten zu Lymphomen & Leukämien

Amy Sparwasser, Stock-Fotografie-ID: 1455291856

ASH 2025

ORLANDO | 06.-09. Dezember 2025

Kompetenznetz Maligne Lymphome

Lymphom Kompetenz KOMPAKT

KML KONGRESSE

Expert:innen berichten zu Lymphomen & Leukämien

Prof. Dr. med. Björn Chapuy
Charité Universitätsmedizin Berlin

Diffuses großzelliges B-Zell-Lymphom (DLBCL)

Offenlegung potentieller Interessenskonflikte

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

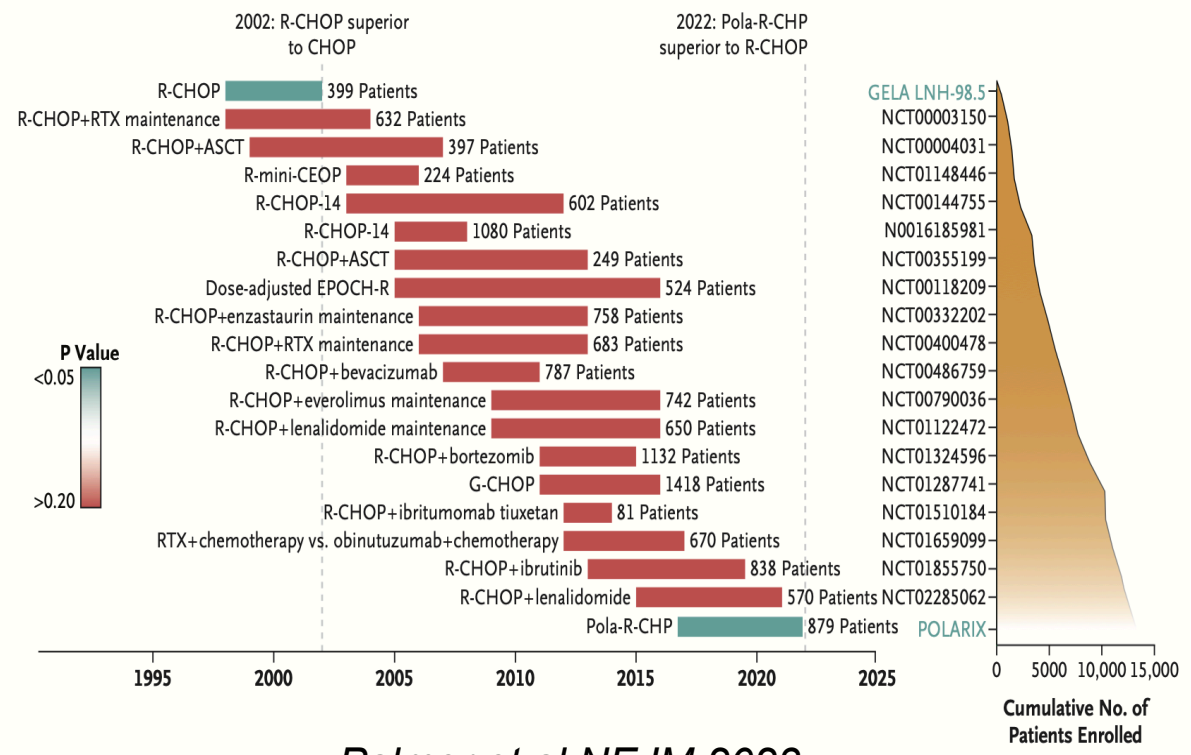
Anstellungsverhältnis, Führungsposition	Charité - Universitätsmedizin Berlin; Beirat German Lymphoma Alliance
Beratungs-/ Gutachtertätigkeit	AbbVie, BMS, Gilead, Incyte, J&J, Regeneron, Roche, Sobi
Besitz von Geschäftsanteilen, Aktien oder Fonds	-
Patent, Urheberrecht, Verkaufslizenz	Verschiedene Patente zur Molekulaen Subtypisierung grosszelliger Lymphoome, wie z.B. DLBC*lass*
Honorare	AbbVie, Art tempi, Astra Zeneca, BMS, Incyte, J&J, Gilead, KML, Regeneron, Roche, Sobi, Ono
Finanzierung wissenschaftlicher Untersuchungen	Roche unterstützt die R-Pola-Glo Studie
Andere finanzielle Beziehungen	-
Immaterielle Interessenkonflikte	-

Kapitel 1

Erstlinentherapie

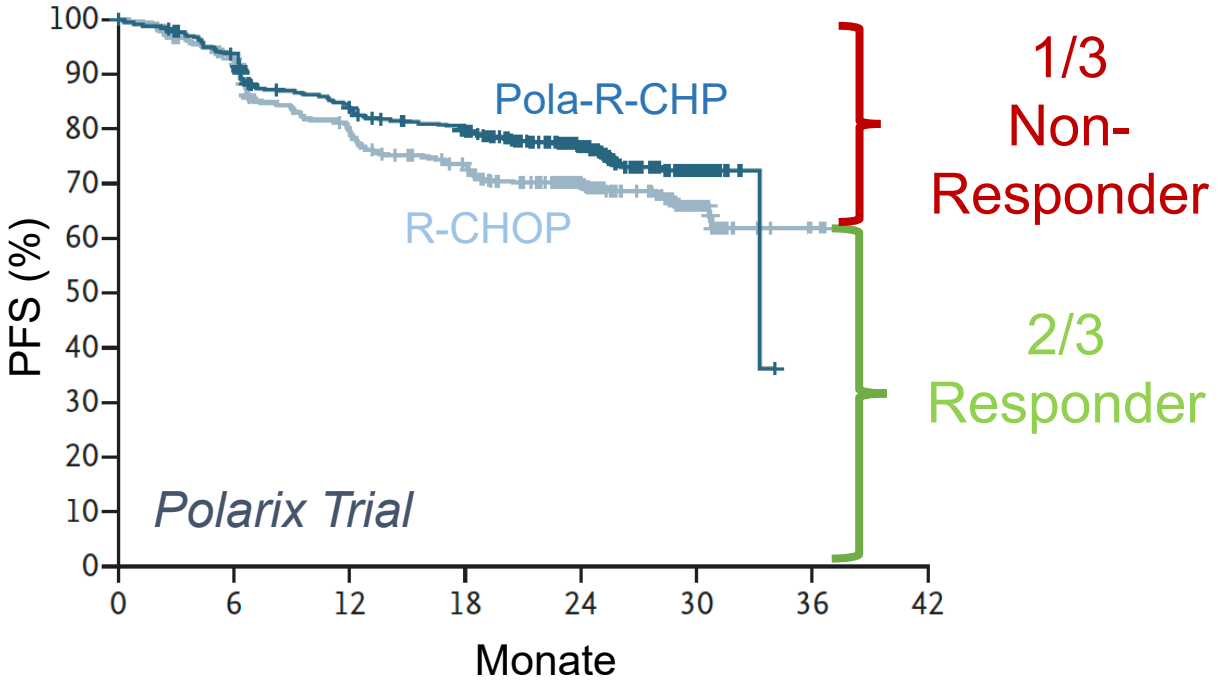
Empirische Entwicklung/Optimierung von R-CHOP

50 Jahre CHOP / 25 Jahre R-CHOP



Palmer et al NEJM 2023

Standard of Care
(R-CHOP-based)



Tilly et al. NEJM 2022

Therapieoptimierung in der Erstlinie

R-CHOP + X

R-CHOP + XY

No-CHOP
(Frei von klassischer Chemotherapie)

All comer

z.B.
bsAB
(*SkyGlo/EPOCOR-NHL2*)
GoalSEEK

Risikoadapiterte Intensivierung
z.B.
frühe CART bei IPI4/5
ZUMA23

Subgruppen-spez. Intensivierung
z.B.
BTKi in non-GCB
ESCALADE

All comer
z.B.
Tafa/Len+RCHOP vs. RCHOP
(*FrontMind*)

18-80yo Window of opportunity
z.B.
(SMART-STOP)

Chemolight Elderly/frail
z.B.
(R-Pola-Glo)

Making Cancer History®

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center

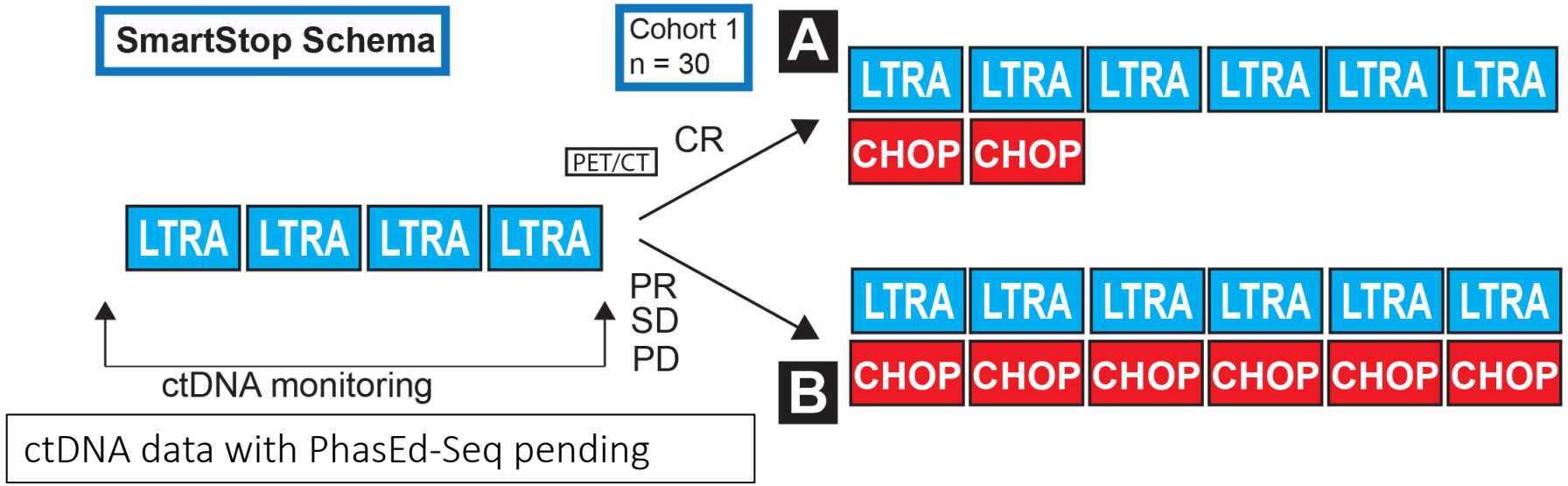
Primary Analysis of the Smart Stop Trial: Lenalidomide, Tafasitamab, Rituximab, and Acalabrutinib Alone and with Combination Chemotherapy in Newly Diagnosed Diffuse Large B-Cell Lymphoma

Jason Westin, Luis Fayad, Raphael Steiner, Sairah Ahmed, Preetesh Jain, Luis Malpica, Ranjit Nair, Sattva Neelapu, Jared Henderson, Frederick Hagemeister, Maria Rodriguez, Chijioke Nze, Fateeha Furqan, Ayushi Chauhan, Mark Hamilton, Anath Lionel, Francisco Vega, Jisha Tom, Isak Durmic, Gita Masand, Rhanna Wilson, Cara Blyth, Christopher Flowers, Michael R Green, Dai Chihara

Department of Lymphoma & Myeloma, MD Anderson Cancer Center

@Lymphoma_Doc

Smart Stop Schema and Endpoints



Primary Endpoints:

1A ORR after 4 LTRA

1B CRR at end of therapy

Doses of "Smart" portion of the clinical trial, cycle = 21 days				
Drug Name	Dose	Route	Dosing per cycle	Day of therapy
Lenalidomide (L)	25mg	PO	Daily	1-10
Tafasitamab (T)	12mg/kg	IV	Weekly	1, 8, 15
Rituximab (R)	375mg/m2	IV	Once	1
Acalabrutinib (A)	100mg	PO	BID	1-21

Lenalidomide, Tafasitamab, Rituximab, Acalabrutinib, NCT04978584, Westin et al, ASH 2023

Safety Summary

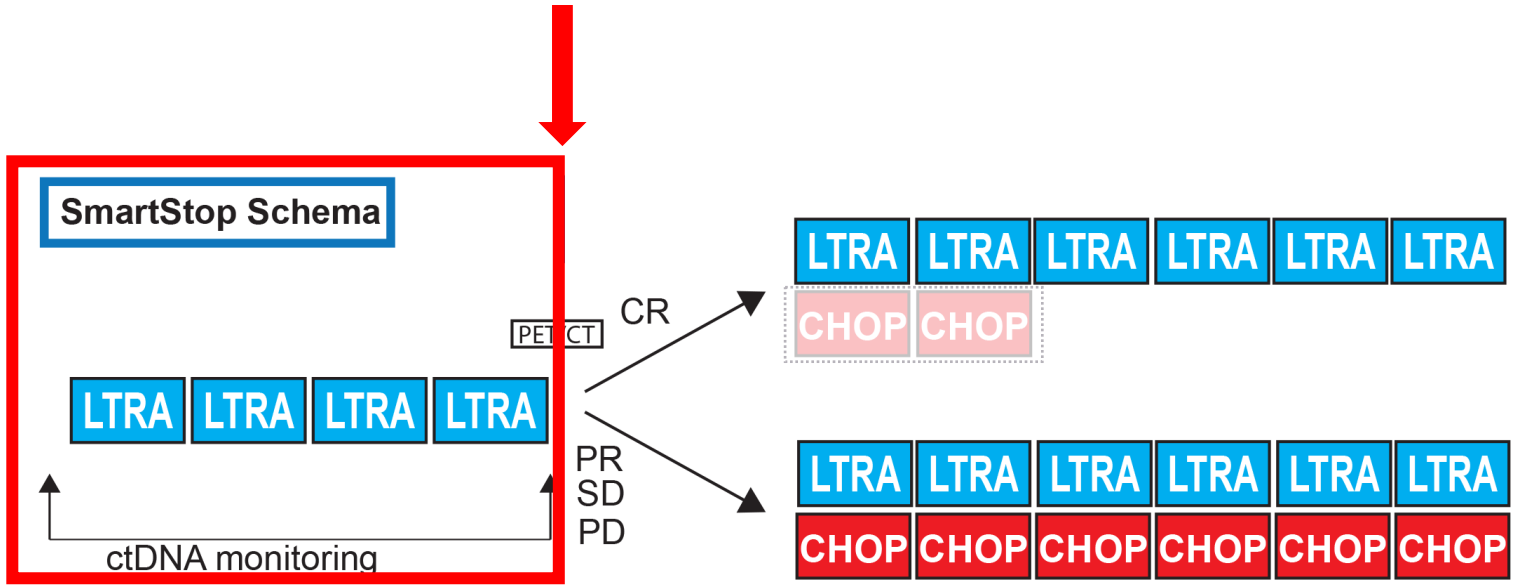
Median of percentage of planned doses which were received		
Lenalidomide	Tafasitamab	Acalabrutinib
88%	93%	100%

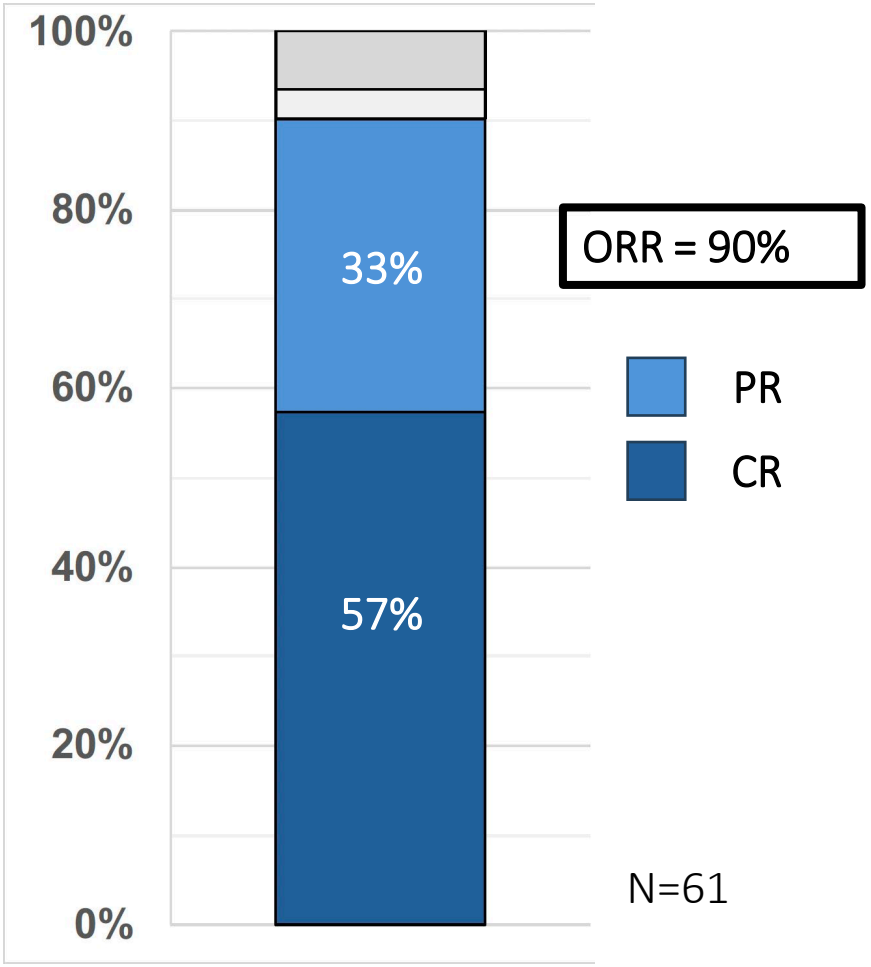
Number of cycles delivered	
LTRA Median (range)	10 (1-10)

AE (N = 61)	Any Grade	Grade ≥3
Anemia	55 (90%)	5 (8%)
Neutropenia	53 (87%)	35 (57%)
Platelet count decreased	47 (77%)	9 (15%)
Fatigue	41 (67%)	1 (2%)
Rash maculo-papular	28 (46%)	4 (7%)
Transaminitis	26 (43%)	0
Nausea	23 (38%)	0
Headache	22 (36%)	0
Creatinine increased	28 (36%)	0
Infections and infestations	20 (33%)	3 (5%)
Infusion related reaction	19 (31%)	1 (2%)
Edema	17 (28%)	0
Constipation	19 (31%)	0
Peripheral sensory neuropathy	14 (23%)	3 (5%)
Cough	11 (18%)	0
Diarrhea	9 (15%)	0
Dizziness	10 (16%)	1 (2%)
Mucositis oral	7 (12%)	0
Vomiting	9 (15%)	4 (7%)
Febrile neutropenia	4 (7%)	3 (5%)
COVID infection	13 (21%)	

AE >10% of any patient, electrolyte or overlapping AEs not shown

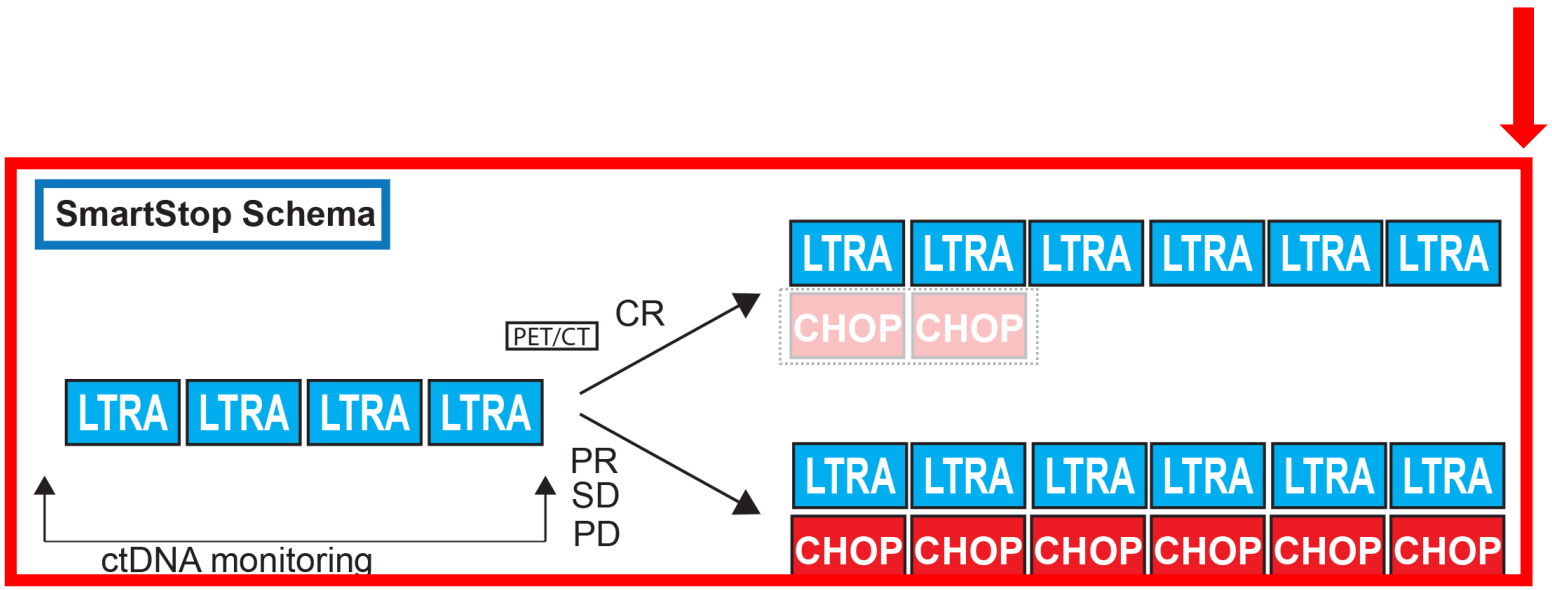
Results:
Primary Endpoint 1A: ORR after LTRA lead in

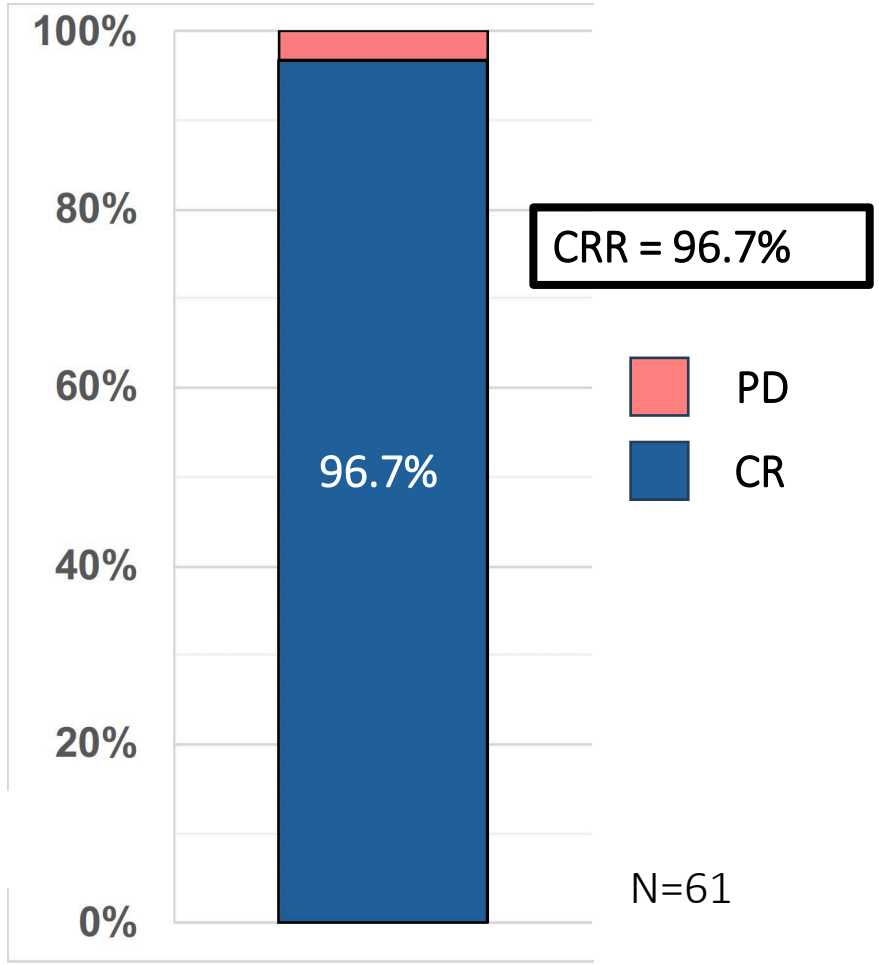




Primary Endpoint 1A: ORR after LTRA is 90%

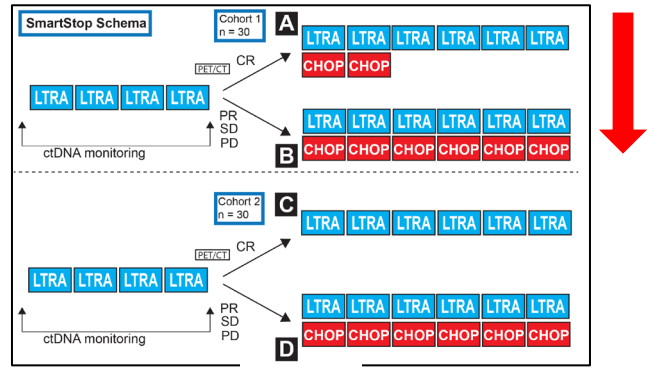
Results:
Primary Endpoint 1B: CR at End of Treatment





Primary Endpoint 1B: CR at End of Treatment is 96.7%

Results:
PFS and OS with Smart Stop (n = 61)



86.5% at 2y

98.4% at 2y

Median follow up for survival is 25.3 months

Conclusions: Smart strategy: targeted therapy first

1. ”Smart” strategy of targeted therapy first: successful, preserves curative intent
   - Smart Stop: Primary endpoints ORR after LTRA: 90%, CR at end of therapy: 96.7%
   - Smart Stop: PFS at 2y: 86.5%, OS at 2y: 98.4%

2. ”Smart” strategy of targeted therapy first: more than half of patients may reduce or remove chemotherapy for newly diagnosed DLBCL

- Lenalidomide, Tafasitamab, Rituximab, Acalabrutinib:
  - 57% CR rate after 4 cycles of LTRA, 89% had durable CR
  - After 2 cycles of CHOP and 6 cycles of LTRA: 0/19 progressed*
  - After 0 cycles of CHOP and 6 cycles of LTRA: 4/16 progressed, all responded to 1L R-chemo

3. ”Smart” strategy of targeted therapy first: does not impact response to chemotherapy
   - Patients without CR with LTRA (43%): 92% achieved CR with CHOP

* 1 patient progressed at month 33 with Hodgkin lymphoma, achieved CR after ABVD + RT

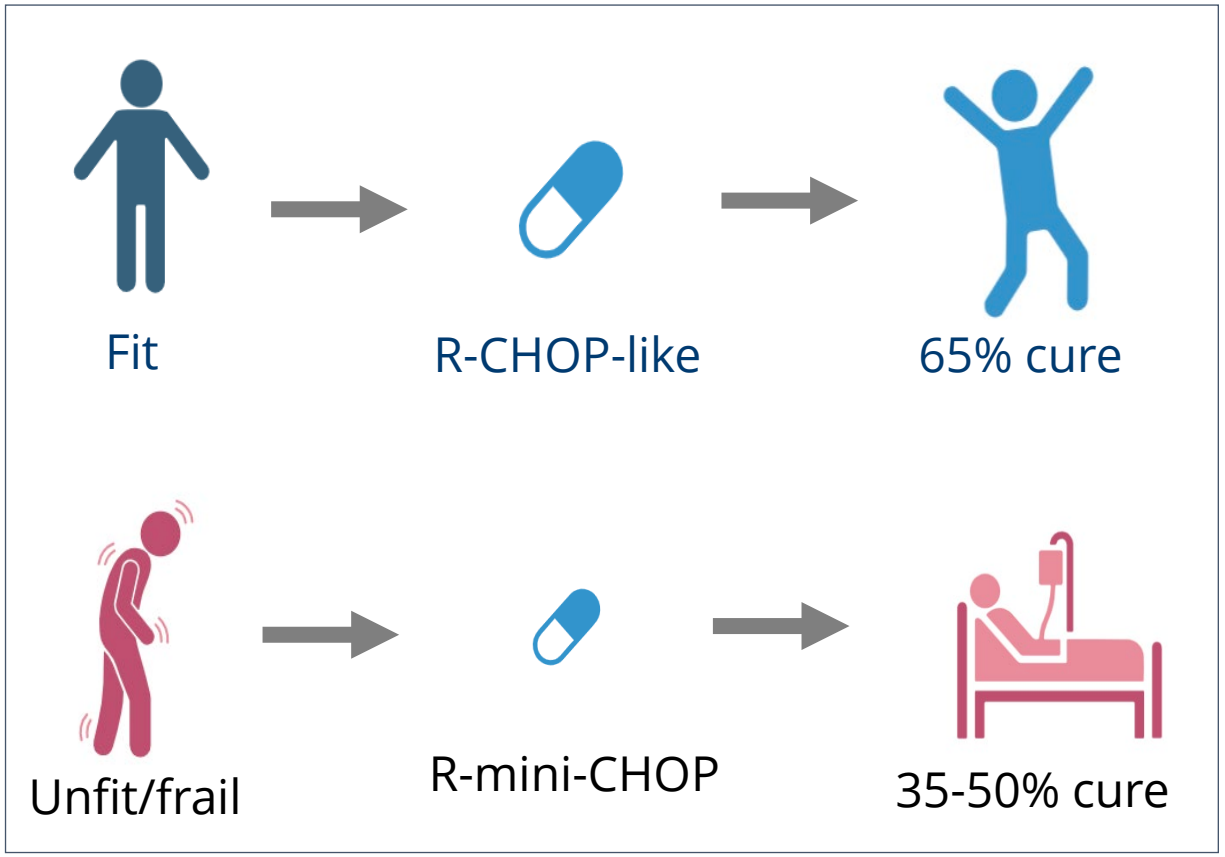
American Society of Hematology
Helping hematologists conquer blood diseases worldwide

ABSTRACT #61

Phase II Frontline Chemolight R-Pola-Glo Trial Induces High and Durable Response Rates in Elderly and Medically Unfit/Frail Patients With Aggressive B-Cell Lymphoma

B. Chapuy, R. Wurm-Kuczera, R. Michael, M. Wang, P. Pichler, A. Huster, A. Kerkhoff, M. Panny, R. Schroers, A. Ossami Saidy, F. Müller, F. Damm, M. Orlinger, P. Staber, C. Schwaenen, L. Wohn, C. Schmitt, M. Hoffmann, M. Hänel, J. Düll, S. Heyn, S. Mayer, T. Weber, P. Reimer, N. Rotter, U. Schnetzke, B. von Tresckow, G. Kammerer, J. Rasvina, B. Lehner, T. Mika, D. Böckle, C. Leng, A.L. Illert, B. Altmann, B. Friedrichs, E.Willenbacher, D. Mougiakakos, C. Pott, S. Al-Batran, A. Rosenwald, D. Hellwig, S. Dietrich, B. Glass, G. Lenz, U. Keller, M. Ziepert, T. Melchardt, R. Greil

Diffuse Large B-cell Lymphoma (DLBCL)

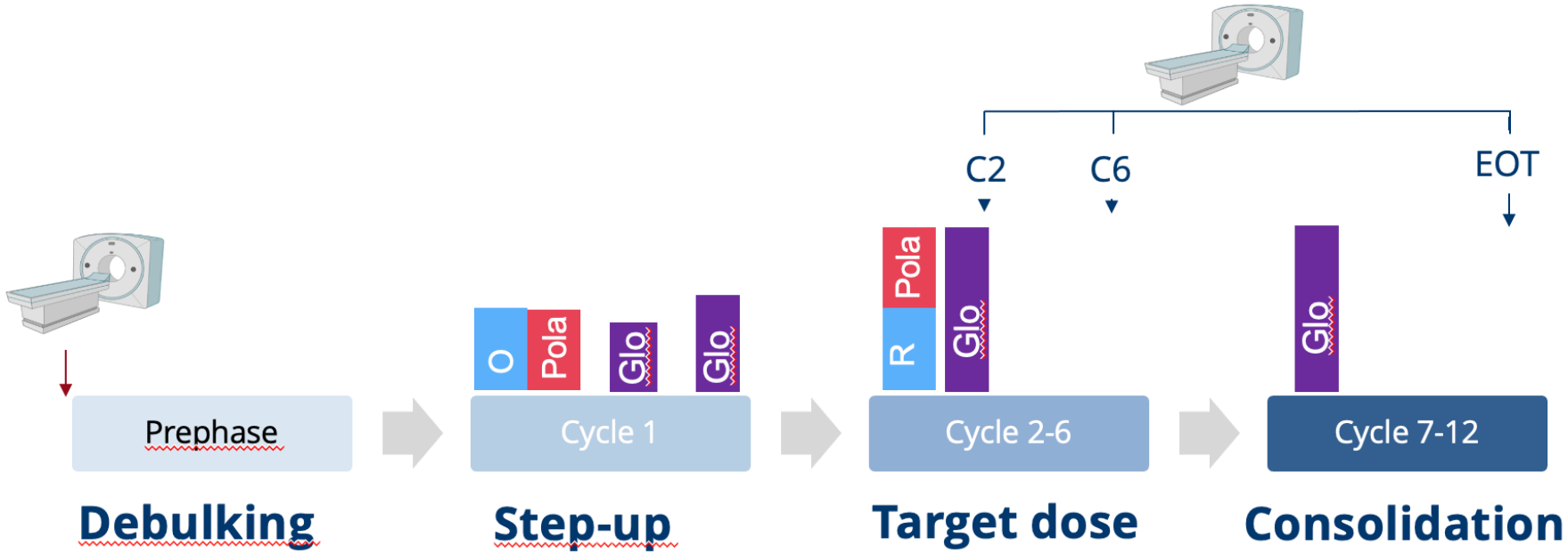


- DLBCL is the most common aggressive lymphoma, typically affecting elderly patients (median age 65 yo).
- Molecularly, DLBCL is a heterogeneous disease characterized by distinct transcriptional and genetic subtypes.
- Immunochemotherapy (R-CHOP-like/Pola-R-CHP) achieves high cure rates, but increased comorbidities in medically unfit and/or frail patients limit outcomes due to the use of less effective regimens.

Unmet Medical Need:
Highly effective therapy for medically unfit and/or frail patients

Image generated using biorender

R-Pola-Glo – Study Design



Indication

- **Untreated** patients >60 yo with LBCL
- Non-eligible for full dose R-CHOP

Study Design

- One-arm, multicenter phase II
- 30 centers in Germany and Austria
- **80 pts** (C1-6 mandatory inpatient)
- Mandatory prophylaxis

Endpoints

- *Primary:* **1y-PFS rate**
- *Secondary:*
  - Efficacy (OS, EFS)
  - Feasibility/Toxicity

R-Pola-Glo – Patients Characteristics

Baseline Parameters

Cohort (N=80)	
Median age age > 85yo	80 (66-92) 19%
Advanced Stage (III/IV)	63% (50/80)
ECOG 2	28% (22/80)
LDH, > ULN	63% (50/80)
IPI 3-5	64% (51/80)

Simplified Geriatric Assessment (sGA)

	FIT	UNFIT		FRAIL
ADL	**≥5***	**<5***	**6***	**<6***
	and	*and/or*	*and*	*and/or*
IADL	**≥6***	**<6***	**8***	**<8***
	and	*and/or*	*and*	*and/or*
CIRS-G	**0 score = 3-4** and **≤8 score = 2**	**≥1 score = 3-4** and/or **>8 score = 2**	**0 score = 3-4** and **<5 score = 2**	**≥1 score = 3-4** and/or **≥5 score = 2**
	and	*and*	*and*	*and*
Age	**<80**	**<80**	**≥80**	**≥80**
R-Pola-Glo (n=79)	6 (7.6)	28 (35.4)	15 (19)	30 (38)

91.3% medical unfit/frail

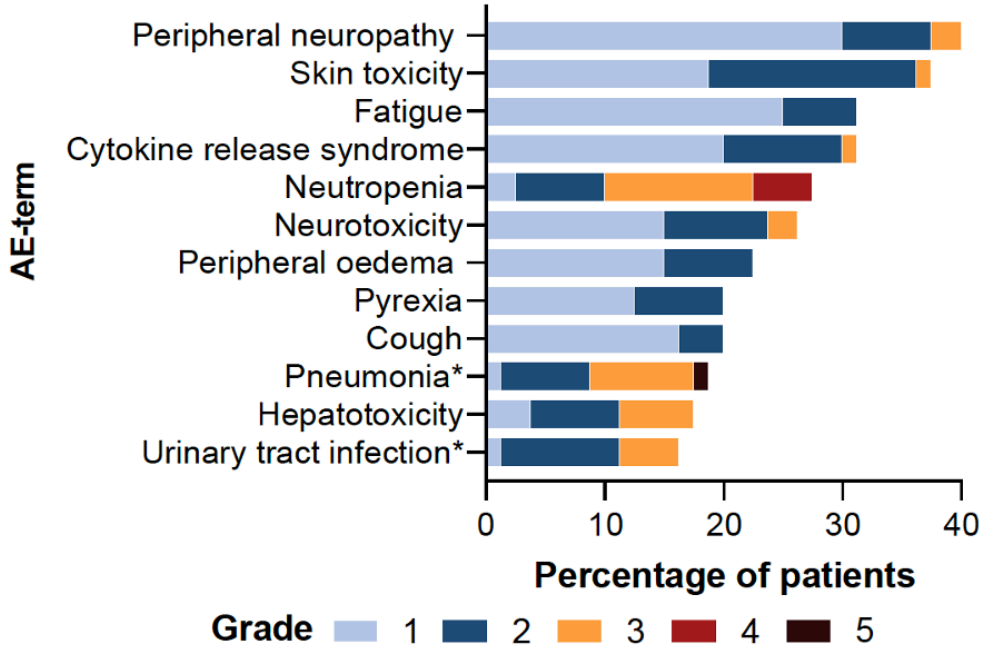
➔ Representative "real world" cohort of medical unfit/frail patients with high treatment complexity.

R-Pola-Glo – Therapy Adherence and Overall Safety

Therapy Adherence and AEs

Cohort (N=80)	
Completing treatment as planned	80% (64/80)
AE, no grade 3-5 in any cycle	34% (27/80)
AE, grade 5	4% (3/80)

Most common AE terms



➔ Treatment was well tolerated with no unexpected adverse event

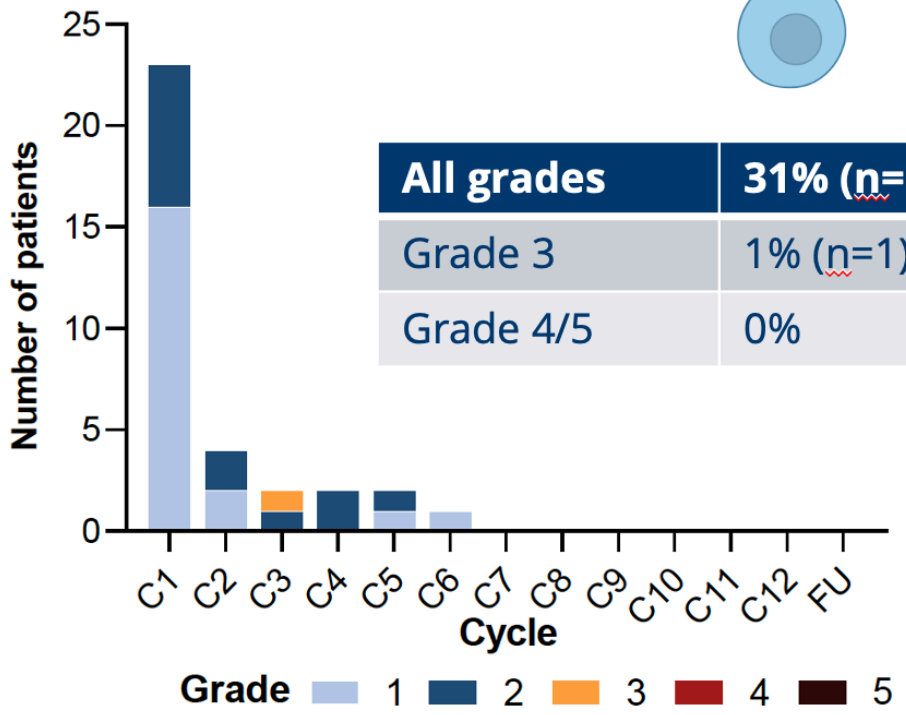
➔ Low treatment-related mortality.

➔ 34% of patients finished treatment with no AE grade 3-5 in any cycle.

R-Pola-Glo – ICANs/CRS

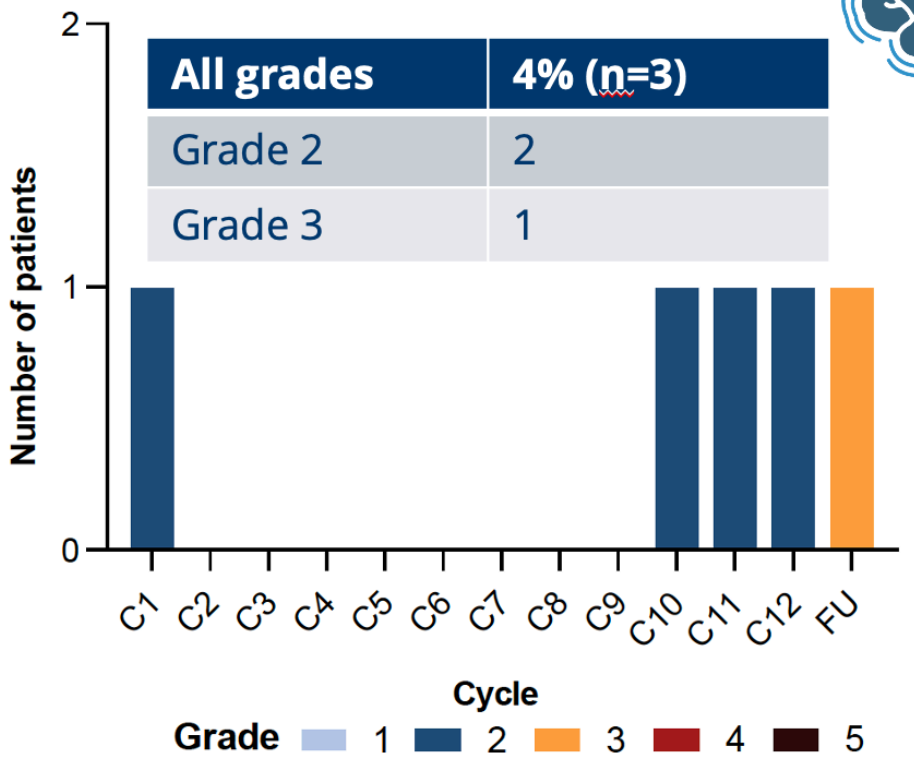
CRS

All grades	31% (n=25)
Grade 3	1% (n=1)
Grade 4/5	0%



ICANs

All grades	4% (n=3)
Grade 2	2
Grade 3	1



➔ CRSs usually occurred at early cycles and low grade, and all resolved completely.

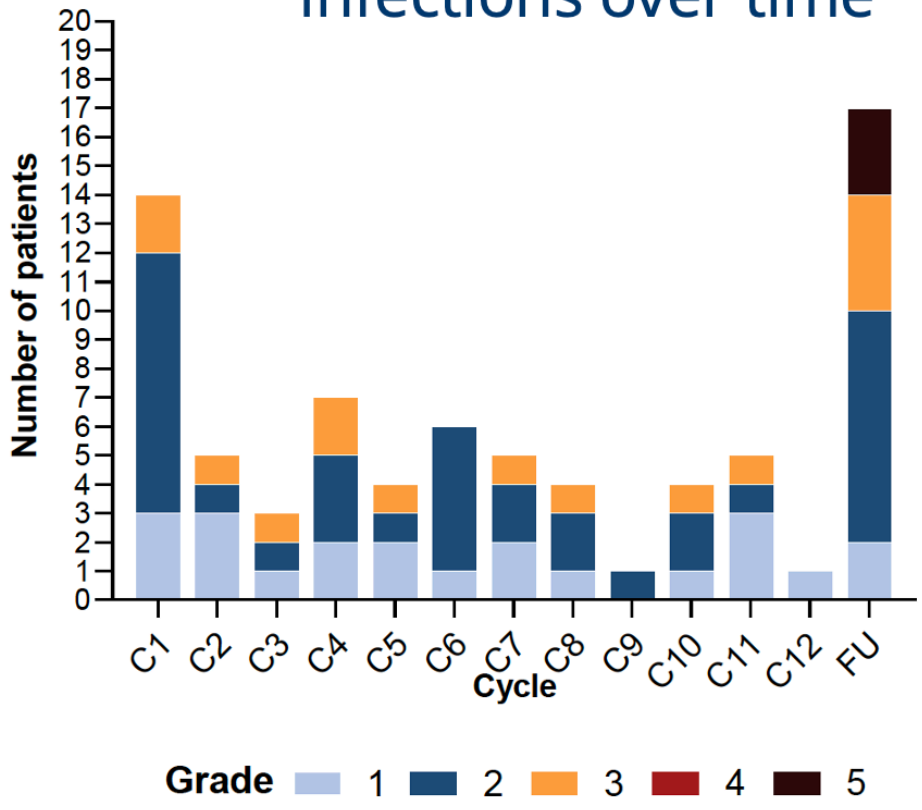
➔ ICANs occurred infrequently.

R-Pola-Glo – Infections over time and Cycle

Infections

Infections	66% (n=53)
Grade 3	19% (n=15)
Grade 4	3% (n=2)
Grade 5, all COVID COVID+RSV Unknown	4% (n=3) 1 1 1

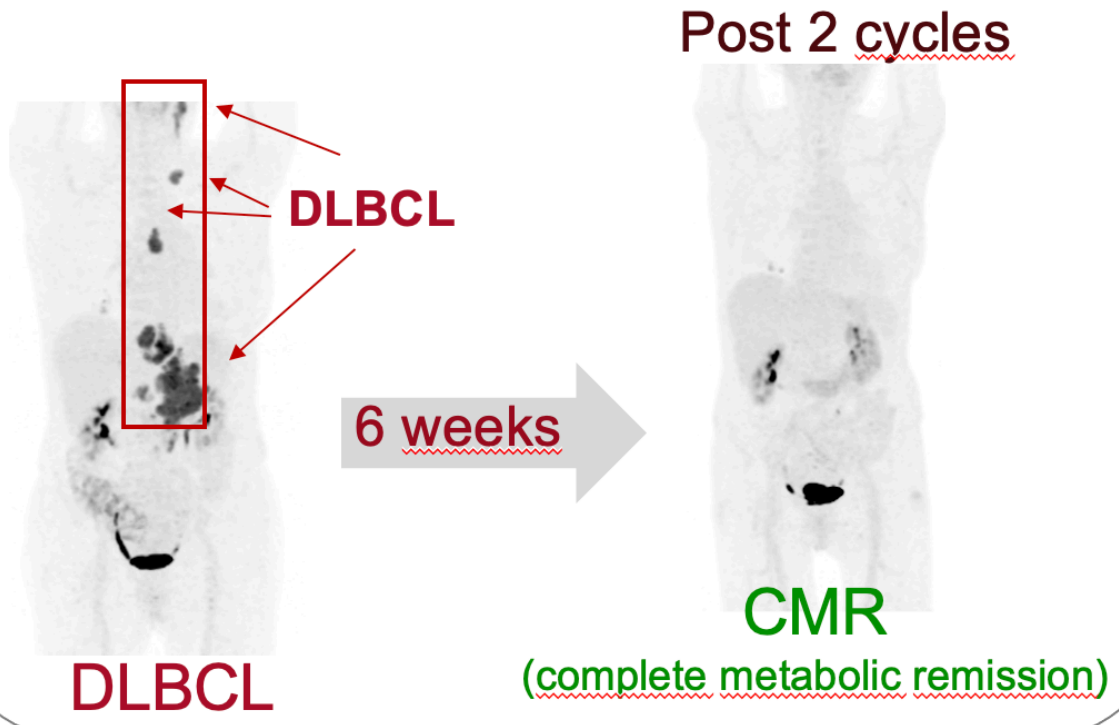
Infections over time



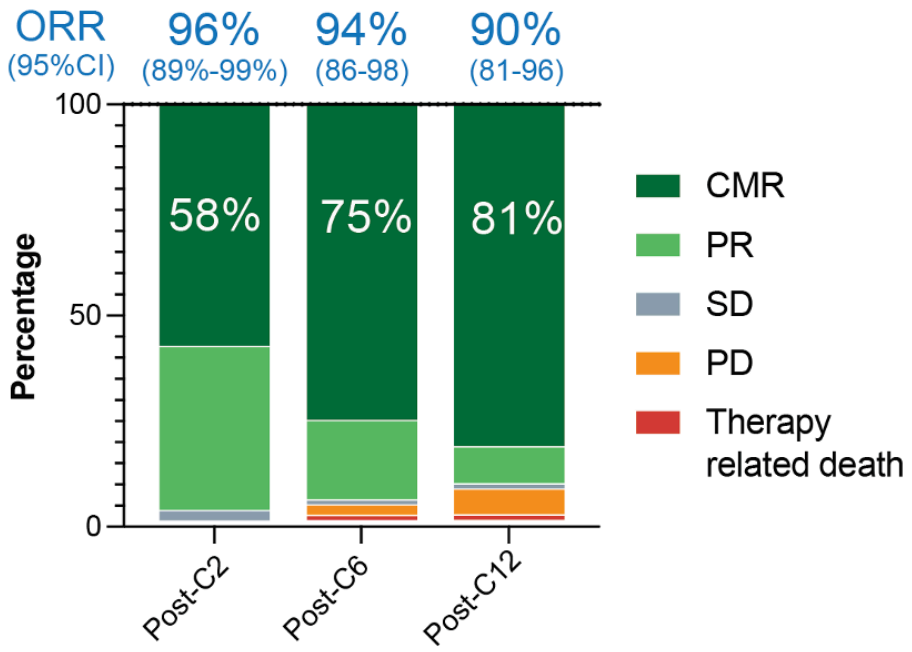
➔ Patients experienced manageable infections; only three grade 5 events occurred.

R-Pola-Glo – Response

Representative Case



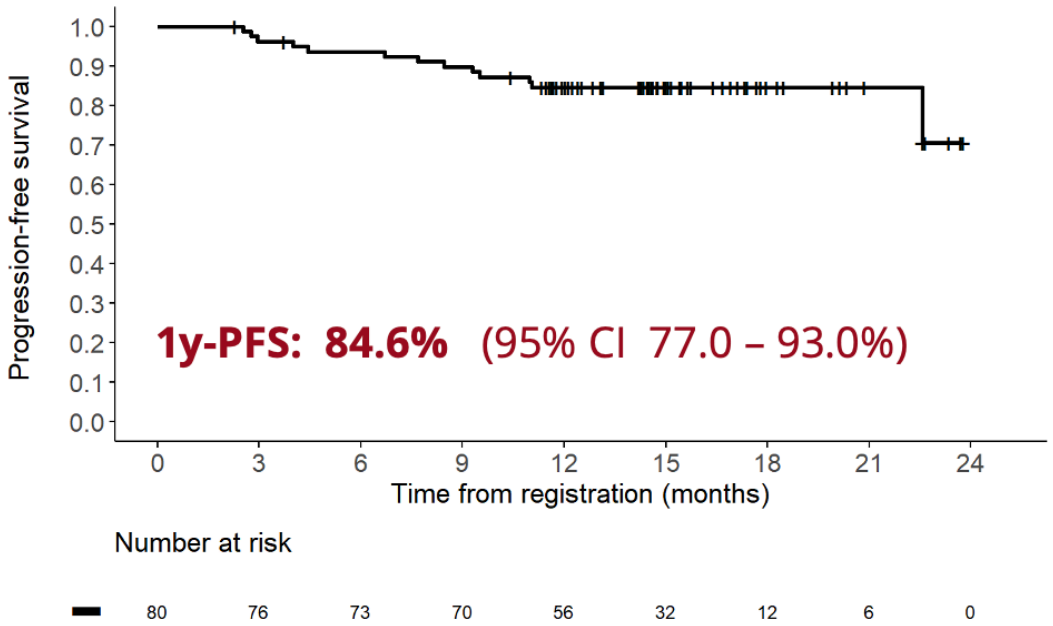
Response Rate (n=80)



- ORR at cycles 2, 6, and EOT were 96%, 94%, and 90%; corresponding CMR rates were 58%, 75%, and 81%, respectively.
- CMR conversions were observed after C6, highlighting the role of glofitamab consolidation.

R-Pola-Glo – Outcome

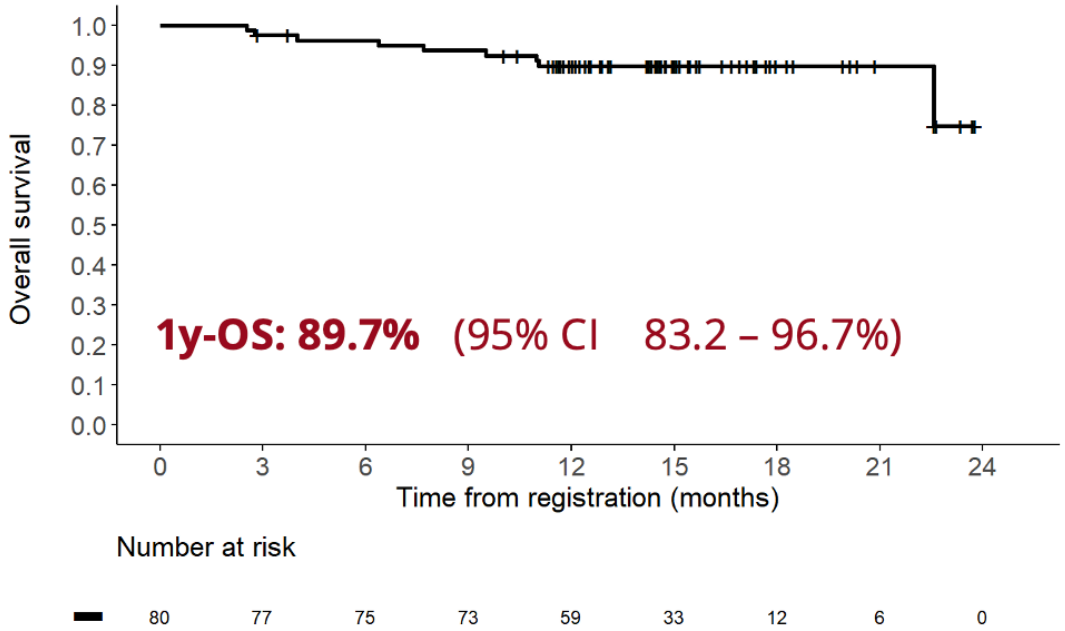
1-year Progression-free Survival (PFS)



1y-PFS: 84.6% (95% CI 77.0 – 93.0%)

Median f/u: 15 months

1-year Overall Survival (OS)



1y-OS: 89.7% (95% CI 83.2 – 96.7%)

➔ With a median follow-up time of 15 months, responses were durable and the 1y-PFS and 1y-OS rates were 85% and 90%, respectively.

➔ At time of analysis (July 2 2025), 89% (71/80) of patients were alive.

R-Pola-Glo – Conclusion

- ➔ R-Pola-Glo achieved high and durable CMR rates with a manageable safety profile.
- ➔ Responses translated into a high 1-year survival rate in elderly/frail and medically unfit patients with aggressive B-cell lymphoma.
- ➔ Our results demonstrates that an anthracycline-free regimen can induce durable remissions in a population considered to be ineligible for standard approaches.
- ➔ R-Pola-Glo demonstrate higher response rates and improved survival outcomes at 1 year compared with regimes considered as SOC, supporting its further clinical evaluation as a frontline option for this vulnerable patient population.

Kapitel 2

Zweitlinientherapie

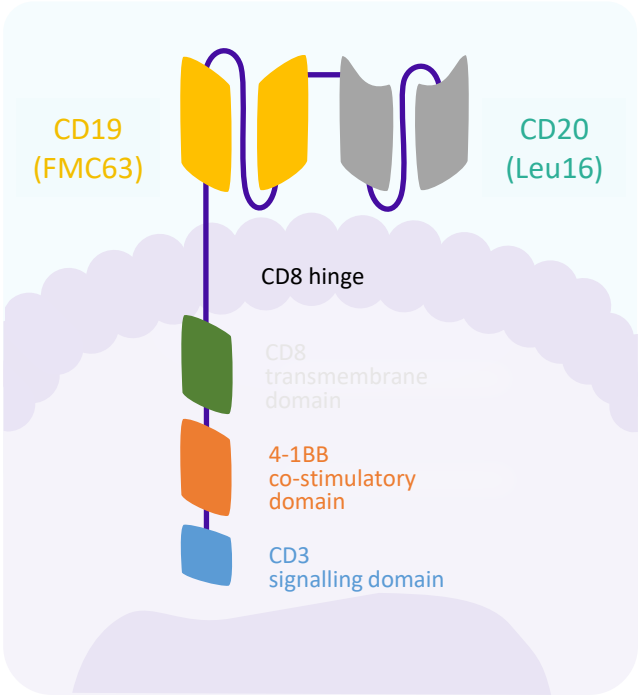
Kapitel 2

Zweitlinientherapie

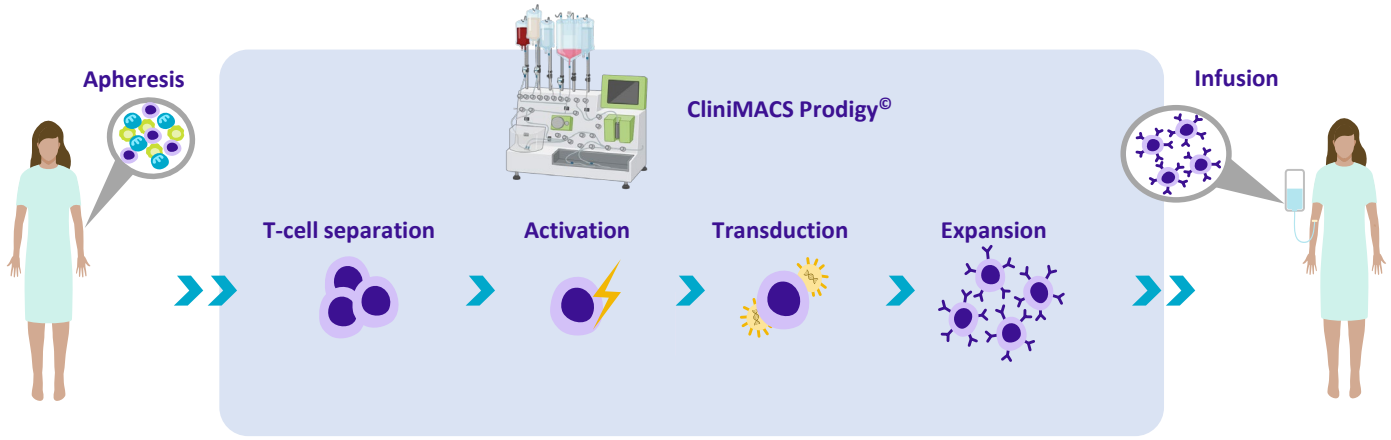
- **Neue CAR-T-Konstrukte**

Zamtocabtagene autoleucel (zamto-cel): a novel tandem CD20-CD19 (directed) CAR-T cell therapy

Tandem CD20-CD19 (directed) CAR-T cell[1] therapy



Produced using a fully automated system and administered as a fresh (non-cryopreserved) formulation[2]



Manufacturing time	**12 days**
Vein-to-vein time	**13–15 days**

CAR, chimeric antigen receptor; CD, cluster of differentiation.

1 Majzner R, and Mackall C. Cancer Discov. 2018;8:1219–26; 2. Shah N, et al. Blood 2024;144;suppl. 1:68–70.

DALY 2-EU study design (N=168): a randomized, multicenter, open-label trial (NCT04844866)

Key eligibility criteria

- Histologically proven DLBCL and other entities[a]
- r/r within 24 months from start of 1L chemoimmunotherapy
- ASCT-ineligible
- ECOG PS ≤ 2

R 1:1

Zamto-cel group

LA

Lympho-depletion (day -5 to -3) prior to infusion → **Zamto-cel** single IV infusion (fresh)

Patients in crossover group to zamto-cel:
- Relapse or progression occurred within ≤1 year of randomization
- Failure to achieve a PR or CR in ≥8 weeks

→ Lympho-depletion → **Zamto-cel** single IV infusion (fresh)

Week 8

Comparator group

LA

R-GemOx 14-day cycles, Cycles 1–4 → **R-GemOx** 14-day cycles, Cycles 5–8

Pola-BR 21-day cycles, Cycles 1–3[b] → Pola-BR 21-day cycles, Cycles 4–6[b]

Follow-up

Key endpoints

Primary
- EFS by IRC

Secondary
- PFS by IRC
- BCRR by IRC
- DoCR by IRC
- OS using RPSFT

Safety
- Type, frequency, and severity of AEs, SAEs, AESIs

Optional corticosteroid bridging therapy for high disease burden
- Oral or IV prednisone 50–100 mg or dexamethasone 30–40 mg QD for up to 4 days
- Stopped ≥7 days before leukapheresis and/or >72 hours before zamto-cel infusion

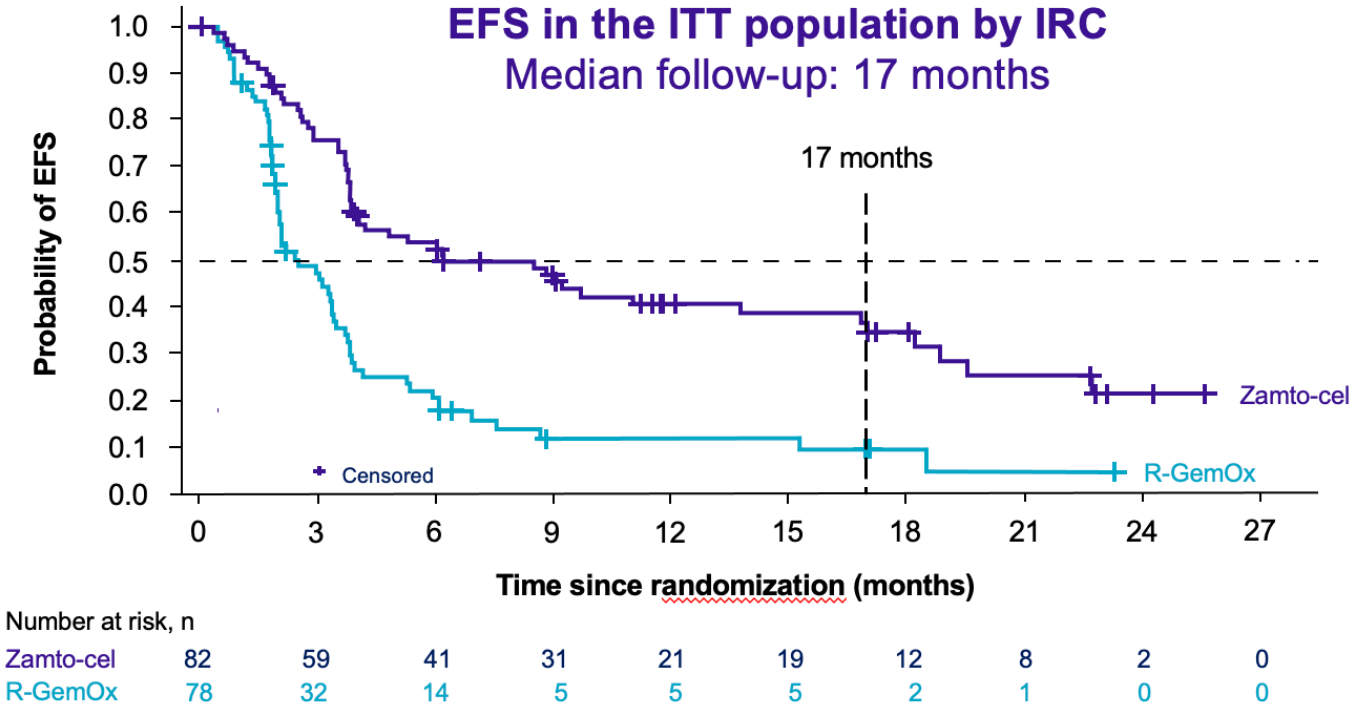
[a] As per 4th WHO classification (2016) the following entities could be included; DLBCL NOS, HGBL with MYC and BCL2 and/or BCL6 rearrangements with DLBCL/blastoid/intermediate histology or HGBL with MYC and BCL2 and/or BCL6 rearrangements (double hit lymphoma/triple hit lymphoma), high-grade BCL NOS, primary (thymic) large mediastinal BCL, disease transformed from an earlier diagnosis of low-grade lymphoma (e.g., an indolent pathology such as follicular lymphoma, marginal zone lymphoma) into DLBCL with DLBCL disease progression subsequent to DLBCL-directed systemic treatment, and follicular lymphoma Grade 3B; [b] Results of the Pola-BR group were not part of the primary analysis and are not discussed in this presentation.

AE, adverse event; AESI, adverse event of special interest; ASCT, autologous stem-cell transplant; BCRR, best complete response rate; CR, complete response; DoCR, duration of complete response; IRC, independent review committee; LA, leukapheresis; Pola-BR, polatuzumab vedotin-bendamustine-rituximab; PR, partial response; R, randomization; R-GemOx, rituximab-gemcitabine-oxaliplatin; RPSFT, rank-preserving structural failure time; SAE, serious adverse event.

ClinicalTrials.gov. NCT04844866.

Borchman et al, ASH 2025

DALY 2-EU primary endpoint: significant EFS benefit with zamto-cel



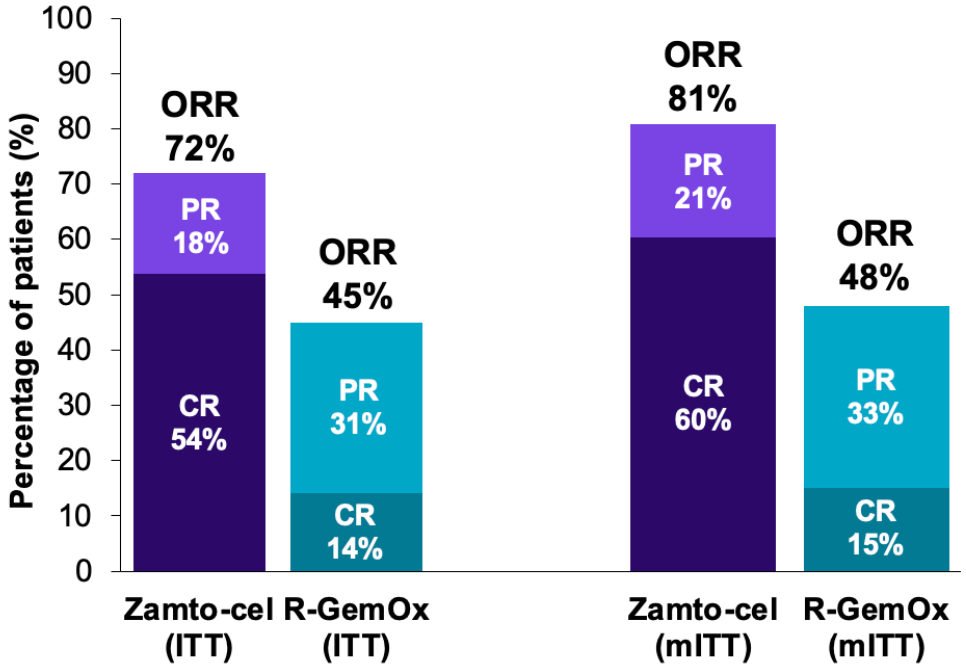
Primary endpoint	Zamto-cel (n=82)	R-GemOx (n=78)
EFS based on IRC assessment[a]		
Median EFS, months (95% CI)	6.21 (3.84, 13.77)	2.53 (1.97, 3.35)
Patients with events, n (%)	52 (63.4)	63 (80.8)
HR (95% CI) p-value	0.39 (0.27, 0.58) p<0.0001	

Zamto-cel arm demonstrated highly statistically significant and clinically meaningful superiority over R-GemOx for EFS, with a HR of 0.39

All p-values are one-sided. [a]EFS was defined as the time between the date of randomization and the date of objective disease progression, failure to achieve PR or CR at or beyond Week 8 after randomization leading to a new anti-lymphoma therapy or death of any cause, whichever occurs first. Treatment effects were estimated as HRs with 95% CIs using a Cox proportional hazards models. P-value was from the log-rank test stratified by IPI. Superiority was concluded if the 1-sided p-value was ≤0.025. CI, confidence interval; EFS, event-free survival; HR, hazard ratio; IRC, independent review committee; ITT, intent-to-treat; R-GemOx, rituximab gemcitabine oxaliplatin.

DALY 2-EU secondary endpoints: CR rate in zamto-cel 3.8x higher than R-GemOx

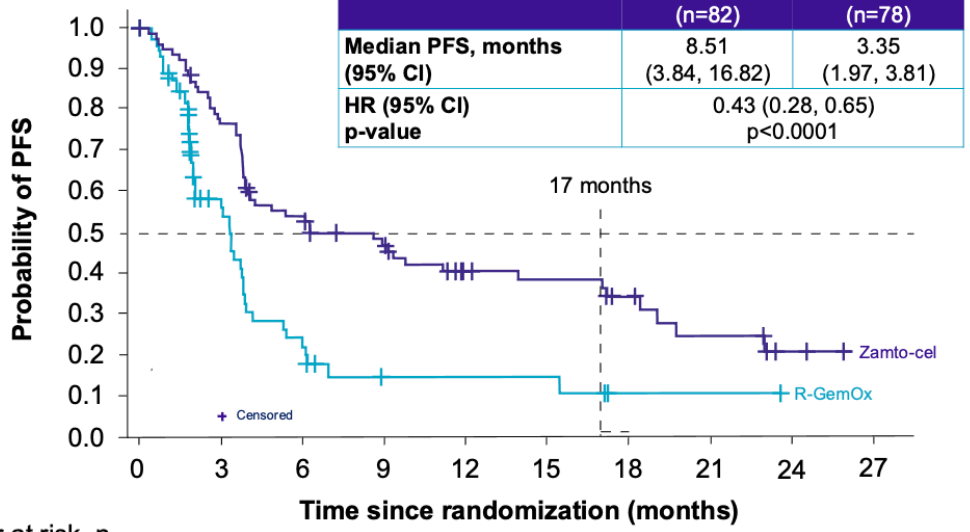
Response rates in the ITT and mITT populations



Median PFS by IRC

Median follow-up: 17 months

	Zamto-cel (n=82)	R-GemOx (n=78)
Median PFS, months (95% CI)	8.51 (3.84, 16.82)	3.35 (1.97, 3.81)
HR (95% CI) p-value	0.43 (0.28, 0.65) p<0.0001	



Number at risk, n

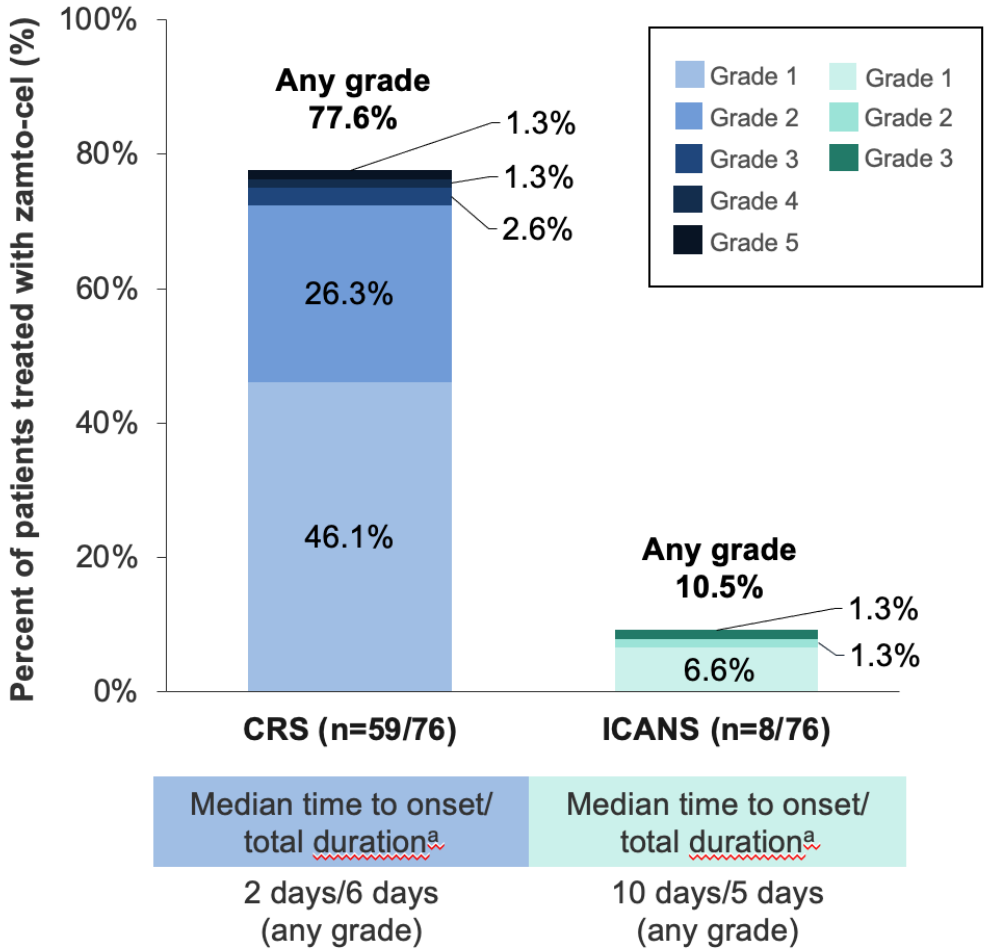
Zamto-cel	82	59	41	31	21	19	12	8	2	0
R-GemOx	78	27	11	4	4	4	1	1	0	0

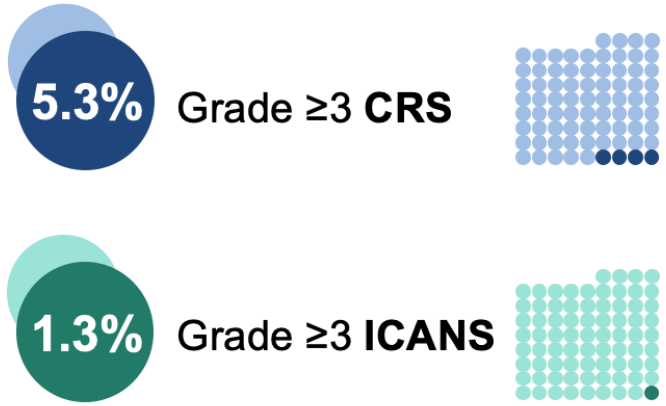
- ✓ **PFS (HR [95% CI]: 0.43 [0.28, 0.65]; p<0.0001) for zamto-cel was statistically superior**
- ✓ **Zamto-cel demonstrated higher CR rate vs. R-GemOx**

CR, complete response; HR, hazard ratio; IRC, independent review committee; (m)ITT, (modified) intent-to-treat; ORR, objective response rate; PFS, progression-free survival; PR, partial response; R-GemOX, rituximab gemcitabine oxaliplatin.

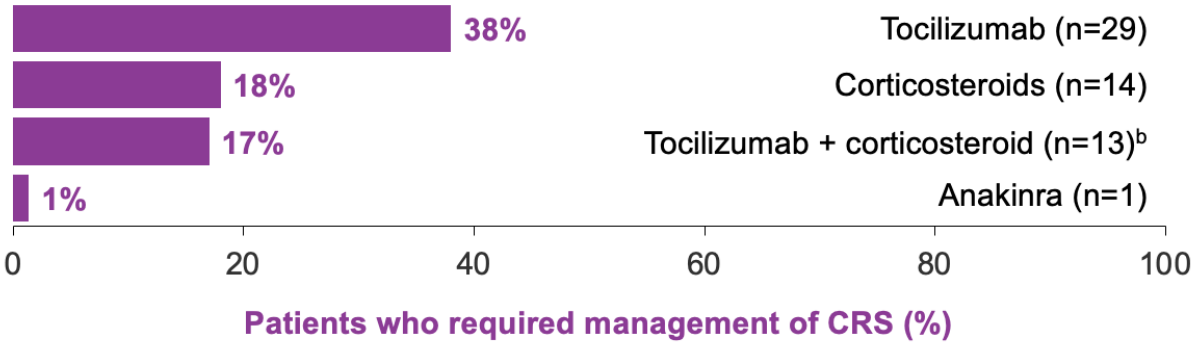
DALY 2-EU:
zamto-cel was well tolerated, with low rates of severe CRS and ICANS

Rates of CRS and ICANS in patients treated with zamto-cel





Management of CRS in patients treated with zamto-cel



[a] Total duration includes gaps between episodes. [b] The 13 patients that received tocilizumab + corticosteroid combination therapy were also counted individually for both tocilizumab (n=13/29) and corticosteroid (n=13/14). AE, adverse event; AESI, adverse events of special interest; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; c R-GemOx, rituximab gemcitabine oxaliplatin.

DALY 2-EU: Summary and conclusions

Zamto-cel:

- The first tandem CD20-CD19 (directed) fresh (non-cryopreserved) CAR-T cell product
- Short manufacturing time of **12 days**, with a vein-to-vein time of 13–15 days

DALY 2-EU:

- Zamto-cel demonstrated **significant and clinically meaningful superiority** over R-GemOx in transplant-ineligible patients at high risk for treatment failure independent of baseline patient and disease characteristics
  - ✓ **EFS HR 0.39, p<0.0001**
  - ✓ **CR rate 54% (ITT) / 60% (mITT)**
- Zamto-cel showed a manageable safety profile
  - ✓ Grade ≥3 CRS in 5.3% of patients (n=4)
  - ✓ Grade ≥3 ICANS in 1.3% patients (n=1, Grade 3)

The favorable risk/benefit profile of zamto-cel supports its use as a preferred 2L treatment option for patients with r/r LBCL and transformed lymphomas

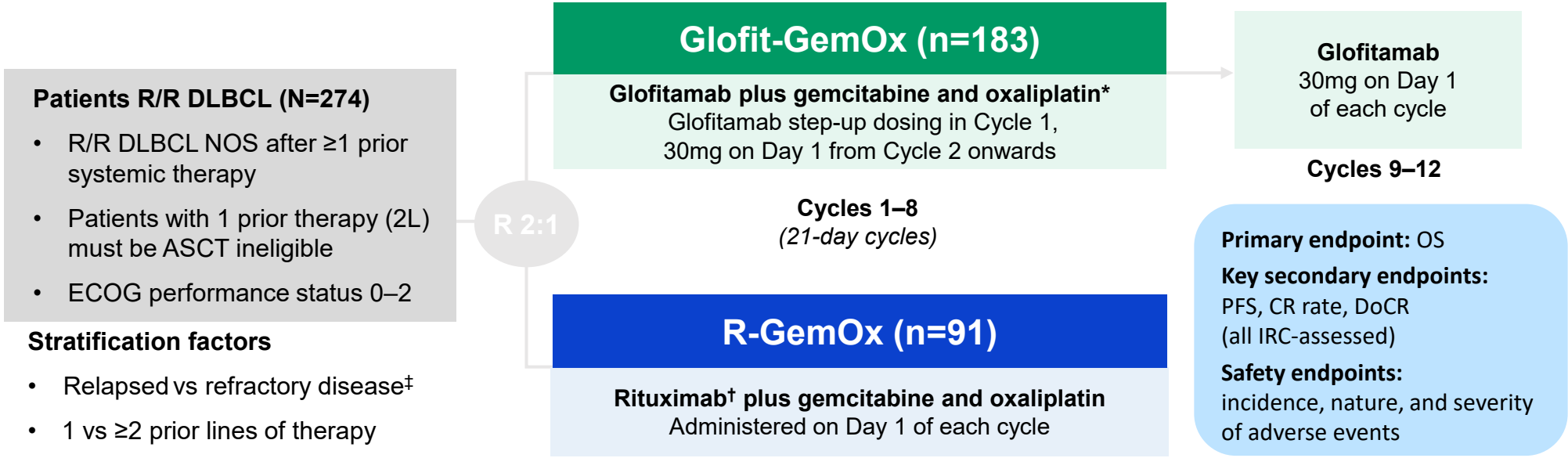
Kapitel 2

Zweitlinientherapie

- Neue CAR-T-Konstrukte
- **3 Jahres Follow up Glo-Gem-Ox**

STARGLO (NCT04408638): a randomized, global, Phase III trial

- In STARGLO, Glofit-GemOx demonstrated clinically meaningful and statistically significant benefits in OS, PFS, and CR rate versus R-GemOx in ASCT-ineligible patients with R/R DLBCL after ≥1 prior line of therapy[1]



We report updated efficacy and safety results from STARGLO, with 3 years of follow-up

*Gemcitabine 1000mg/m^2, oxaliplatin 100mg/m^2. In Cycle 1, obinutuzumab pretreatment on Day 1, GemOx on Day 2, Glofit 2.5mg on Day 8, Glofit 10mg on Day 15; in Cycles 2–8, Glofit 30mg and GemOx on Day 1. †Rituximab 375mg/m^2. ‡Relapsed: disease recurrence after a response that lasted ≥6 months after completion of last line of therapy; refractory: disease that did not respond to, or progressed <6 months after completion, of last line of therapy.
ASCT, autologous stem cell transplant; CR, complete response; DoCR, duration of CR; ECOG, Eastern Cooperative Oncology Group; IRC, independent review committee; PFS, progression-free survival; OS, overall survival; NOS, not otherwise specified; R 2:1, randomized in a 2:1 ratio.

1. Abramson JS, et al. Lancet 2024;404:1940–54.

Abramson et al., Poster presentation #5519, *ASH 2025*

After 3 years of follow-up, clinical benefit with Glofit-GemOx was sustained

- Median OS follow-up was 35.1 months (95% CI: 33.6–37.6)

Outcome	Overall		2L	
	R-GemOx (n=91)	Glofit-GemOx (n=183)	R-GemOx (n=57)	Glofit-GemOx (n=115)
OS, median (95% CI); months	12.5 (7.9–16.5)	25.5 (17.0–NE)	14.4 (10.3–26.8)	NE (22.8–NE)
36-month OS, % (95% CI)	27.4 (17.3–37.5)	47.1 (39.5–54.6)	30.8 (17.7–44.0)	54.6 (45.2–64.0)
PFS, median (95% CI); months	3.3 (2.3–5.6)	14.4 (8.8–27.4)	5.5 (2.6–9.7)	20.4 (9.2–NE)
30-month PFS, % (95% CI)	15.2 (0.9–29.5)	38.1 (29.8–46.3)	26.3 (10.3–42.4)	41.5 (30.8–52.2)
ORR, n (%)	37 (40.7)	125 (68.3)	28 (49.1)	83 (72.2)
CR, n (%)	23 (25.3)	107 (58.5)	16 (28.1)	73 (63.5)
DoCR, median (95% CI); months	24.2 (6.9–NE)	NE (27.2–NE)	NE (6.5–NE)	NE (24.8–NE)

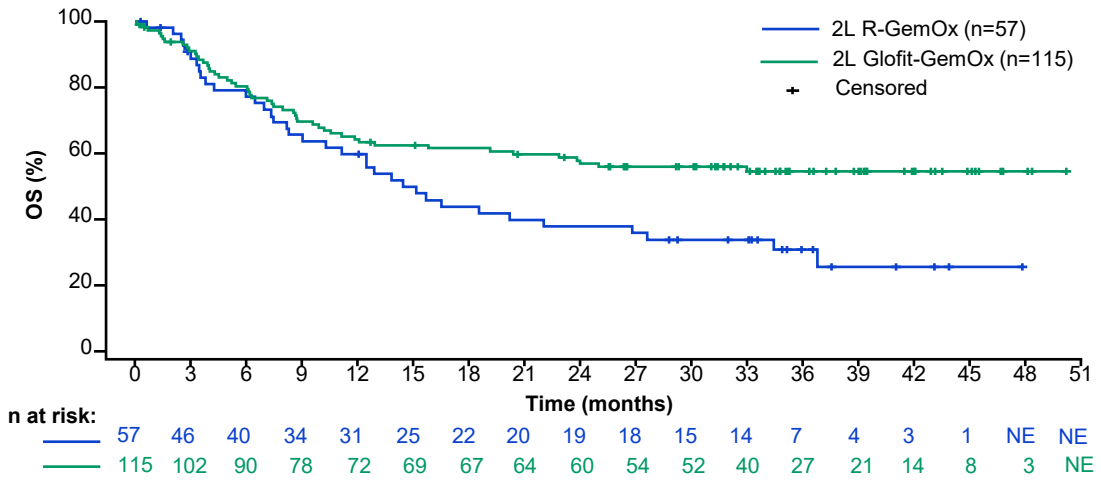
Survival and response outcomes were superior with Glofit-GemOx versus R-GemOx

Data cut-off: May 1, 2025. CI, confidence interval; NE, not estimable; ORR, overall response rate.

Abramson et al., Poster presentation #5519, *ASH 2025*

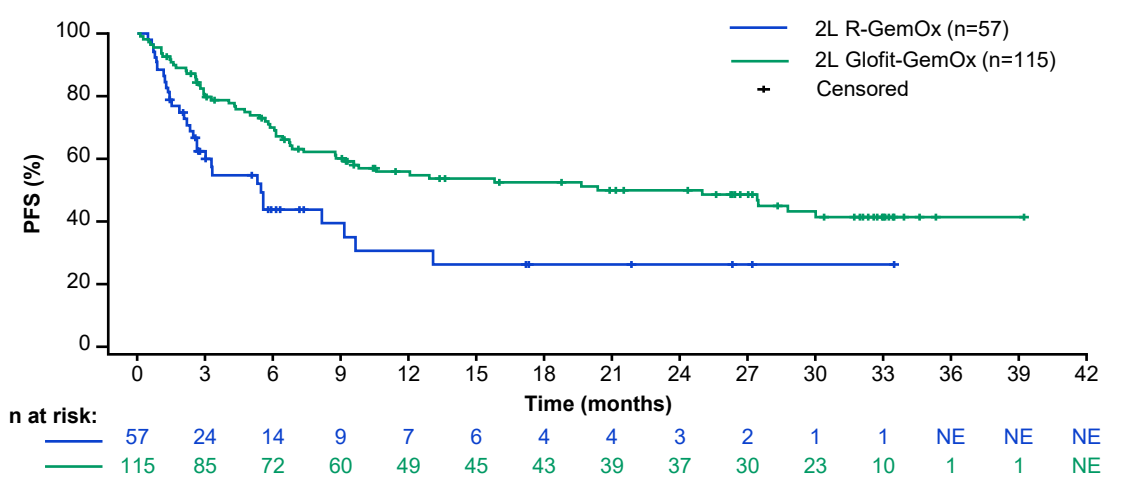
Glofit-GemOx treatment was particularly beneficial in the 2L setting

Overall survival



	R-GemOx 2L (n=57)	Glofit-GemOx 2L (n=115)
OS, median (95% CI); months	14.4 (10.3–26.8)	NE (22.8–NE)
36-month OS, % (95% CI)	30.8 (17.7–44.0)	54.6 (45.2–64.0)

Progression-free survival



	R-GemOx 2L (n=57)	Glofit-GemOx 2L (n=115)
PFS, median (95% CI); months	5.5 (2.6–9.7)	20.4 (9.2–NE)
30-month PFS, % (95% CI)	26.3 (10.3–42.4)	41.5 (30.8–52.2)

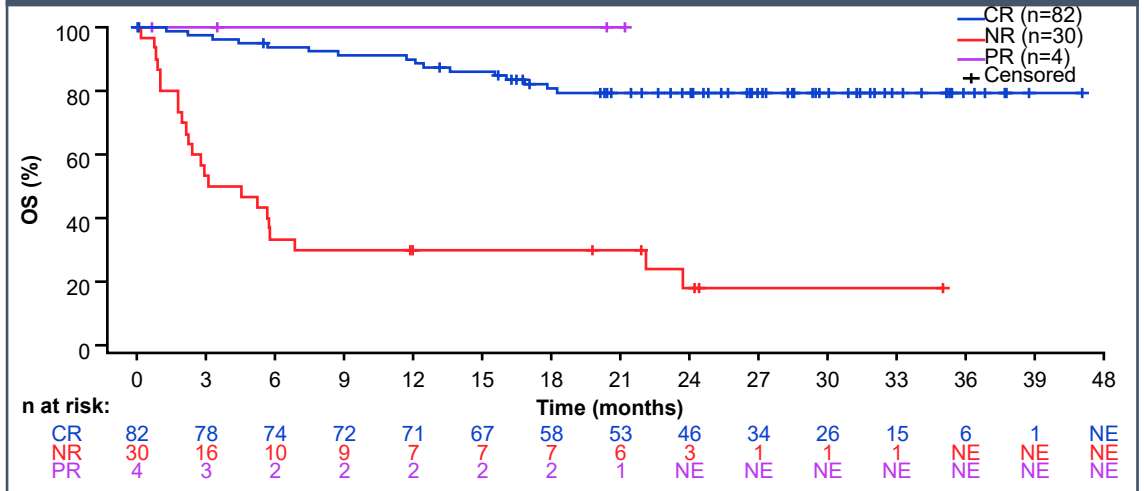
A pronounced efficacy benefit was observed for Glofit-GemOx versus R-GemOx in the 2L setting

Data cut-off: May 1, 2025.

Abramson et al., Poster presentation #5519, *ASH 2025*

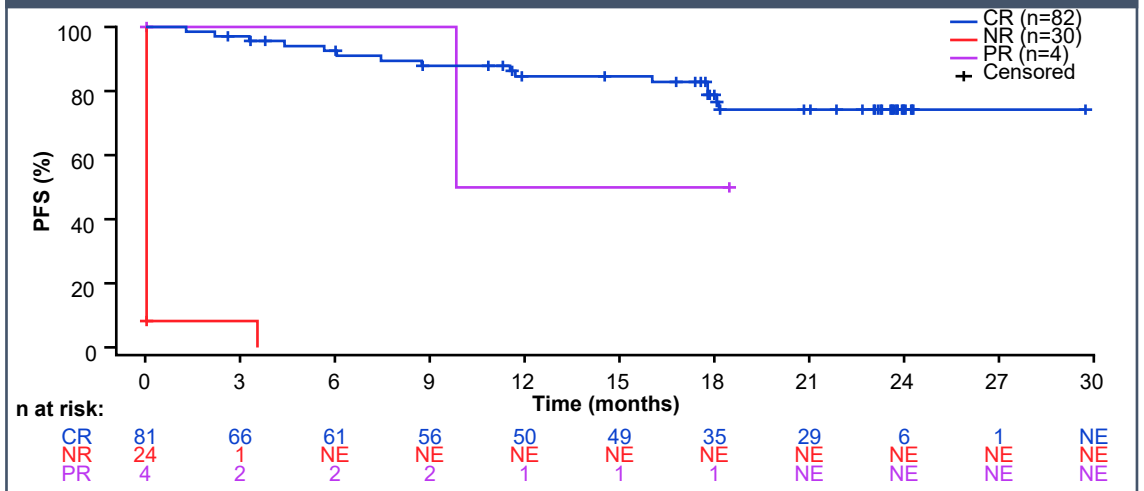
Landmark analysis by response at EOT in patients treated with Glofit-GemOx

Overall survival



Landmark OS from EOT in patients with CR at EOT	n=82
OS, median (95% CI); months	Not reached (NE)
24-month OS, % (95% CI)	79.4 (70.3–88.4)

Progression-free survival



Landmark PFS from EOT in patients with CR at EOT	n=82
PFS, median (95% CI); months	Not reached (NE)
24-month PFS, % (95% CI)	74.2 (62.6–85.8)

The majority of Glofit-GemOx-treated patients who reached CR remained alive and progression free 2 years after EOT

Data cut-off: May 1, 2025. EOT, end-of-treatment; NR, no response; PR, partial response.

Abramson et al., Poster presentation #5519*, ASH 2025*

Conclusions

- After 3 years of follow-up, substantial clinical benefits with Glofit-GemOx treatment were sustained, demonstrating superior OS, PFS, and CR rates compared with R-GemOx in ASCT-ineligible patients with R/R DLBCL
  - A pronounced efficacy benefit was observed for Glofit-GemOx versus R-GemOx in patients treated in the 2L setting
  - Most patients with a CR at EOT remained alive and progression free 2 years after EOT
- No new safety signals were identified, and no evidence of cumulative toxicity or new long-term AEs were observed

Sustained survival benefits and durable remissions support Glofit-GemOx as a potentially curative, off-the-shelf treatment option for patients with ASCT-ineligible R/R DLBCL

Abramson et al., Poster presentation #5519*, ASH 2025*

Zusammenfassung | Take-Home-Messages

Erstlinientherapie

- Keine Praxisveränderung - R-Pola-CHP/CHOP-like Therapien bleiben SOC
- Zielgerichte Substanzen werden zunehmend in molekular definierten Subgruppen in klinischen Studien getestet
- Chemotherapie-freie/arme Konzepte werden in klinischen Studien exploriert und zeigen besonders bei älteren/medizinisch Unfitten Patienten ein sehr vielversprechendes Wirkungs-/Nebenwirkunsprofil

Rezidiv Therapie

- Mehrere duale/bizistronische CART-Produkte, vorwiegend mit CD19/CD20 oder CD19/CD22, zeigen in klin. Studien : gute, deutlich über derzeitige SOC liegende Wirksamkeit bei gutem Toxizitätsprofil.
- Zamtocel ist ein CD19/CD20 CAR welches durch kurze vein-to-vein Zeit aufgrund der dezentralen Produktion, ein spannendes CAR Produkt darstellt, welches nun gegen den SOC getestet werden muss
- Glo-Gem-Ox zeigt auch in den 3 Jahresdaten ein weiterhin bestehendes Plateau und stellt somit für nicht hochdosisfähige Patienten eine potenziell kurative Therapieoption dar.

Die Kurzpräsentationen sind online unter

www.lymphome.de/ash2025

Für den Inhalt verantwortlich:

Prof. Dr. med. Björn Chapuy

Charité Universitätsmedizin Berlin

Kompetenznetz Maligne Lymphome

Lymphom Kompetenz KOMPAKT

KML KONGRESSE

Expert:innen berichten zu Lymphomen & Leukämien

Das Informationsprojekt wird unterstützt von den Firmen:

abbvie

AMGEN

AstraZeneca

Bristol Myers Squibb™

GSK

Incyte

Lilly

Roche

Diese hatten keinen Einfluss auf die Inhalte.