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# Mosunetuzumab (Mosun) or glofitamab (Glofit) in combination with golcadomide (Golca) demonstrates a manageable safety profile and encouraging efficacy in patients with relapsed or refractory (R/R) B-cell non-Hodgkin lymphoma (B-NHL)

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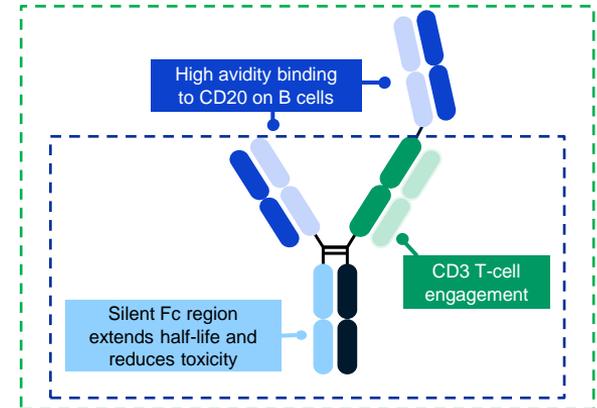
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# Background

- **Mosunetuzumab and glofitamab**
  - **CD20xCD3 T-cell engaging bispecific antibodies** with approved indications in R/R FL or R/R DLBCL<sup>1–6</sup>
  - Both demonstrated high response rates and manageable safety as monotherapy in patients with R/R FL or DLBCL in pivotal Phase 2 studies<sup>7–10</sup>
- **Golcadomide** is a potential first-in-class **oral CELMoD™** designed for the treatment of lymphoma, and is currently in Phase 3 development\*
  - Drives the closed, active conformation of cereblon to induce rapid and deep degradation of Ikaros and Aiolos (B-cell lineage transcription factors), leading to direct cell killing and immunomodulatory activity<sup>11–14</sup>
  - Has shown manageable safety and encouraging efficacy in the ongoing Phase 1b/2 CC-99282-NHL-001 study<sup>15</sup>

**Glofitamab:** CD20xCD3 bispecific antibody with 2:1 format<sup>1</sup>

**Mosunetuzumab:** CD20xCD3 bispecific antibody (1:1 format)<sup>2</sup>

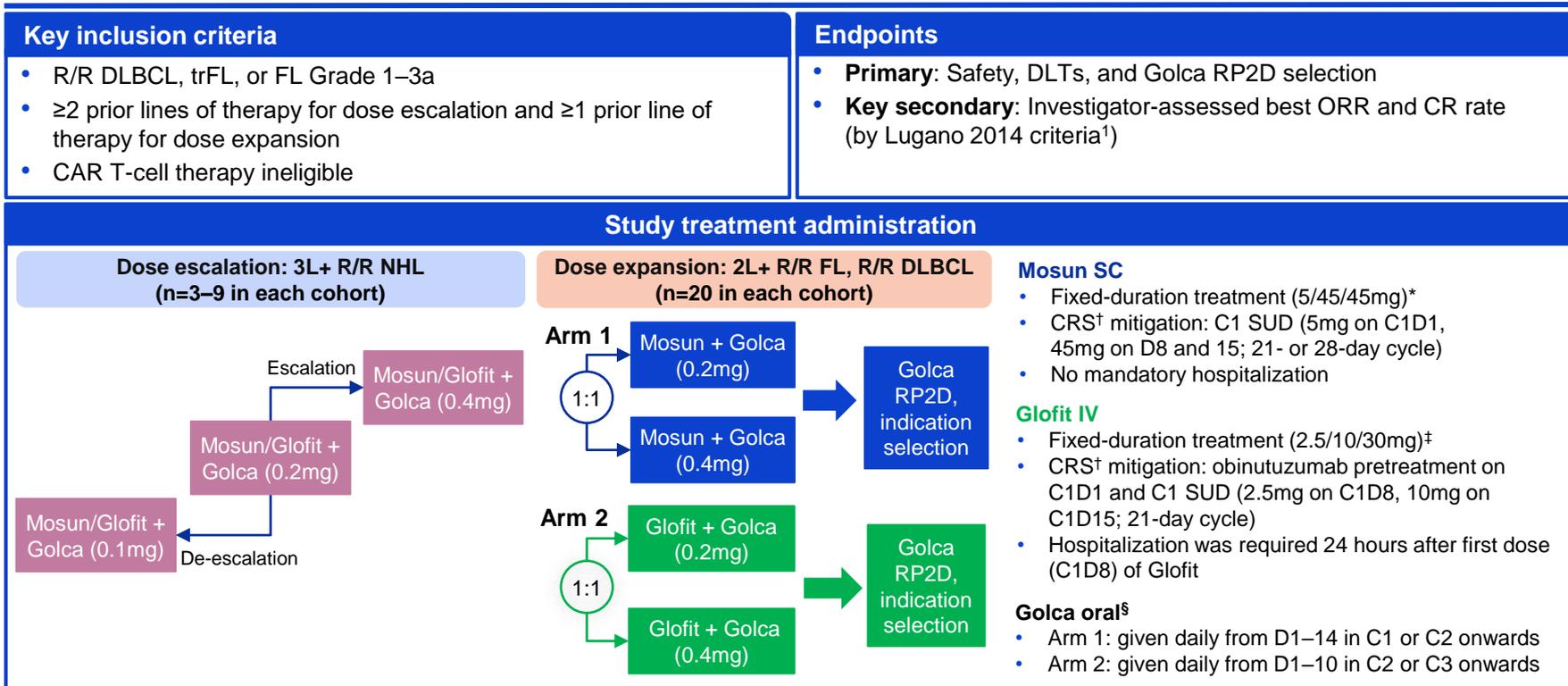


**We report preliminary safety and efficacy data from a Phase 1b study (NCT05169515) of Golca combined with Mosun or Glofit in patients with R/R B-NHL**

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\*By Bristol Myers Squibb.  
CELMoD, cereblon E3 ligase modulator;  
DLBCL, diffuse large B-cell lymphoma;  
FL, follicular lymphoma.

# Study design



\*Mosun was administered with SUD during C1 and at 45mg on D1 of C2–12 (28-day cycle). <sup>†</sup>CRS events were graded by American Society for Transplantation and Cellular Therapy criteria. <sup>‡</sup>Glofit was administered with SUD during C1 and at the target dose (30mg) on D1 of C2–12 (21-day cycles). <sup>§</sup>The initial Golca dose was 0.2mg. 2L+, second-line or later; 3L+, third-line or later; C, cycle; CAR, chimeric antigen receptor; CR, complete response; CRS, cytokine release syndrome; D, day; DLT, dose limiting toxicity; IV, intravenous; ORR, overall response rate; RP2D, recommended Phase 2 dose; SC, subcutaneous; SUD, step-up dosing; trFL, transformed follicular lymphoma.

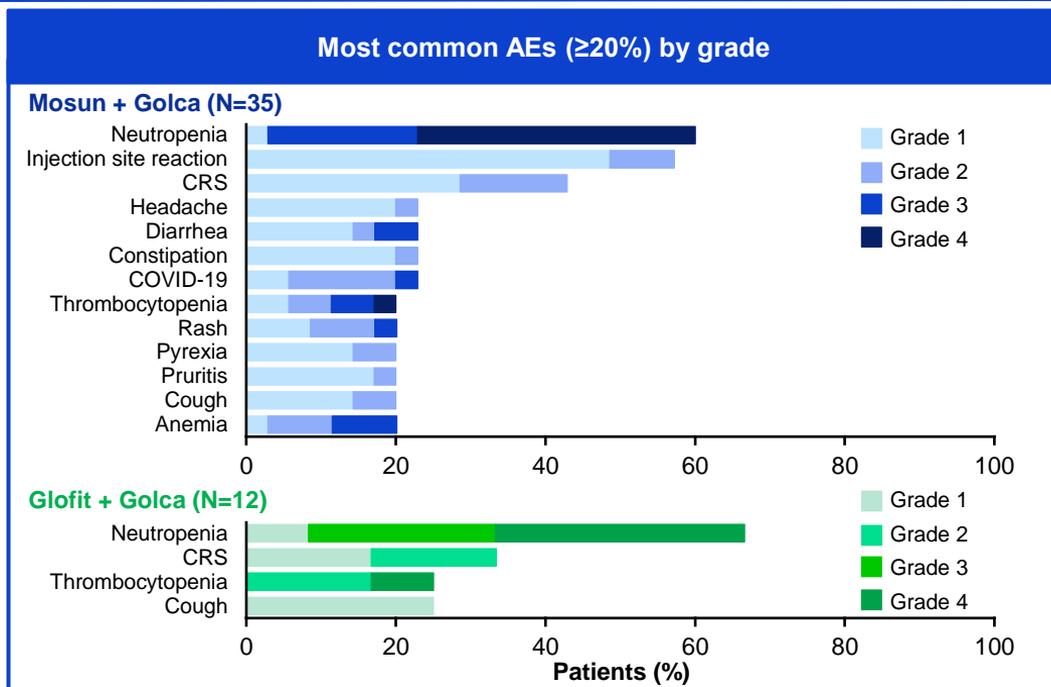
1. Cheson BD, et al. J Clin Oncol 2014;32:3059–68;  
2. Lee DW, et al. Biol Blood Marrow Transplant 2019;25:625–38.

# Baseline characteristics

n (%) unless otherwise stated		Mosun + Golca (N=35)	Glofit + Golca (N=12)
<b>Median age, years (range)</b>		63.0 (30–83)	59.5 (37–76)
<b>Male</b>		22 (62.9)	6 (50.0)
<b>Race</b>	Asian	2 (5.7)	0
	Black or African American	2 (5.7)	0
	White	29 (82.9)	11 (91.7)
	Not reported or unknown	2 (5.7)	1 (8.3)
<b>Ethnicity</b>	Hispanic or Latino	1 (2.9)	2 (16.7)
	Not Hispanic or Latino	28 (80.0)	10 (83.3)
	Not reported or unknown	6 (17.1)	0
<b>ECOG PS</b>	0	19 (54.3)	8 (66.7)
	1	16 (45.7)	4 (33.3)
<b>Ann Arbor stage III/IV</b>		32 (91.4)	9 (75.0)
<b>NHL histology</b>	FL	20 (57.1)	9 (75.0)
	trFL/DLBCL	14 (40.0)	3 (25.0)
<b>Median lines of prior therapy, n (range)</b>		3.0 (1–6)	2.0 (1–4)
<b>Prior therapies</b>	CAR T-cell therapy	10 (28.6)	5 (41.7)
	Anti-CD20	34 (97.1)	12 (100)
	ASCT	2 (5.7)	1 (8.3)
	IMiDs	11 (31.4)	4 (33.3)

# Safety overview

n (%) unless otherwise stated	Mosun + Golca (N=35)	Glofit + Golca (N=12)
AE	35 (100)	12 (100)
Grade 3/4 AE	26 (74.3)	8 (66.7)
Serious AE	23 (65.7)	6 (50.0)
AESI*	13 (37.1)	4 (33.3)
Grade 5 (fatal) AE	0	0
<b>AE leading to treatment discontinuation</b>	6 (17.1) <sup>†</sup>	0
<b>AE leading to dose modification/interruption</b>	19 (54.3) <sup>‡</sup>	6 (50.0) <sup>§</sup>



The safety profile was manageable with low rates of AEs leading to treatment discontinuation; neutropenia was the most common AE

\*Protocol defined AESIs. <sup>†</sup>Neutropenia (n=4), thrombocytopenia (n=1), anemia (n=1) and disseminated intravascular coagulation (n=1). <sup>‡</sup>Infections including COVID-19 (n=7), neutropenia (n=6), febrile neutropenia (n=2), pneumonia (n=1), folliculitis (n=1), bronchospasm (n=1), CRS (n=1), injection site reaction (n=1), chest pain (n=1), influenza (1), atrial fibrillation (n=1) and supraventricular tachycardia (n=1). <sup>§</sup>Neutropenia (n=1), febrile neutropenia (n=1), sinusitis (n=1) and nausea (n=1). AE, adverse event; AESI, AEs of special interest.

# AEs of special interest

n (%)	Mosun + Golca (N=35)*	Glofit + Golca (N=12)*
Grade ≥2 injection site reaction	3 (8.6)	NA
Grade ≥3 tumor lysis syndrome	1 (2.90)	0
Any grade PT ICANS <sup>†</sup>	0	1 (8.3) <sup>‡</sup>
Grade ≥3 neutropenia <sup>§</sup>	20 (57.1)	7 (58.3)
Grade ≥3 febrile neutropenia	4 (11.4)	1 (8.3)
Any grade infections	22 (62.9)	4 (33.3)
Grade ≥3	4 (11.4)	1 (8.3)
Elevated liver enzymes <sup>¶</sup>	2 (5.7)	2 (16.7)

No new safety signals were observed

\*There were no reports of HLH or Grade ≥3 tumor flare. <sup>†</sup>ICANS as a preferred term. <sup>‡</sup>Grade 2 ICANS per ASTCT grading criteria. Event was resolved 6 days after AE onset date. <sup>§</sup>Neutropenia/neutrophil count decreased. <sup>¶</sup>Includes alanine aminotransferase and aspartate transaminase. ASTCT, American Society for Transplantation and Cellular Therapy criteria; HLH, hemophagocytic lymphohistiocytosis; ICANS, immune effector cell-associated neurotoxicity syndrome; NA, not applicable; PT, preferred term.

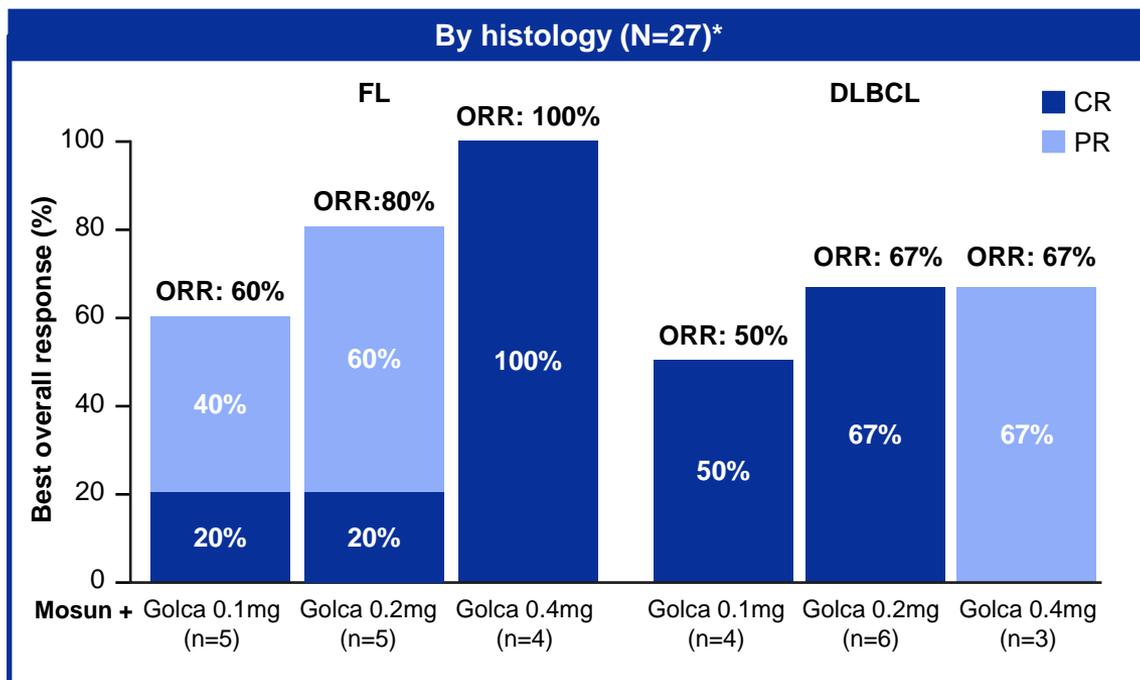
# CRS summary and management

n (%) unless otherwise stated	Mosun + Golca			Glofit + Golca		
	All patients (N=35)	Golca initiation		All patients (N=12)	Golca initiation	
		C1 (n=11)	C2 (n=24)		C2 (n=5)	C3 (n=7)
<b>CRS* by ASTCT criteria<sup>1</sup></b>						
Any grade	15 (42.9)	5 (45.5)	10 (41.7)	4 (33.3)	1 (20.0)	3 (42.9)
Grade 1	10 (28.6)	4 (36.4)	6 (25.0)	2 (16.7)	1 (20.0)	1 (14.3)
Grade 2	5 (14.3)	1 (9.1)	4 (16.7)	2 (16.7)	0	2 (28.6)
Grade 3	0	0	0	0	0	0
<b>Median time since recent dose of Mosun/Glofit, days (range)</b>	1 (0–4)	1 (0–2)	1 (0–4)	1 (0–1)	1 (0–1)	1 (0–1)
<b>Median CRS duration, days (range)</b>	4 (1–9)	1.8 (1–3)	5 (1–9)	3 (2–4)	2 (2–2)	2.5 (2–4)
<b>CRS management</b>						
Corticosteroids	4 (11.4)	1 (9.1)	3 (12.5)	2 (16.7)	0	2 (28.6)
Tocilizumab	5 (14.3)	1 (9.1)	4 (16.7)	3 (25.0)	0	3 (42.9)
Low-flow oxygen	2 (5.7)	1 (9.1)	1 (4.2)	1 (14.3)	0	1 (14.3)
Fluids	3 (8.6)	0	3 (12.5)	0	0	0

All CRS events were low grade and resolved

\*No CRS events led to treatment discontinuation.

# Best overall response in Arm 1: Mosun + Golca

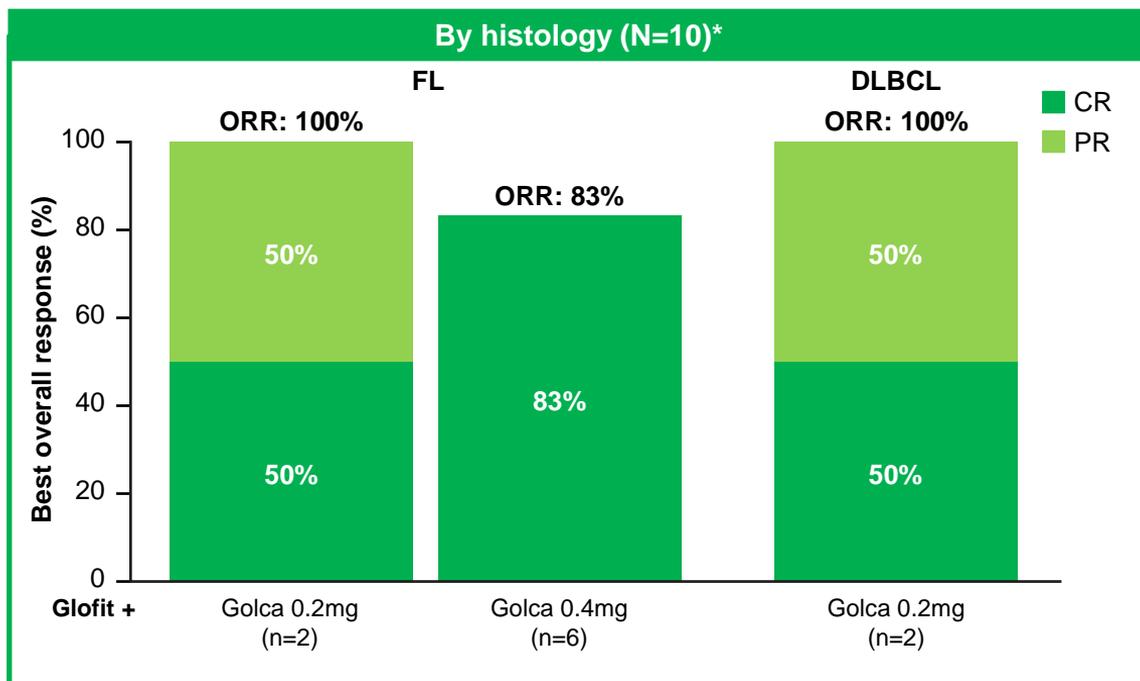


- Median time to first response for all patients (N=27)\*: 2.6 months (range: 2–4)
- Response in patients who received prior CAR T-cell therapy (n=8):
  - Overall, 5 patients achieved a CR
    - Two patients had FL and one achieved CR
    - Six patients had DLBCL and four achieved a CR

High response rates were observed in patients with FL and DLBCL including those who received prior CAR T-cell therapy

\*Efficacy-evaluable population. PR, partial response.

# Best overall response in Arm 2: Glofit + Golca

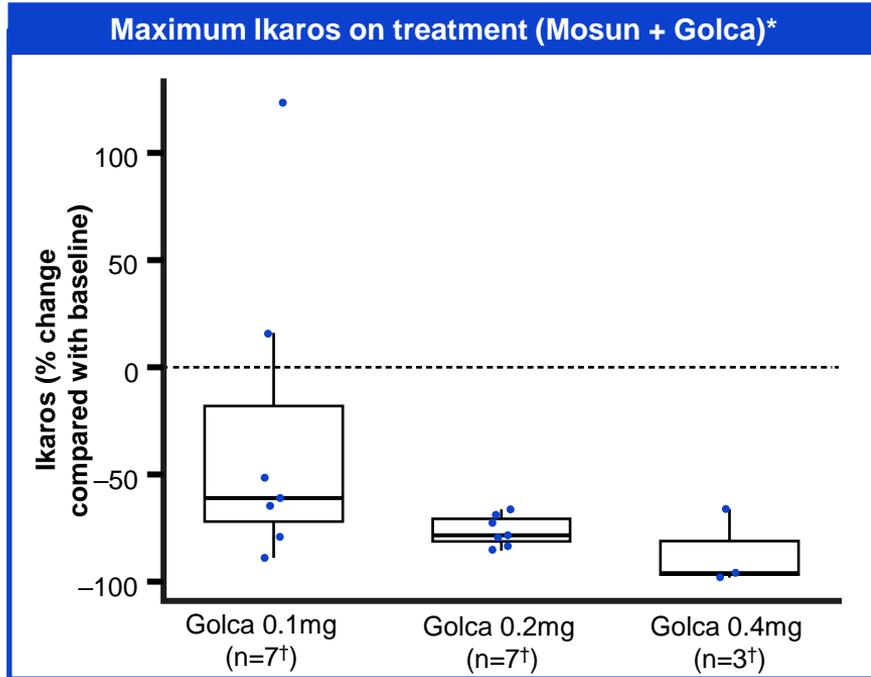


- Median time to first response for all patients (N=10)\*: 1.9 months (range: 1–3)
- All four patients who received prior CAR T-cell therapy had a response:
  - Overall, 3 patients achieved a CR, and one had a PR
    - Two patients had FL and achieved a CR
    - Two patients had DLBCL; one achieved CR and one had a PR

High response rates were observed across FL and DLBCL subtypes

\*Efficacy-evaluable population.

# Ikaros degradation across Golca dose levels



- Decrease in Ikaros expression compared with baseline was observed in peripheral T cells following 0.2mg and 0.4mg Golca doses in Arm 1
- Analysis of Ikaros expression in Arm 2 is ongoing
- Variable Ikaros changes were observed with 0.1mg Golca dose
- Similar findings were observed in Aiolos expression on T cells

Expected degradation of Golca target (Ikaros) was observed in combination with Mosun

Box and whiskers plot: horizontal dash line represents the baseline value. Box plot represents median and the interquartile range in each cohort.

\*Maximum percentage change is calculated as (isotype subtracted MESF on treatment sample / isotype subtracted MESF baseline sample \* 100) - 100. On treatment timepoints included 4 hours, 7 days, and 14 days following the start of Golca dosing. †Patients from Arm 1 dose escalation cohorts are included. MESF, molecules of equivalent soluble fluorochrome.

# Conclusions

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- Early data suggest Mosun/Glofit + Golca is a clinically active regimen with a manageable safety profile
  - No new safety signals were observed
  - CRS events were low grade
  - Neutropenia was common, with low rates of febrile neutropenia
  - ICANS occurred in one patient and was low grade
- High response rates were observed across B-NHL subtypes and across different doses of Golca
- Consistent decrease in Ikaros expression was observed with  $\geq 0.2$ mg Golca dose levels
- These novel combination regimens show promising activity in patients with heavily pretreated B-NHL in this ongoing study

# Acknowledgments

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