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# Glofitamab (COLUMVI<sup>®</sup>)

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Presentation to the Oncologic Drugs Advisory Committee

BLA 761309/S-001

Genentech, Inc.

**Charles Fuchs, MD, MPH**  
*Senior Vice President*  
*Global Head of Oncology & Hematology*  
*Drug Development*



# Presenters and Responders



**Jeremy Abramson, MD**

*Director, Jon and Jo Ann Hagler Center for Lymphoma  
Massachusetts General Hospital Cancer Center  
Professor of Medicine, Harvard Medical School*



**Krish Patel, MD**

*Director of Lymphoma Research  
Sarah Cannon Research Institute (SCRI)*



**Haifaa Abdulhaq, MD**

*Professor, University of California San Francisco (UCSF)  
Director of Hematology, UCSF Fresno*



**Michelle Boyer, PhD**

*Global Head for Lymphoma/CLL Clinical Development  
Genentech*



**Venkat Sethuraman, PhD**

*Global Head of Data Science and Analytics  
Genentech*



**Michelle Byrtek, PhD**

*Senior Director Biostatistics  
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**David Carlile, PhD**

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Genentech*



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*Global Development Leader, Glofitamab  
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**James Relf, MD**

*Principal Clinical Safety Director, Glofitamab  
Genentech*



**Ashley Weber, PharmD**

*Regulatory Director, Glofitamab  
Genentech*

# Relapsed/Refractory Diffuse Large B-cell Lymphoma (R/R DLBCL) Represents a Critical Unmet Need

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- Cancer immunotherapy has transformed the treatment landscape
- Nonetheless, ~40% of DLBCL patients progress after 1st line therapy<sup>1</sup>
- Cellular therapy is not a treatment option for ~75% of US patients<sup>2</sup>

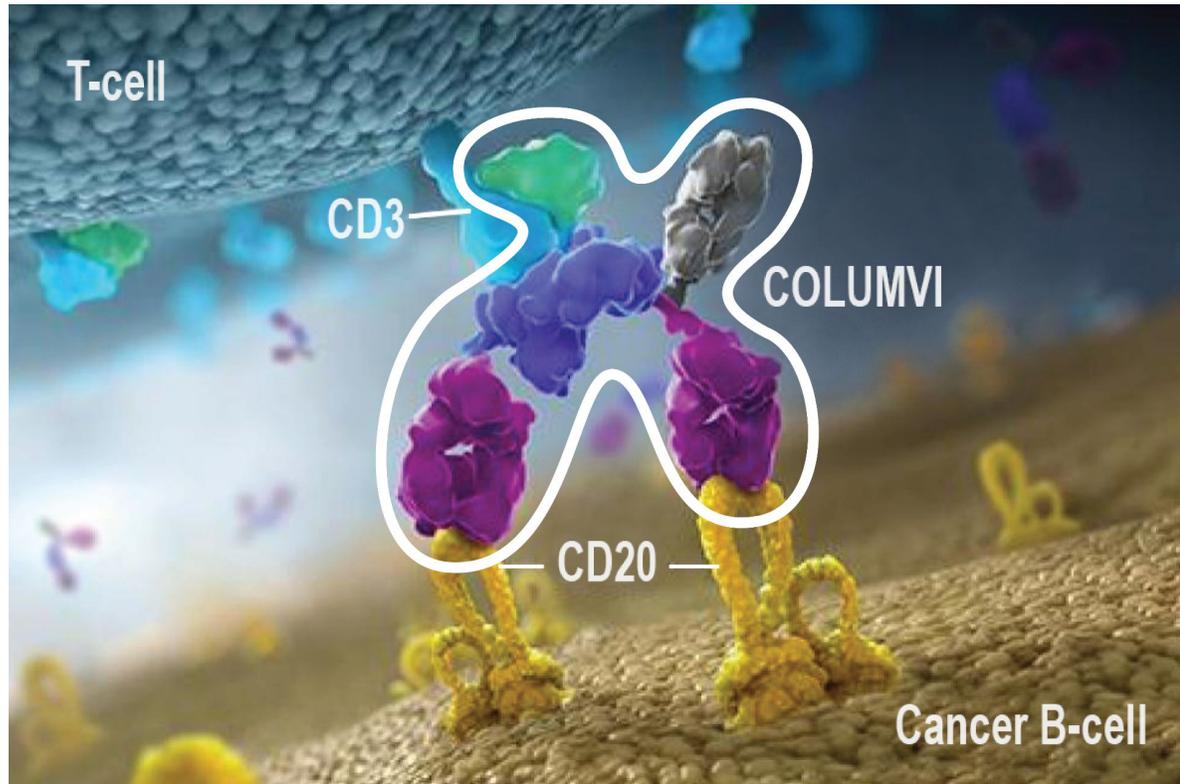
**Limited effective treatment options for the majority of US patients  
with R/R DLBCL**

<sup>1</sup> Sehn LH, Salles G. N Engl J Med 2021;384(9):842-858.

<sup>2</sup> Westin J and Sehn LH. Blood 2022;139(18):2737–2746.

# Glofitamab Harnesses a Patient's T-Cells to Kill Cancer Cells

## A transformative treatment option

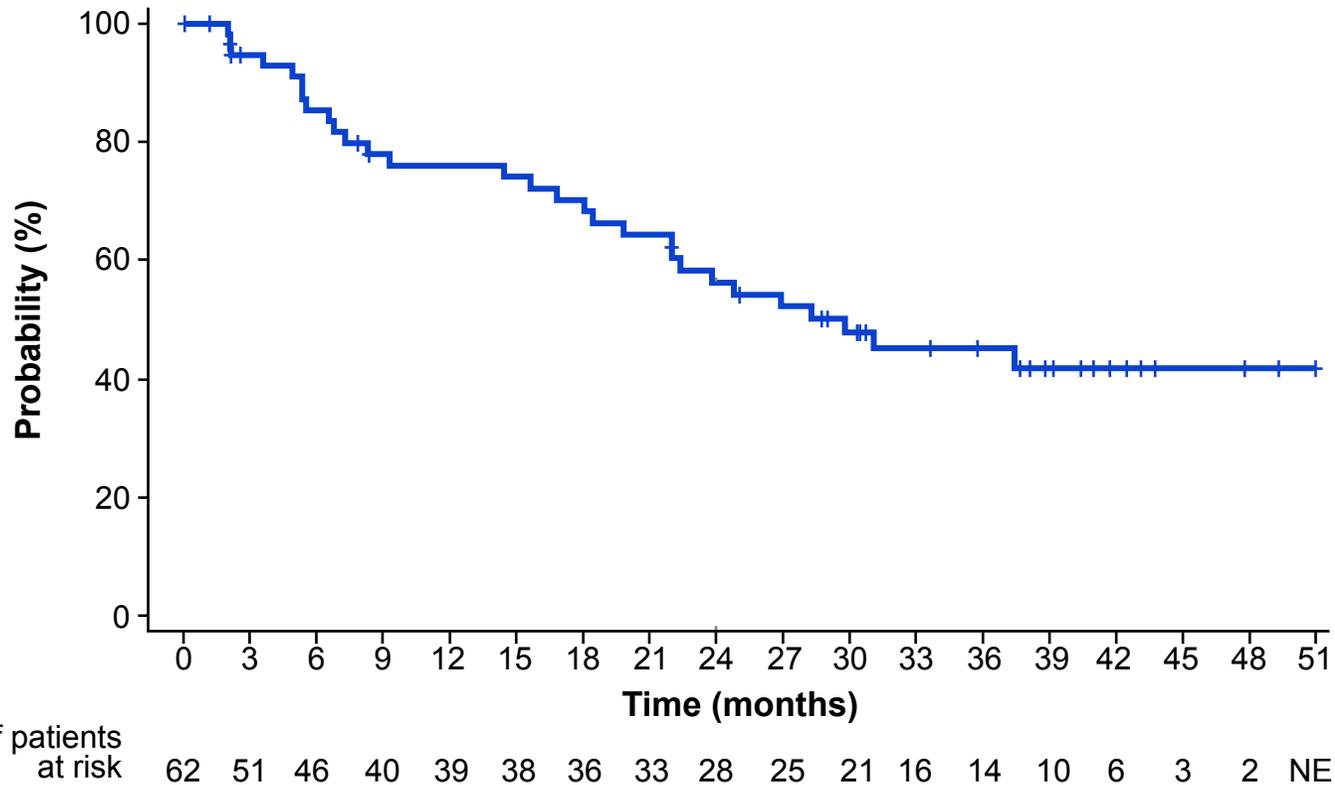


### Mode of Action

- CD20xCD3 (2:1 format) bispecific antibody
- Forms an “immunologic synapse” between CD3 on activated T-cells and CD20 on malignant B-cells
- Results in potent lysis of B-cells

# Glofitamab Monotherapy Delivers Durable Complete Responses in 3L+ DLBCL<sup>1</sup>

## Median Duration of CR: 29.8 months



	<b>N=155</b>
<b>CR rate, n (%)</b> [95% CI]	62 (40%) [32.2–48.2]
<b>ORR, n (%)</b> [95% CI]	80 (52%) [43.5–59.7]

<sup>1</sup> Dickinson MJ, et al. N Engl J Med. 2022;387(24):2220–31; CCOD: 17 May 2024.  
CR, complete response; DoCR, duration of complete response; ORR, overall response rate.

# Glofitamab has Established Benefit in R/R DLBCL

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## Accelerated Approval 3L+ DLBCL

### **Glofitamab monotherapy in 3L+ DLBCL**

- FDA Accelerated Approval in June 2023
- Approved in >60 countries
- Approximately 6,000 patients, including >2,000 US patients, treated in the post marketing setting

## Confirmation of Clinical Benefit in R/R DLBCL

### **STARGLO (Phase 3): Glofitamab + GemOx in 2L+ DLBCL**

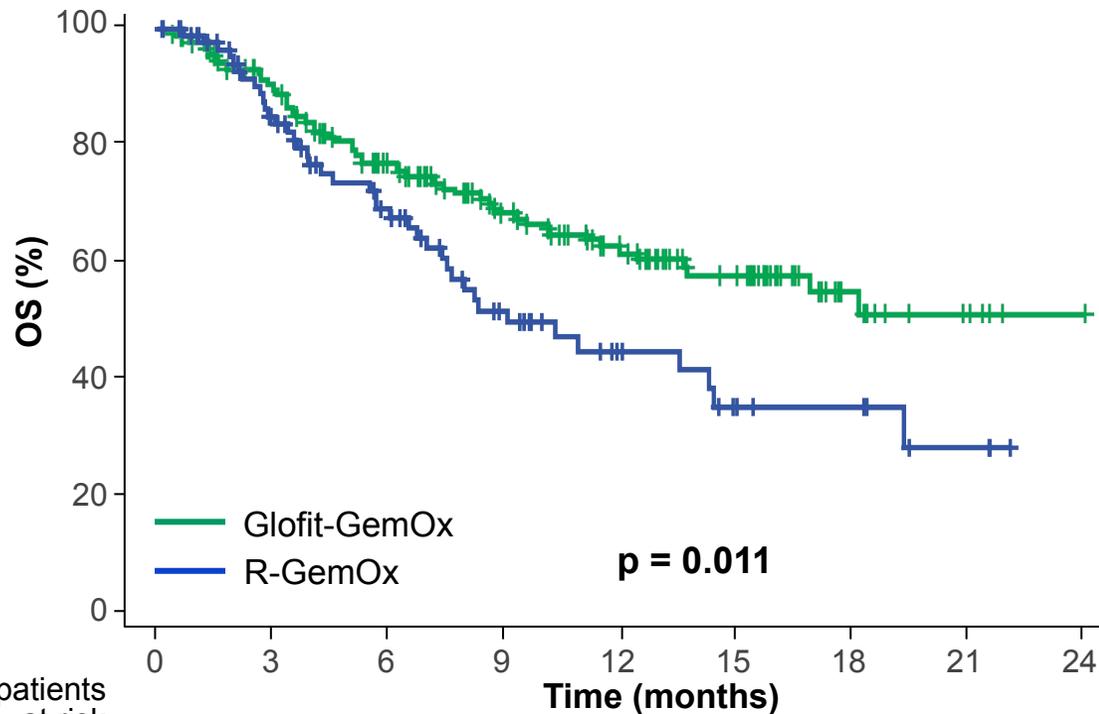
- Expands the clinical benefit into 2L DLBCL

# STARGLO Met Primary Endpoint of Overall Survival

Designed to Produce Globally Applicable Results

**41% reduction in risk of death**

- 63% reduction in disease progression
- Approved in > 30 countries
- NCCN Category 1



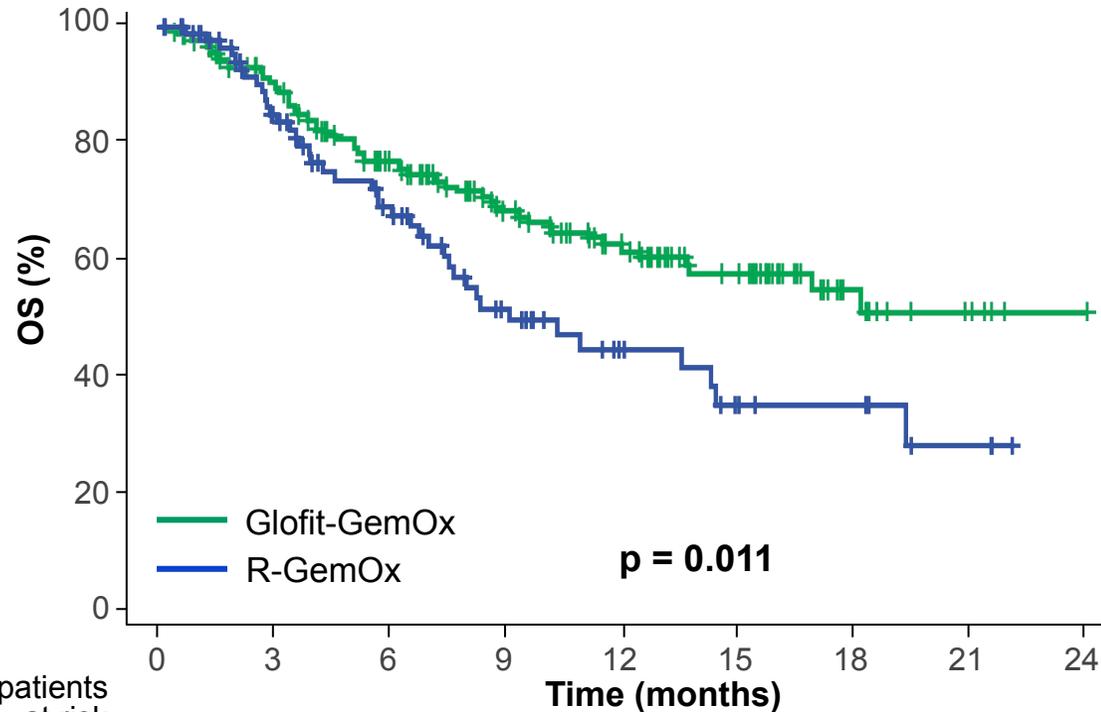
No. of patients  
at risk

	0	3	6	9	12	15	18	21	24
<b>R-GemOx</b>	91	63	43	26	15	9	7	3	NE
<b>Glofit-GemOx</b>	183	146	110	77	57	38	14	5	1

# STARGLO: Points for Consideration

41% reduction in risk of death

- Variability across exploratory subgroups



No. of patients at risk

<b>R-GemOx</b>	91	63	43	26	15	9	7	3	NE
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# Sponsor Position on FDA Appraisal of Asian vs. Non-Asian Subgroups in STARGLO

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- Differences in the Asian subgroup:
  - Patient and disease characteristics
  - Treatments and assessments
- *Did these factors influence the results?*

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- R-GemOx outcomes in historical literature: 8-13.5 months
  - Asia **consistent** with mOS 8.2 months
  - Non-Asia well **in excess** with mOS 27.8 months

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**Glofit-GemOx delivers a consistent treatment benefit across all regions**

# Agenda

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**DLBCL Background & Unmet Need**

**Jeremy Abramson, MD**

*Massachusetts General Hospital Cancer Center*

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**STARGLO Efficacy & Safety**

**Michelle Boyer, PhD**

*Genentech*

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**STARGLO Subgroup Analyses**

**Venkat Sethuraman, PhD**

*Genentech*

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**Clinical Perspective**

**Krish Patel, MD**

*Sarah Cannon Research Institute*

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**Closing Remarks**

**Charles Fuchs, MD, MPH**

*Genentech*

# Disease Background & Unmet Need in DLBCL

Jeremy Abramson, MD

Massachusetts General Hospital Cancer Center, Boston, MA, USA

# Disclosures

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- Consulting for AbbVie, ADC Therapeutics, AstraZeneca, BeiGene, BMS, Celgene, Foresight Diagnostics, Genentech, Gilead, Interius, Miltenyi Biotec, Novartis, Roche, Takeda
- Research support (to institution) from Allogene, AstraZeneca, BMS, Celgene, Celleris, Genentech, Merck, Mustang Bio, Pfizer, Regeneron, Seagen, Takeda

# DLBCL is an Aggressive Life-threatening Disease

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- DLBCL is the most common lymphoma in the US and worldwide
  - Incidence (US) = ~19,000<sup>1, 2</sup> annually
  - Estimated deaths due to DLBCL (US) = ~5,800<sup>1, 2</sup> annually
- Majority of patients are older and require urgent treatment
- Disease characteristics, management, available therapies and outcome of DLBCL is similar worldwide

<sup>1</sup> SEER 2018-2022 (<https://seer.cancer.gov/statfacts/html/dlbcl.html>).

<sup>2</sup> US Census Bureau (<https://www.census.gov/popclock>).

# Cure is the Treatment Goal in DLBCL

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## 1L DLBCL

- Approximately 60% of patients are **cured** with 1L therapy<sup>1</sup>
- 40% have **refractory or relapsed disease**<sup>2</sup>
- Primary refractory disease reduces chance for cure

## R/R DLBCL

- Treatment goals:
  - Maximize depth of response (**CR**)
  - Minimize need for subsequent therapy (**EFS**)
  - Offer potential for cure (**OS**)

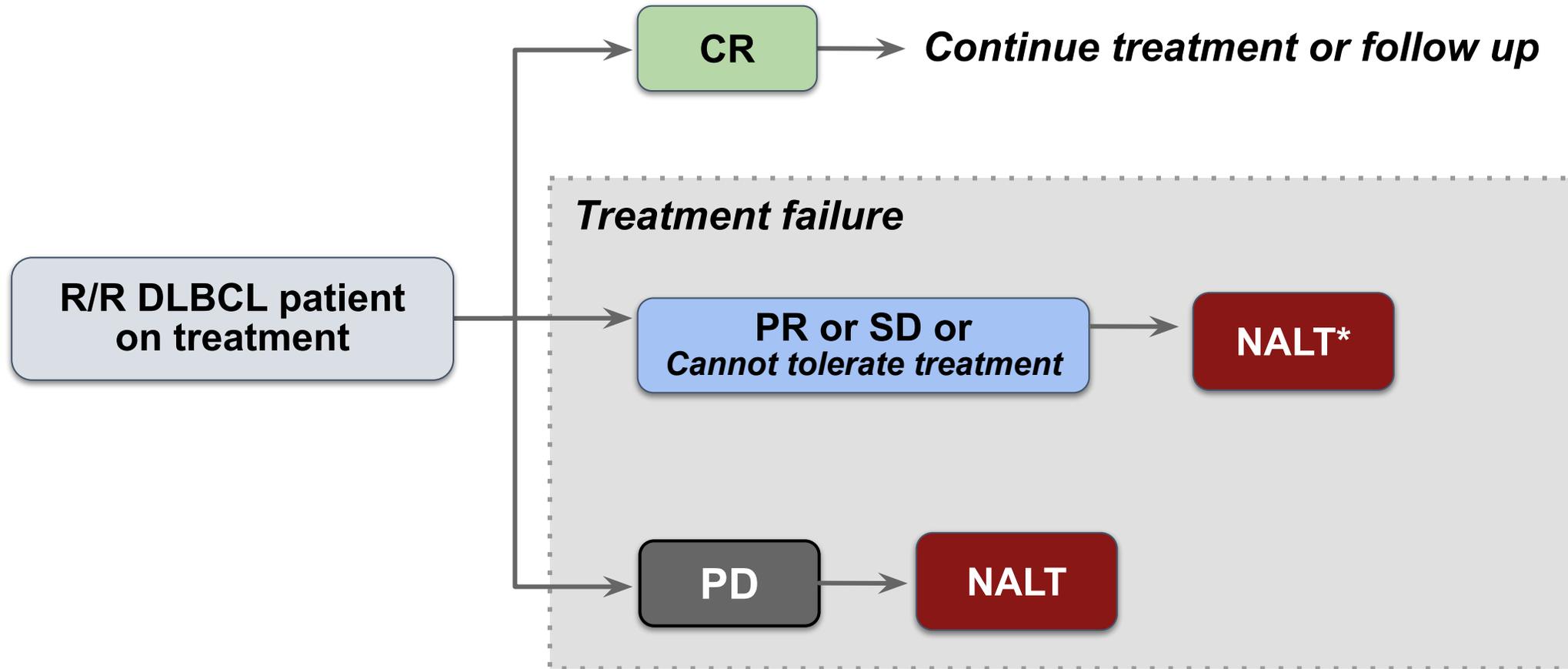
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CR, Complete Response, EFS, Event Free Survival, OS, Overall Survival

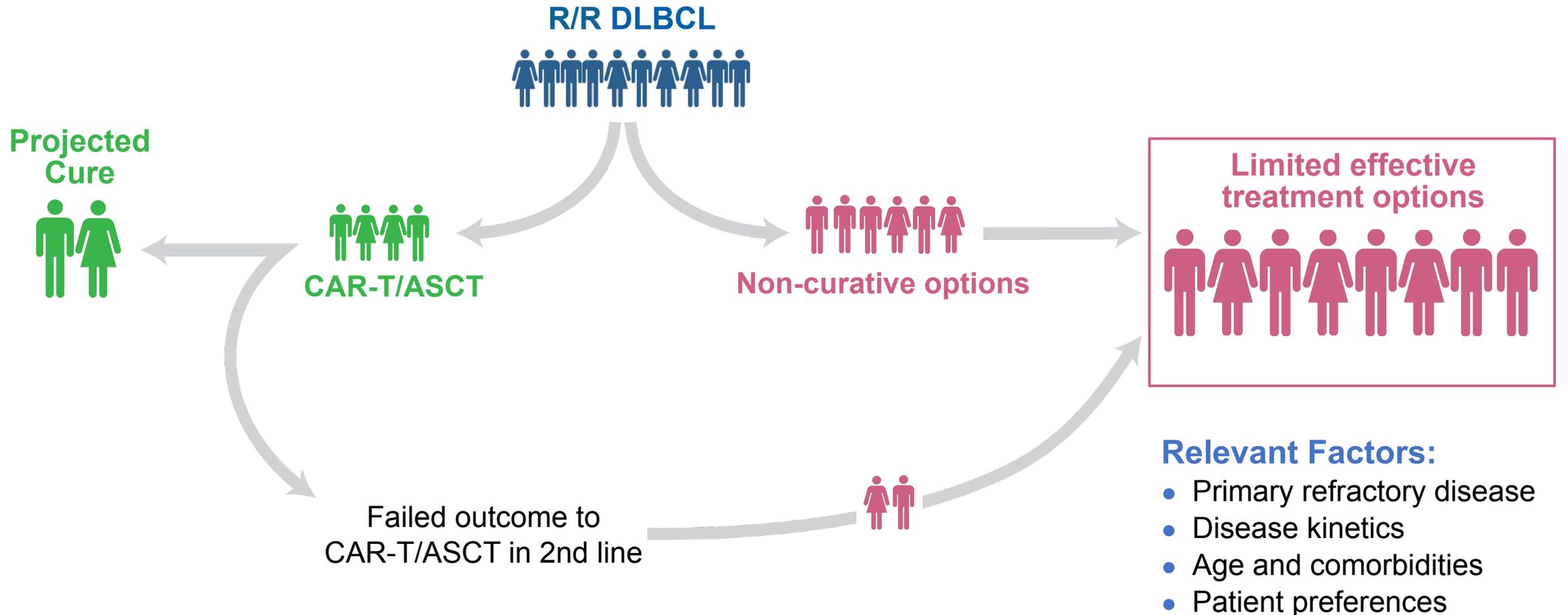
# Complete Response (CR) is the Path to Cure

Partial Response (PR) or Stable Disease (SD) are Considered Treatment Failure



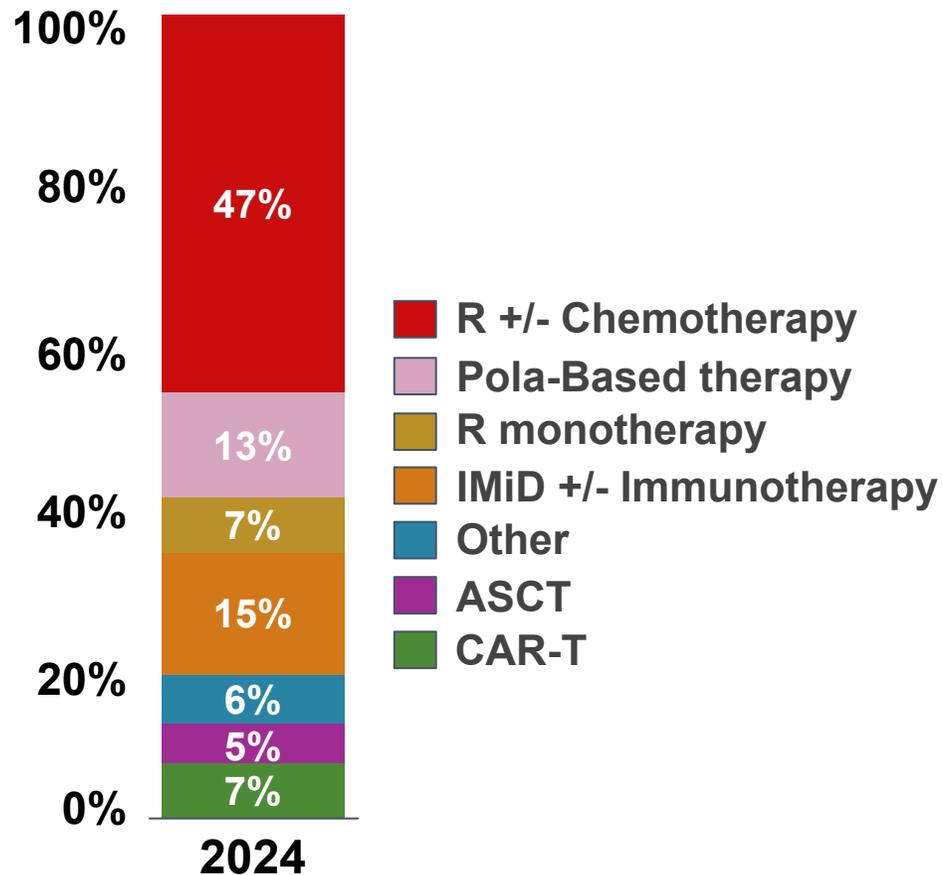
\*As per NCCN guidance, New Anti-Lymphoma Therapy (NALT) recommended if no CR or treatment intolerance.  
National Comprehensive Cancer Network. Clinical practice guidelines in oncology (NCCN Guidelines®) B-cell lymphomas (Version 2.2025).  
NALT, New Anti-Lymphoma Therapy; PD, progressive disease

# Majority of R/R DLBCL Patients have Limited Effective Treatment Options



# R-Chemo is the Most Common Treatment in 2L DLBCL in the US

Distribution of 2L therapies 2024  
(n=2,544)<sup>1</sup>



- CAR-T utilization is limited
- R-Chemo is most prevalent
  - *R-GemOx ~18% of US patients*<sup>2</sup>
- R-Chemo CR rate: 14-28%<sup>3,4,5</sup>

<sup>1</sup> Adopted from Shadman M et al. Blood 2024; 144(S):2362. <sup>2</sup> Garg M et al. Clin Lymphoma Myeloma Leuk 2024; 24(5):e181-e190.

<sup>3</sup> Gisselbrecht C et al. J Clin Oncol 2010 28:4184-4190. <sup>4</sup> Crump M et al, J Clin Oncol 2014 32(31):3490-3496; <sup>5</sup> Elstrom R et al, Leuk Lymphoma 2012 53(8):1469-1473.

IMiD, immunomodulatory drugs (eg. lenalidomide); Pola, polatuzumab vedotin; R, rituximab.

# Addressing an Unmet Medical Need with Glofit-GemOx

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- Urgent need for new treatments that offer potential path to cure
- Glofitamab monotherapy demonstrates durable remissions in later lines, even in difficult to treat patients
- STARGLO was designed to address the needs of the majority of US patients with R/R DLBCL

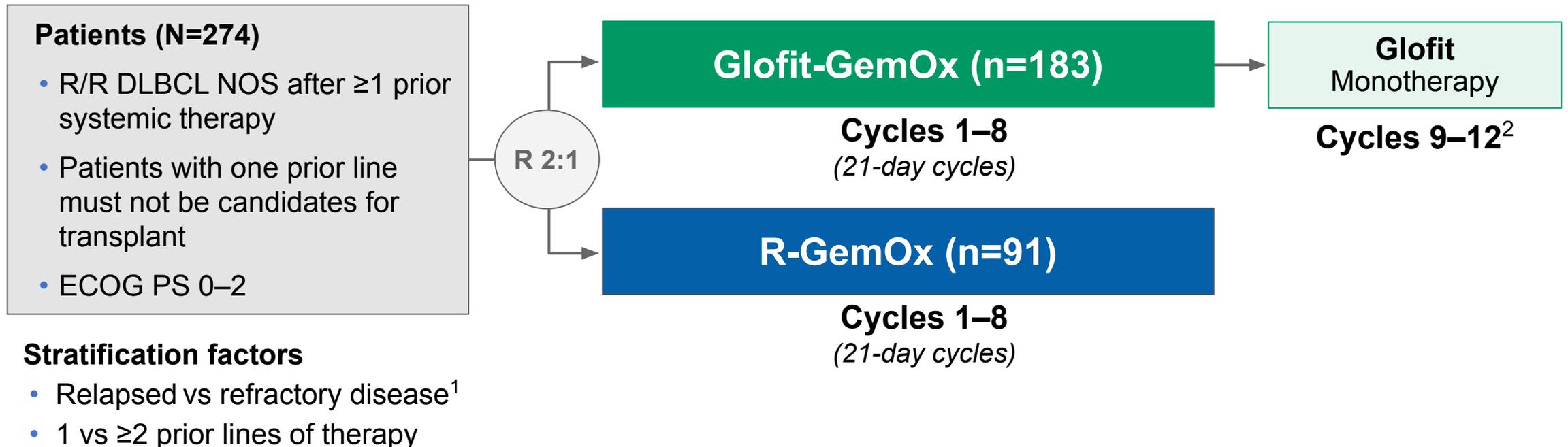
# STARGLO

Michelle Boyer, PhD

Global Head for Lymphoma/CLL Clinical Development

Genentech

# STARGLO: Randomized Phase 3, Open-Label Clinical Trial

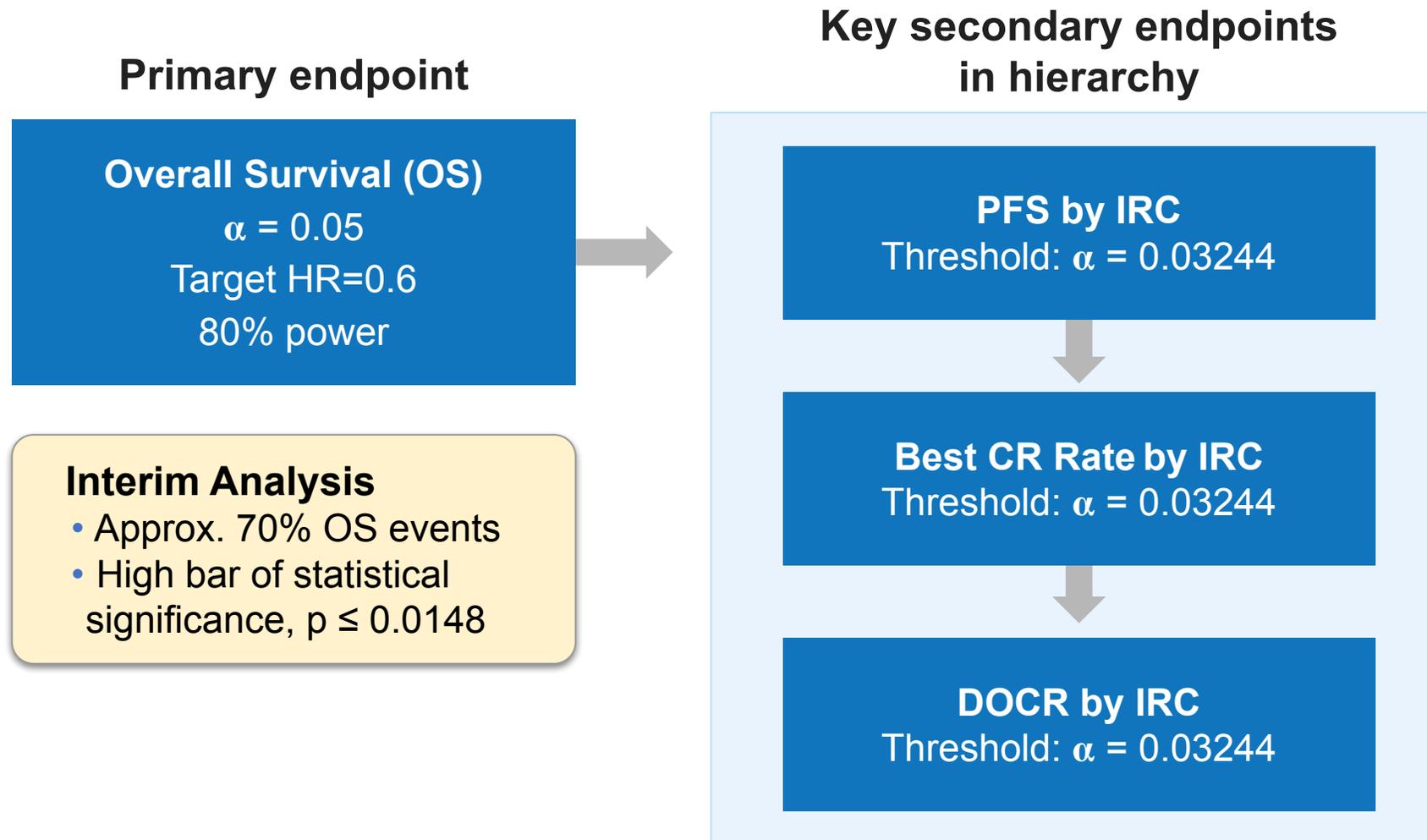


<sup>1</sup> Relapsed disease: recurrence following a response  $\geq 6$  months after end of last line of therapy; refractory disease: no response or progression  $< 6$  months after end of last line of therapy.

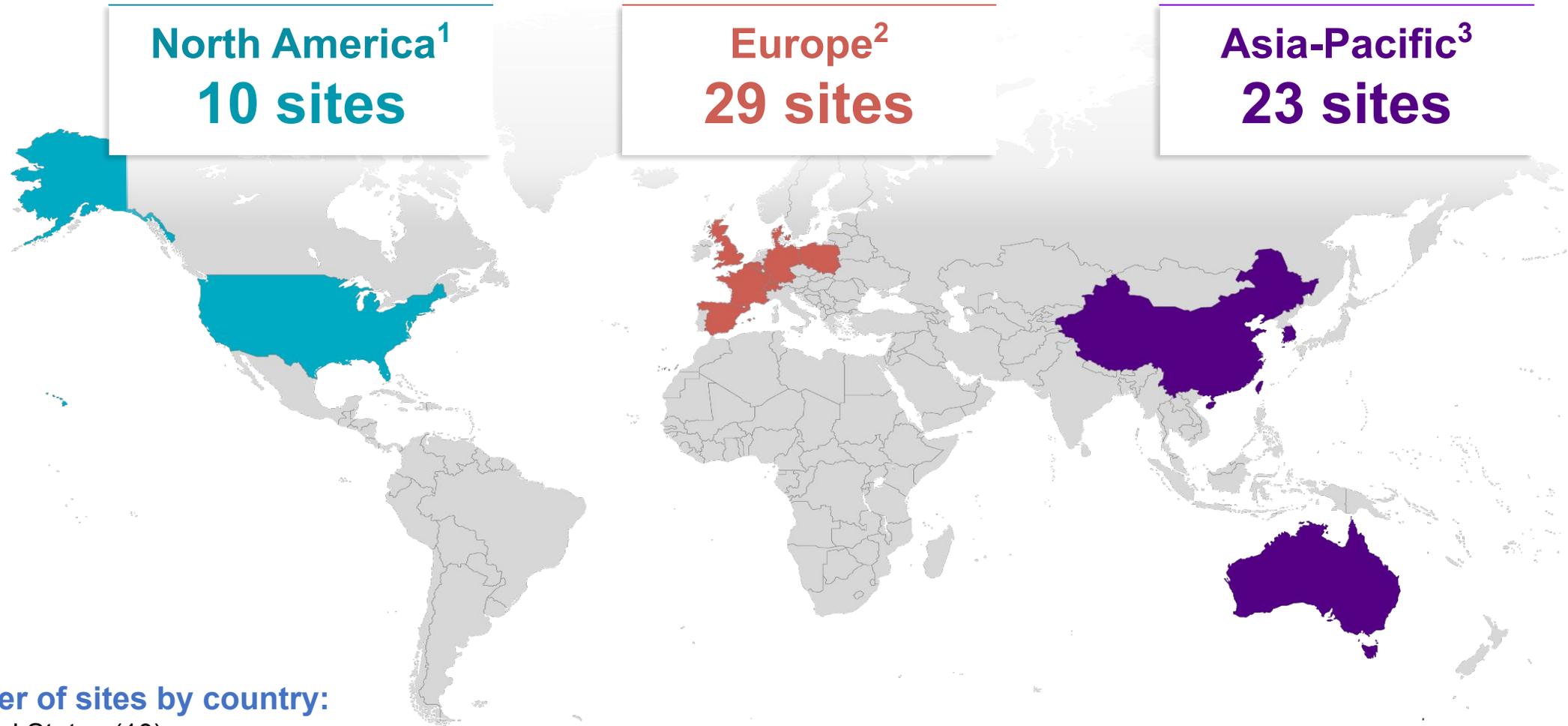
<sup>2</sup> 21-day cycles.

ECOG PS, Eastern Cooperative Oncology Group performance status; NOS, not otherwise specified; R 2:1, patients randomized in a 2:1 ratio.

# Primary Endpoint of Overall Survival as a Key Outcome to Demonstrate Treatment Advantage



# Multiregional Clinical Trial (MRCT) Conducted Across 13 Countries



## Number of sites by country:

1. United States (10)
2. France (5), Poland (5), Spain (5), UK (5), Germany (3), Denmark (2), Belgium (2), Switzerland (2)
3. China (8), Australia (6), S. Korea (6), Taiwan (3)

# Difficult to Treat Population, Representative of Unmet Need

n (%), unless otherwise stated		R-GemOx (n=91)	Glofit-GemOx (n=183)
<b>Age, years</b>	Median (range)	68 (20–84)	68 (22–88)
	≥65 years	56 (61.5)	116 (63.4)
<b>Sex</b>	Male	53 (58.2)	105 (57.4)
<b>Number of prior lines of therapy</b>	1	57 (62.6)	115 (62.8)
	≥2	34 (37.4)	68 (37.2)
<b>Response to last prior therapy</b>	Refractory	54 (59.3)	112 (61.2)
<b>Primary refractory</b> (no response, relapse ≤ 6mo)	Yes	47 (51.6)	106 (57.9)
<b>Primary refractory / Early relapse</b> (no response, relapse ≤ 12mo)	Yes	63 (69.2)	134 (73.2)
<b>Race</b>	Asian	51 (56.0)	86 (47.0)
	Black or African American	1 (1.1)	2 (1.1)
	White	33 (36.3)	82 (44.8)
	Unknown	6 (6.6)	13 (7.1)
<b>Region</b>	Asia Pacific	55 (60.4)	106 (57.9)
	Europe	26 (28.6)	62 (33.9)
	North America	10 (11.0)	15 (8.2)
<b>ECOG PS</b>	0-1	80 (90.9)	161 (89.4)
	2	8 (9.1)	19 (10.6)
<b>Ann Arbor stage</b>	III–IV	70 (76.9)	123 (67.2)
<b>International Prognostic Index (IPI)</b>	3-5	47 (51.6)	87 (47.5)

# All Patients in STARGLO were not Considered Candidates for Transplant

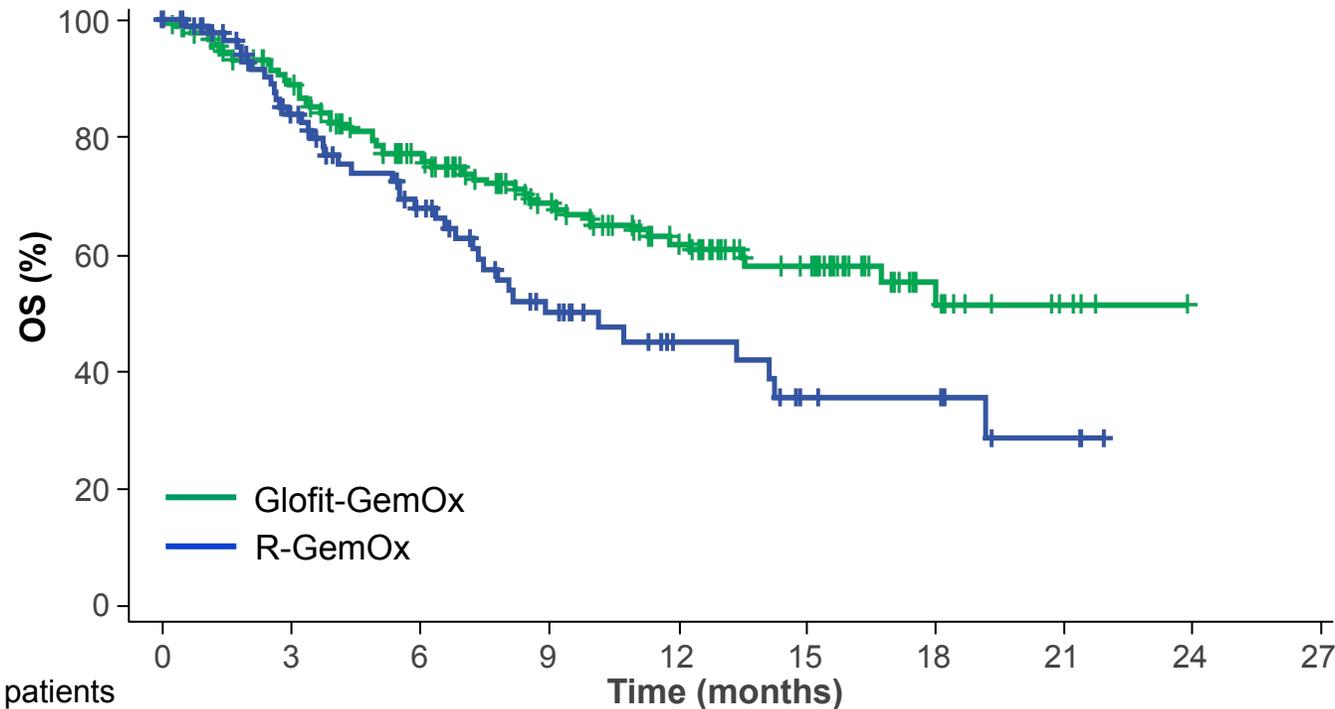
Reason for transplant ineligibility, n (%)	ITT N = 274
≥2 prior lines of therapy	102 (37.2%)
Age	100 (36.5%)
Comorbidities	29 (10.6%)
<b>Patient refused high-dose chemo followed by ASCT</b>	<b>29 (10.6%)</b>
ECOG PS > 2	7 (2.6%)
Other	7 (2.6%)

# EFFICACY

# STARGLO Met Primary Endpoint of Overall Survival

## 41% Reduction in Risk of Death

### Primary Analysis



No. of patients at risk

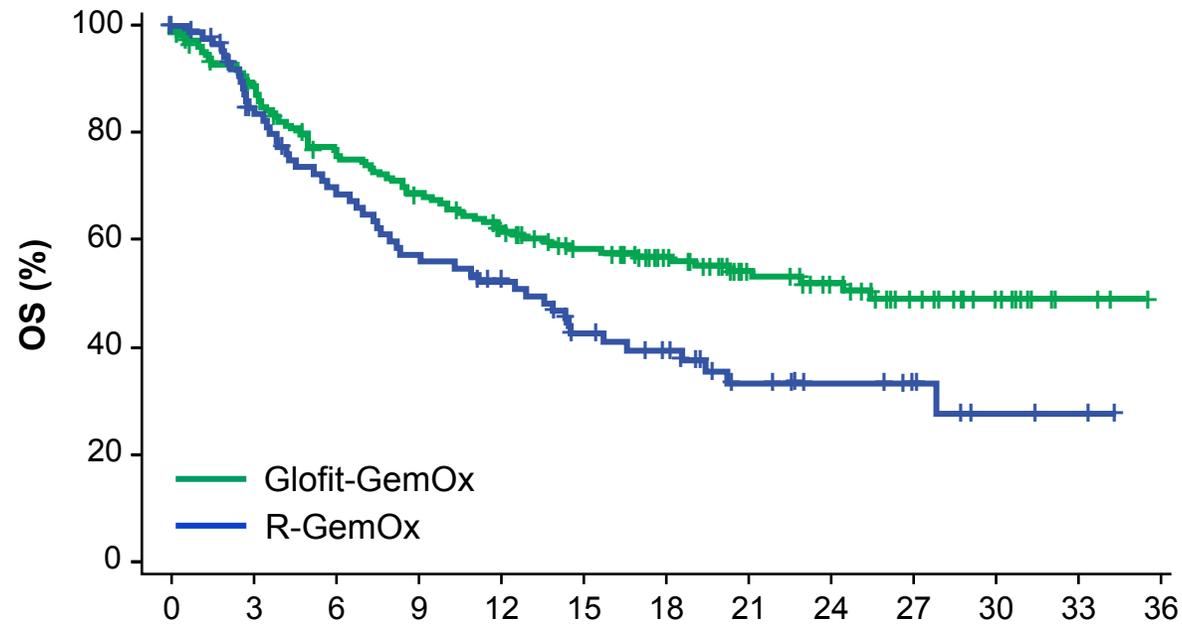
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<b>R-GemOx</b>	91	63	43	26	15	9	7	3	NE	NE
<b>Glofit-GemOx</b>	183	146	110	77	57	38	14	5	1	NE

### Primary Analysis (median follow-up: 11.3 months)

	<b>R-GemOx (n=91)</b>	<b>Glofit-GemOx (n=183)</b>
OS, median (95% CI); months	9 (7.3–14.4)	NR (13.8–NE)
HR (95% CI)	<b>0.59</b> (0.40–0.89)	
p-value	0.011	

# Longer OS Follow-up Shows Continued Survival Benefit

## Updated Analysis



No. of patients at risk	Time (months)												
	0	3	6	9	12	15	18	21	24	27	30	33	36
<b>R-GemOx</b>	91	68	55	46	40	29	23	14	10	8	3	2	NE
<b>Glofit-GemOx</b>	183	159	135	119	104	86	71	51	40	26	11	3	NE

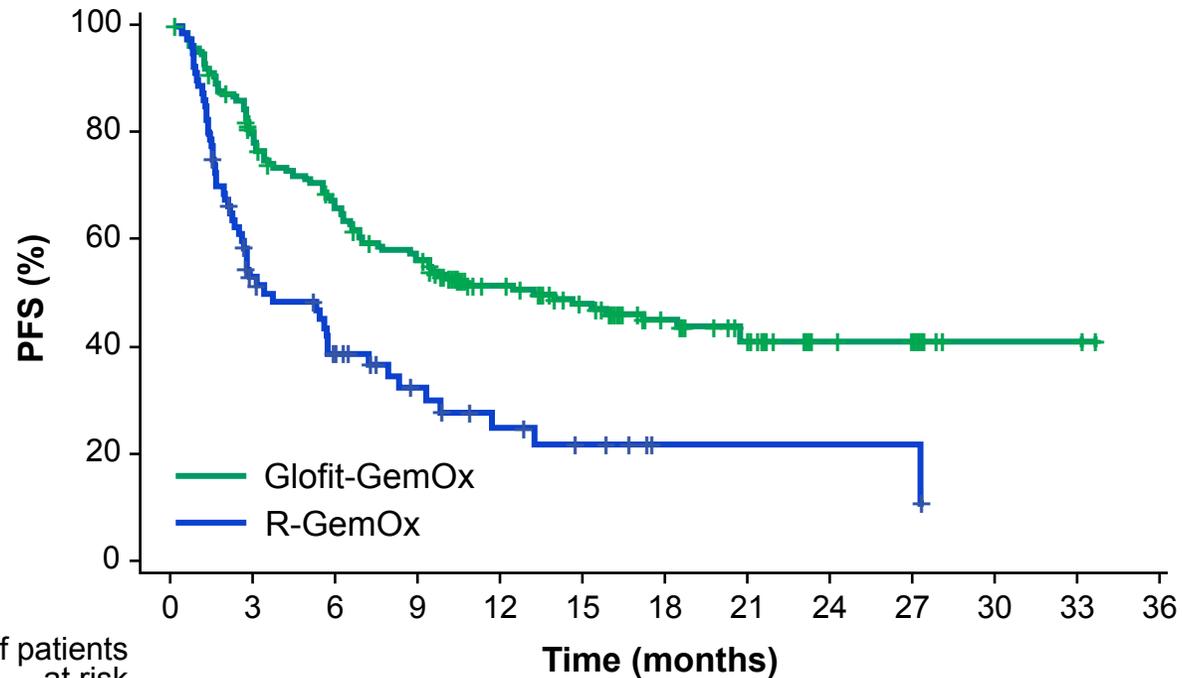
## Updated Analysis (median follow-up: 20.7 months)

	<b>R-GemOx (n=91)</b>	<b>Glofit-GemOx (n=183)</b>
OS, median (95% CI); months	12.9 (7.9–18.5)	25.5 (18.3–NE)
HR (95% CI)	<b>0.62</b> (0.43–0.88)	
24-month OS (95% CI)	33.5% (22.2–44.9)	52.8% (44.8–60.7)

# STARGLO Met Secondary Endpoint of Progression-free Survival

## 63% Reduction in Risk of Progression

### Updated Analysis



No. of patients at risk

	0	3	6	9	12	15	18	21	24	27	30	33	36
<b>R-GemOx</b>	91	34	22	14	9	6	2	2	2	2	NE	NE	NE
<b>Glofit-GemOx</b>	183	130	107	89	66	54	37	26	14	10	2	1	NE

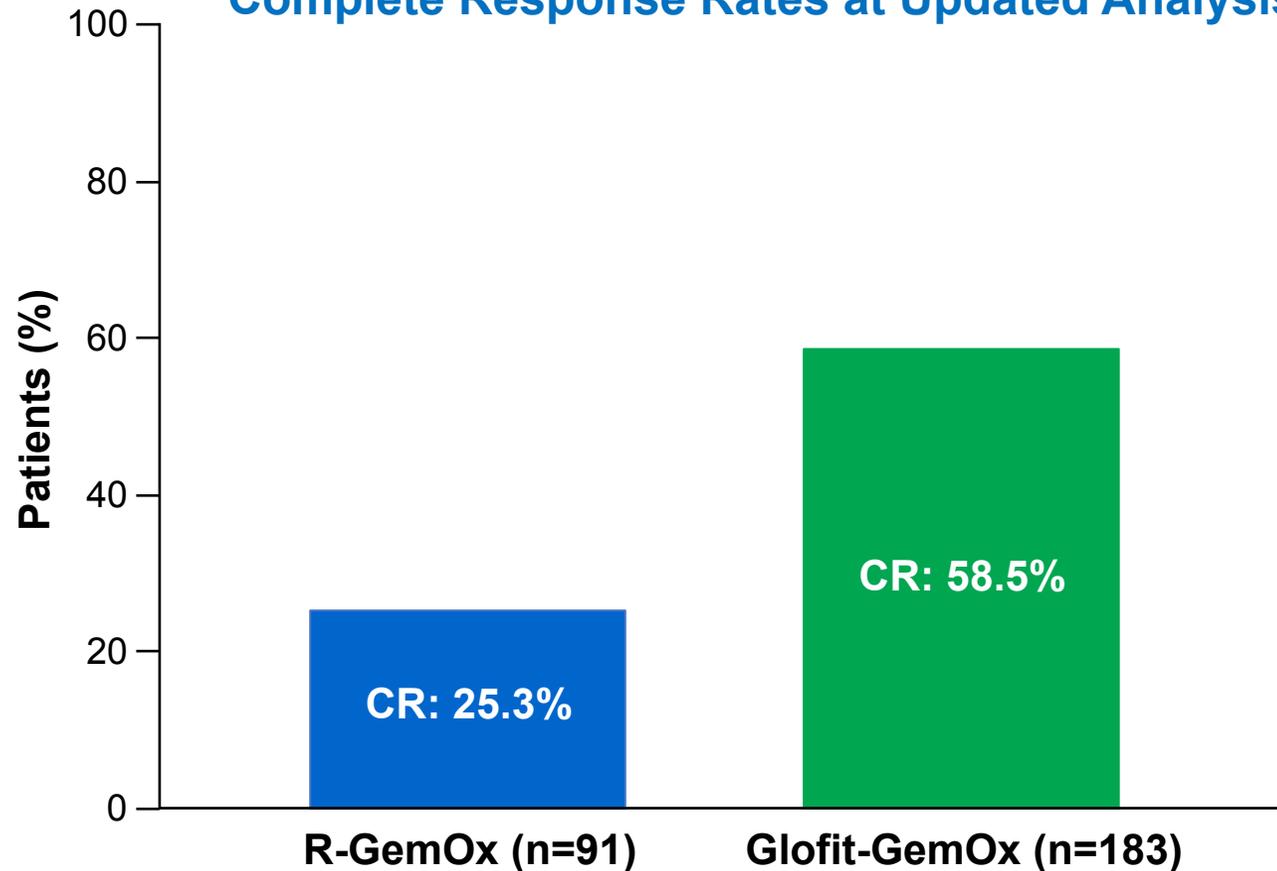
	<b>R-GemOx (n=91)</b>	<b>Glofit-GemOx (n=183)</b>
<b>Primary Analysis</b> (median follow-up: 9.6 months)		
PFS, median (95% CI); months	3.3 (2.5–5.6)	12.1 (6.8–18.3)
HR (95% CI)	<b>0.37</b> (0.25–0.55)	
p-value	<0.000001	
<b>Updated Analysis</b> (median follow-up: 16.1 months)		
PFS, median (95% CI); months	3.6 (2.5–7.1)	13.8 (8.7–20.5)
HR (95% CI)	<b>0.40</b> (0.28–0.57)	

**PFS concordance:** 93% between investigator and IRC on PD (91% on PFS timing within 30 days)

# STARGLO Met Secondary Endpoint of Complete Response

33% increase in CR rate

## Complete Response Rates at Updated Analysis



## Difference in CR rates

Primary Analysis	
Difference in CR rate (95% CI)	<b>28.3%</b> (16.3, 40.3)
p-value	<0.0001
Updated Analysis	
Difference in CR rate (95% CI)	<b>33.2%</b> (20.9, 45.5)

# A Comprehensive Assessment of the Safety Profile for Glofit-GemOx

Overview of Safety in STARGLO	R-GemOx (n=88)	Glofit-GemOx Glofit exposed (n=172)
<b>Median Number of Cycles<sup>1</sup></b> (range)	4 (1–8)	11 (1–13)
<b>Median duration of treatment</b> (days)	64 (1-183)	218 (1-296)
Grade 5 AEs	4 (4.5%)	12 (7.0%)
Fatal COVID-19 AE	0	3 (1.7%)
AE leading to withdrawal from glofitamab/rituximab	11 (12.5%)	36 (20.9%)
COVID-19 AE leading to discontinuation	5 (5.7%)	23 (13.4%)
Serious AEs	15 (17.0%)	90 (52.3%)
<b>Common Grade 3-4 AEs (&gt;10%)</b>		
Anemia	8 (9.1%)	29 (16.9%)
Neutropenia	16 (18.2%)	61 (35.5%)
Thrombocytopenia	15 (17.0%)	47 (27.3%)
<b>Known risks associated with glofitamab</b>		
CRS (ASTCT grading) <sup>2</sup>	0	76 (44.2%)
Grade 1	-	54 (31.4%)
Grade 2	-	18 (10.5%)
Grade 3	-	4 (2.3%)
ICANS (clinically adjudicated) <sup>3</sup>	N/A	4 (2.3%)
Infections	26 (29.5%)	95 (55.2%)

<sup>1</sup> For rituximab and glofitamab, respectively; <sup>2</sup> No Grade 4 or 5 CRS events were reported; <sup>3</sup> Potential cases were identified using the ICANS adverse event group term (AEGT).  
ASTCT, American Society for Transplantation and Cellular Therapy grading criteria; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome

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Grade 5 AEs	4 (4.5%)	12 (7.0%)
Fatal COVID-19 AE	0	3 (1.7%)
AE leading to withdrawal from glofitamab/rituximab	11 (12.5%)	36 (20.9%)
COVID-19 AE leading to discontinuation	5 (5.7%)	23 (13.4%)
Serious AEs	15 (17.0%)	90 (52.3%)
<b>Common Grade 3-4 AEs (&gt;10%)</b>		
Anemia	8 (9.1%)	29 (16.9%)
Neutropenia	16 (18.2%)	61 (35.5%)
Thrombocytopenia	15 (17.0%)	47 (27.3%)
<b>Known risks associated with glofitamab</b>		
CRS (ASTCT grading) <sup>2</sup>	0	76 (44.2%)
Grade 1	-	54 (31.4%)
Grade 2	-	18 (10.5%)
Grade 3	-	4 (2.3%)
ICANS (clinically adjudicated) <sup>3</sup>	N/A	4 (2.3%)
Infections	26 (29.5%)	95 (55.2%)

<sup>1</sup> For rituximab and glofitamab, respectively; <sup>2</sup> No Grade 4 or 5 CRS events were reported; <sup>3</sup> Potential cases were identified using the ICANS adverse event group term (AEGT).  
ASTCT, American Society for Transplantation and Cellular Therapy grading criteria; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome

# A Comprehensive Assessment of the Safety Profile for Glofit-GemOx

Overview of Safety in STARGLO	R-GemOx (n=88)	Glofit-GemOx Glofit exposed (n=172)
<b>Median Number of Cycles<sup>1</sup></b> (range)	4 (1–8)	11 (1–13)
<b>Median duration of treatment</b> (days)	64 (1-183)	218 (1-296)
Grade 5 AEs	4 (4.5%)	12 (7.0%)
Fatal COVID-19 AE	0	3 (1.7%)
AE leading to withdrawal from glofitamab/rituximab	11 (12.5%)	36 (20.9%)
COVID-19 AE leading to discontinuation	5 (5.7%)	23 (13.4%)
Serious AEs	15 (17.0%)	90 (52.3%)
<b>Common Grade 3-4 AEs (&gt;10%)</b>		
Anemia	8 (9.1%)	29 (16.9%)
Neutropenia	16 (18.2%)	61 (35.5%)
Thrombocytopenia	15 (17.0%)	47 (27.3%)
<b>Known risks associated with glofitamab</b>		
CRS (ASTCT grading) <sup>2</sup>	0	76 (44.2%)
Grade 1	-	54 (31.4%)
Grade 2	-	18 (10.5%)
Grade 3	-	4 (2.3%)
ICANS (clinically adjudicated) <sup>3</sup>	N/A	4 (2.3%)
Infections	26 (29.5%)	95 (55.2%)

<sup>1</sup> For rituximab and glofitamab, respectively; <sup>2</sup> No Grade 4 or 5 CRS events were reported; <sup>3</sup> Potential cases were identified using the ICANS adverse event group term (AEGT).  
ASTCT, American Society for Transplantation and Cellular Therapy grading criteria; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome

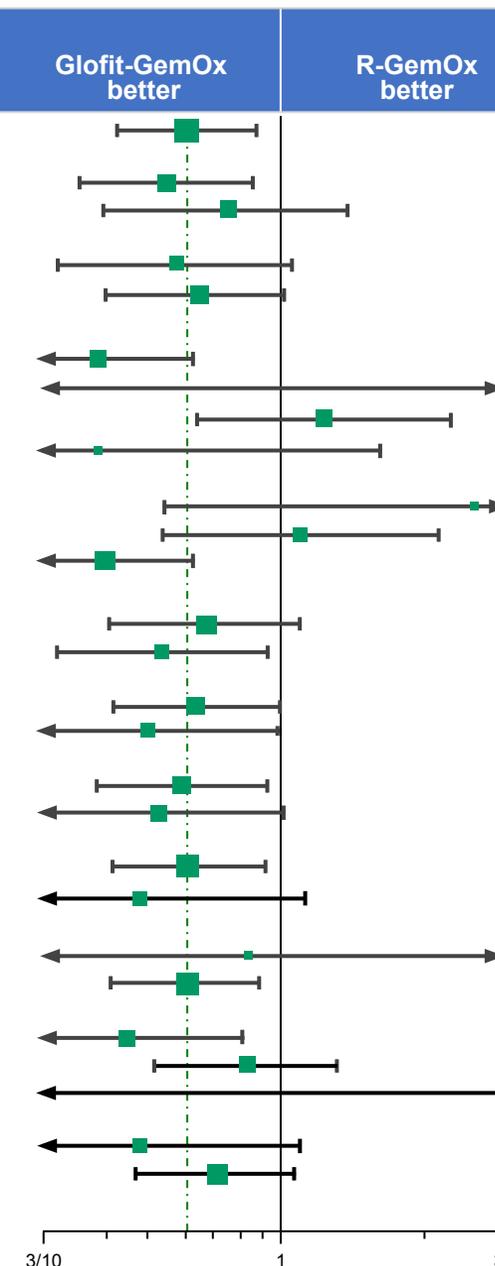
# A Comprehensive Assessment of the Safety Profile for Glofit-GemOx

Overview of Safety in STARGLO	R-GemOx (n=88)	Glofit-GemOx Glofit exposed (n=172)
<b>Median Number of Cycles<sup>1</sup></b> (range)	4 (1–8)	11 (1–13)
<b>Median duration of treatment</b> (days)	64 (1-183)	218 (1-296)
Grade 5 AEs	4 (4.5%)	12 (7.0%)
Fatal COVID-19 AE	0	3 (1.7%)
AE leading to withdrawal from glofitamab/rituximab	11 (12.5%)	36 (20.9%)
COVID-19 AE leading to discontinuation	5 (5.7%)	23 (13.4%)
Serious AEs	15 (17.0%)	90 (52.3%)
<b>Common Grade 3-4 AEs (&gt;10%)</b>		
Anemia	8 (9.1%)	29 (16.9%)
Neutropenia	16 (18.2%)	61 (35.5%)
Thrombocytopenia	15 (17.0%)	47 (27.3%)
<b>Known risks associated with glofitamab</b>		
CRS (ASTCT grading) <sup>2</sup>	0	76 (44.2%)
Grade 1	-	54 (31.4%)
Grade 2	-	18 (10.5%)
Grade 3	-	4 (2.3%)
ICANS (clinically adjudicated) <sup>3</sup>	N/A	4 (2.3%)
<b>Infections</b>	<b>26 (29.5%)</b>	<b>95 (55.2%)</b>

<sup>1</sup> For rituximab and glofitamab, respectively; <sup>2</sup> No Grade 4 or 5 CRS events were reported; <sup>3</sup> Potential cases were identified using the ICANS adverse event group term (AEGT).  
ASTCT, American Society for Transplantation and Cellular Therapy grading criteria; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome

# Exploratory OS Subgroup Results were Consistent and Showed a Trend in Favor of Glofit-GemOx

Baseline Risk Factors	Total n	R-GemOx (n=91)			Glofit-GemOx (n=183)			HR	95% Wald CI	Glofit-GemOx better	R-GemOx better
		n	Events	Median (mos)	n	Events	Median (mos)				
<b>All Patients</b>	274	91	52	12.9	183	80	25.5	0.62	(0.44, 0.89)		
<b>Sex</b>											
Male	158	53	36	10.3	105	51	20.4	0.56	(0.37, 0.86)		
Female	116	38	16	20.2	78	29	NE	0.76	(0.41, 1.40)		
<b>Age group</b>											
<65	102	35	19	9.0	67	29	NE	0.59	(0.33, 1.06)		
≥65	172	56	33	14.3	116	51	22.9	0.65	(0.42, 1.01)		
<b>Race</b>											
Asian	137	51	35	8.2	86	36	NE	0.40	(0.25, 0.65)		
Black or African American	3	1	0	NE	2	1	NE	>999.99	(0.00, NE)		
White	115	33	13	27.8	82	39	18.3	1.24	(0.66, 2.33)		
Unknown	19	6	4	12.9	13	4	NE	0.40	(0.10, 1.61)		
<b>Enrollment by geographic region</b>											
North America	25	10	2	NE	15	8	13.3	2.62	(0.56, 12.34)		
Europe	88	26	11	13.8	62	29	21.2	1.09	(0.54, 2.18)		
Asia-Pacific	161	55	39	8.3	106	43	NE	0.41	(0.27, 0.64)		
<b>No. of previous lines of systemic therapy for DLBCL</b>											
1	172	57	28	15.7	115	44	NE	0.68	(0.42, 1.09)		
≥2	102	34	24	6.7	68	36	18.3	0.55	(0.33, 0.93)		
<b>Relapse or refractory to last line of therapy</b>											
Refractory	166	54	36	7.5	112	61	11.9	0.65	(0.43, 0.99)		
Relapsed	108	37	16	27.8	71	19	NE	0.51	(0.26, 0.98)		
<b>Primary refractory</b>											
Yes	153	47	34	7.3	106	59	10.2	0.60	(0.40, 0.92)		
No	121	44	18	27.8	77	21	NE	0.54	(0.29, 1.01)		
<b>Primary Refractory or Relapse within 12 mos after 1L therapy</b>											
Yes	197	63	42	8.2	134	69	14.4	0.62	(0.43, 0.92)		
No	77	28	10	NE	49	11	NE	0.47	(0.20, 1.12)		
<b>Prior CAR T-cell therapy</b>											
Yes	21	8	4	27.8	13	6	13.7	0.84	(0.23, 3.01)		
No	253	83	48	12.9	170	74	NE	0.62	(0.43, 0.89)		
<b>IPI score</b>											
(0–2)	131	41	20	18.5	90	28	NE	0.46	(0.26, 0.82)		
(3–5)	134	47	31	12.9	87	50	11.1	0.84	(0.53, 1.31)		
Unknown	9	3	1	0.6	6	2	NE	0.18	(0.01, 2.93)		
<b>Ann Arbor staging at study entry</b>											
Stage I/II	80	20	9	18.5	60	20	NE	0.49	(0.22, 1.08)		
Stage III/IV	193	70	43	12.9	123	60	21.2	0.72	(0.49, 1.07)		
Unknown	1	1	0	NE				NE	NE		

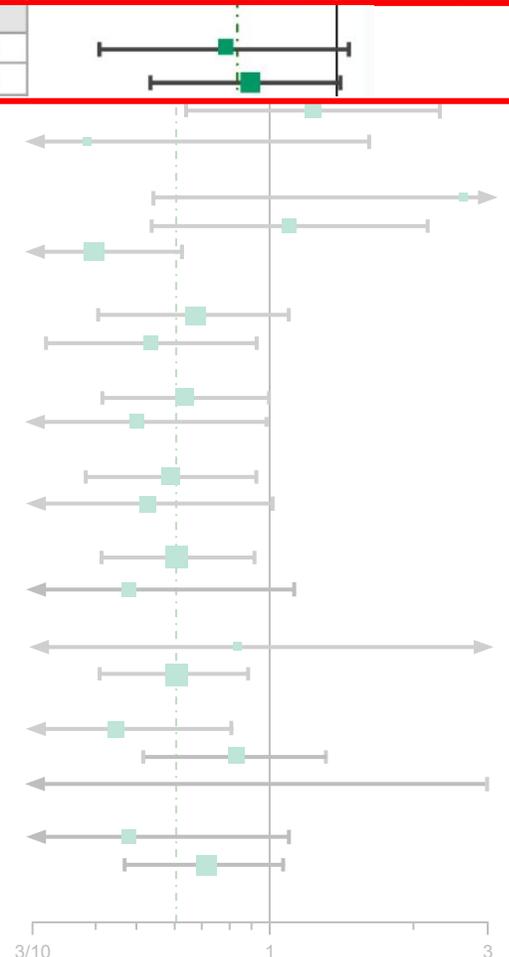


# Consistent Benefit Across Age

Baseline Risk Factors	Total n	R-GemOx (n=91)			Glofit-GemOx (n=183)			HR	95% Wald CI	Glofit-GemOx better	R-GemOx better
		n	Events	Median (mos)	n	Events	Median (mos)				
All Patients	274	91	52	12.9	183	80	25.5	0.62	(0.44, 0.89)		
Sex											

Baseline Risk Factors	Total n	R-GemOx (n=91)			Glofit-GemOx (n=183)			HR	95% Wald CI	Glofit-GemOx better	R-GemOx better
		n	Events	Median (mos)	n	Events	Median (mos)				
<b>Age group</b>											
<65	102	35	19	9.0	67	29	NE	0.59	(0.33, 1.06)		
≥65	172	56	33	14.3	116	51	22.9	0.65	(0.42, 1.01)		

White	115	33	13	27.8	82	39	18.3	1.24	(0.66, 2.33)	
Unknown	19	6	4	12.9	13	4	NE	0.40	(0.10, 1.61)	
<b>Enrollment by geographic region</b>										
North America	25	10	2	NE	15	8	13.3	2.62	(0.56, 12.34)	
Europe	88	26	11	13.8	62	29	21.2	1.09	(0.54, 2.18)	
Asia-Pacific	161	55	39	8.3	106	43	NE	0.41	(0.27, 0.64)	
<b>No. of previous lines of systemic therapy for DLBCL</b>										
1	172	57	28	15.7	115	44	NE	0.68	(0.42, 1.09)	
≥2	102	34	24	6.7	68	36	18.3	0.55	(0.33, 0.93)	
<b>Relapse or refractory to last line of therapy</b>										
Refractory	166	54	36	7.5	112	61	11.9	0.65	(0.43, 0.99)	
Relapsed	108	37	16	27.8	71	19	NE	0.51	(0.26, 0.98)	
<b>Primary refractory</b>										
Yes	153	47	34	7.3	106	59	10.2	0.60	(0.40, 0.92)	
No	121	44	18	27.8	77	21	NE	0.54	(0.29, 1.01)	
<b>Primary Refractory or Relapse within 12 mos after 1L therapy</b>										
Yes	197	63	42	8.2	134	69	14.4	0.62	(0.43, 0.92)	
No	77	28	10	NE	49	11	NE	0.47	(0.20, 1.12)	
<b>Prior CAR T-cell therapy</b>										
Yes	21	8	4	27.8	13	6	13.7	0.84	(0.23, 3.01)	
No	253	83	48	12.9	170	74	NE	0.62	(0.43, 0.89)	
<b>IPI score</b>										
(0-2)	131	41	20	18.5	90	28	NE	0.46	(0.26, 0.82)	
(3-5)	134	47	31	12.9	87	50	11.1	0.84	(0.53, 1.31)	
Unknown	9	3	1	0.6	6	2	NE	0.18	(0.01, 2.93)	
<b>Ann Arbor staging at study entry</b>										
Stage I/II	80	20	9	18.5	60	20	NE	0.49	(0.22, 1.08)	
Stage III/IV	193	70	43	12.9	123	60	21.2	0.72	(0.49, 1.07)	
Unknown	1	1	0	NE				NE	NE	



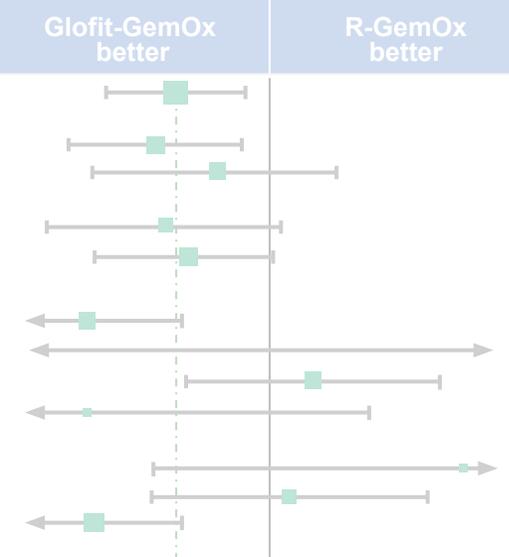
# Consistent Benefit Across Clinically Significant Prognostic Stratification Factors

Baseline Risk Factors	Total n	R-GemOx (n=91)			Glofit-GemOx (n=183)			HR	95% Wald CI	Glofit-GemOx better	R-GemOx better
		n	Events	Median (mos)	n	Events	Median (mos)				
<b>All Patients</b>	274	91	52	12.9	183	80	25.5	0.62	(0.44, 0.89)		
<b>Sex</b>											
Male	158	53	36	10.3	105	51	20.4	0.56	(0.37, 0.86)		
Female	116	38	16	20.2	78	29	NE	0.76	(0.41, 1.40)		
<b>Age group</b>											
<65	102	35	19	9.0	67	29	NE	0.59	(0.33, 1.06)		
≥65	172	56	33	14.3	116	51	22.9	0.65	(0.42, 1.01)		
<b>Race</b>											
Asian	137	51	35	8.2	86	36	NE	0.40	(0.25, 0.65)		
Black or African American	3	1	0	NE	2	1	NE	>999.99	(0.00, NE)		
White	115	33	13	27.8	82	39	18.3	1.24	(0.66, 2.33)		
Unknown	19	6	4	12.9	13	4	NE	0.40	(0.10, 1.61)		

Baseline Risk Factors	Total n	R-GemOx (n=91)			Glofit-GemOx (n=183)			HR	95% Wald CI	Glofit-GemOx better	R-GemOx better
		n	Events	Median (mos)	n	Events	Median (mos)				
<b>No. of previous lines of systemic therapy for DLBCL</b>											
1	172	57	28	15.7	115	44	NE	0.68	(0.42, 1.09)		
≥2	102	34	24	6.7	68	36	18.3	0.55	(0.33, 0.93)		
<b>Relapse or refractory to last line of therapy</b>											
Refractory	166	54	36	7.5	112	61	11.9	0.65	(0.43, 0.99)		
Relapsed	108	37	16	27.8	71	19	NE	0.51	(0.26, 0.98)		
<b>Primary Refractory or Relapse within 12 mos after 1L therapy</b>											
Yes	197	63	42	8.2	134	69	14.4	0.62	(0.43, 0.92)		
No	77	28	10	NE	49	11	NE	0.47	(0.20, 1.12)		
<b>Prior CAR T-cell therapy</b>											
Yes	21	8	4	27.8	13	6	13.7	0.84	(0.23, 3.01)		
No	253	83	48	12.9	170	74	NE	0.62	(0.43, 0.89)		
<b>IPI score</b>											
(0-2)	131	41	20	18.5	90	28	NE	0.46	(0.26, 0.82)		
(3-5)	134	47	31	12.9	87	50	11.1	0.84	(0.53, 1.31)		
Unknown	9	3	1	0.6	6	2	NE	0.18	(0.01, 2.93)		
<b>Ann Arbor staging at study entry</b>											
Stage I/II	80	20	9	18.5	60	20	NE	0.49	(0.22, 1.08)		
Stage III/IV	193	70	43	12.9	123	60	21.2	0.72	(0.49, 1.07)		
Unknown	1	1	0	NE				NE	NE		

# Consistent Benefit in Relapsed and Primary Refractory Patients

Baseline Risk Factors	Total n	R-GemOx (n=91)			Glofit-GemOx (n=183)			HR	95% Wald CI	Glofit-GemOx better	R-GemOx better
		n	Events	Median (mos)	n	Events	Median (mos)				
<b>All Patients</b>	274	91	52	12.9	183	80	25.5	0.62	(0.44, 0.89)		
<b>Sex</b>											
Male	158	53	36	10.3	105	51	20.4	0.56	(0.37, 0.86)		
Female	116	38	16	20.2	78	29	NE	0.76	(0.41, 1.40)		
<b>Age group</b>											
<65	102	35	19	9.0	67	29	NE	0.59	(0.33, 1.06)		
≥65	172	56	33	14.3	116	51	22.9	0.65	(0.42, 1.01)		
<b>Race</b>											
Asian	137	51	35	8.2	86	36	NE	0.40	(0.25, 0.65)		
Black or African American	3	1	0	NE	2	1	NE	>999.99	(0.00, NE)		
White	115	33	13	27.8	82	39	18.3	1.24	(0.66, 2.33)		
Unknown	19	6	4	12.9	13	4	NE	0.40	(0.10, 1.61)		
<b>Enrollment by geographic region</b>											
North America	25	10	2	NE	15	8	13.3	2.62	(0.56, 12.34)		
Europe	88	26	11	13.8	62	29	21.2	1.09	(0.54, 2.18)		
Asia-Pacific	161	55	39	8.3	106	43	NE	0.41	(0.27, 0.64)		
<b>No. of previous lines of systemic therapy for DLBCL</b>											



Baseline Risk Factors	Total n	R-GemOx (n=91)			Glofit-GemOx (n=183)			HR	95% Wald CI	Glofit-GemOx better	R-GemOx better
		n	Events	Median (mos)	n	Events	Median (mos)				
<b>Primary refractory</b>											
Yes	153	47	34	7.3	106	59	10.2	0.60	(0.40, 0.92)		
No	121	44	18	27.8	77	21	NE	0.54	(0.29, 1.01)		
Yes	197	63	42	8.2	134	69	14.4	0.62	(0.43, 0.92)		
No	77	28	10	NE	49	11	NE	0.47	(0.20, 1.12)		
<b>Prior CAR T-cell therapy</b>											
Yes	21	8	4	27.8	13	6	13.7	0.84	(0.23, 3.01)		
No	253	83	48	12.9	170	74	NE	0.62	(0.43, 0.89)		
<b>IPI score</b>											
(0-2)	131	41	20	18.5	90	28	NE	0.46	(0.26, 0.82)		
(3-5)	134	47	31	12.9	87	50	11.1	0.84	(0.53, 1.31)		
Unknown	9	3	1	0.6	6	2	NE	0.18	(0.01, 2.93)		
<b>Ann Arbor staging at study entry</b>											
Stage I/II	80	20	9	18.5	60	20	NE	0.49	(0.22, 1.08)		
Stage III/IV	193	70	43	12.9	123	60	21.2	0.72	(0.49, 1.07)		
Unknown	1	1	0	NE				NE	NE		



# Directional Inconsistencies by Race and Geographical Region

Baseline Risk Factors	Total n	R-GemOx (n=91)			Glofit-GemOx (n=183)			HR	95% Wald CI	Glofit-GemOx better	R-GemOx better
		n	Events	Median (mos)	n	Events	Median (mos)				
All Patients	274	91	52	12.9	183	80	25.5	0.62	(0.44, 0.89)		
<b>Sex</b>											
Male	158	53	36	10.3	105	51	20.4	0.56	(0.37, 0.86)		
Female	116	38	16	20.2	78	29	NE	0.76	(0.41, 1.40)		
<b>Age group</b>											
<65	102	35	19	9.0	67	29	NE	0.59	(0.33, 1.06)		
>65	172	56	33	14.3	116	51	22.0	0.65	(0.42, 1.01)		

Baseline Risk Factors	Total n	R-GemOx (n=91)			Glofit-GemOx (n=183)			HR	95% Wald CI	Glofit-GemOx better	R-GemOx better
		n	Events	Median (mos)	n	Events	Median (mos)				
<b>Race</b>											
Asian	137	51	35	8.2	86	36	NE	0.40	(0.25, 0.65)		
Black or African American	3	1	0	NE	2	1	NE	>999.99	(0.00, NE)		
White	115	33	13	27.8	82	39	18.3	1.24	(0.66, 2.33)		
Unknown	19	6	4	12.9	13	4	NE	0.40	(0.10, 1.61)		
<b>Enrollment by geographic region</b>											
North America	25	10	2	NE	15	8	13.3	2.62	(0.56, 12.34)		
Europe	88	26	11	13.8	62	29	21.2	1.09	(0.54, 2.18)		
Asia-Pacific	161	55	39	8.3	106	43	NE	0.41	(0.27, 0.64)		

<b>Primary refractory</b>											
Yes	153	47	34	7.3	106	59	10.2	0.60	(0.40, 0.92)		
No	121	44	18	27.8	77	21	NE	0.54	(0.29, 1.01)		
<b>Primary Refractory or Relapse within 12 mos after 1L therapy</b>											
Yes	197	63	42	8.2	134	69	14.4	0.62	(0.43, 0.92)		
No	77	28	10	NE	49	11	NE	0.47	(0.20, 1.12)		
<b>Prior CAR T-cell therapy</b>											
Yes	21	8	4	27.8	13	6	13.7	0.84	(0.23, 3.01)		
No	253	83	48	12.9	170	74	NE	0.62	(0.43, 0.89)		
<b>IPI score</b>											
(0-2)	131	41	20	18.5	90	28	NE	0.46	(0.26, 0.82)		
(3-5)	134	47	31	12.9	87	50	11.1	0.84	(0.53, 1.31)		
Unknown	9	3	1	0.6	6	2	NE	0.18	(0.01, 2.93)		
<b>Ann Arbor staging at study entry</b>											
Stage I/II	80	20	9	18.5	60	20	NE	0.49	(0.22, 1.08)		
Stage III/IV	193	70	43	12.9	123	60	21.2	0.72	(0.49, 1.07)		
Unknown	1	1	0	NE				NE	NE		

# Efficacy by Pre-specified Region

	North America (N=25)		Europe (N=88)		Asia-Pacific (N=161)		ITT (N=274)	
	R-GemOx N = 10	Glofit-GemOx N = 15	R-GemOx N = 26	Glofit-GemOx N = 62	R-GemOx N = 55	Glofit-GemOx N = 106	R-GemOx N = 91	Glofit-GemOx N = 183
<b>OS</b>								
Median, months	NR	13.3	13.8	21.2	8.3	NR	12.9	25.5
95% CI	(7.5, NE)	(5.2, NE)	(11.1, NE)	(10.5, NE)	(5.5, 14.5)	(20.4, NE)	(7.9, 18.5)	(18.3, NE)
HR (95% CI)	<b>2.62 (0.56, 12.34)</b>		<b>1.09 (0.54, 2.18)</b>		<b>0.41 (0.27, 0.64)</b>		<b>0.62 (0.43, 0.88)</b>	
<b>IRC-assessed PFS</b>								
Median, months	27.1	7.5	7.8	9.2	2.5	20.5	3.6	13.8
95% CI	(3.3, NE)	(2.5, NE)	(2.6, NE)	(6.1, 17.0)	(1.5, 5.2)	(9.3, NE)	(2.5, 7.1)	(8.7, 20.5)
HR (95% CI)	<b>2.25 (0.48, 10.54)</b>		<b>0.84 (0.44, 1.59)</b>		<b>0.27 (0.17, 0.42)</b>		<b>0.40 (0.28, 0.57)</b>	
<b>IRC-assessed CR</b>								
CRR	40.0%	40.0%	34.6%	58.1%	18.2%	61.3%	25.3%	58.5%
95% CI (%)	(12.2, 73.8)	(16.3, 67.7)	(17.2, 55.7)	(44.9, 70.5)	(9.1, 30.9)	(51.4, 70.6)	(16.8, 35.5)	(51.0, 65.7)
Difference	<b>0%</b>		<b>23.5%</b>		<b>43.1%</b>		<b>33.2%</b>	

# Efficacy by Pre-specified Region: **Asia-Pacific**

	North America (N=25)		Europe (N=88)		Asia-Pacific (N=161)		ITT (N=274)	
	R-GemOx N = 10	Glofit-GemOx N = 15	R-GemOx N = 26	Glofit-GemOx N = 62	R-GemOx N = 55	Glofit-GemOx N = 106	R-GemOx N = 91	Glofit-GemOx N = 183
<b>OS</b> Median, months 95% CI	NR (7.5, NE)	13.3 (5.2, NE)	13.8 (11.1, NE)	21.2 (10.5, NE)	8.3 (5.5, 14.5)	NR (20.4, NE)	12.9 (7.9, 18.5)	25.5 (18.3, NE)
HR (95% CI)	<b>2.62 (0.56, 12.34)</b>		<b>1.09 (0.54, 2.18)</b>		<b>0.41 (0.27, 0.64)</b>		<b>0.62 (0.43, 0.88)</b>	
<b>IRC-assessed PFS</b> Median, months 95% CI	27.1 (3.3, NE)	7.5 (2.5, NE)	7.8 (2.6, NE)	9.2 (6.1, 17.0)	2.5 (1.5, 5.2)	20.5 (9.3, NE)	3.6 (2.5, 7.1)	13.8 (8.7, 20.5)
HR (95% CI)	<b>2.25 (0.48, 10.54)</b>		<b>0.84 (0.44, 1.59)</b>		<b>0.27 (0.17, 0.42)</b>		<b>0.40 (0.28, 0.57)</b>	
<b>IRC-assessed CR</b> CRR 95% CI (%)	40.0% (12.2, 73.8)	40.0% (16.3, 67.7)	34.6% (17.2, 55.7)	58.1% (44.9, 70.5)	18.2% (9.1, 30.9)	61.3% (51.4, 70.6)	25.3% (16.8, 35.5)	58.5% (51.0, 65.7)
Difference	<b>0%</b>		<b>23.5%</b>		<b>43.1%</b>		<b>33.2%</b>	

# Efficacy by Pre-specified Region: **Europe**

	North America (N=25)		Europe (N=88)		Asia-Pacific (N=161)		ITT (N=274)	
	R-GemOx N = 10	Glofit-GemOx N = 15	R-GemOx N = 26	Glofit-GemOx N = 62	R-GemOx N = 55	Glofit-GemOx N = 106	R-GemOx N = 91	Glofit-GemOx N = 183
<b>OS</b> Median, months 95% CI	NR (7.5, NE)	13.3 (5.2, NE)	13.8 (11.1, NE)	21.2 (10.5, NE)	8.3 (5.5, 14.5)	NR (20.4, NE)	12.9 (7.9, 18.5)	25.5 (18.3, NE)
HR (95% CI)	<b>2.62 (0.56, 12.34)</b>		<b>1.09 (0.54, 2.18)</b>		<b>0.41 (0.27, 0.64)</b>		<b>0.62 (0.43, 0.88)</b>	
<b>IRC-assessed PFS</b> Median, months 95% CI	27.1 (3.3, NE)	7.5 (2.5, NE)	7.8 (2.6, NE)	9.2 (6.1, 17.0)	2.5 (1.5, 5.2)	20.5 (9.3, NE)	3.6 (2.5, 7.1)	13.8 (8.7, 20.5)
HR (95% CI)	<b>2.25 (0.48, 10.54)</b>		<b>0.84 (0.44, 1.59)</b>		<b>0.27 (0.17, 0.42)</b>		<b>0.40 (0.28, 0.57)</b>	
<b>IRC-assessed CR</b> CRR 95% CI (%)	40.0% (12.2, 73.8)	40.0% (16.3, 67.7)	34.6% (17.2, 55.7)	58.1% (44.9, 70.5)	18.2% (9.1, 30.9)	61.3% (51.4, 70.6)	25.3% (16.8, 35.5)	58.5% (51.0, 65.7)
Difference	<b>0%</b>		<b>23.5%</b>		<b>43.1%</b>		<b>33.2%</b>	

# Efficacy by Pre-specified Region: North America

	North America (N=25)		Europe (N=88)		Asia-Pacific (N=161)		ITT (N=274)	
	R-GemOx N = 10	Glofit-GemOx N = 15	R-GemOx N = 26	Glofit-GemOx N = 62	R-GemOx N = 55	Glofit-GemOx N = 106	R-GemOx N = 91	Glofit-GemOx N = 183
<b>OS</b> Median, months 95% CI	NR (7.5, NE)	13.3 (5.2, NE)	13.8 (11.1, NE)	21.2 (10.5, NE)	8.3 (5.5, 14.5)	NR (20.4, NE)	12.9 (7.9, 18.5)	25.5 (18.3, NE)
HR (95% CI)	<b>2.62 (0.56, 12.34)</b>		<b>1.09 (0.54, 2.18)</b>		<b>0.41 (0.27, 0.64)</b>		<b>0.62 (0.43, 0.88)</b>	
<b>IRC-assessed PFS</b> Median, months 95% CI	27.1 (3.3, NE)	7.5 (2.5, NE)	7.8 (2.6, NE)	9.2 (6.1, 17.0)	2.5 (1.5, 5.2)	20.5 (9.3, NE)	3.6 (2.5, 7.1)	13.8 (8.7, 20.5)
HR (95% CI)	<b>2.25 (0.48, 10.54)</b>		<b>0.84 (0.44, 1.59)</b>		<b>0.27 (0.17, 0.42)</b>		<b>0.40 (0.28, 0.57)</b>	
<b>IRC-assessed CR</b> CRR 95% CI (%)	40.0% (12.2, 73.8)	40.0% (16.3, 67.7)	34.6% (17.2, 55.7)	58.1% (44.9, 70.5)	18.2% (9.1, 30.9)	61.3% (51.4, 70.6)	25.3% (16.8, 35.5)	58.5% (51.0, 65.7)
Difference	<b>0%</b>		<b>23.5%</b>		<b>43.1%</b>		<b>33.2%</b>	

# Comprehensive Investigation of Regional Subgroups

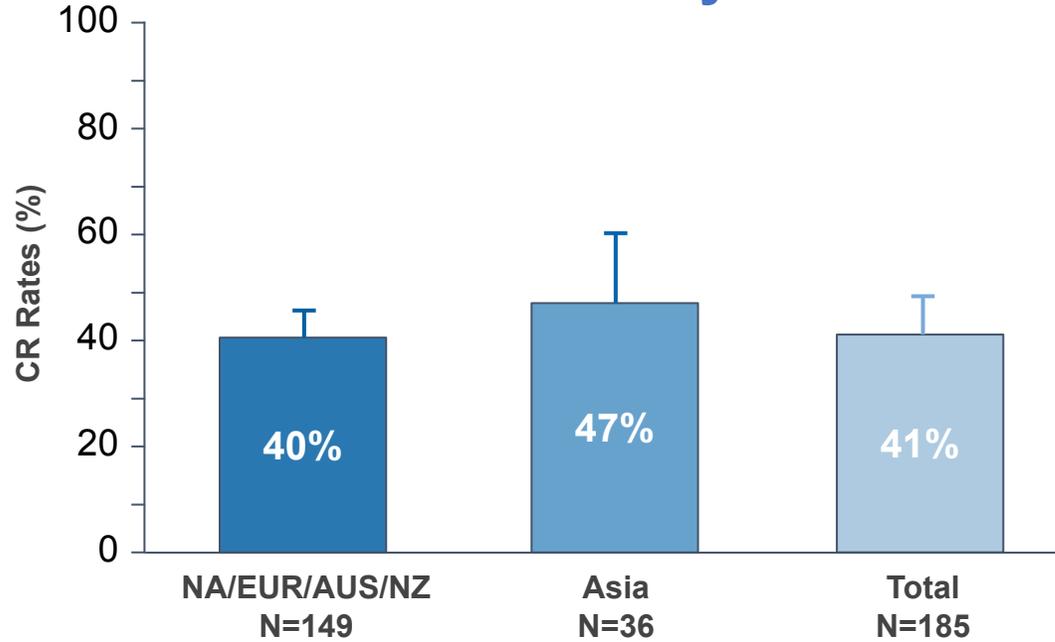
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## Investigations

- Prior knowledge of Glofitamab activity
  - Efficacy
  - Clinical pharmacology
- Baseline characteristics in the STARGLO study

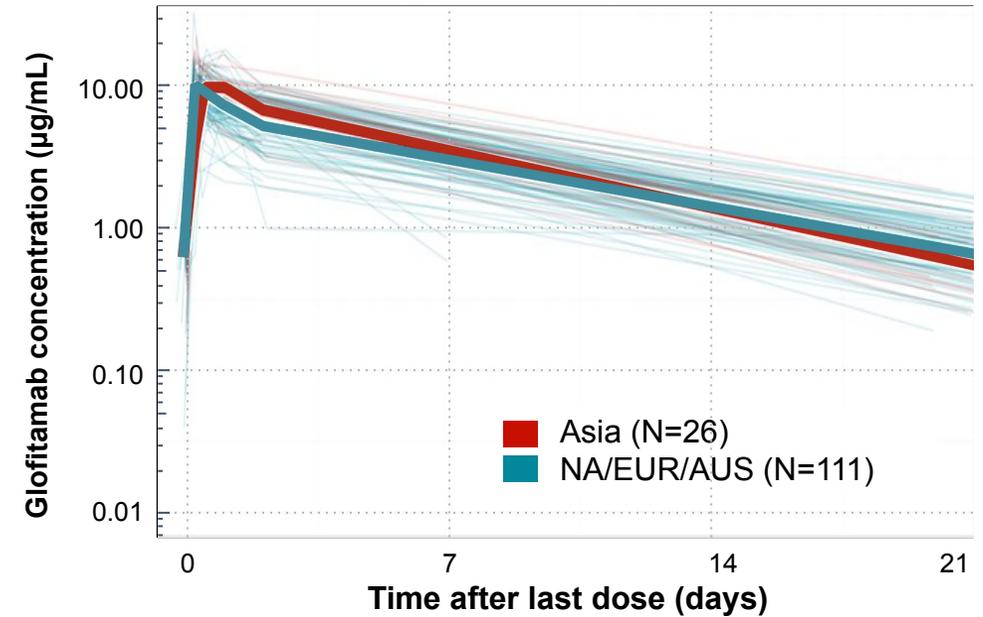
# No Regional Differences Observed in Efficacy or PK with Glofitamab Monotherapy

## Efficacy



- Comparable efficacy/CR rates between regions

## Clinical Pharmacokinetics



- Comparable Glofitamab concentrations and PK profiles between regions in the monotherapy studies

**Similar to monotherapy, Glofitamab PK was also consistent across regions in the STARGLO study**

# Imbalances in High-Risk Disease Characteristics Observed in North America Subgroup

	North America (N=25)		Europe (N=88)		Asia-Pacific (N=161)	
	R-GemOx (N=10)	Glofit-GemOx (N=15)	R-GemOx (N=26)	Glofit-GemOx (N=62)	R-GemOx (N=55)	Glofit-GemOx (N=106)
<b>Age ≥65 yrs, n (%)</b>	7 (70.0)	13 (86.7)	18 (69.2)	48 (77.4)	31 (56.4)	55 (51.9)
<b>Male, n (%)</b>	5 (50.0)	11 (73.3)	18 (69.2)	35 (56.5)	30 (54.5)	59 (55.7)
<b>≥2 prior lines of therapy, n (%)</b>	4 (40.0)	6 (40.0)	8 (30.8)	21 (33.9)	22 (40.0)	41 (38.7)
<b>Refractory to last line of therapy, n (%)</b>	5 (50.0)	11 (73.3)	14 (53.8)	32 (51.6)	35 (63.6)	69 (65.1)
<b>Primary refractory disease, n (%)</b>	4 (40.0)	12 (80.0)	13 (50.0)	31 (50.0)	30 (54.5)	63 (59.4)
<b>Primary refractory or early relapse, n (%)</b>	5 (50.0)	12 (80.0)	14 (53.8)	33 (53.2)	33 (60.0)	67 (63.2)
<b>IPI score 3-5 (Derived), n (%)</b>	5 (50.0)	10 (66.7)	13 (50.0)	30 (48.4)	29 (52.7)	47 (44.3)
<b>Ann Arbor stage III-IV, n (%)</b>	6 (60.0)	12 (80.0)	20 (76.9)	46 (74.2)	44 (80.0)	65 (61.3)
<b>Bulky disease (≥ 10cm), n (%)</b>	1 (10.0)	3 (20.0)	6 (23.1)	9 (14.5)	7 (12.7)	11 (10.4)

Primary refractory: no response, relapse ≤ 6mo.  
 Primary refractory or early relapse: no response, relapse ≤ 12mo.  
 IPI, International Prognostic Index.

# Imbalances in High-Risk Disease Characteristics Observed in North America Subgroup

	North America (N=25)		Europe (N=88)		Asia-Pacific (N=161)	
	R-GemOx (N=10)	Glofit-GemOx (N=15)	R-GemOx (N=26)	Glofit-GemOx (N=62)	R-GemOx (N=55)	Glofit-GemOx (N=106)
<b>Age ≥65 yrs, n (%)</b>	7 (70.0)	13 (86.7)	18 (69.2)	48 (77.4)	31 (56.4)	55 (51.9)
<b>Male, n (%)</b>	5 (50.0)	11 (73.3)	18 (69.2)	35 (56.5)	30 (54.5)	59 (55.7)
<b>≥2 prior lines of therapy, n (%)</b>	4 (40.0)	6 (40.0)	8 (30.8)	21 (33.9)	22 (40.0)	41 (38.7)
<b>Refractory to last line of therapy, n (%)</b>	5 (50.0)	11 (73.3)	14 (53.8)	32 (51.6)	35 (63.6)	69 (65.1)
<b>Primary refractory disease, n (%)</b>	4 (40.0)	12 (80.0)	13 (50.0)	31 (50.0)	30 (54.5)	63 (59.4)
Primary refractory or early relapse, n (%)			14 (53.8)	33 (53.2)	33 (60.0)	67 (63.2)
IPI score 3-5 (Derived), n (%)				30 (48.4)	29 (55.0)	47 (29.2)
Ann Arbor stage III-IV, n (%)				46 (74.2)	44 (80.0)	65 (61.3)
Bulky disease (≥ 10cm), n (%)				9 (14.5)	7 (12.7)	11 (10.4)
<b>Overall Deaths</b>						
Primary refractory						
Relapsed						

	R-GemOx N=10	Glofit-GemOx N=15
<b>Overall Deaths</b>	<b>2</b>	<b>8</b>
Primary refractory	2 (100%)	8 (100%)
Relapsed	0	0

# STARGLO Subgroup Analysis

Venkat Sethuraman, PhD  
Senior Vice President  
Global Head of Data Science and Analytics  
Genentech

# Comprehensive Investigation of Larger Regional Subgroups

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## Investigations of STARGLO data

- Baseline characteristics
- Performance of treatment and control arms
- New Anti-Lymphoma Therapy (NALT)

# Baseline Characteristics More Balanced in Two Subgroups

Residual imbalances may still confound comparisons

	NA/EUR/AUS (N=143)		Asia (N=131)		ITT (N=274)	
	R-GemOx N=44	Glofit-GemOx N=99	R-GemOx N=47	Glofit-GemOx N=84	R-GemOx N=91	Glofit-GemOx N=183
<b>Age ≥ 65 yrs, n (%)</b>	31 (70.5)	82 (82.8)	25 (53.2)	34 (40.5)	56 (61.5)	116 (63.4)
<b>Male, n (%)</b>	27 (61.4)	59 (59.6)	26 (55.3)	46 (54.8)	53 (58.2)	105 (57.4)
<b>≥ 2 prior lines of therapy, n (%)</b>	15 (34.1)	31 (31.3)	19 (40.4)	37 (44.0)	34 (37.4)	68 (37.2)
<b>Refractory to last line of therapy, n (%)</b>	24 (54.5)	56 (56.6)	30 (63.8)	56 (66.7)	54 (59.3)	112 (61.2)
<b>Primary refractory disease, n (%)</b>	21 (47.7)	55 (55.6)	26 (55.3)	51 (60.7)	47 (51.6)	106 (57.9)
<b>Primary refractory or early relapse, n (%)</b>	26 (59.1)	65 (65.7)	37 (78.7)	69 (82.1)	63 (69.2)	134 (73.2)
<b>IPI score 3-5, n (%)</b>	25 (56.8)	51 (51.5)	22 (46.8)	36 (42.9)	47 (51.6)	87 (47.5)
<b>Ann Arbor stage III-IV, n (%)</b>	34 (77.3)	72 (72.7)	36 (76.6)	51 (60.7)	70 (76.9)	123 (67.2)
<b>Bulky disease (≥ 10cm), n (%)</b>	9 (20.5)	15 (15.2)	5 (10.6)	8 (9.5)	14 (15.4)	23 (12.6)

IPI, International Prognostic Index.

Primary refractory: no response, relapse ≤ 6mo

Primary refractory or early relapse: no response, relapse ≤ 12mo

# Baseline Characteristics More Balanced in Two Subgroups

Residual imbalances may still confound comparisons

	NA/EUR/AUS (N=143)		Asia (N=131)		ITT (N=274)	
	R-GemOx N=44	Glofit-GemOx N=99	R-GemOx N=47	Glofit-GemOx N=84	R-GemOx N=91	Glofit-GemOx N=183
<b>Age ≥ 65 yrs, n (%)</b>	31 (70.5)	82 (82.8)	25 (53.2)	34 (40.5)	56 (61.5)	116 (63.4)
<b>Male, n (%)</b>	27 (61.4)	59 (59.6)	26 (55.3)	46 (54.8)	53 (58.2)	105 (57.4)
<b>≥ 2 prior lines of therapy, n (%)</b>	15 (34.1)	31 (31.3)	19 (40.4)	37 (44.0)	34 (37.4)	68 (37.2)
<b>Refractory to last line of therapy, n (%)</b>	24 (54.5)	56 (56.6)	30 (63.8)	56 (66.7)	54 (59.3)	112 (61.2)
<b>Primary refractory disease, n (%)</b>	21 (47.7)	55 (55.6)	26 (55.3)	51 (60.7)	47 (51.6)	106 (57.9)
<b>Primary refractory or early relapse, n (%)</b>	26 (59.1)	65 (65.7)	37 (78.7)	69 (82.1)	63 (69.2)	134 (73.2)
<b>IPI score 3-5, n (%)</b>	25 (56.8)	51 (51.5)	22 (46.8)	36 (42.9)	47 (51.6)	87 (47.5)
<b>Ann Arbor stage III-IV, n (%)</b>	34 (77.3)	72 (72.7)	36 (76.6)	51 (60.7)	70 (76.9)	123 (67.2)
<b>Bulky disease (≥ 10cm), n (%)</b>	9 (20.5)	15 (15.2)	5 (10.6)	8 (9.5)	14 (15.4)	23 (12.6)

IPI, International Prognostic Index.

Primary refractory: no response, relapse ≤ 6mo

Primary refractory or early relapse: no response, relapse ≤ 12mo

# Multivariable Analysis Shows Consistent Treatment Benefit of Glofit-GemOx After Adjusting for Factors Highlighted by FDA

## Factors highlighted by FDA

Age, race, ethnicity, cell of origin, prior CAR-T, refused transplant, refractory or relapsed within 12 months of 1L therapy

Overall Survival	Adjusted Hazard Ratio	95% CI	p-value
Glofit-GemOx vs. R-GemOx	0.59	(0.41, 0.86)	0.005

# Primary and Key Secondary Endpoints More Consistent with ITT

	NA/EUR/AUS (N=143)		Asia (N=131)		ITT (N=274)	
	R-GemOx N=44	Glofit-GemOx N=99	R-GemOx N=47	Glofit-GemOx N=84	R-GemOx N=91	Glofit-GemOx N=183
<b>OS</b>						
Median, months (95% CI)	27.8 (12.5, NE)	21.2 (11.9, NE)	8.2 (4.5, 14.3)	NR (19.2, NE)	12.9 (7.9, 18.5)	25.5 (18.3, NE)
HR (95% CI)	<b>1.06 (0.61, 1.84)</b>		<b>0.39 (0.25, 0.63)</b>		<b>0.62 (0.43, 0.88)</b>	
<b>IRC-assessed PFS</b>						
Median, months (95% CI)	7.8 (3.6, NE)	9.2 (6.4, 18.3)	2.0 (1.4, 2.7)	20.4 (9.3, NE)	3.6 (2.5, 7.1)	13.8 (8.7, 20.5)
HR (95% CI)	<b>0.81 (0.48, 1.35)</b>		<b>0.25 (0.15, 0.40)</b>		<b>0.40 (0.28, 0.57)</b>	
<b>IRC-assessed CR</b>						
CRR, % (95% CI)	34.1% (20.5, 49.9)	56.6% (46.2, 66.5)	17.0% (7.7, 30.8)	60.7% (49.5, 71.2)	25.3% (16.8, 35.5)	58.5% (51.0, 65.7)
Difference (95% CI)	<b>22.5% (3.8, 41.2)</b>		<b>43.7% (27.1, 60.3)</b>		<b>33.2% (20.9, 45.5)</b>	

# CR Rate and PFS Show Consistent Benefit in Favor of Glofit-GemOx Across Regions

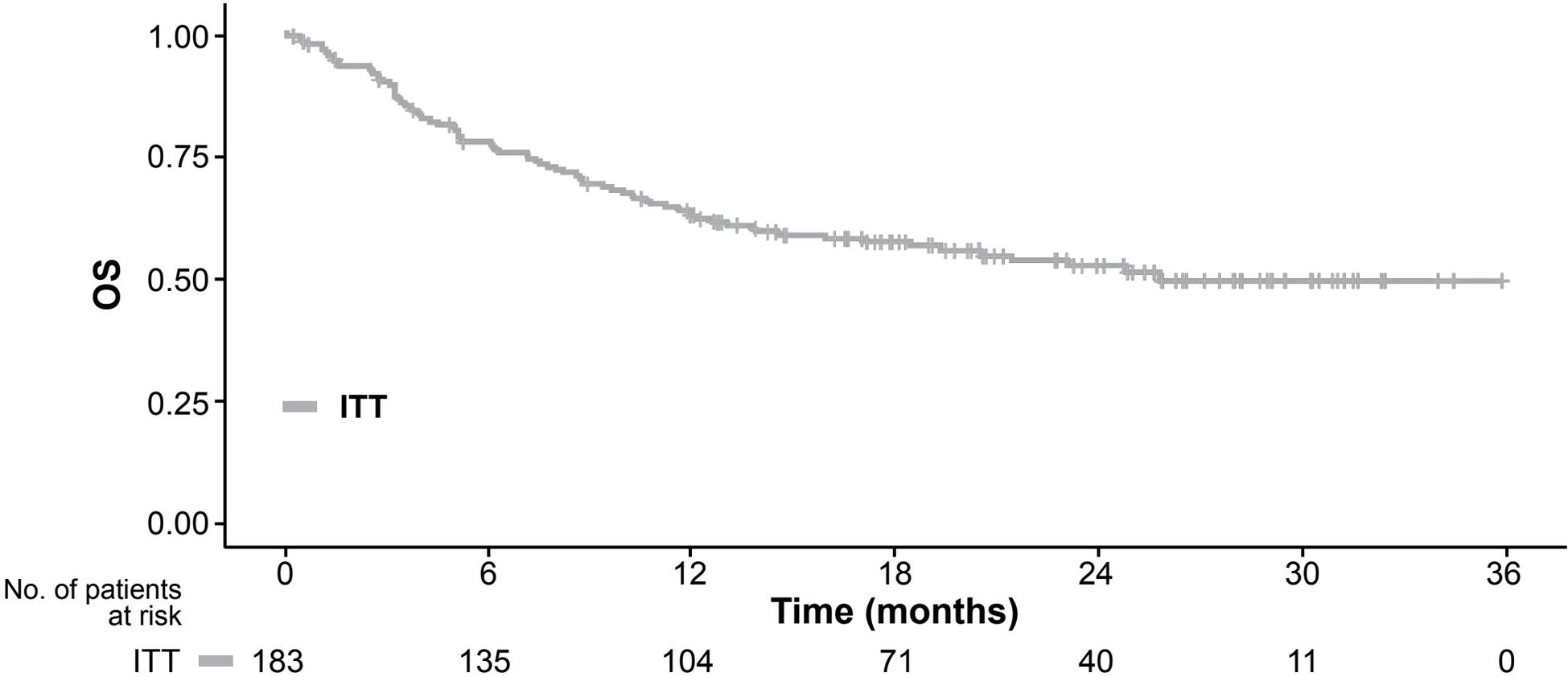
	NA/EUR/AUS (N=143)		Asia (N=131)		ITT (N=274)	
	R-GemOx N=44	Glofit-GemOx N=99	R-GemOx N=47	Glofit-GemOx N=84	R-GemOx N=91	Glofit-GemOx N=183
<b>OS</b>						
Median, months (95% CI)	27.8 (12.5, NE)	21.2 (11.9, NE)	8.2 (4.5, 14.3)	NR (19.2, NE)	12.9 (7.9, 18.5)	25.5 (18.3, NE)
HR (95% CI)	<b>1.06 (0.61, 1.84)</b>		<b>0.39 (0.25, 0.63)</b>		<b>0.62 (0.43, 0.88)</b>	
<b>IRC-assessed PFS</b>						
Median, months (95% CI)	7.8 (3.6, NE)	9.2 (6.4, 18.3)	2.0 (1.4, 2.7)	20.4 (9.3, NE)	3.6 (2.5, 7.1)	13.8 (8.7, 20.5)
HR (95% CI)	<b>0.81 (0.48, 1.35)</b>		<b>0.25 (0.15, 0.40)</b>		<b>0.40 (0.28, 0.57)</b>	
<b>IRC-assessed CR</b>						
CRR, % (95% CI)	34.1% (20.5, 49.9)	56.6% (46.2, 66.5)	17.0% (7.7, 30.8)	60.7% (49.5, 71.2)	25.3% (16.8, 35.5)	58.5% (51.0, 65.7)
Difference (95% CI)	<b>22.5% (3.8, 41.2)</b>		<b>43.7% (27.1, 60.3)</b>		<b>33.2% (20.9, 45.5)</b>	

# Observed OS HR in NA/EUR/AUS Warrants

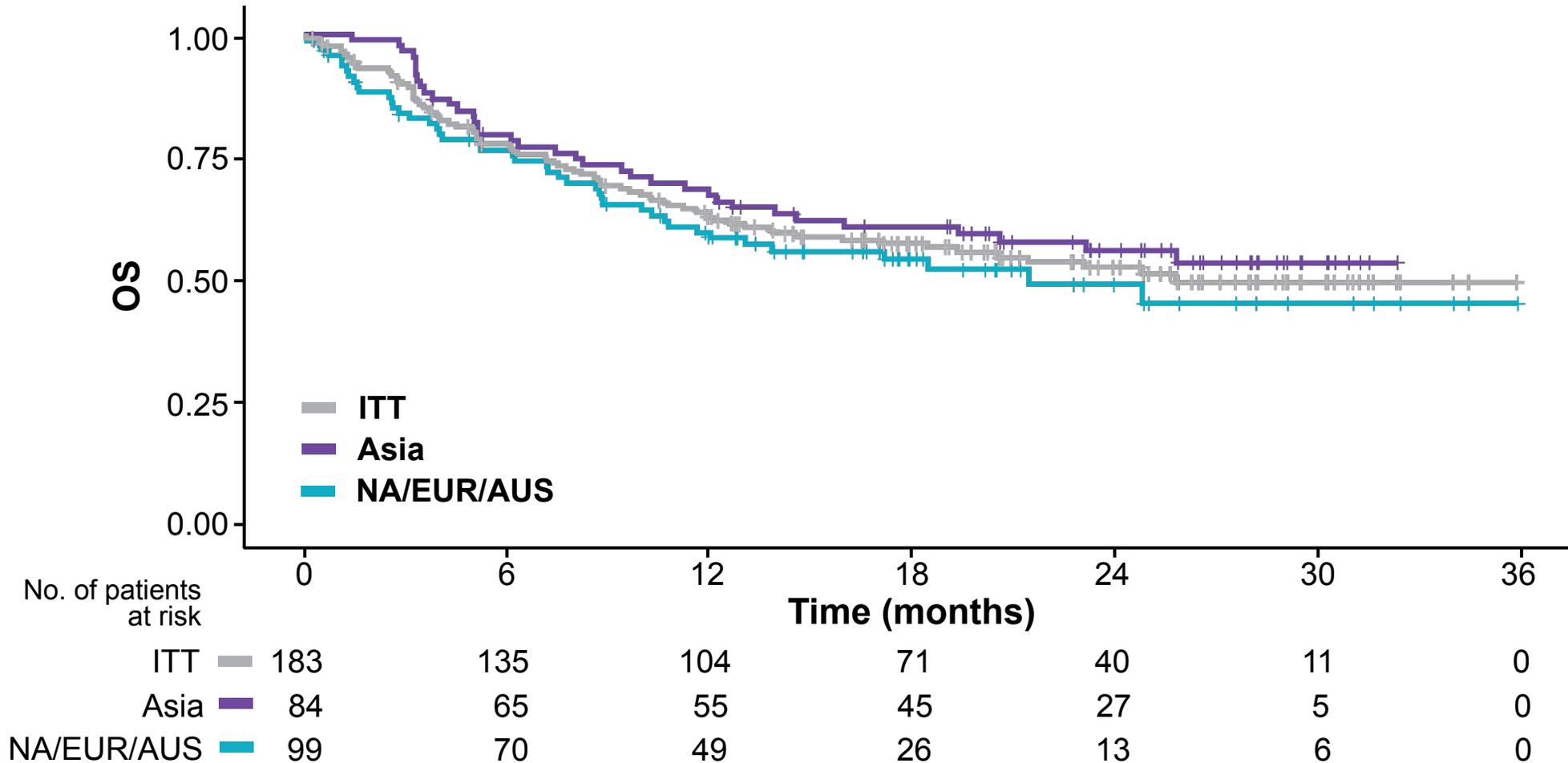
## Further Investigation

	NA/EUR/AUS (N=143)		Asia (N=131)		ITT (N=274)	
	R-GemOx N=44	Glofit-GemOx N=99	R-GemOx N=47	Glofit-GemOx N=84	R-GemOx N=91	Glofit-GemOx N=183
<b>OS</b>						
Median, months (95% CI)	27.8 (12.5, NE)	21.2 (11.9, NE)	8.2 (4.5, 14.3)	NR (19.2, NE)	12.9 (7.9, 18.5)	25.5 (18.3, NE)
HR (95% CI)	<b>1.06 (0.61, 1.84)</b>		<b>0.39 (0.25, 0.63)</b>		<b>0.62 (0.43, 0.88)</b>	
<b>IRC-assessed PFS</b>						
Median, months (95% CI)	7.8 (3.6, NE)	9.2 (6.4, 18.3)	2.0 (1.4, 2.7)	20.4 (9.3, NE)	3.6 (2.5, 7.1)	13.8 (8.7, 20.5)
HR (95% CI)	<b>0.81 (0.48, 1.35)</b>		<b>0.25 (0.15, 0.40)</b>		<b>0.40 (0.28, 0.57)</b>	
<b>IRC-assessed CR</b>						
CRR, % (95% CI)	34.1% (20.5, 49.9)	56.6% (46.2, 66.5)	17.0% (7.7, 30.8)	60.7% (49.5, 71.2)	25.3% (16.8, 35.5)	58.5% (51.0, 65.7)
Difference (95% CI)	<b>22.5% (3.8, 41.2)</b>		<b>43.7% (27.1, 60.3)</b>		<b>33.2% (20.9, 45.5)</b>	

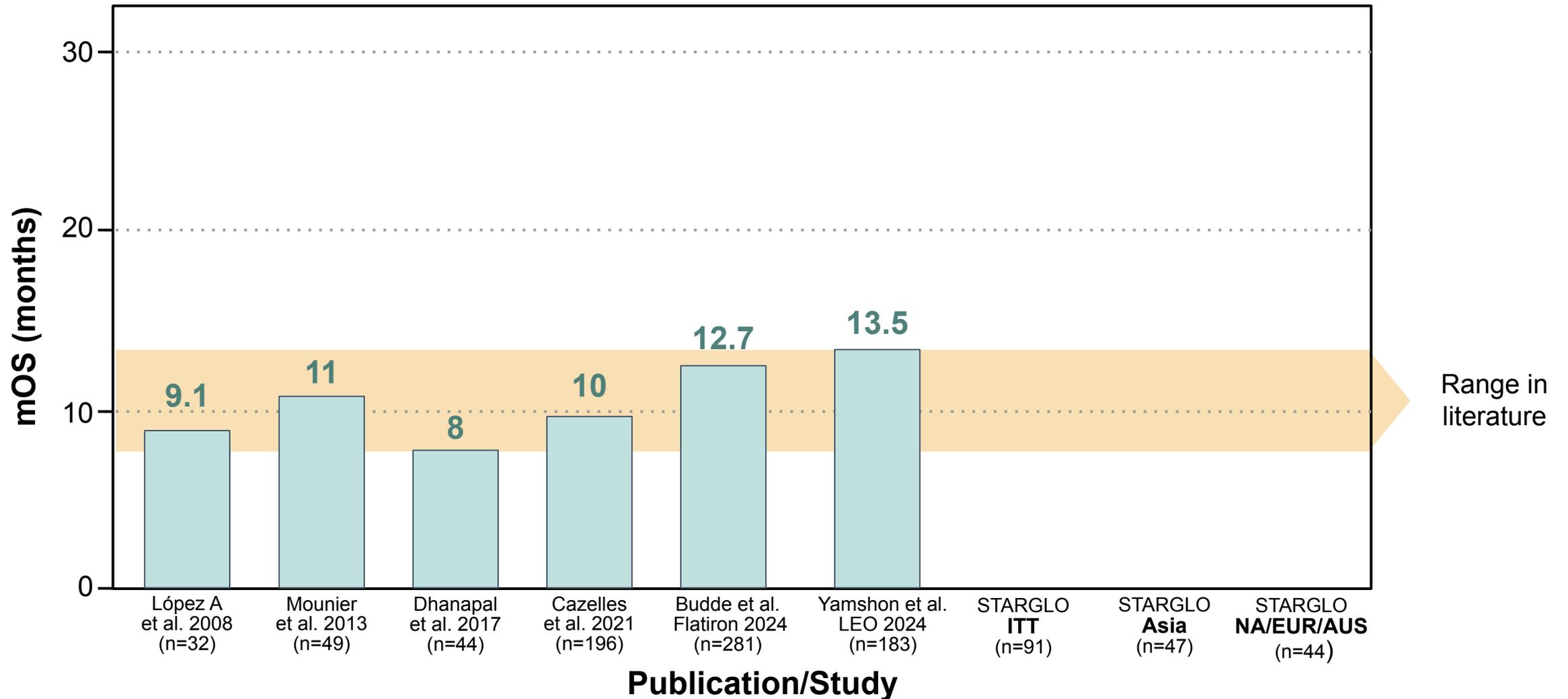
# Observed Consistency in OS of Glofit-GemOx Across Regions



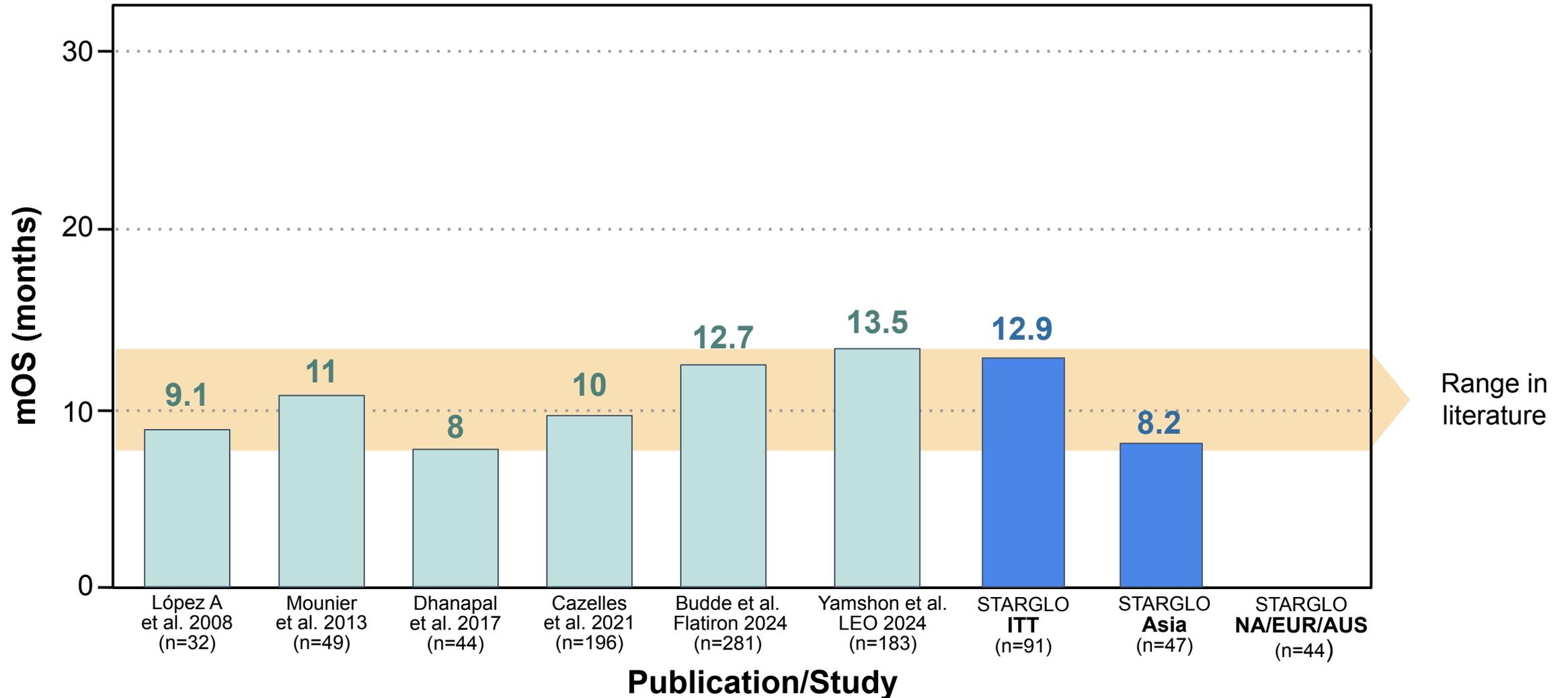
# Observed Consistency in OS of Glofit-GemOx Across Regions



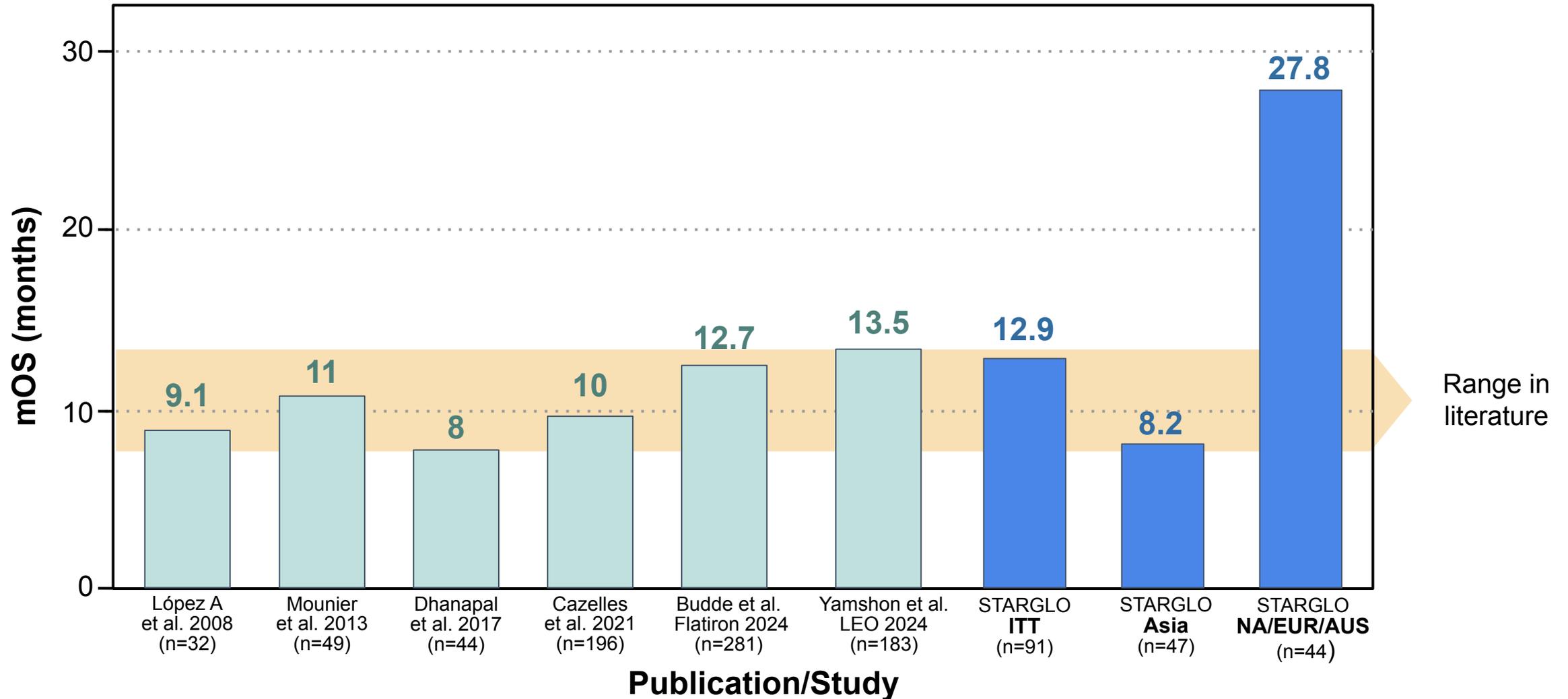
# Median OS Across R-GemOx Historical Controls



# Median OS Across R-GemOx Historical Controls, STARGLO ITT, and Regional Subgroups



# Median OS Across R-GemOx Historical Controls, STARGLO ITT, and Regional Subgroups



# NALT Utilization Across Regions

	NA/EUR/AUS (N=143)		Asia (N=131)		ITT (N=274)	
	R-GemOx N=44	Glofit-GemOx N=99	R-GemOx N=47	Glofit-GemOx N=84	R-GemOx N=91	Glofit-GemOx N=183
<b>Patients with at least one NALT, n (%)</b>	<b>24 (54.5%)</b>	27 (27.3%)	<b>28 (59.6%)</b>	19 (22.6%)	<b>52 (57.1%)</b>	46 (25.1%)
<b>Cellular Therapy/Novel agents</b>						
CAR-T	9 (20.5%)	7 (7.1%)	3 (6.4%)	1 (1.2%)	12 (13.2%)	8 (4.4%)
Bispecifics	8 (18.2%)	2 (2.0%)	7 (14.9%)	0	15 (16.5%)	2 (1.1%)
CD19 immunotherapy	3 (6.8%)	8 (8.1%)	2 (4.3%)	1 (1.2%)	5 (5.5%)	9 (4.9%)
SCT	1 (2.3%)	0	0	2 (2.4%)	1 (1.1%)	2 (1.1%)
<b>Standard treatments</b>						
Other systemic therapy	14 (31.8%)	21 (21.2%)	18 (38.3%)	14 (16.7%)	32 (35.2%)	35 (19.1%)
Radiotherapy/procedures	5 (11.4%)	2 (2.0%)	9 (19.1%)	4 (4.8%)	14 (15.4%)	6 (3.3%)

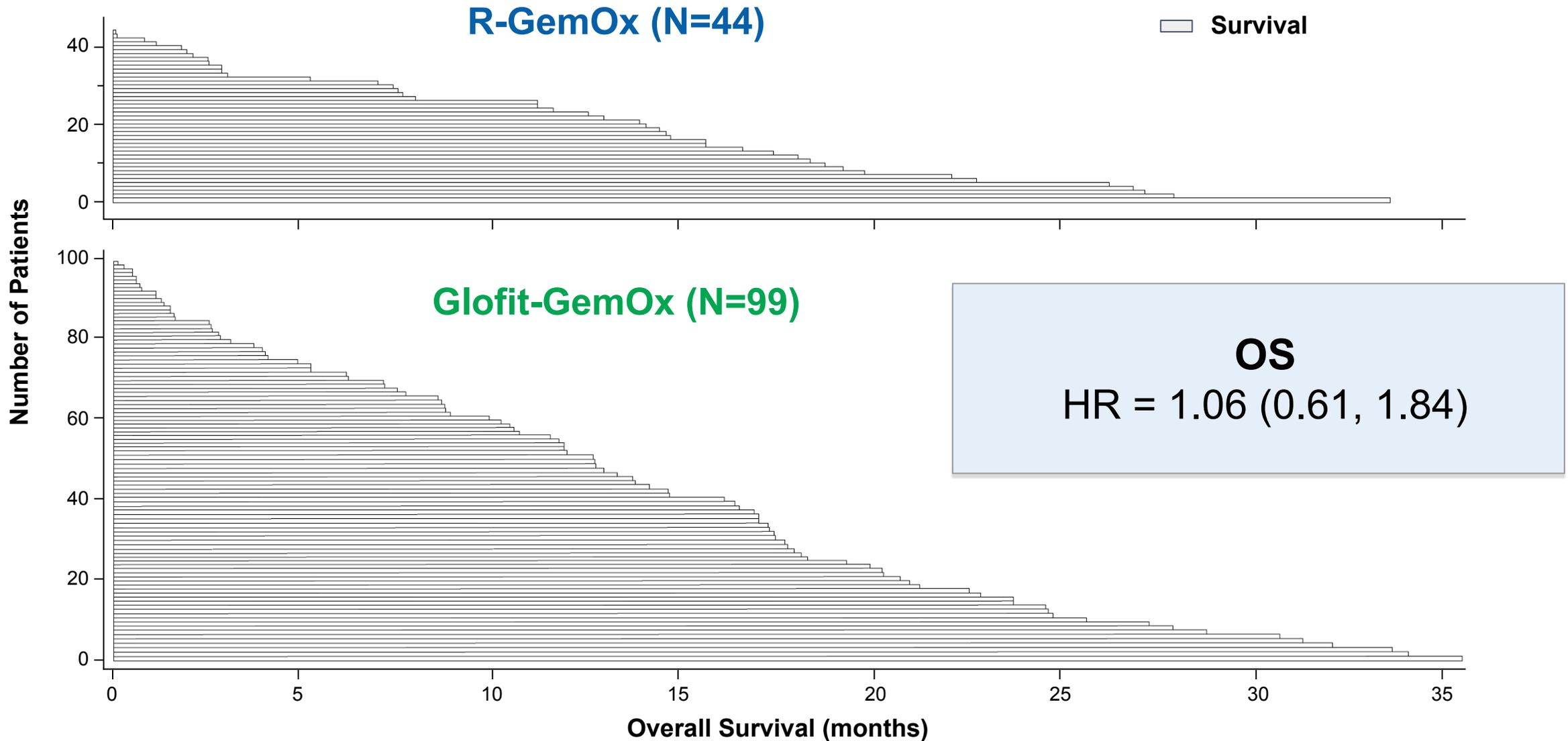
# NALT Utilization Higher in R-GemOx Patients Across Regions

	NA/EUR/AUS (N=143)		Asia (N=131)		ITT (N=274)	
	R-GemOx N=44	Glofit-GemOx N=99	R-GemOx N=47	Glofit-GemOx N=84	R-GemOx N=91	Glofit-GemOx N=183
<b>Patients with at least one NALT, n (%)</b>	<b>24 (54.5%)</b>	27 (27.3%)	<b>28 (59.6%)</b>	19 (22.6%)	<b>52 (57.1%)</b>	46 (25.1%)
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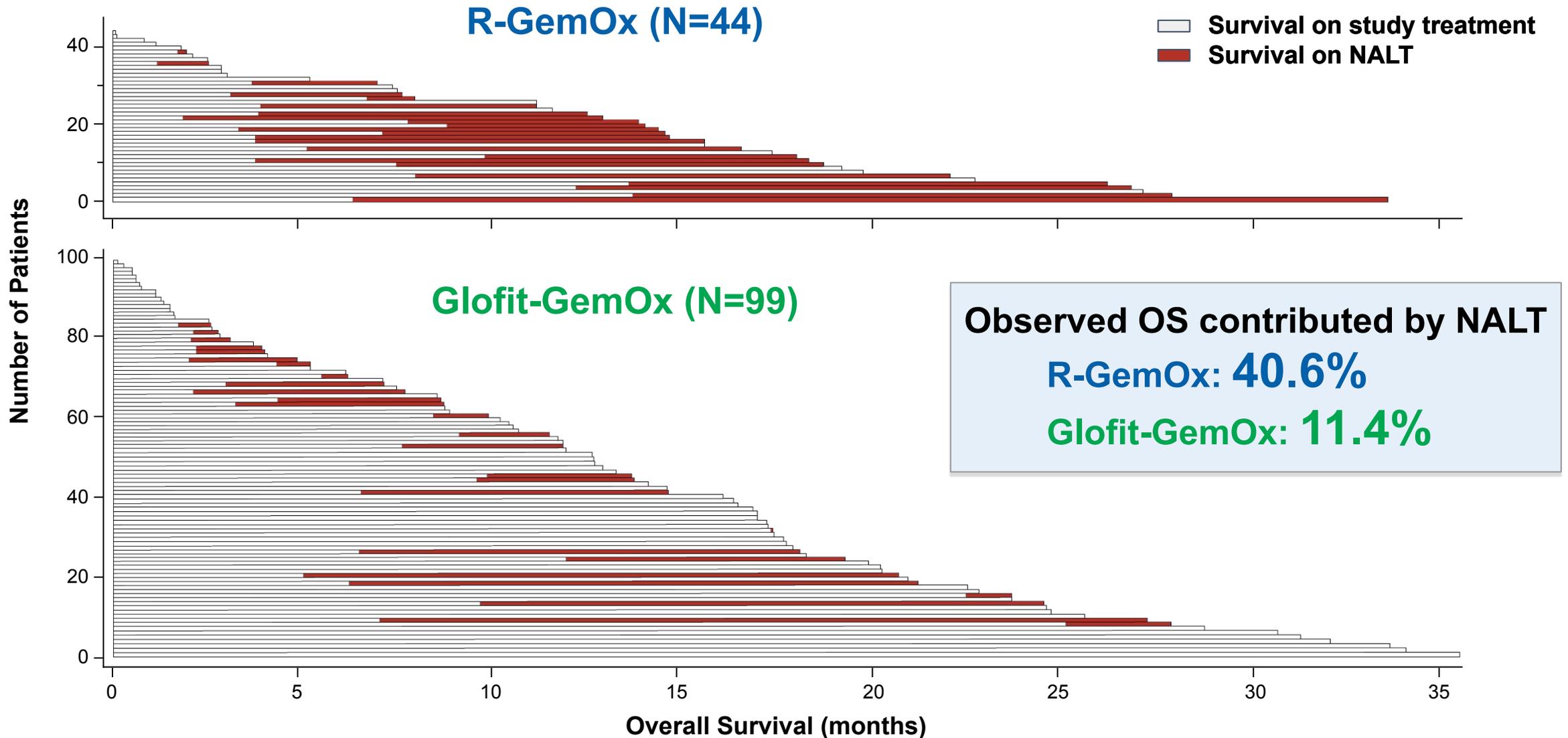
# R-GemOx Patients in NA/EUR/AUS Received More Highly Efficacious NALT

	NA/EUR/AUS (N=143)		Asia (N=131)		ITT (N=274)	
	R-GemOx N=44	Glofit-GemOx N=99	R-GemOx N=47	Glofit-GemOx N=84	R-GemOx N=91	Glofit-GemOx N=183
<b>Patients with at least one NALT, n (%)</b>	24 (54.5%)	27 (27.3%)	28 (59.6%)	19 (22.6%)	52 (57.1%)	46 (25.1%)
<b>Cellular Therapy/Novel agents</b>						
CAR-T	9 (20.5%)	7 (7.1%)	3 (6.4%)	1 (1.2%)	12 (13.2%)	8 (4.4%)
Bispecifics	8 (18.2%)	2 (2.0%)	7 (14.9%)	0	15 (16.5%)	2 (1.1%)
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SCT	1 (2.3%)	0	0	2 (2.4%)	1 (1.1%)	2 (1.1%)
<b>Standard treatments</b>						
Other systemic therapy	14 (31.8%)	21 (21.2%)	18 (38.3%)	14 (16.7%)	32 (35.2%)	35 (19.1%)
Radiotherapy/procedures	5 (11.4%)	2 (2.0%)	9 (19.1%)	4 (4.8%)	14 (15.4%)	6 (3.3%)

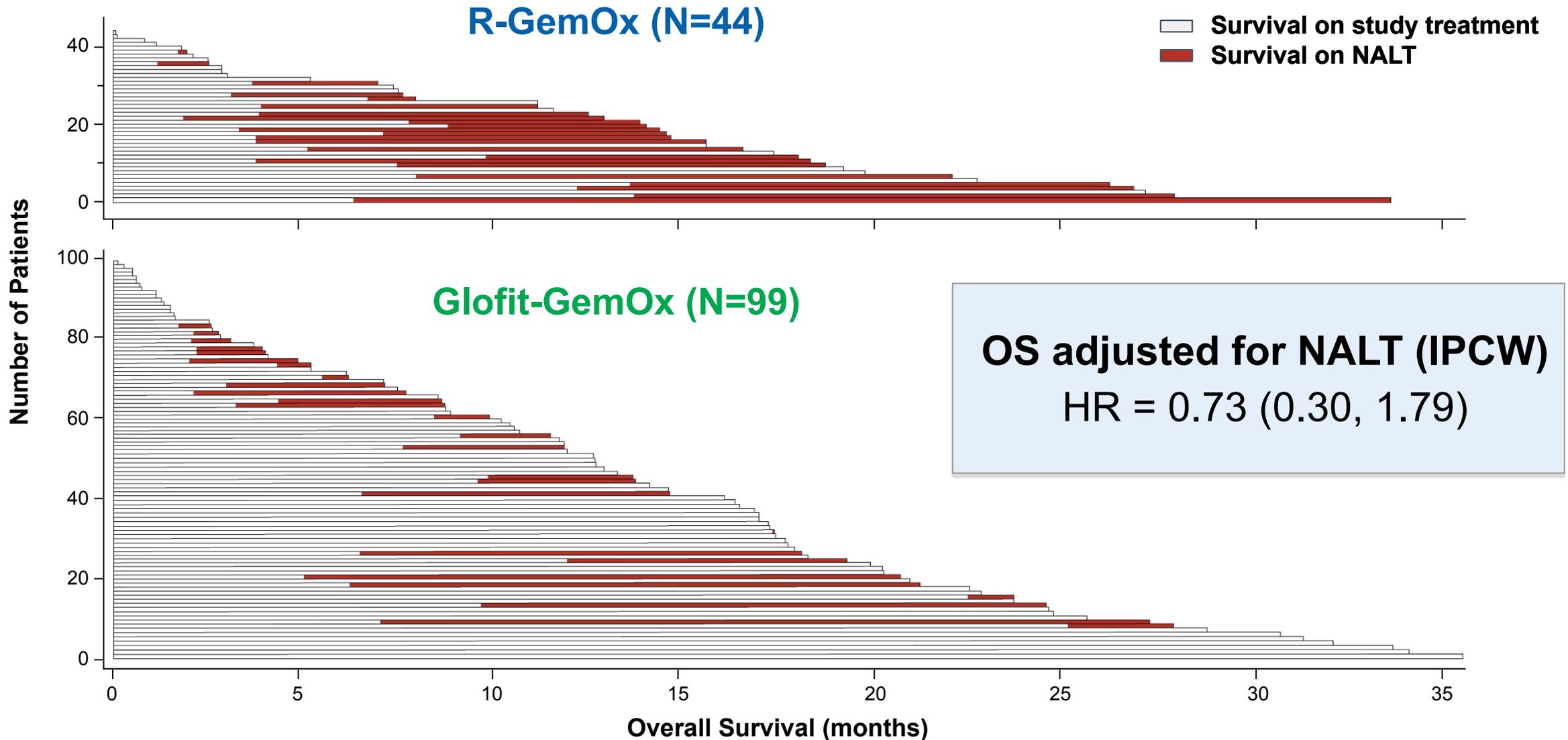
# Observed Survival Across Treatment Arms in NA/EUR/AUS



# Large Proportion of Survival Benefit in R-GemOx Arm in NA/EUR/AUS is Driven by NALT

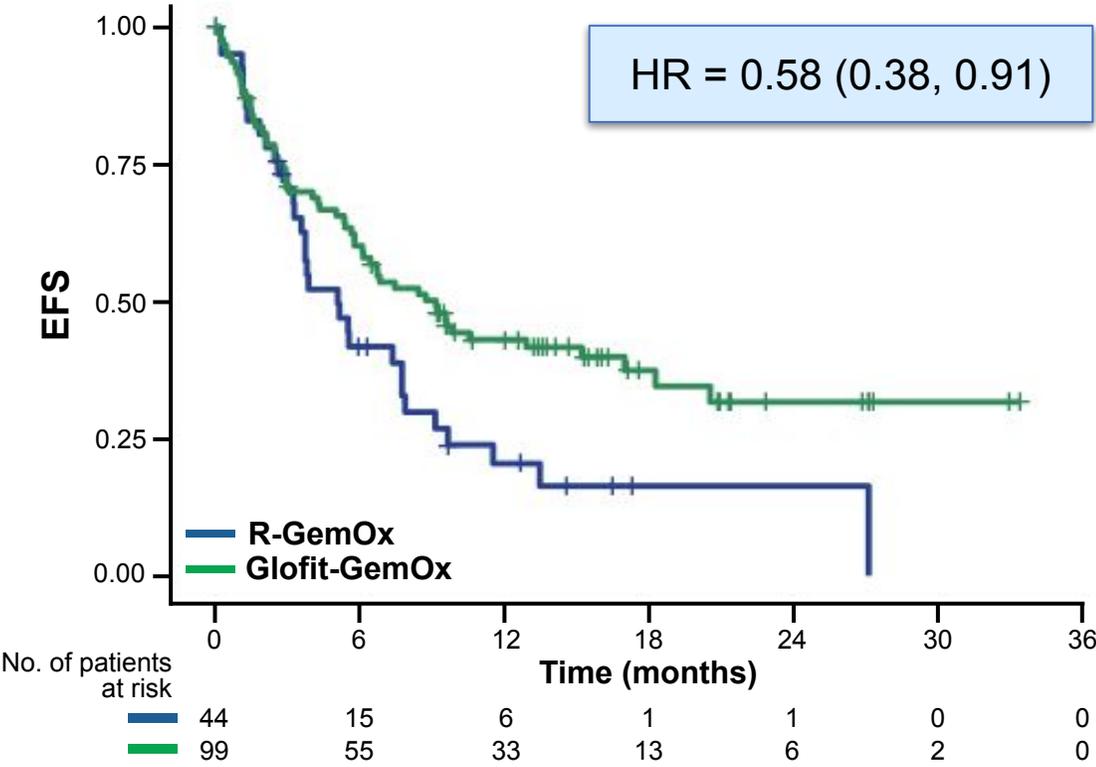


# Consistent OS Benefit in NA/EUR/AUS After Adjusting for NALT



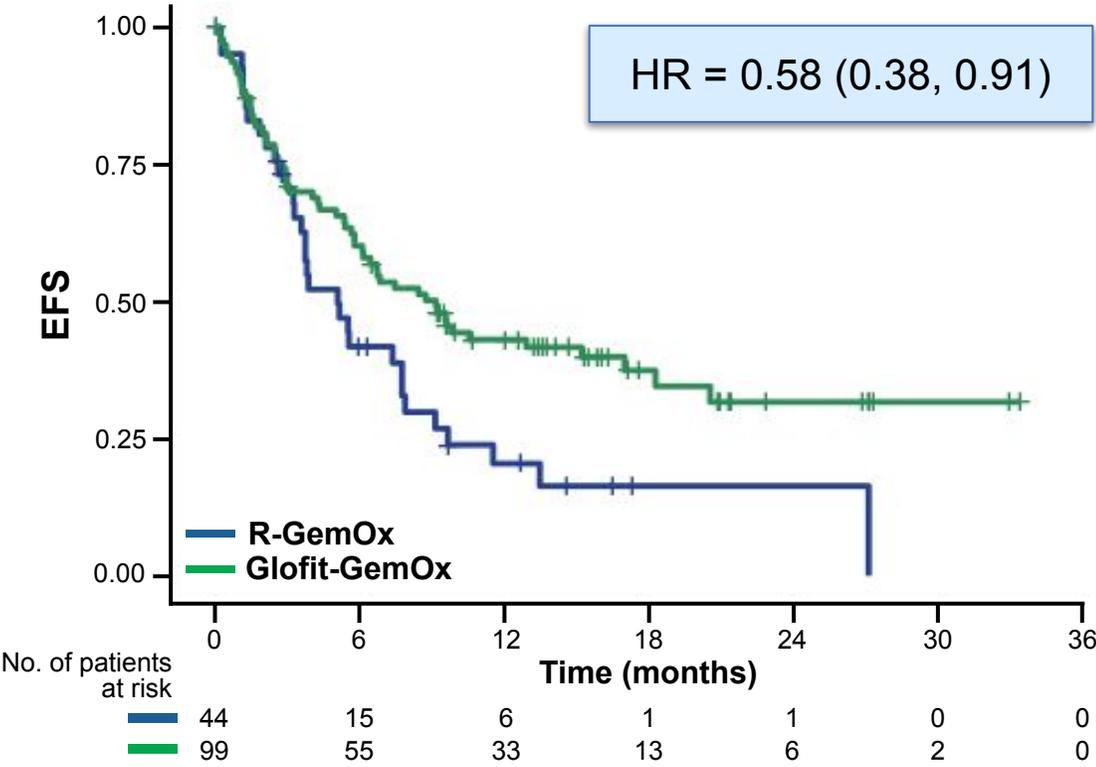
# Glofit-GemOx Shows a Consistent Benefit in NA/EUR/AUS in EFS and CR Rate

## Event-free Survival

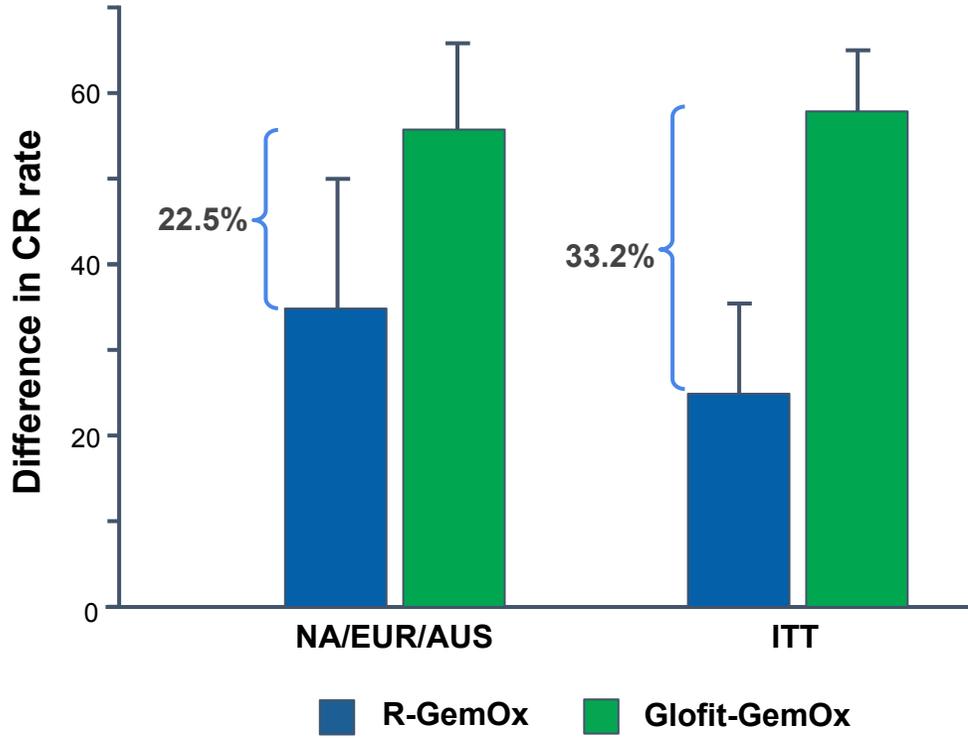


# Glofit-GemOx Shows a Consistent Benefit in NA/EUR/AUS in EFS and CR Rate

### Event-free Survival



### CR rate



Error bars on CR rate plot represent upper 95% confidence intervals

# STARGLO Overall Population Shows Statistically Significant and Robust Results Applicable to US Patients

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- Subgroup point estimate is not a sound assessment of the true treatment benefit in the US
- Multivariable analysis shows consistency in the OS outcome
- The outlying performance of R-GemOx in NA/EUR/AUS explained by NALT
- Glofit-GemOx performs consistently across regions
- In clinically relevant endpoints, Glofit-GemOx provides benefit vs. R-GemOx

# DLBCL Clinical Perspective / US Applicability

Krish Patel, MD

Sarah Cannon Research Institute (SCRI)

# Disclosures

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- Consulting fees from Abbvie, Adaptive, ADC, AstraZeneca, Beigene, BMS, Caribou, Fate Therapeutics, Genentech/Roche, Janssen/Pharmacyclics, Kite, Lilly/Loxo, Merck, Pfizer, Sana, Xencor
- Research funding (paid to my institution) for ongoing clinical trials with Accutar, Adaptive, Adicet, AstraZeneca, BMS, Caribou, Century, CRISPR, Fate Therapeutics, Genentech/Roche, Janssen/Pharmacyclics, Kite, Lilly/Loxo, Merck, Nurix, Pfizer, Sana, Xencor

# Therapy Selection in 2L DLBCL Patients

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## Goal of Therapy is Cure

- Maximize depth of response (CR)
- Minimize need for subsequent therapy (EFS)
- Offer potential for cure (OS)

## Patient Characteristics

- Primary refractory disease
- Disease kinetics
- Age and comorbidities
- COO not relevant

## Treatment Selection

- Guided by efficacy, safety, access, and patient-focused care

# Clinical Interpretation of STARGLO Results

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## Efficacy

- Highly efficacious **with OS benefit** even in patients with poor prognosis
- **CR** rates and **EFS** benefit are clinically meaningful endpoints

## Safety Profile

- **Consistent** with Glofitamab monotherapy
- Safety profile can be **effectively managed** in the community setting

## Accessibility

- Bispecific T-cell engagers are **widely accessible** to patients in the community setting
- CAR-T and ASCT are not widely accessible to patients in the community setting

# STARGLO Population is Representative of US Patients

	STARGLO	Flatiron <sup>1</sup> US RWD Majority Community	LEO <sup>2</sup> US RWD Academic
Patient Baseline Characteristics	Glofit / R + GemOx (n=274)	R-GemOx cohort (n=281)	R-GemOx cohort (n=183)
Age in years (median, range)	68 (20-88)	71 (22-85)	68 (21-88)
ECOG PS 0-1	88%	71%	79%
IPI Score 3-5	49%	Not reported	56%
Number of prior lines of therapy (median, range)	1 (1-4)	1 (1-7)	2 (1-7)
Primary refractory	56%	69%	72%

<sup>1</sup> Budde L et al. Blood 2024;144(S1):2373; <sup>2</sup> Yamshon S et al. Am J Hematol 2025;100(4):606-615.

ECOG PS, Eastern Cooperative Oncology Group performance status; IPI, International Prognostic Index; RWD, Real World Data.

Primary refractory: no response, relapse ≤ 6mo.

# Treatment Options for Transplant Ineligible DLBCL Patients

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	<b>CAR-T 2L transplant ineligible (PILOT<sup>1</sup>)</b>
<b>CR rate, % (95% CI)</b>	46% (34, 58)
<b>Median EFS, months (95% CI)</b>	8.2 (4.4, 13.3)
<b>Median PFS, months (95% CI)</b>	10.5 (5.1, 13.9)
<b>Median OS, months (95% CI)</b>	NE (14.7, NE)

# Treatment Options for Transplant Ineligible DLBCL Patients

	CAR-T 2L transplant ineligible (PILOT <sup>1</sup> )	R-Chemo (eg R-GemOx <sup>2</sup> )
<b>CR rate, % (95% CI)</b>	46% (34, 58)	25.3% (17, 36)
<b>Median EFS, months (95% CI)</b>	8.2 (4.4, 13.3)	2.8 (2.3, 5.1)
<b>Median PFS, months (95% CI)</b>	10.5 (5.1, 13.9)	3.6 (2.5, 7.1)
<b>Median OS, months (95% CI)</b>	NE (14.7, NE)	12.9 (7.9, 18.5)

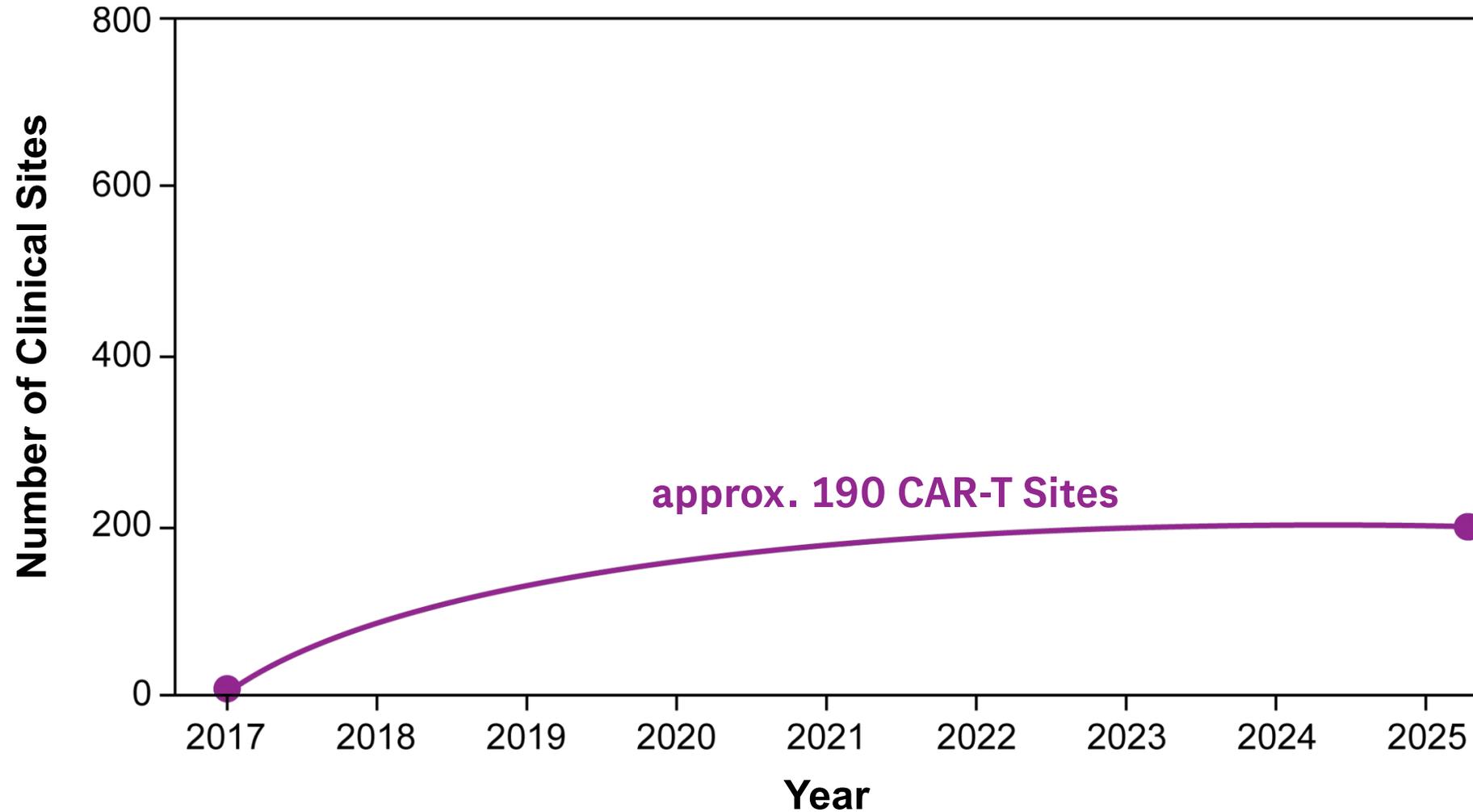
<sup>1</sup> Sehgal A et al. Lancet Oncol 2022;23(8):1066-1077; <sup>2</sup> STARGLO data is from updated analysis, CCOD: 16Feb2024.

# Treatment Options for Transplant Ineligible DLBCL Patients

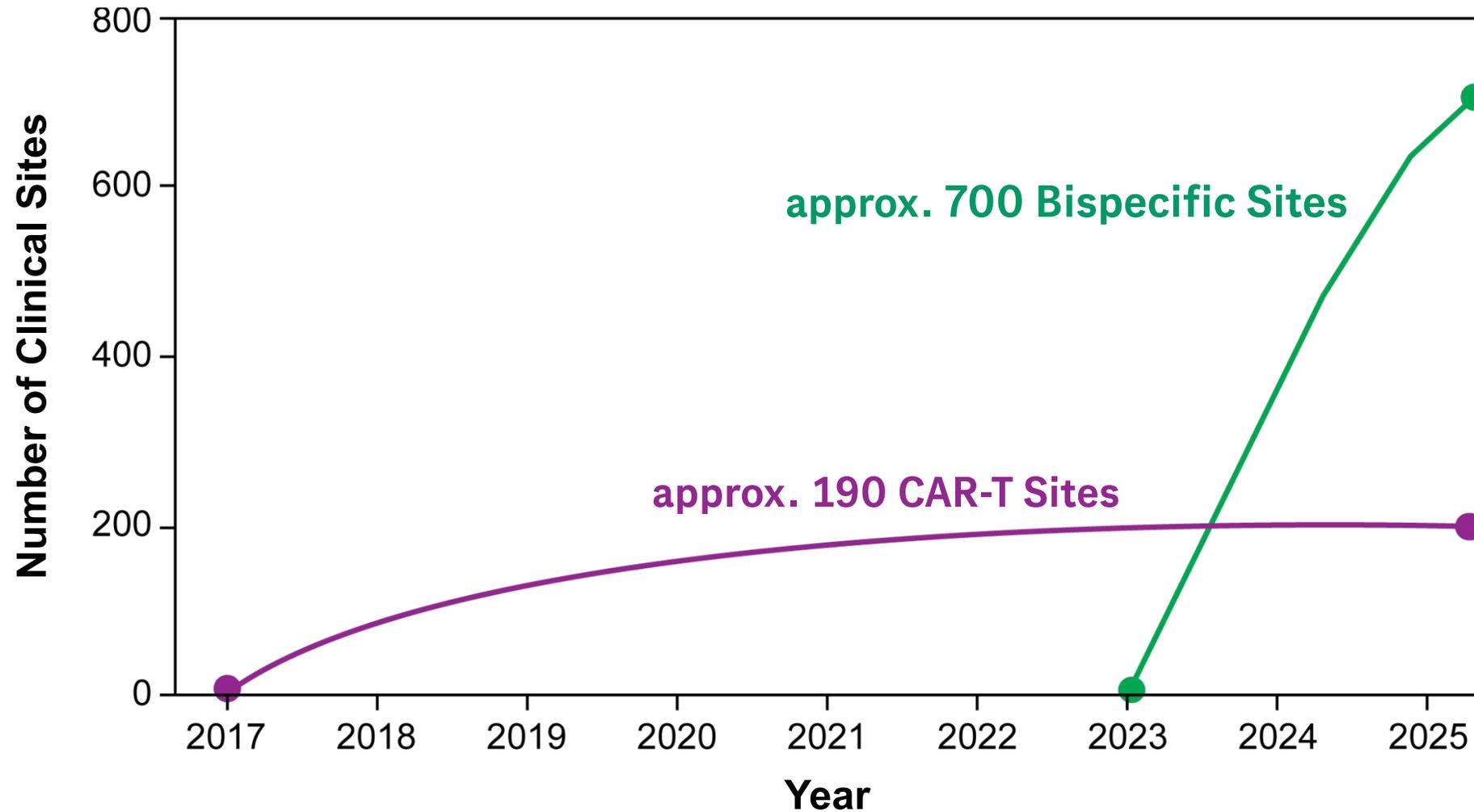
	CAR-T 2L transplant ineligible (PILOT <sup>1</sup> )	Glofit-GemOx <sup>2</sup>
<b>CR rate, % (95% CI)</b>	46% (34, 58)	58.5% (51, 66)
<b>Median EFS, months (95% CI)</b>	8.2 (4.4, 13.3)	10.5 (7.4, 20.4)
<b>Median PFS, months (95% CI)</b>	10.5 (5.1, 13.9)	13.8 (8.7, 20.5)
<b>Median OS, months (95% CI)</b>	NE (14.7, NE)	25.5 (18.3, NE)

**Glofit-GemOx will offer an efficacious option tailored to the patient and the care setting**

# Access to Effective Lymphoma Therapies in US



# Access to Effective Lymphoma Therapies in US



# STARGLO Results are Applicable to US Patients

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## Patient Population

- STARGLO is representative of US patients

## Benefit-Risk

- Glofit-GemOx delivers a high rate of CR, reduces need for subsequent treatment and offers potential for cure
- Manageable safety profile

## Accessibility

- Patients need immediately available options
- Glofit-GemOx can be delivered across the US

**US patients will benefit from Glofit-GemOx**

# Sponsor's Position on Glofitamab for R/R DLBCL

Charles Fuchs, MD, MPH

Senior Vice President

Global Head of Oncology and Hematology Drug Development

Genentech

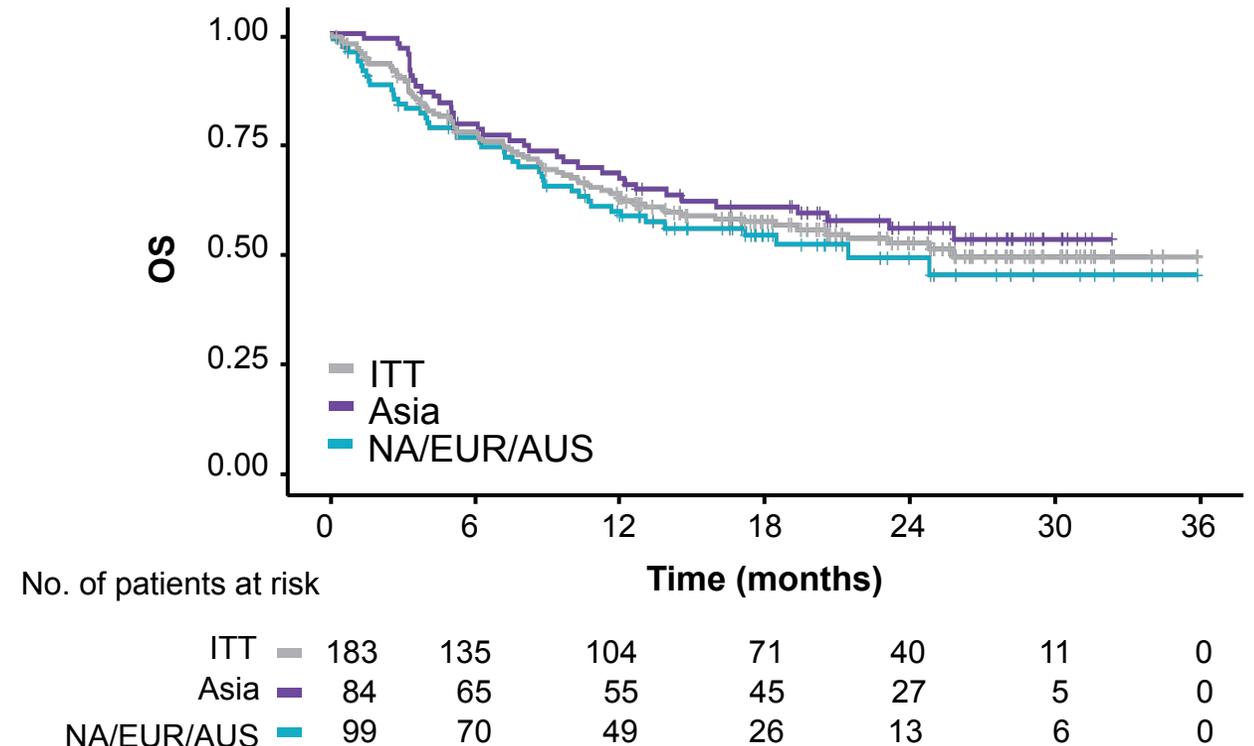
# Relevance of STARGLO Results

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- Urgent need for immediately available, efficacious therapies
- Glofit-GemOx delivers durable CRs translating into OS benefit

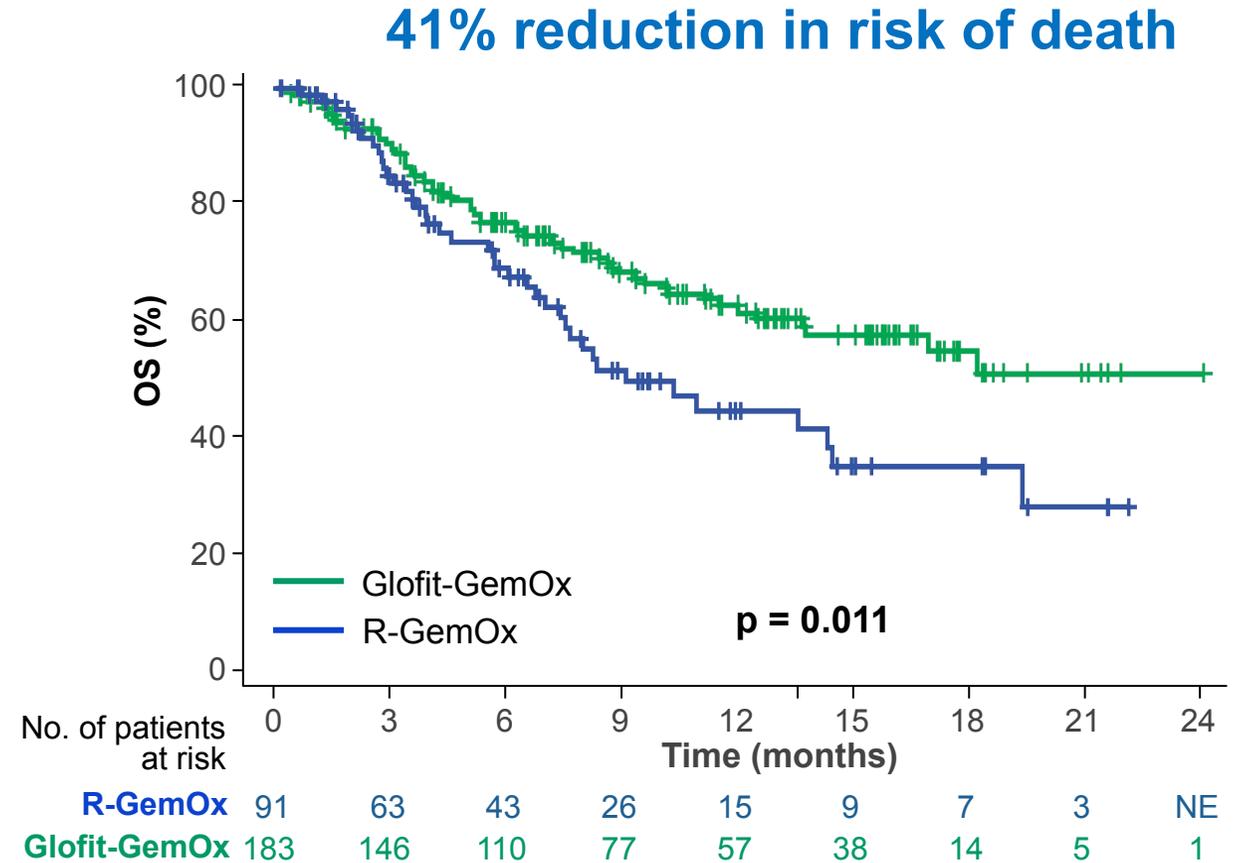
# STARGLO Results are Transformative and Applicable to US Patients

- Exploratory subgroup point estimates are unreliable
- No biological or clinical evidence for regional differences
- Glofit-GemOx delivers consistent survival outcome across regions



# STARGLO Results are Transformative and Applicable to US Patients

- Approved >30 countries
- NCCN Category 1
- STARGLO delivers the highest level of evidence and supports US approval



Glofitamab (COLUMVI<sup>®</sup>)

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# FDA Table 19: Summary of Evidence of Inconsistencies Identified Between Subgroups Defined by Region in STARGLO

Factors	Notable Differences		Asian Region	Non-Asian Region
Differential treatment effect	OS Hazard ratio		0.39 (0.25, 0.63)	1.06 (0.61, 1.84)
	PFS Hazard ratio		0.25 (0.15, 0.41)	0.81 (0.48, 1.35)
	CR Risk Difference		43.7% (27.0%, 60.3%)	22.5% (3.8%, 41.2%)
	ORR Risk Difference		45.9% (28.5%, 63.3%)	8.8% (-10.2%, 27.8%)
	Interaction Test		p-value <0.05 for OS, PFS, and ORR	
Patient and disease-related factors	Demographics	Median Age	62	71
		Race (Asian)	100%	4%
		Ethnicity (Hispanic)	2%	9%
	Disease burden and histology	R/R within 12 months of 1L therapy	81%	64%
		COO (ABC-DLBCL)	70%	42%
	Treatment history	Prior therapy (CAR-T)	2%	13%
		Refused transplant	65%	7%
Treatment and Assessments	Exposure (in R-GemOx arm), median		1.1 months	3.1 months
	Concordance in response assessments		Concordance in PFS assessments lowest in R-GemOx arm of Asia region	
	Timing of efficacy assessments (earlier than scheduled for the first assessment in R-GemOx arm)		56%	22%
	Use of NALT (CAR-T) in R-GemOx		3 (7%)	9 (21%)
	Use of NALT (CAR-T) in Glofit-GemOx		1 (1%)	7 (8%)

Source: FDA summary

# FDA Table 19: Summary of Evidence of Inconsistencies Identified Between Subgroups Defined by Region in STARGLO

Evidence provided by Sponsor				
Factors				
Differential treatment effect		<p align="center"><b>When taking NALT into consideration, we see consistent OS, PFS, EFS and CR rates in favor of Glofit-Gemox.</b></p>		
factors	Treatment history	COO (ABC-DLBCL)	70%	42%
		Prior therapy (CAR-T)	2%	13%
		Refused transplant	65%	7%
Treatment and Assessments	Exposure (in R-GemOx arm), median		1.1 months	3.1 months
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Evidence provided by Sponsor	
Patient and disease-related factors	<p><b><u>Multivariable model adjusting for all 7 factors:</u></b></p> <ul style="list-style-type: none"> <li><b>OS HR: 0.59 (0.41, 0.86), p = 0.005</b></li> </ul>
	<ul style="list-style-type: none"> <li><b>10.6% of the ITT population refused ASCT (19.8% Asia, 2.1% in Non-Asia)</b></li> </ul>

Treatment and Assessments	median	Concordance in PFS assessments lowest in R-GemOx arm of Asia region	
	Concordance in response assessments		
	Timing of efficacy assessments (earlier than scheduled for the first assessment in R-GemOx arm)	56%	22%
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	Disease burden and histology	R/R within 12 months of 1L therapy	81%	64%
		COO (ABC-		

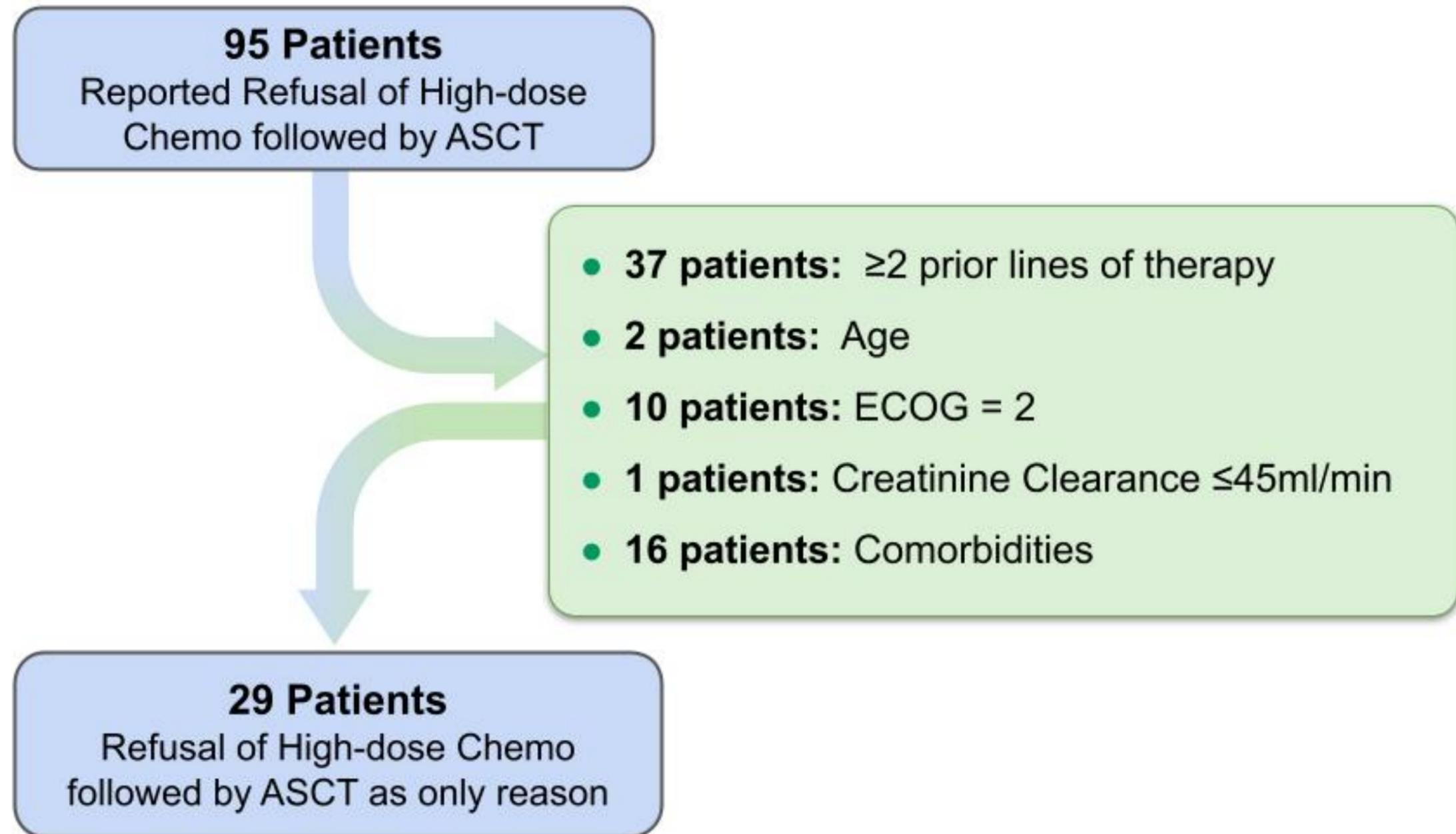
Evidence provided by Sponsor	
Treatment and Assessments	<ul style="list-style-type: none"> <li>• All Investigators managed patients as per clinical need and global standards</li> <li>• More patients with early relapse enrolled in the R-GemOx arm in Asia than Non-Asia</li> </ul>
	<ul style="list-style-type: none"> <li>• All study sites had access to CAR-T</li> <li>• CAR-T utilization is varied and reflects real world practice</li> </ul>

GemOx

Source: FDA summary

# Identification of Patients with the Only Reason for Non-Candidacy for ASCT Being Refusal

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# Efficacy Results Excluding Patients Refusing ASCT (N=95)

Result are Consistent with ITT

<i>Sensitivity analysis</i>	ASCT Refusal (N=95)		All Other Patients (N=179)		ITT Population (N=274)	
	R-GemOx (N=30)	Glofit-GemOx (N=65)	R-GemOx (N=61)	Glofit-GemOx (N=118)	R-GemOx (N=91)	Glofit-GemOx (N=183)
<b>Overall Survival</b>						
Median OS, months (95% CI)	10.3 (5.5, NE)	NE (15.8, NE)	13.5 (7.6, 18.5)	24.5 (12.9, NE)	12.9 (7.9, 18.5)	25.5 (18.5, NE)
HR (95% CI)	<b>0.65 (0.35, 1.22)</b>		<b>0.62 (0.41, 0.95)</b>		<b>0.62 (0.43, 0.88)</b>	
<b>IRC-Assessed Progression-Free Survival</b>						
Median PFS, months (95% CI)	5.6 (2.7, NE)	NE (7.4, NE)	2.6 (2.0, 5.6)	9.6 (6.7, 20.4)	3.6 (2.5, 7.1)	13.6 (8.7, 20.5)
HR (95% CI)	<b>0.58 (0.30, 1.10)</b>		<b>0.42 (0.28, 0.63)</b>		<b>0.40 (0.28, 0.57)</b>	
<b>IRC-Assessed Complete Response Rate</b>						
Complete responders, % (95% CI)	33.3% (17.3, 52.8)	60% (47.1, 72.0)	21.3% (11.9, 33.7)	57.6% (48.2, 66.7)	25.3 (16.8, 35.5)	58.5 (51.0, 65.7)
Difference in CR rate, %	<b>26.7%</b>		<b>36.3%</b>		<b>33.3%</b>	

# Efficacy Results Excluding Patients Refusing ASCT (N=29)

Result are Consistent with ITT

<i>Sensitivity analysis</i>	ASCT Refusal (N=29)		All Other Patients (N=245)		ITT Population (N=274)	
	R-GemOx (N=6)	Glofit-GemOx (N=23)	R-GemOx (N=85)	Glofit-GemOx (N=160)	R-GemOx (N=91)	Glofit-GemOx (N=183)
<b>Overall Survival</b>						
Median OS, months (95%, CI)	NE (9.0, NE)	NE (NE)	12.5 (7.3, 16.5)	22.9 (12.9, NE)	12.9 (7.9, 18.5)	25.5 (18.5, NE)
HR (95% CI)	<b>0.67 (0.13, 3.46)</b>		<b>0.65 (0.45, 0.93)</b>		<b>0.62 (0.43, 0.88)</b>	
<b>IRC-Assessed Progression-Free Survival</b>						
Median PFS, months (95%, CI)	NE (2.6, NE)	NE (NE)	3.6 (2.2, 5.6)	9.8 (6.7, 17.0)	3.6 (2.5, 7.1)	13.6 (8.7, 20.5)
HR (95% CI)	<b>0.48 (0.09, 2.50)</b>		<b>0.47 (0.33, 0.67)</b>		<b>0.40 (0.28, 0.57)</b>	
<b>IRC-Assessed Complete Response Rate</b>						
Complete responders, % (95% CI)	33% (4, 78)	70% (47, 87)	25% (16, 35)	57% (49, 65)	25% (17, 36)	59% (51, 66)
Difference in CR rate, %	<b>36%</b>		<b>32%</b>		<b>33%</b>	

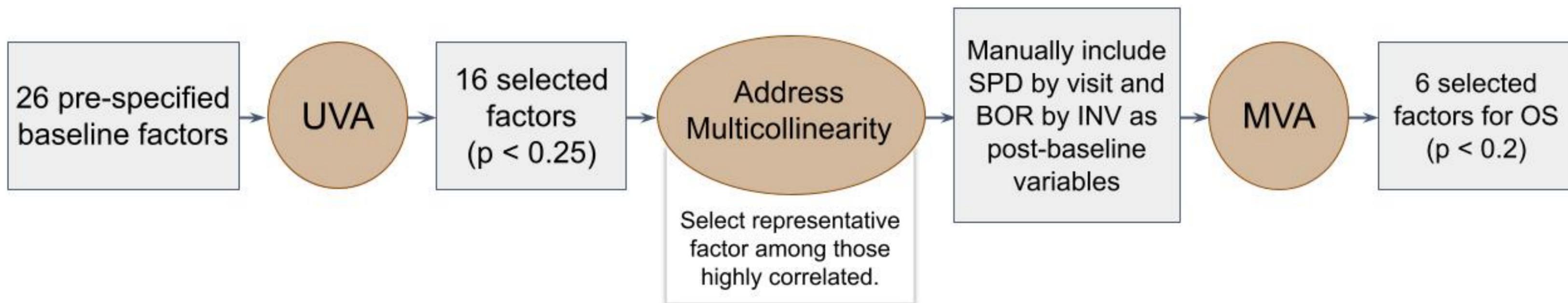
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- Multivariable analysis shows consistency in the OS outcome
- The outlying performance of R-GemOx in NA/EUR/AUS explained by NALT
- Glofit-GemOx performs consistently across regions
- In clinically relevant endpoints, Glofit-GemOx provides benefit vs. R-GemOx

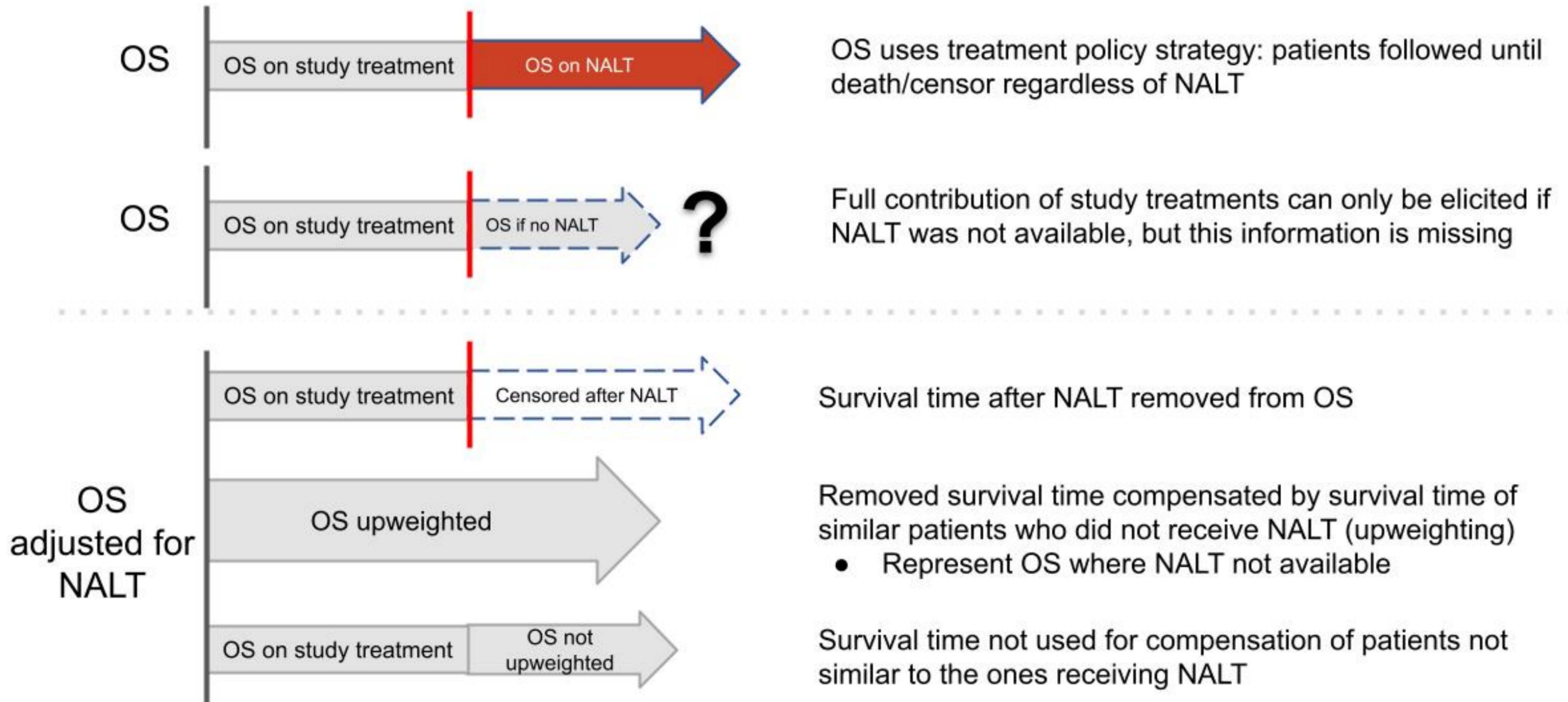
Adjusting for NALT using IPCW:  $p > 0.05$  in the treatment effect between Asian and Non-Asian countries.

# Variable Selection for IPCW



Factors selected for IPCW: IPI, ECOG, Ann Arbor, BOR by INV, and the stratification factors (no. prior lines of therapy, refractory status to last line of therapy).

# Inverse Probability of Censoring Weighting (IPCW) Adjustment Methodology



# Cell of Origin Status is not Prognostic in R/R DLBCL Patients Treated with Standard Chemoimmunotherapy, Including R-GemOx

Study	Population	COO methodology	Prognostic significance
<b>STARGLO</b>	<b>Non-transplant</b>	<b>Histopathology (n=242) GEP (n=161)</b>	<b>NOT prognostic</b>
<b>Desai et al 2022<sup>1</sup></b>	<b>Non-transplant (65%) HD chemo + transplant (35%)</b>	<b>Histopathology (n=259) GEP (n=133)</b>	<b>NOT prognostic</b> <ul style="list-style-type: none"> <li>including specific analysis of the non-transplant patient population</li> </ul>
<b>Cazelles et al 2021<sup>2</sup></b>	<b>Non-transplant: <i>R-GemOx</i></b>	<b>Histopathology (n=169)</b>	<b>NOT prognostic</b>
<b>Mounier et al 2013<sup>3</sup></b>	<b>Non-transplant: <i>R-GemOx</i></b>	<b>Histopathology (n=35)</b>	<b>NOT prognostic</b>

1. Desai et al. 2022; Hematol Oncol. 2023 Feb;41(1):39-49. doi: 10.1002/hon.3098. Epub 2022 Nov 7. PMID: 36305717; PMCID: PMC10037910.

2. Cazelles et al 2021; Leukemia & Lymphoma, 62(9), 2161–2168. <https://doi.org/10.1080/10428194.2021.1901090>

3. Mounier et al 2013; Hematologica Vol. 98 No. 11 (2013): November, 2013 <https://doi.org/10.3324/haematol.2013.090597>