Mosunetuzumab plus polatuzumab vedotin (Mosun-Pola) versus rituximab, gemcitabine and oxaliplatin (R-GemOx) in patients with relapsed/refractory large B-cell lymphoma (R/R LBCL): Updated efficacy and safety from the Phase 3 SUNMO study including in second-line (2L) versus third-line plus (3L+) patient subgroups

Key takeaways

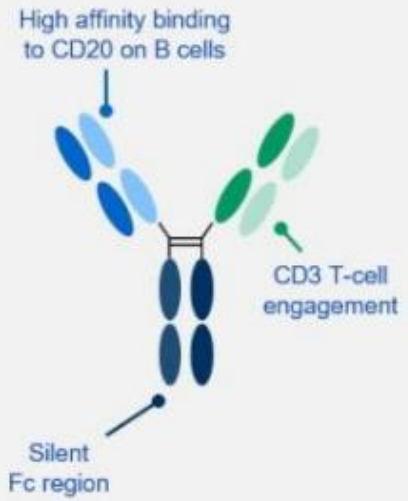
- Mosun-Pola, a fixed-duration, targeted combination, continues to demonstrate durable benefits in patients with R/R LBCL from the Phase 3 SUNMO study
- In subgroup analyses, high efficacy was observed in patients in the 2L setting, regardless of primary refractory or early relapse status
- No new AEs were reported;[1] low CRS rates and a manageable safety profile were demonstrated across age groups

Background

- Patients with R/R LBCL unable to receive curative-intent therapies such as CAR T-cell therapy or ASCT have a poor prognosis[1,2]
  - Barriers may include lack of response to prior therapy, potential toxicities, age, frailty, and/or logistical challenges
- In the Phase 3 SUNMO study (NCT05171647), Mosun-Pola, a combination of a bispecific antibody with an ADC, demonstrated clinically meaningful and statistically significant benefits over R-GemOx:
  - Risk of death or progression was reduced by 59%, and the CR rate was doubled[3]
  - CRS events were infrequent and low grade[3]
  - Improved quality of life was observed across multiple domains[4]

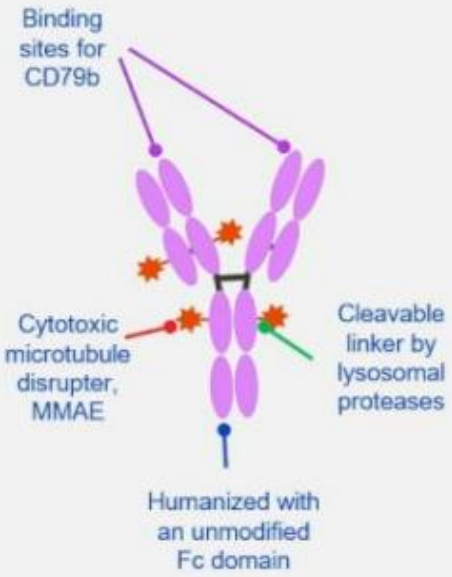
Mosunetuzumab

CD20xCD3 bispecific antibody[5]



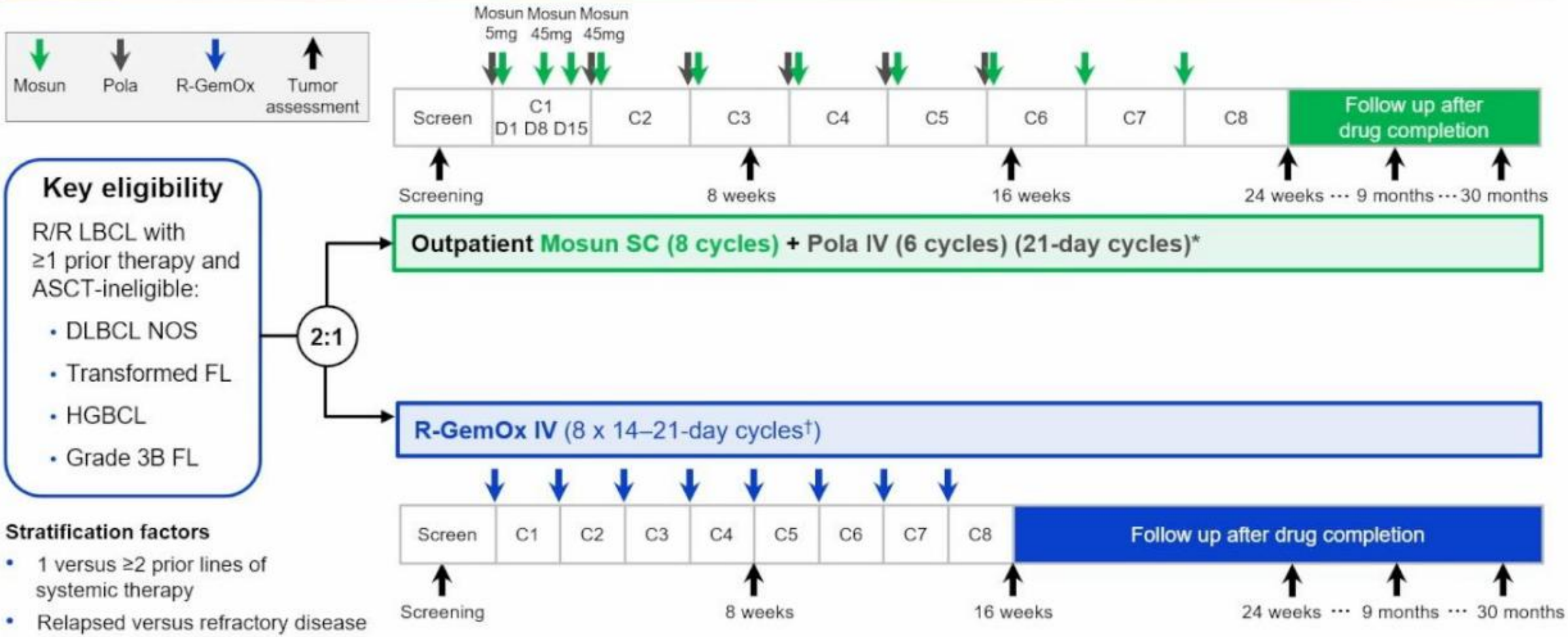
Polatuzumab vedotin

CD79b targeting antibody-drug conjugate[6]



We present updated efficacy and safety for **Mosun-Pola** versus R-GemOx in **transplant-ineligible patients** with **R/R LBCL**, including in **2L and elderly (≥65 years) subgroups**

Study design



Key eligibility

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

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

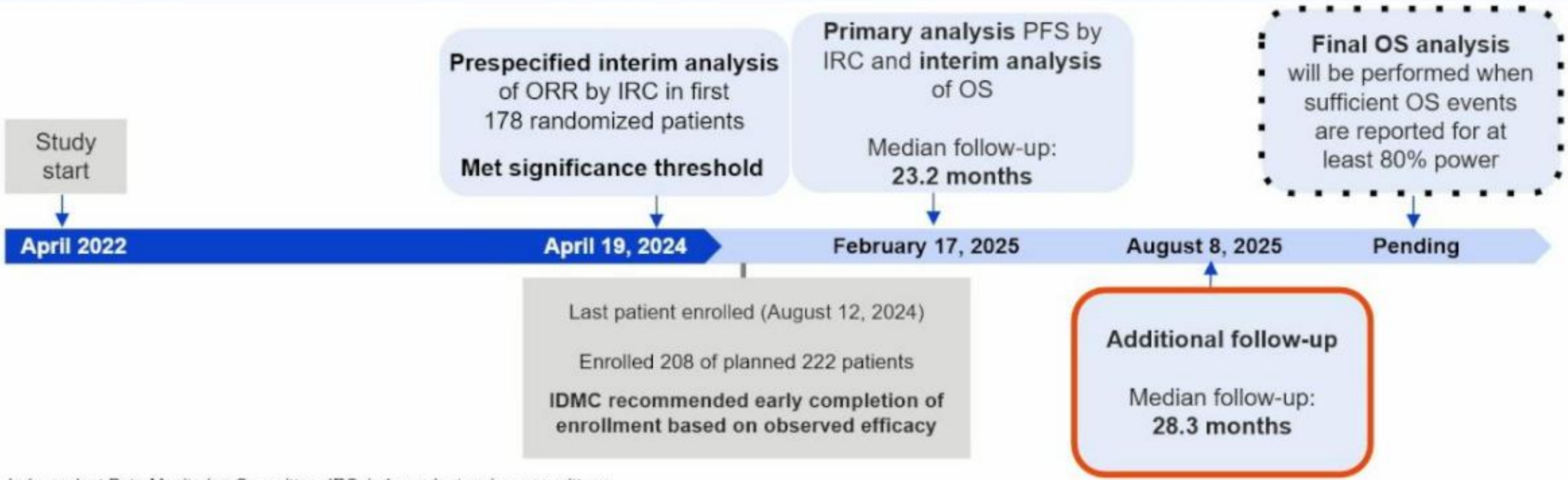
Stratification factors

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

*Corticosteroid premedication was administered prior to each dose in C1 and was optional in subsequent cycles; †14-day cycles unless delayed to 21-day cycles if needed in case of hematologic toxicity. C, cycle; D, day; DLBCL, diffuse large B-cell lymphoma; FL, follicular lymphoma; HGBCL, high-grade B-cell lymphoma; IV, intravenous; NOS, not otherwise specified; SC, subcutaneous.

SUNMO: Key endpoints and analysis timeline

Key endpoints	
Dual primary endpoints	ORR by IRC assessment PFS by IRC assessment
Key secondary endpoint	OS
Safety endpoints	Incidence, nature, and severity of AEs



IDMC, Independent Data Monitoring Committee; IRC, independent review committee; ORR, objective response rate; OS, overall survival; PFS, progression-free survival.

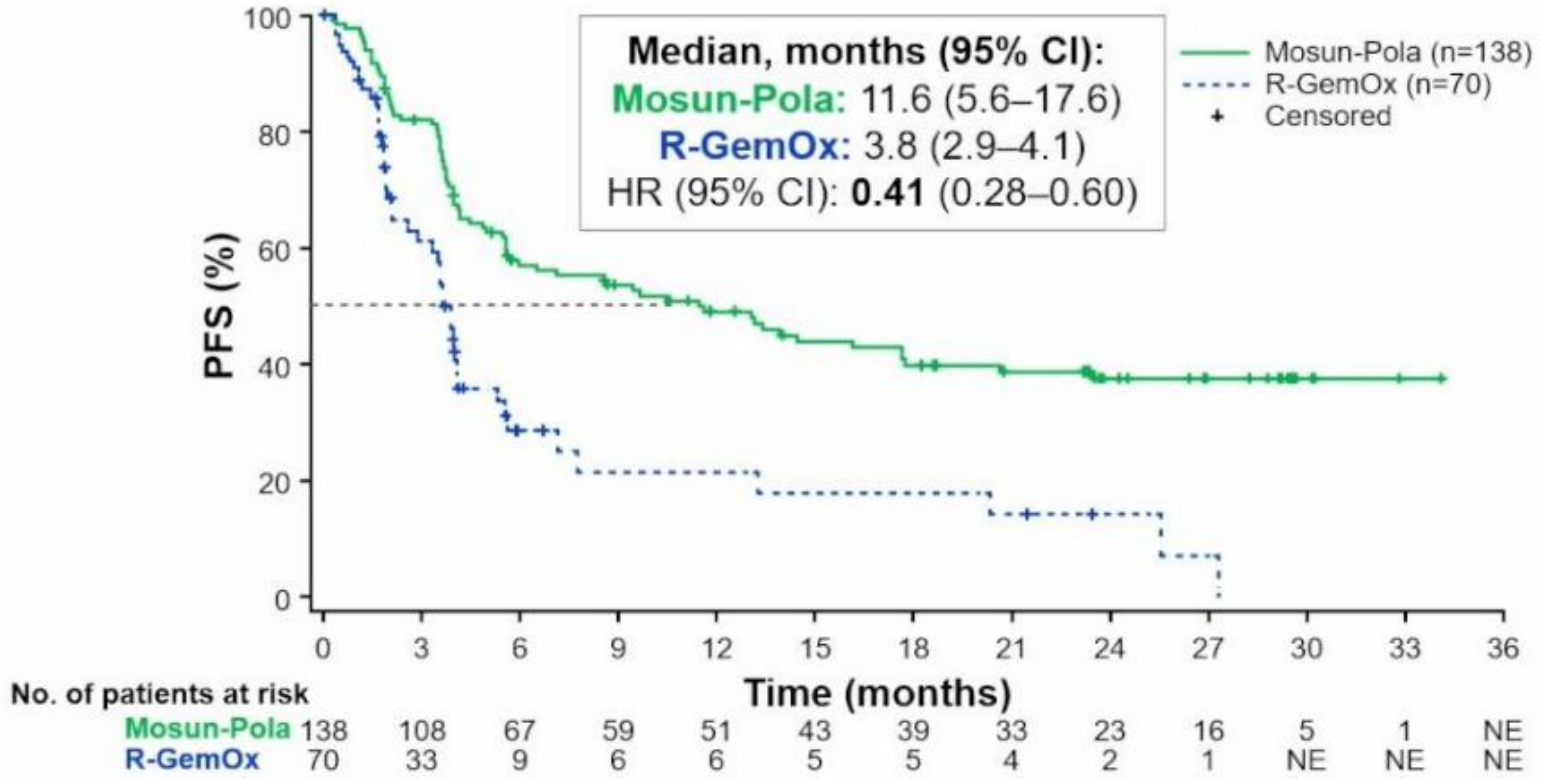
Baseline characteristics: ITT population and by line of therapy

% (n), unless otherwise stated		ITT		2L		3L+	
		Mosun-Pola (n=138)	R-GemOx (n=70)	Mosun-Pola (n=61)	R-GemOx (n=30)	Mosun-Pola (n=77)	R-GemOx (n=40)
Age, years	Median (range)	62 (23–87)	63 (29–85)	67 (28–87)	68.5 (48–82)	58 (23–80)	61.5 (29–85)
	≥65 years	39.1% (54)	45.7% (32)	60.7% (37)	60.0% (18)	22.1% (17)	35.0% (14)
Sex	Male	55.1% (76)	64.3% (45)	49.2% (30)	50.0% (15)	59.7% (46)	75.0% (30)
ECOG PS	0	50.0% (69)	57.1% (40)	59.0% (36)	50.0% (15)	42.9% (33)	62.5% (25)
	1	37.0% (51)	41.4% (29)	29.5% (18)	46.7% (14)	42.9% (33)	37.5% (15)
	2	13.0% (18)	1.4% (1)	11.5% (7)	3.3% (1)	14.3% (11)	0
NHL subtypes	DLBCL	79.0% (109)	77.1% (54)	80.3% (49)	73.3% (22)	77.9% (60)	80.0% (32)
	HGBCL	18.8% (26)	20.0% (14)	19.7% (12)	23.3% (7)	18.2% (14)	17.5% (7)
	FL3b	2.2% (3)	2.9% (2)	0	3.3% (1)	3.9% (3)	2.5% (1)
Transformed FL*	Yes	12.6% (17)	8.8% (6)	13.1% (8)	10.3% (3)	12.2% (9)	7.7% (3)
Ann Arbor Stage	I–II	24.6% (34)	20.0% (14)	27.9% (17)	23.3% (7)	22.1% (17)	17.5% (7)
	III–IV	75.4% (104)	80.0% (56)	72.1% (44)	76.7% (23)	77.9% (60)	82.5% (33)
Bulky disease (≥10cm)	Yes	20.3% (28)	7.1% (5)	21.3% (13)	3.3% (1)	19.5% (15)	10.0% (4)
Primary refractory	Yes	57.2% (79)	60.0% (42)	52.5% (32)	53.3% (16)	61.0% (47)	65.0% (26)
Refractory to last prior therapy	Yes	71.0% (98)	68.6% (48)	52.5% (32)	53.3% (16)	85.7% (66)	80.0% (32)

Clinical cut-off date: August 8, 2025.
*Three patients in the Mosun-Pola arm and two patients in the R-GemOx arm had FL3b and were not included in the denominator for transformed FL.
ECOG PS, Eastern Cooperative Oncology Group performance status; ITT, intent-to-treat; NHL, non-Hodgkin's lymphoma.

Mosun-Pola continued to demonstrate a durable PFS benefit after a median follow-up of 28.3 months

Primary endpoint: PFS by IRC in ITT



Clinical cut-off date: August 8, 2025.
PFS is censored at earliest of NALT or two or more missing tumor assessments, whichever occurred first.
CI, confidence interval; HR, hazard ratio; NALT, new anti-lymphoma therapy; NE, not evaluable.

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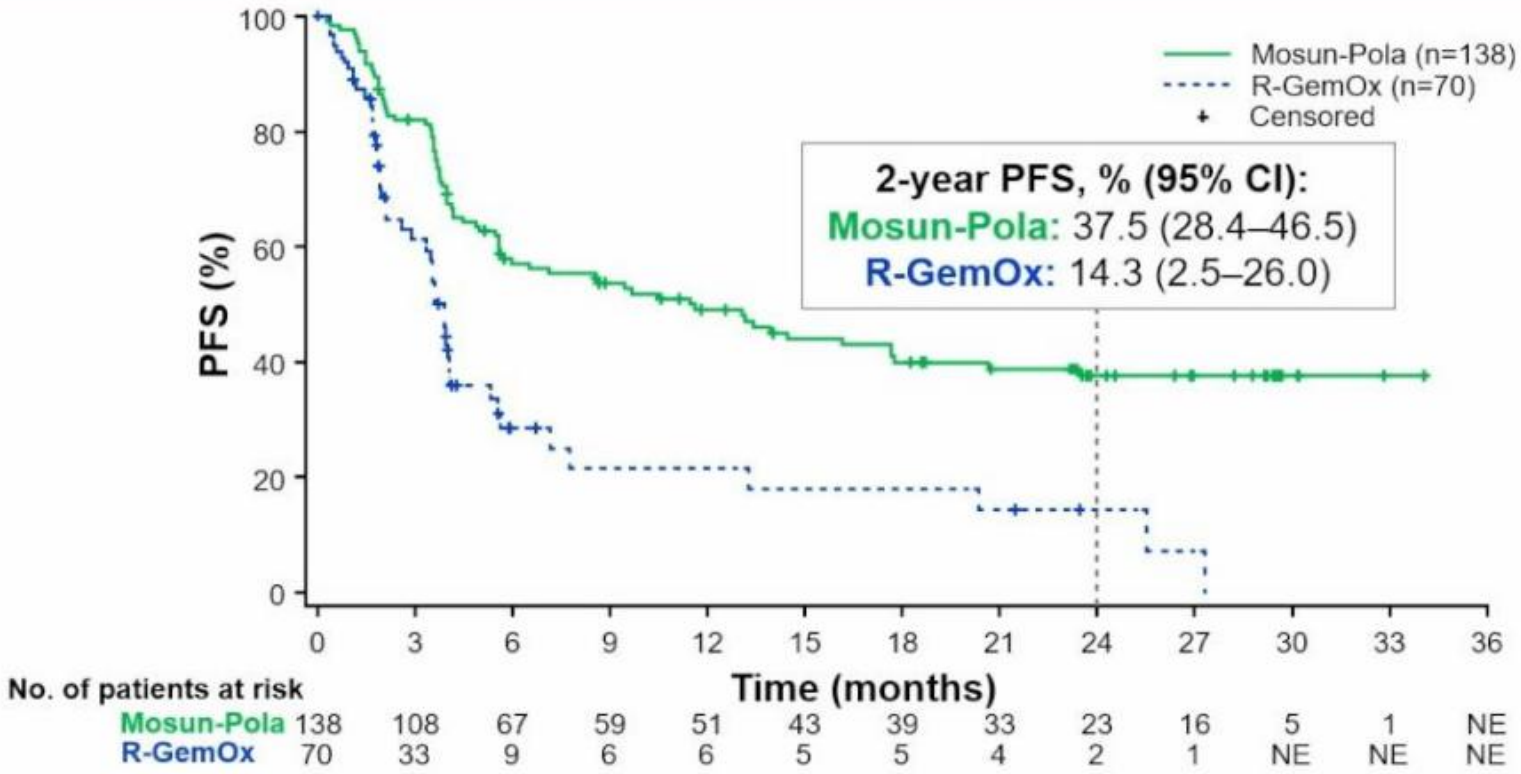

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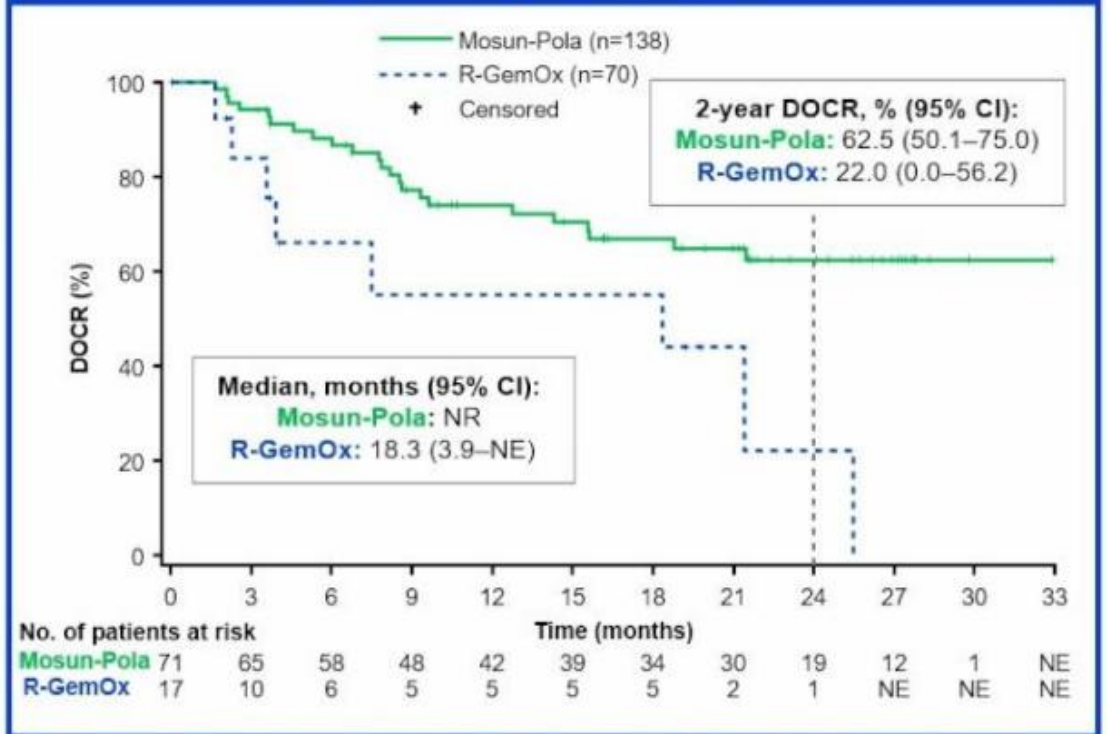
Mosun-Pola continued to demonstrate superior efficacy with durable remissions

IRC-assessed efficacy % (95% CI), unless otherwise stated	Mosun-Pola (n=138)	R-GemOx (n=70)
ORR	70.3% (61.9–77.8)	40.0% (28.5–52.4)
CR	51.4% (42.8–60.0)	24.3% (14.8–36.0)
DOR		
Median, months	18.8 (11.5–NE)	6.0 (3.7–23.9)
2-year rate	47.9% (37.0–58.8)	15.4% (0.0–39.8)
DOCR		
Median, months	NR	18.3 (3.9–NE)
2-year rate	62.5% (50.1–74.9)	22.0% (0.0–56.2)

DOCR by IRC in ITT



More than 60% of CR patients treated with Mosun-Pola remained in remission at 2 years after CR

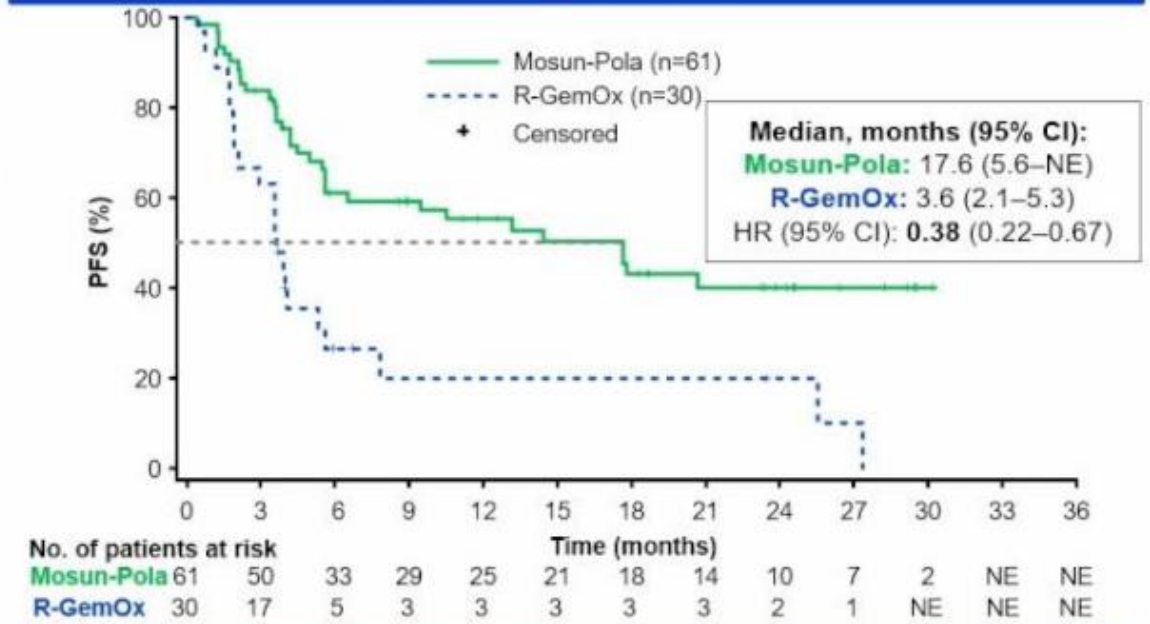
Clinical cut-off date: August 8, 2025.
DOCR, duration of complete response; DOR, duration of response; NR, not reached.

Mosun-Pola demonstrated high efficacy in the 2L setting

IRC-assessed efficacy % (95% CI), unless otherwise stated	2L Mosun-Pola (n=61)	2L R-GemOx (n=30)
Median PFS, months (95% CI)	17.6 (5.6–NE)	3.6 (2.1–5.3)
ORR	75.4% (62.7–85.5)	36.7% (19.9–56.1)
CR	60.7% (47.3–72.9)	20.0% (7.7–38.6)
Median DOR, months (95% CI)	18.8 (11.3–NE)	6.0 (3.9–NE)
Median DOCR, months (95% CI)	NR (15.6–NE)	21.4 (3.9–NE)

Clinical cut-off date: August 8, 2025.

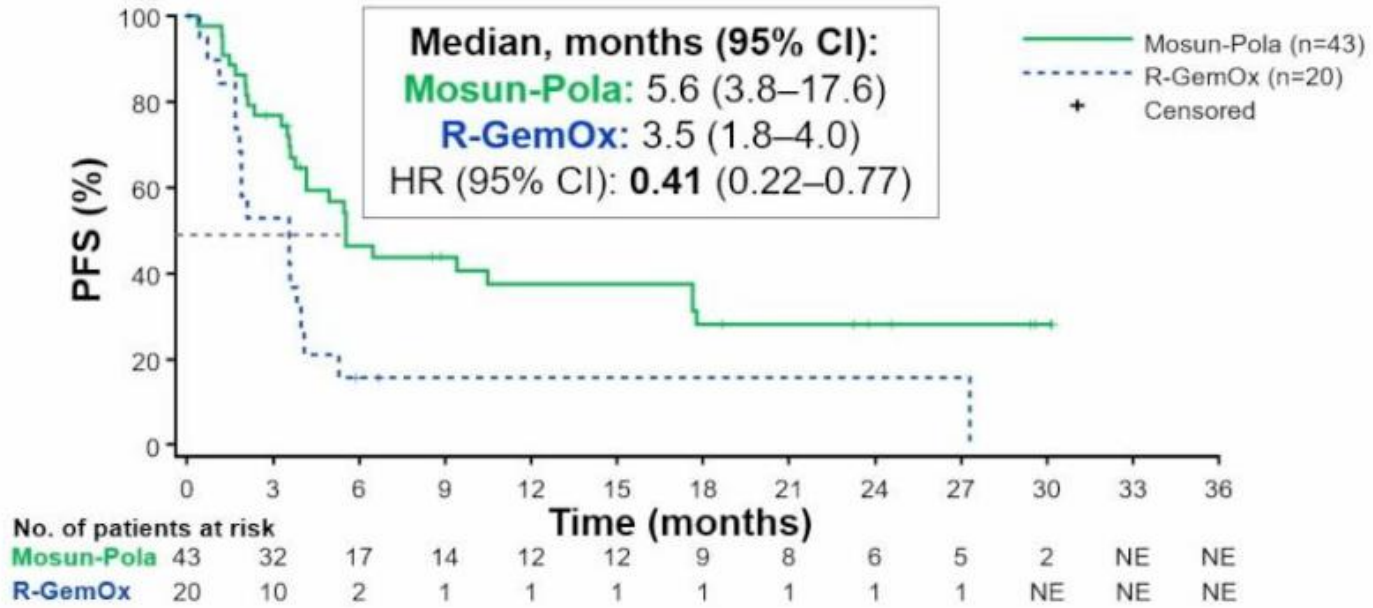
PFS by IRC: 2L



- A PFS HR of 0.38 was demonstrated in the 2L population
  - The 2-year PFS rate was doubled with Mosun-Pola versus R-GemOx: 40.3% vs 20.1%
  - Median DOCR was not reached with Mosun-Pola

Improvement of PFS and response rates in 2L patients with primary refractory/early relapse disease

PFS by IRC: 2L primary refractory/early relapse

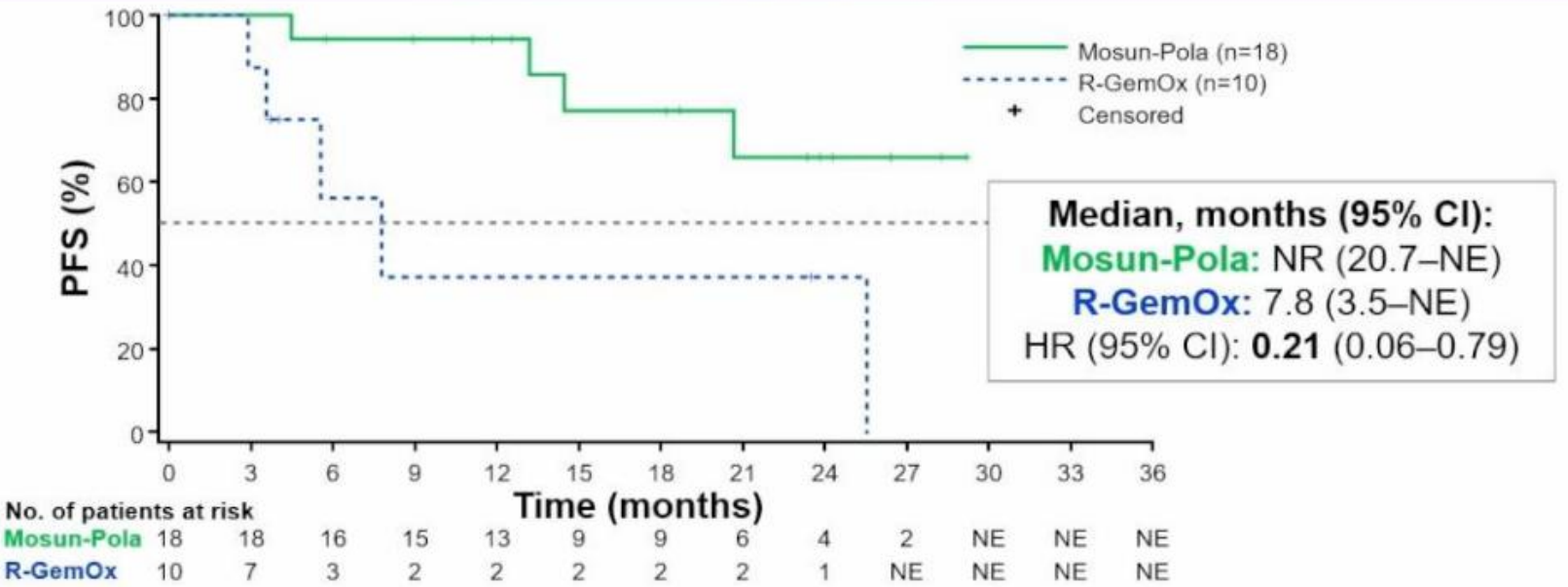


IRC-assessed response, % (95% CI)	Mosun-Pola (n=43)	R-GemOx (n=20)
ORR	67.4% (51.5–80.9)	25.0% (8.7–49.1)
CR	46.5% (31.2–62.4)	15.0% (3.2–37.9)

Clinical cut-off date: August 8, 2025.

Improvement of PFS and response rates in 2L patients with late relapse disease

PFS by IRC: 2L late relapse



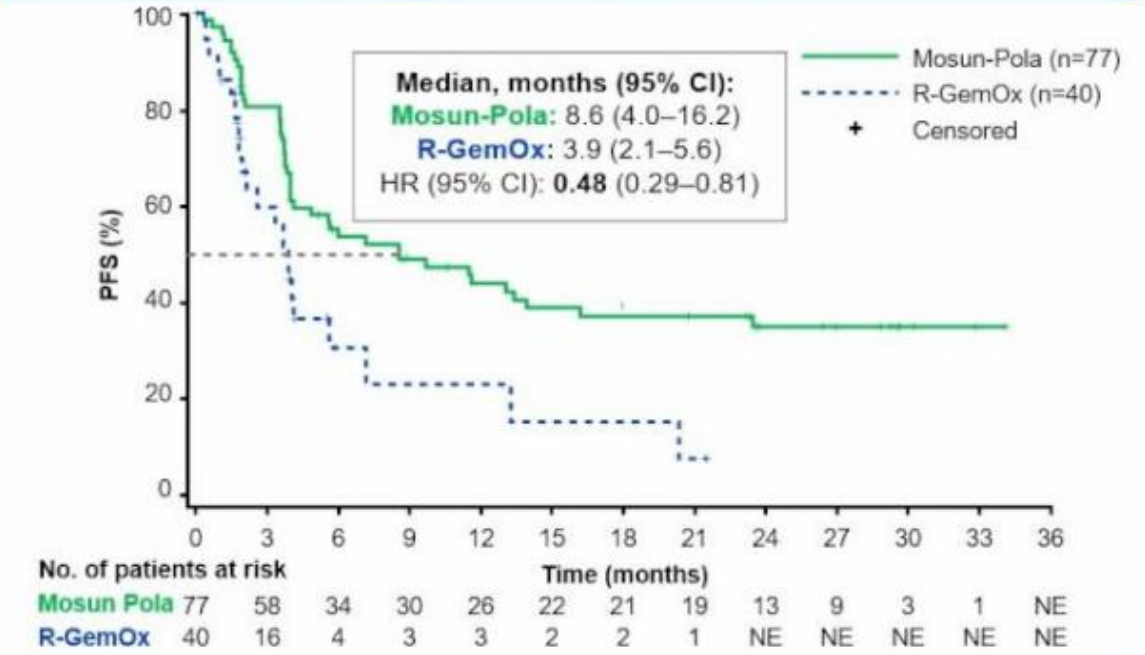
IRC-assessed response, % (95% CI)	Mosun-Pola (n=18)	R-GemOx (n=10)
ORR	94.4% (72.7–99.9)	60.0% (26.2–87.8)
CR	94.4% (72.7–99.9)	30.0% (6.7–65.3)

Consistent treatment benefit observed in 3L+ LBCL

IRC-assessed efficacy % (95% CI), unless otherwise stated	3L+ Mosun-Pola (n=77)	3L+ R-GemOx (n=40)
Median PFS, months (95% CI)	8.6 (4.0–16.2)	3.9 (2.1–5.6)
ORR	66.2% (54.6–76.6)	42.5% (27.0–59.1)
CR	44.2% (32.8–55.9)	27.5% (14.6–43.9)
Median DOR, months (95% CI)	21.5 (9.5–NE)	5.4 (2.3–18.3)
Median DOCR, months (95% CI)	NR (21.5–NE)	7.5 (2.3–NE)

Clinical cut-off date: August 8, 2025.

PFS by IRC: 3L+ LBCL

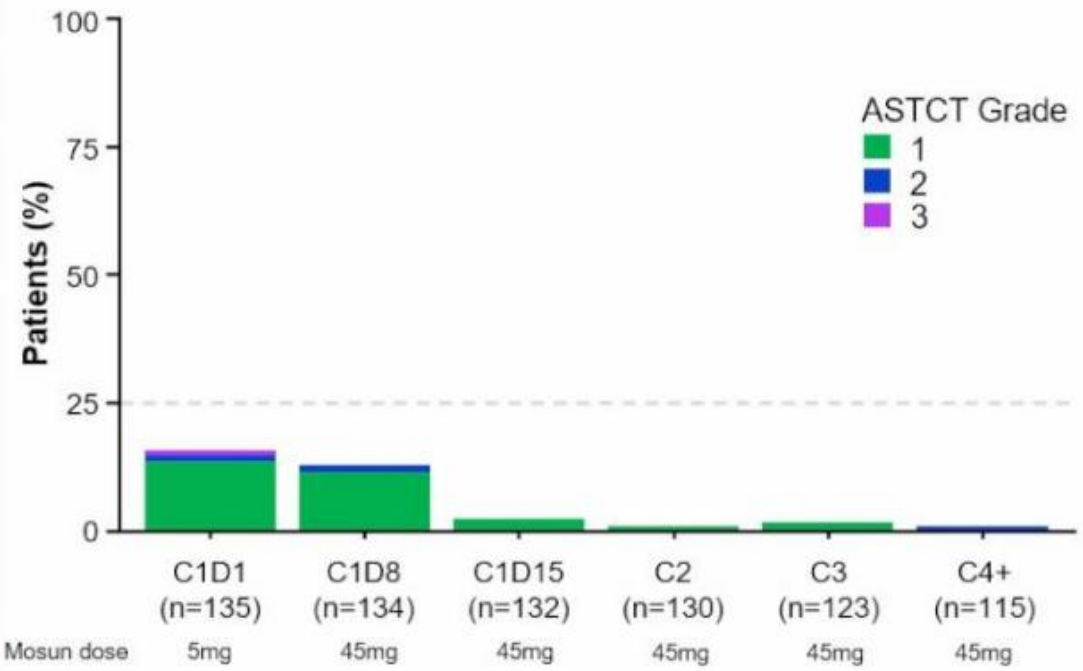


- Median PFS was more than doubled in the 3L+ population with Mosun-Pola versus R-GemOx
- High response rates and durable remissions were achieved with Mosun-Pola; median DOCR not reached

No new safety signals were detected and CRS was infrequent, early, and low grade

Patients with CRS AE, % (n) unless otherwise stated	Mosun-Pola (n=135)
Any grade	25.9% (35)
Grade 1	21.5% (29)
Grade 2	3.7% (5)
Grade 3	0.7% (1)
Any serious event of CRS*	5.2% (7)
Median onset to first CRS, days (range)	3 (1–6)
Median duration, days (range)	3 (1–11)
Tocilizumab for CRS management	4.4% (6)
Corticosteroids for CRS management	3.7% (5)

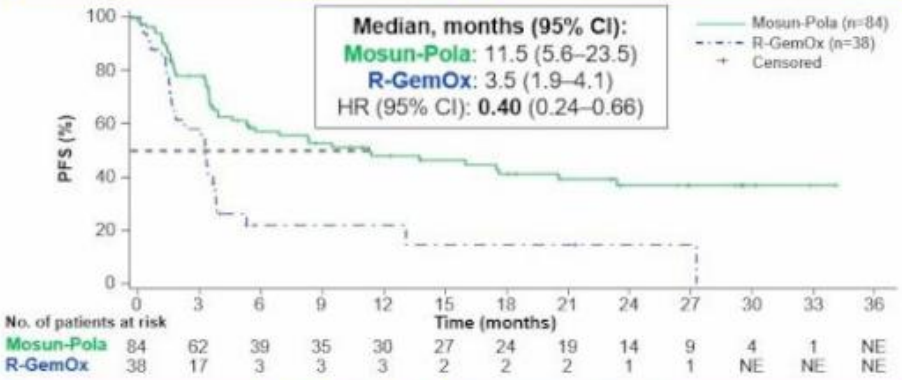
CRS by cycle and grade in the Mosun-Pola arm



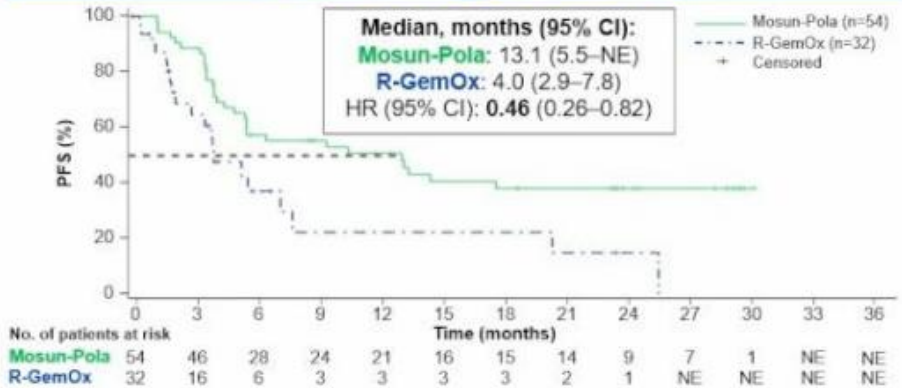
Clinical cut-off date: August 8, 2025.
*Events that required new or prolonged hospitalization.
ASTCT, American Society of Transplantation and Cellular Therapy.

Efficacy and safety of Mosun-Pola were comparable across age groups

PFS: <65 years old



PFS: ≥65 years old



% (n)	<65 years old		≥65 years old	
	Mosun-Pola (n=82)	R-GemOx (n=33)	Mosun-Pola (n=53)	R-GemOx (n=31)
Serious AEs	32.9% (27)	24.2% (8)	34.0% (18)	25.8% (8)
Grade ≥3 AE	63.4% (52)	69.7% (23)	66.0% (35)	58.1% (18)
Grade 5 AE	4.9% (4)	6.1% (2)	5.7% (3)	6.5% (2)
CRS	28.0% (23)	–	22.6% (12)	–
Neutropenia	48.8% (40)	60.6% (20)	41.5% (22)	48.4% (15)
Serious infections	14.6% (12)	15.2% (5)	18.9% (10)	12.9% (4)
Peripheral neuropathy	26.8% (22)	39.4% (13)	20.8% (11)	41.9% (13)

Clinical cut-off date: August 8, 2025.

Conclusions

Fixed-duration Mosun-Pola continues to demonstrate high efficacy in patients with ASCT-ineligible R/R LBCL

- Despite baseline imbalances favoring the control arm, the 2-year PFS rate with Mosun-Pola was more than double that of R-GemOx
- In the 2L setting, Mosun-Pola reduced the risk of death or progression by 62% versus R-GemOx, with meaningful efficacy improvements regardless of primary refractory/early relapse status
- A consistent benefit was observed in the 3L+ setting and in both younger and elderly patient subgroups

No new safety signals were detected with Mosun-Pola with additional follow-up

- **Mosun-Pola** continues to demonstrate the **lowest incidence and severity of CRS among T-cell directed therapies**
- The safety profile of Mosun-Pola was manageable across age groups

Mosun-Pola is a highly effective, targeted combination therapy that can be delivered across diverse outpatient treatment settings