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

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Summary

In the Phase 3 SUNMO study, **Mosun-Pola** demonstrated **clinically meaningful and statistically significant benefits** over R-GemOx in patients with R/R LBCL

Updated analyses **with fixed-duration Mosun-Pola** demonstrate **durable benefits, in addition to high efficacy in patients in the 2L setting**, regardless of primary refractory or early relapse status

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

No new safety signals were reported since the previous analysis; **low cytokine release syndrome (CRS) rates and comparable efficacy were demonstrated across age groups**

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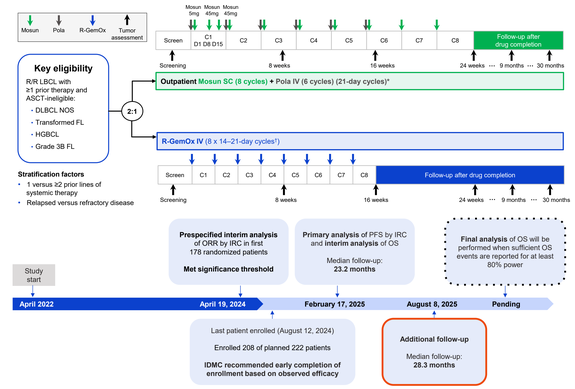
Background

- Patients with R/R LBCL unable to receive curative-intent therapies, such as chimeric antigen receptor T-cell therapy or autologous stem cell transplant (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 and an antibody-drug conjugate, demonstrated clinically meaningful and statistically significant benefits over R-GemOx in transplant-ineligible patients with R/R LBCL.[3,4]
- We present updated efficacy and safety data from the SUNMO study, including 2L and elderly (≥65 years) subgroups.

Methods

- Patients with R/R LBCL ineligible for ASCT were randomized 2:1 to receive Mosun-Pola or R-GemOx (**Figure 1**)
  - Dual primary endpoints were independent review committee (IRC)-assessed progression-free survival (PFS) and objective response rate (ORR)
  - Secondary endpoints included complete response (CR) rate, duration of response (DOR), duration of CR (DOCR), and safety; overall survival (OS) was not assessed, as the data cut-off was prior to the pre-defined final OS analysis
  - Subgroup analyses were performed based on the number of prior therapies (1 vs ≥2) and age at study entry (<65 vs ≥65 years old).

Figure 1. Study design and analysis timeline



*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 NOS, diffuse large B-cell lymphoma, not otherwise specified; FL, follicular lymphoma; HGBCL, high-grade B-cell lymphoma; IDMC, Independent Data Monitoring Committee; IV, intravenous; SC, subcutaneous.

As of August 8, 2025, a total of 208 patients were randomized (Mosun-Pola, n=138; R-GemOx, n=70)

- Median follow-up was 28.3 months.
- Baseline characteristics were broadly similar between the two treatment arms
  - Notable differences included a higher proportion of patients in the Mosun-Pola arm with an ECOG PS of 2 or bulky disease (**Table 1**).

Table 1. 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)

*Three patients in the Mosun-Pola arm and two patients in the R-GemOx arm had Grade 3b FL 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 lymphoma.

Mosun-Pola continued to demonstrate superior efficacy with durable remissions

- In the ITT population, Mosun-Pola reduced the risk of death or disease progression by 59% (PFS hazard ratio [HR]: 0.41; [95% confidence interval [CI]: 0.28–0.60]; **Figure 2**).
- CR rates with Mosun-Pola were 51.4% versus 24.3% with R-GemOx (**Table 2**).
- In the Mosun-Pola arm, 62.5% of patients with a CR remained in remission 2 years after their initial CR compared with 22.0% for R-GemOx (**Table 2**).

Figure 2. PFS by IRC (primary endpoint) in ITT population

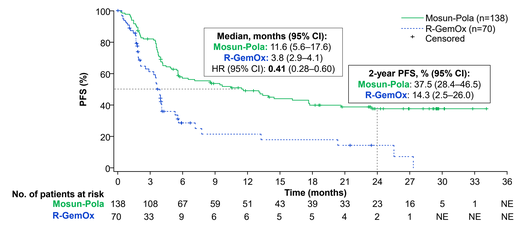


Table 2. Summary of IRC-assessed efficacy endpoints in ITT population

% (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)

PFS is censored at earliest of NALT or two or more missing tumor assessments, whichever occurs first.
NALT, new anti-lymphoma therapy; NE, not evaluable; NR, not reached.

Mosun-Pola demonstrated high efficacy in the 2L setting

- In the 2L setting, with over half of the patients having primary refractory disease, Mosun-Pola demonstrated a PFS HR of 0.38 (95% CI: 0.22–0.67; **Figure 3**)
  - Median PFS was 17.6 months for Mosun-Pola versus 3.6 months for R-GemOx
  - Median DOCR was not reached with Mosun-Pola (**Table 3**).

Figure 3. PFS by IRC in the 2L setting

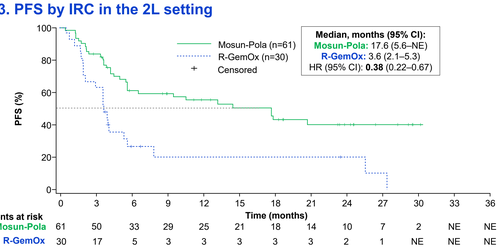


Table 3. Summary of IRC-assessed efficacy endpoints in the 2L setting

% (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)

- Improvements of PFS and response rates were observed regardless of primary refractory/early relapse status
  - In 2L, in patients with primary refractory or early relapsed disease, Mosun-Pola demonstrated a PFS HR of 0.41, ORR of 67.4%, and CR rate of 46.5%
  - In 2L, in patients with late relapsed disease, Mosun-Pola demonstrated a PFS HR of 0.21; the ORR and CR rate were both 94.4%.

Consistent treatment benefit with Mosun-Pola in 3L+ LBCL

- Median PFS was more than doubled (8.6 vs 3.9 months; HR: 0.48) in the 3L+ setting with Mosun-Pola versus R-GemOx (**Figure 4**).
- The ORR and CR rate with Mosun-Pola were 66.2% and 44.2%, respectively; median DOCR was not reached (**Table 4**).

Figure 4. PFS by IRC in the 3L+ setting

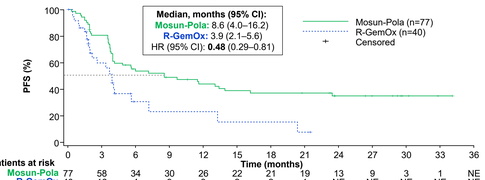


Table 4. Summary of IRC-assessed efficacy endpoints in the 3L+ setting

% (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)

The efficacy and safety of Mosun-Pola was comparable across age groups

- No new safety signals were detected in the safety population since the previous report;[3] any grade CRS occurred in 25.9% of patients, with Grade ≥2 CRS in 4.4%.
- The efficacy and safety profile of Mosun-Pola was consistent in elderly patients (≥65 years old; **Figure 5** and **Table 5**).

Figure 5. PFS by IRC in age-based subgroups

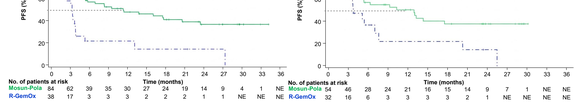


Table 5. Summary of safety in age-based subgroups

% (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)

AE, adverse event.

Conclusions

- Fixed-duration Mosun-Pola continues to demonstrate high efficacy in patients with ASCT-ineligible R/R LBCL
  - 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;[3] the safety profile was manageable across age groups.
- Mosun-Pola is a highly effective, targeted combination therapy that can be delivered across diverse outpatient treatment settings.

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