

# Mosunetuzumab plus polatumab vedotin (Mosun-Pola) compared with rituximab plus gemcitabine and oxaliplatin (R-GemOx) in autologous stem cell transplant (ASCT)-ineligible patients with relapsed/refractory (R/R) large B-cell lymphoma (LBCL): primary results of the Phase III SUNMO trial

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## Summary

Mosun-Pola showed promising outcomes as an outpatient regimen in patients with R/R LBCL in a Phase II study

Here we report primary results from the Phase III SUNMO trial, which met its primary endpoints of significantly improved PFS and ORR for Mosun-Pola versus R-GemOx in patients with transplant-ineligible R/R LBCL

SUNMO is the first positive Phase III trial without conventional chemotherapy, supporting the use of Mosun-Pola as a fixed-duration, outpatient, off-the-shelf regimen for patients with transplant-ineligible R/R LBCL

The safety profile of Mosun-Pola was consistent with the known risk of the individual study drugs and there were no significant CRS events (Grade 2 or higher) in 96% of patients

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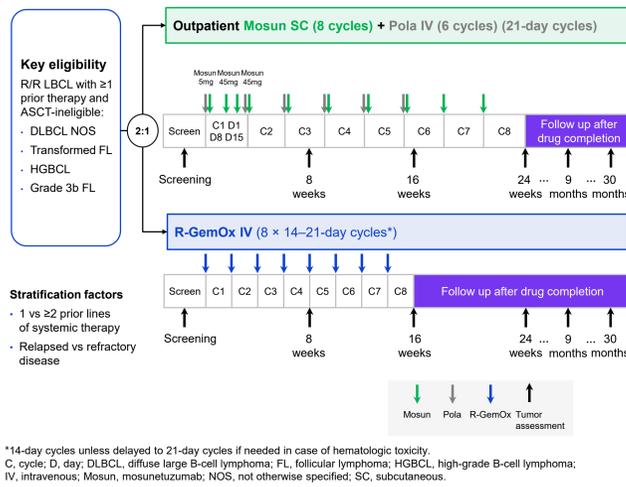
## Background

- Patients with R/R LBCL unable to receive curative-intent therapies such as chimeric antigen receptor (CAR) T-cell therapy or ASCT have a poor prognosis<sup>1</sup>
  - Barriers to curative therapies may include rapidly progressing disease, lack of response to prior therapy, age, comorbidities, and/or logistical barriers,<sup>1,2</sup> and toxicities of T-cell directed therapies, such as cytokine release syndrome (CRS), may limit access for patients and burden healthcare systems.<sup>2,3</sup>
- Mosunetuzumab, a CD20xCD3 T-cell engaging bispecific antibody, plus polatumab vedotin, a CD79b targeting antibody-drug conjugate, showed promising outcomes as an outpatient regimen in a Phase II study.<sup>4,5</sup>
- Here we present the efficacy and safety of Mosun-Pola versus rituximab plus R-GemOx in transplant-ineligible patients with R/R LBCL after ≥1 prior line of therapy from the Phase III SUNMO trial (NCT05171647).

### SUNMO (NCT05171647) is a global, randomized, Phase III trial

- Patients with R/R LBCL who were ASCT ineligible were randomized 2:1 to receive 8 cycles of Mosun-Pola (every 21 days) or R-GemOx (every 14 days; Figure 1).
- Primary endpoints were progression-free survival (PFS) by independent review committee (IRC) and objective response rate (ORR); overall survival (OS) was a key secondary endpoint.

Figure 1. Study overview.



### At data cut-off (February 17, 2025), 208 patients were randomized and median follow-up was 23.2 months (range: 0–32)

- Overall, 43.8% of patients had received 1 prior therapy and 73.6% had primary refractory disease or early relapse (disease relapse <12 months from first-line therapy; Table 1).

Table 1. Baseline characteristics.

% (n), unless stated	Mosun-Pola (n=138)	R-GemOx (n=70)
<b>Median age, years (range)</b>	62 (23–87)	63 (29–85)
≥65 years	39.1 (54)	45.7 (32)
<b>Male</b>	55.1 (76)	64.3 (45)
<b>Race</b>		
Asian	40.6 (56)	37.1 (26)
Black or African American	2.9 (4)	1.4 (1)
White	44.2 (61)	54.3 (38)
Other/Unknown	12.3 (17)	7.1 (5)
<b>ECOG PS</b>		
0–1	87.0 (120)	98.6 (69)
2	13.0 (18)	1.4 (1)
<b>NHL subtypes</b>		
DLBCL	79.0 (109)	77.1 (54)
HGBCL	18.8 (26)	20.0 (14)
FL3b	2.2 (3)	2.9 (2)
<b>Transformed FL*</b>	12.6 (17)	8.8 (6)
<b>Ann Arbor stage</b>		
I–II	24.6 (34)	20.0 (14)
III–IV	75.4 (104)	80.0 (56)
<b>Bulky disease (≥10cm)</b>	20.3 (28)	7.1 (5)
<b>Number of prior lines of therapy</b>		
Median (range)	2 (1–9)	2 (1–5)
1	44.2 (61)	42.9 (30)
≥2	55.8 (77)	57.1 (40)
<b>Primary refractory</b>	57.2 (79)	60.0 (42)
<b>Refractory to last prior therapy</b>	70.3 (97)	68.6 (48)

\*n=3 Mosun-Pola and n=2 R-GemOx had FL3b and were not included in the denominator for transformed FL. ECOG PS, Eastern Cooperative Oncology Group performance status; NHL, non-Hodgkin lymphoma.

### Mosun-Pola significantly prolonged PFS versus R-GemOx

- PFS was significantly improved at 11.5 months (95% confidence interval [CI]: 5.6–17.6) for Mosun-Pola versus 3.8 months (95% CI: 2.9–4.1) for R-GemOx, demonstrating a 59% risk reduction for progression or death (hazard ratio [HR], 0.41, 95% CI: 0.28–0.61; P-value <0.0001; Figure 2).
- PFS benefit was consistent across prespecified subgroups (Figure 3), including patients receiving second-line therapy (HR, 0.38, 95% CI: 0.22–0.67), and patients with primary refractory disease or early relapse (HR, 0.44, 95% CI: 0.29–0.67).

Figure 2. PFS by IRC.

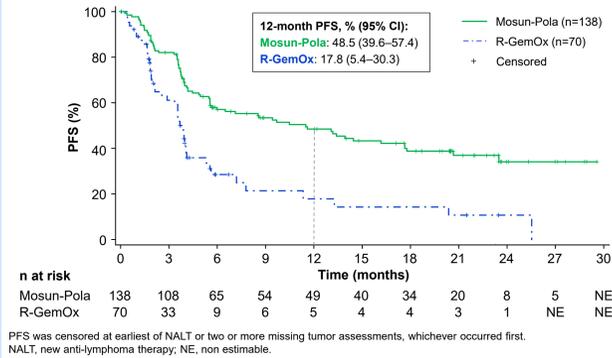
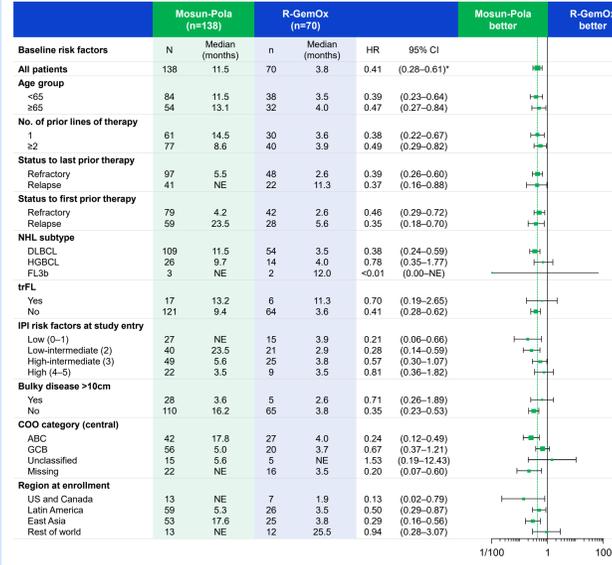


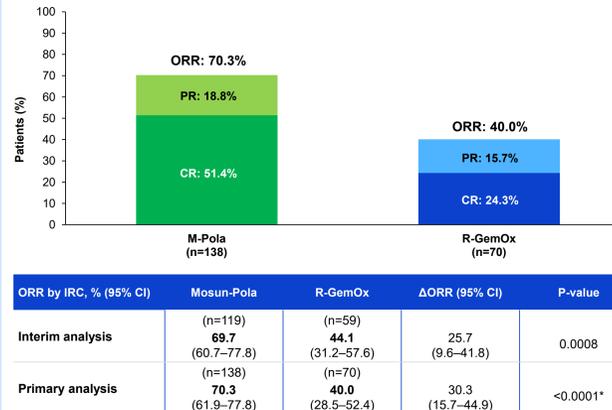
Figure 3. Exploratory subgroup analysis of PFS.



### ORR was significantly improved with Mosun-Pola compared with R-GemOx

- Response rates at the primary analysis were 70.3% with Mosun-Pola and 40.0% with R-GemOx, a significant improvement of >30% (P-value <0.0001; Figure 4).
- Mosun-Pola doubled the complete response (CR) rate versus R-GemOx (51.4% vs 21.3%; Figure 4).

Figure 4. ORR by IRC.



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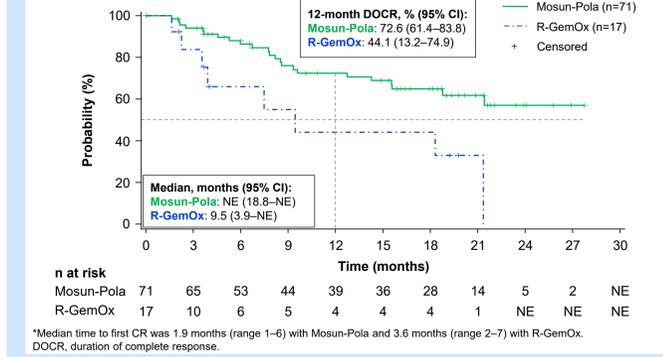
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## Disclosures

... consulting/advisory role (AbbVie, ADC Therapeutics, Allogene, AstraZeneca, Bristol Myers Squibb, Genentech, Inc., Janssen, Kite Pharma/Gilead, Morphosys/Incyte, Novartis, Nuvix, Pfizer, Regeneron), research funding (AbbVie, ADC Therapeutics, Allogene, AstraZeneca, Bristol Myers Squibb, Genentech, Inc., Janssen, Kite/Gilead, Morphosys/Incyte, Novartis, Nuvix, Pfizer, Regeneron); research funding (Sanofi, BiGene, Boryong, F. Hoffmann-La Roche Ltd, Kyowa-Kirin, Dongji, ...)

- Mosun-Pola achieved duration of remission in most patients with a CR, and nearly 75% of patients with a CR were still in remission with Mosun-Pola at 1 year (Figure 5).

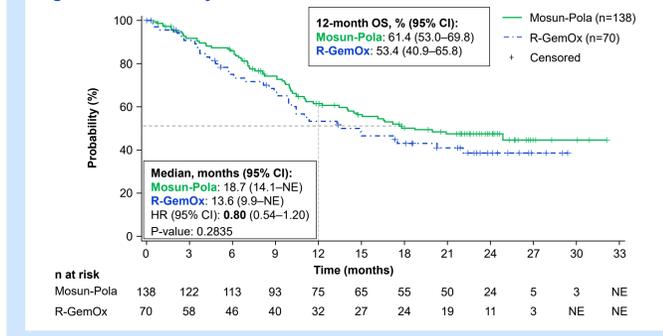
Figure 5. Duration of CR.\*



### Interim analysis showed prolonged OS with Mosun-Pola versus R-GemOx

- OS numerically favored Mosun-Pola versus R-GemOx (HR: 0.80) at the interim OS analysis (Figure 6).

Figure 6. Interim analysis of OS.



### Adverse event (AE) rates are comparable between Mosun-Pola and R-GemOx, with fewer AEs leading to treatment discontinuation in the Mosun-Pola arm

- In safety-evaluable patients (Mosun-Pola, n=135; R-GemOx, n=64), rates of thrombocytopenia (8.9% vs 65.6%) and peripheral neuropathy (24.4% vs 42.2%) were lower with Mosun-Pola versus R-GemOx (Table 2).
- CRS events occurred in 25.9% of Mosun-Pola-treated patients (Grade 1, 21.5%; Grade 2, 3.7%; Grade 3, 0.7%; median [range] duration 3 [1–11] days) and there were no immune effector-cell associated neurotoxicity syndrome events.

Table 2. Safety overview.

% (n), unless stated	Mosun-Pola (n=135)	R-GemOx (n=64)
<b>Number of cycles, median (range)</b>	8.0 (1–8)	5.0 (1–8)
<b>Any AE</b>	97.0 (131)	95.3 (61)
Treatment-related AE	93.3 (126)	89.1 (57)
<b>SAEs</b>	33.3 (45)	25.0 (16)
Treatment-related SAE	24.4 (33)	20.3 (13)
<b>Grade 3/4 AE</b>	58.5 (79)	57.8 (37)
Treatment-related Grade 3–4 AE	52.6 (71)	51.6 (33)
<b>Grade 5 AE</b>	5.2 (7)	6.3 (4)
Treatment-related Grade 5 AE*	1.5 (2)	3.1 (2)
<b>AE leading to any study drug discontinuation†</b>	2.2 (3)	4.7 (3)

\*Mosun-Pola: COVID-19 and COVID-19 pneumonia (n=1 each); R-GemOx: COVID-19 pneumonia and pneumonia (n=1 each).  
†Mosun-Pola: pneumonitis, infusion-related reaction, and cytomegalovirus infection reactivation (n=1 each); R-GemOx: delirium, embolism, and respiratory syncytial virus infection (n=1 each).

## Conclusions

- SUNMO is the first positive Phase III trial without conventional chemotherapy; Mosun-Pola reduced the risk of death or progression by 59%, tripled the median PFS and doubled the CR rate versus R-GemOx.
- Mosun-Pola has the lowest CRS incidence and severity among T-cell directed therapies to date, with 96% of patients not having significant CRS; this may expand patient access to a highly effective therapy and allow broad outpatient usage.
- Mosun-Pola is a fixed duration outpatient regimen that combines a bispecific antibody with an antibody-drug conjugate, which provided clinically meaningful and statistically significant improvements in PFS and response in patients with transplant-ineligible R/R LBCL.