Subcutaneous mosunetuzumab plus polatuzumab vedotin is associated with improvements in health-related quality of life versus rituximab-gemcitabine-oxaliplatin in patients with relapsed/refractory large B-cell lymphoma: Results from the Phase III SUNMO study

To be presented by Brannon Flores on behalf of the authors

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Summary

In the Phase III randomized SUNMO study, mosunetuzumab plus polatuzumab vedotin (Mosun-Pola) significantly improved overall response rate (ORR) and progression-free survival (PFS) compared with rituximab-gemcitabine-oxaliplatin (R-GemOx) in patients with relapsed/refractory (R/R) large B-cell lymphoma (LBCL)

Here we report the impact of treatment on health-related quality of life (HRQoL) in patients from SUNMO using patient-reported outcomes (PROs)

These PRO data suggest HRQoL benefits with Mosun-Pola, an outpatient-based regimen with a favorable efficacy and safety profile

Mosun-Pola achieved clinically meaningful improvements in multiple aspects of HRQoL and delayed deterioration in physical functioning, lymphoma symptoms and peripheral neuropathy versus R-GemOx

Background

- Pretreatment PROs can provide prognostic information for overall survival (OS) and PFS in patients with LBCL.[1]
- In the SUNMO study (NCT05171647), Mosun-Pola significantly improved ORR and PFS compared with standard-of-care R-GemOx, in patients with R/R LBCL[2]
  - The safety profile of Mosun-Pola was notable for reduced chemotherapy toxicity and the lowest cytokine release syndrome incidence across T-cell engaging therapies in a Phase III setting.
- Here we report PROs from SUNMO to assess the impact of treatment on HRQoL.

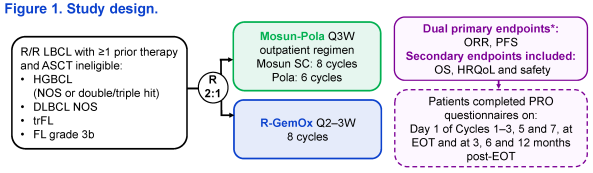
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SUNMO is a global, randomized, Phase III study

- Patients with autologous stem cell transplant (ASCT)-ineligible R/R LBCL were randomly assigned (2:1) to receive Mosun-Pola or R-GemOx (**Figure 1**).
- HRQoL was measured using:
  - The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) for global health status, functioning, and core symptom scales (scale range 0–100; higher score = better functioning and global health status and worse symptoms)[3]
  - The Functional Assessment of Cancer Therapy-Lymphoma Lymphoma subscale (FACT-Lym LYMS) for lymphoma symptoms (scale range 0–60; higher score = fewer lymphoma symptoms)[4]
  - The FACT Gynecologic Oncology Group-Neurotoxicity (FACT/GOG-NTX) for peripheral neuropathy (scale range 0–44; higher score = fewer symptoms).[5,6]
- Minimal clinically important difference (MCID) was defined as a 10-point change for EORTC QLQ-C30 and 3-point change for FACT-Lym and FACT/GOG-NTX.
- HRQoL questionnaire completion rates, time to deterioration (TTD) and change from baseline (CfB) were estimated at each assessment.

Figure 1. Study design.



*Assessed by an independent review committee; DLBCL, diffuse-large B-cell lymphoma; EOT, end of treatment; FL, follicular lymphoma; HGBCL, high-grade B-cell lymphoma; NOS, not otherwise specified; Q2W, every 2 weeks; Q3W, every 3 weeks; R, randomized; trFL, transformed follicular lymphoma.

Overall, 208 patients were randomized (Mosun-Pola, n=138; R-GemOx, n=70)

- At baseline, there were higher rates of patients with an Eastern Cooperative Oncology Group performance status (ECOG PS) of 2 and bulky disease in the Mosun-Pola arm compared with patients in the R-GemOx arm (**Table 1**).
- PRO questionnaire completion rates were high (>95%) in both treatment arms, from baseline to EOT.

Table 1. Baseline demographics and clinical characteristics.

n (%), unless otherwise stated		Mosun-Pola (n=138)	R-GemOx (n=70)
Age, years	Median (range) ≥65 years	62 (23–87) 54 (39.1)	63 (29–85) 32 (45.7)
Sex	Male	76 (55.1)	45 (64.3)
Race	Asian Black or African American White Other/Unknown	56 (40.6) 4 (2.9) 61 (44.2) 17 (12.3)	26 (37.1) 1 (1.4) 38 (54.3) 5 (7.1)
Ethnicity	Not Hispanic or Latino Hispanic or Latino Not reported	88 (63.8) 47 (34.1) 3 (2.2)	48 (68.6) 22 (31.4) 0
ECOG PS	0–1 2	120 (87.0) 18 (13.0)	69 (98.6) 1 (1.4)
Non-Hodgkin lymphoma subtypes	DLBCL HGBCL FL grade 3b	109 (79.0) 26 (18.8) 3 (2.2)	54 (77.1) 14 (20.0) 2 (2.9)
TrFL	Yes	17 (12.3)	6 (8.6)
Ann Arbor stage	III–IV	104 (75.4)	56 (80.0)
Bulky disease (>10 cm)	Yes	28 (20.3)	5 (7.1)
No. of prior lines of therapy	Median (range) 1 ≥2	2 (1–9) 61 (44.2) 77 (55.8)	2 (1–5) 30 (42.9) 40 (57.1)
Primary refractory	Yes	79 (57.2)	42 (60.0)
Refractory to last prior therapy	Yes	97 (70.3)	48 (68.6)

At baseline, low-to-mild levels of symptom severity were reported in both arms

- Patients in the Mosun-Pola arm had worse pain and fatigue symptoms at baseline compared with patients in the R-GemOx arm (**Table 2**).

Table 2. Mean scores at baseline in select domains.

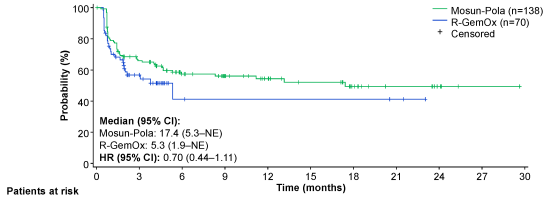
Mean (SD)	Mosun-Pola (n=138)	R-GemOx (n=70)
Physical functioning*	72.6 (26.4)	79.1 (20.1)
Lymphoma symptoms†	44.7 (10.1)	45.9 (10.2)
Pain*	30.9 (32.8)	23.3 (24.8)
Fatigue*	33.9 (28.7)	25.6 (20.8)

*By EORTC QLQ-C30 (higher scores = better physical functioning or worse lymphoma symptoms, including pain and fatigue). †By FACT-Lym LYMS (higher score = fewer symptoms). SD, standard deviation.

Mosun-Pola delayed time to worsening in physical functioning, lymphoma symptoms, fatigue and peripheral neuropathy versus R-GemOx

- In the Mosun-Pola arm, median TTD in physical functioning was delayed by >1 year compared with the R-GemOx arm (17.4 vs 5.3 months; hazard ratio [HR], 0.7; 95% confidence interval [CI]: 0.4–1.1; **Figure 2**).

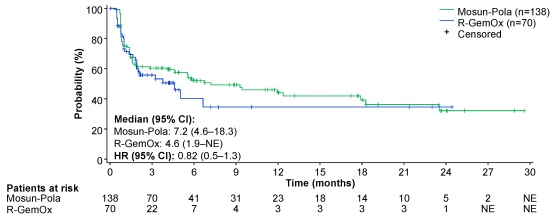
Figure 2. TTD in EORTC QLQ-C30 physical functioning.



EORTC QLQ-C30 higher scores = better functioning.
HR and 95% CI for deterioration was estimated using a stratified Cox proportional hazards model. Patients who did not have an observed deterioration at the time of the clinical data cutoff date were censored at the last non-missing assessment date. Patients without a post-baseline assessment were censored at randomization. Figure remains unchanged from Budde et al., 2025.[2] NE, not estimable.

- Median TTD for lymphoma symptoms was delayed by >2 months in the Mosun-Pola arm compared with the R-GemOx arm (7.2 vs 4.6 months; HR, 0.8; 95% CI: 0.5–1.3; **Figure 3**).

Figure 3. TTD in FACT-Lym LYMS lymphoma symptoms.



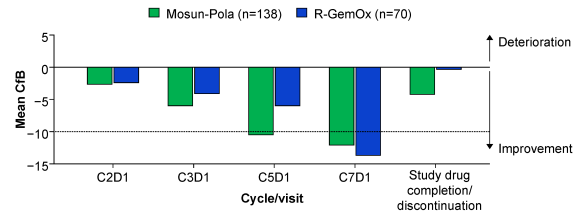
FACT-Lym LYMS higher score = fewer lymphoma symptoms.

- Median TTD for fatigue was 1.9 months (95% CI: 1.4–4.0) in the Mosun-Pola arm and 1.6 months (95% CI: 1.0–3.8) in the R-GemOx arm (HR, 0.8; 95% CI: 0.5–1.2).
- Median TTD for peripheral neuropathy was 4.4 months (95% CI: 3.0–6.0) in the Mosun-Pola arm and 2.0 months (95% CI: 1.0–6.4) in the R-GemOx arm (HR, 0.7; 95% CI: 0.5–1.1).

Mosun-Pola-treated patients experienced earlier improvements in pain versus R-GemOx-treated patients

- Patients receiving Mosun-Pola had clinically meaningful improvements in mean scores for pain two cycles earlier than patients receiving R-GemOx (**Figure 4**)
  - At Cycle 5, CfB improvements in pain for Mosun-Pola exceeded the MCID (pain: −10.0); the mean CfB in the Mosun-Pola and R-GemOx arms was −10.5 and −6.0, respectively
  - By Cycle 7, improvements in pain exceeded the MCID in both arms (Mosun-Pola, −12.1; R-GemOx, −13.7).

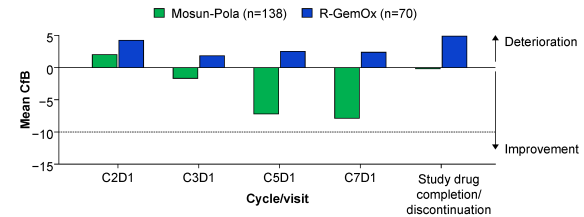
Figure 4. Improvement in EORTC QLQ-C30 pain.



EORTC QLQ-C30 higher scores = worse symptoms for pain. Post-EOT timepoints were not included due to low patient numbers in the follow-up period.

- Although mean baseline fatigue scores were higher in the Mosun-Pola arm (33.9 vs R-GemOx, 25.6), fatigue improved in the Mosun-Pola arm, whilst remaining stable in the R-GemOx arm (**Figure 5**)
  - Mean CfB scores at C7D1 approached the MCID for Mosun-Pola and worsened in the R-GemOx arm (−7.8 vs +2.4, respectively)
  - Mean fatigue scores were relatively low (defined as ≤25.0) in both arms at EOT (Mosun-Pola, 24.0; R-GemOx, 26.2).

Figure 5. Improvement in EORTC QLQ-C30 fatigue.



EORTC QLQ-C30 higher scores = worse symptoms for fatigue. Post-EOT timepoints were not included due to low patient numbers in the follow-up period.

- Mosun-Pola had clinically meaningful improvements in mean scores two cycles later than R-GemOx for lymphoma symptoms:
  - At Cycle 3, CfB improvements in lymphoma symptoms for R-GemOx exceeded the MCID (3.0); the mean CfB in the Mosun-Pola and R-Gem-Ox arms were +2.5 and +3.4, respectively
  - By Cycle 5, improvements in lymphoma symptoms exceeded the MCID in both arms (Mosun-Pola, +4.8; R-GemOx, +4.1).
- Mosun-Pola-treated patients also had clinically meaningful improvements in:
  - Mean scores by EORTC QLQ-C30 for financial difficulties (CfB Cycle 5, −10.4)
  - Emotional functioning (Cycle 5, +10.4)
  - Constipation (Cycle 7, −10.2).
- In the R-GemOx arm, mean scores for financial difficulties, emotional functioning and constipation remained similar to baseline levels.

Conclusions

- In this R/R LBCL population with a high disease burden, Mosun-Pola demonstrated benefits across multiple aspects of HRQoL compared with R-GemOx, particularly in maintaining/improving physical functioning, lymphoma symptoms, fatigue, and peripheral neuropathy.
- Patients treated with Mosun-Pola achieved clinically meaningful improvements in PROs, with scores exceeding the MCID in several domains and exhibiting a delay in deterioration of >1 year for physical functioning, and >2 months for lymphoma symptoms and peripheral neuropathy versus R-GemOx.
- Mosun-Pola provides a patient-centric, outpatient regimen, without conventional chemotherapy, for patients with transplant-ineligible R/R LBCL
  - Combining significantly improved efficacy with a favorable safety profile and enhanced HRQoL provides a holistic approach to fulfill the unmet need in this patient population.

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