2023 ASCO ANNUAL MEETING

Phase 1 Results with Anti-CD19 Allogeneic CAR T ALLO-501/501A in Relapsed/Refractory Large B-Cell Lymphoma (r/r LBCL)

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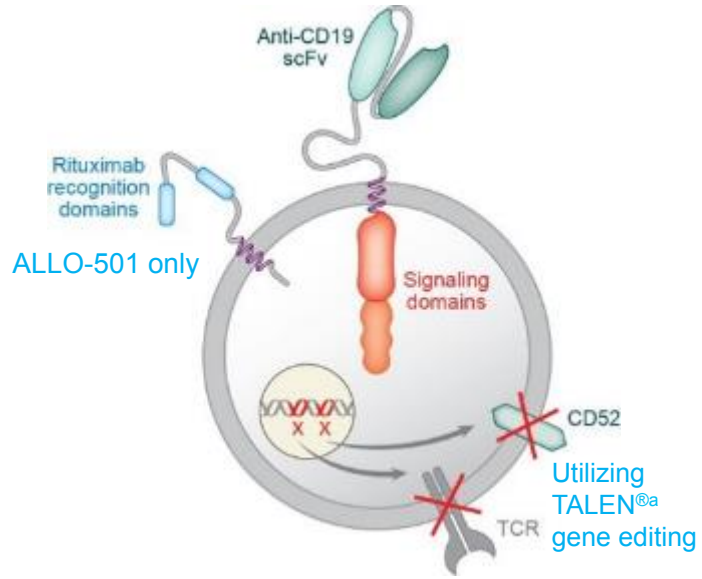
Background on ALLO-501 & ALLO-501A

- ALLO-501A is an HLA-unmatched, off-the-shelf, anti-CD19 allogeneic CAR T cell product administered as a one-time treatment that is capable of inducing durable remissions in r/r LBCL patients. ALLO-501 is similar to ALLO-501A except for the inclusion of a rituximab off switch.
- Two studies, ALPHA and ALPHA2, were undertaken to evaluate ALLO-501 and ALLO-501A. These trials have established a manageable safety profile that compares favorably to anti-CD19 autologous CAR T cell therapies, which, despite their impressive results, are still available at only a limited number of specialized centers.
- This update focuses on results in CAR T-naïve patients with r/r LBCL treated with the selected Phase 2 treatment regimen with allogeneic CAR T cells manufactured using the process selected for evaluation in an ongoing Phase 2 trial (ALPHA2).



Selected Phase 2 Treatment Regimen

3-day lymphodepletion with FCA90	Single-dose of ALLO-501A or ALLO-501	Follow-up (ongoing)
F: fludarabine 30 mg/m^2/day **C:** cyclophosphamide 300 mg/m^2/day **A:** ALLO-647 30 mg/day (total dose: 90 mg)	120-360 x 10^6 viable CAR+ cells	

[a] TALEN® gene editing is a technology pioneered and controlled by Cellectis.

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Baseline Characteristics of Subgroup & Phase 1 and Subgroup Safety Results

- 12 patients were included in the subgroup
- 3 days from enrollment to treatment initiation (median)
- 100% of patients received product per product specs

- No Gr≥3 CRS or ICANS events
- No GvHD events

Baseline Characteristics for Patients Treated With Selected Phase 2 Regimen (N=12)	
Age, median	60 years
Stage IV disease	67%
ECOG PS of 1	92 %
Baseline LDH > ULN	67 %
IPI score >2	50 %
Germinal center subtype	50 %
Double or triple hit	33 %
Median # prior regimens	3
Prior transplant	50%
Extranodal disease	58%

ECOG = Eastern Cooperative Oncology Group; IPI = International Prognostic Index; IRR = infusion-related reactions; LDH = lactate dehydrogenase; ULN = upper limit of normal.

Adverse Events of Interest	All r/r CAR T-naïve LBCL[a] (N=33)		Patients Treated With Phase 2 Selected Regimen (N=12)	
	All Gr n (%)	Gr≥3 n (%)	All Gr n (%)	Gr≥3 n (%)
CRS	8 (24)	0	4 (33)	0
ICANS	0	0	0	0
Neurotoxicity	13 (39)	2 (6)	4 (33)	0
GvHD	0	0	0	0
IRR	16 (49)	3 (9)	8 (67)	0
Infection[b]	19 (58)	5 (15)	8 (67)	1 (8)
Prolonged Gr≥3 Cytopenia	-	4 (12)	-	2 (17)

CRS = cytokine release syndrome; GvHD = graft-versus-host disease; ICANS = immune effector cell-associated neurotoxicity syndrome; IRR = infusion-related reactions.
[a] All patients received product manufactured in the same way as the selected Phase 2 process. [b] Infections include low grade viral infections, some of which are detected on weekly surveillance. No fatal infections or PJP/MAC/TB were seen.

Data cutoff: April 20, 2023

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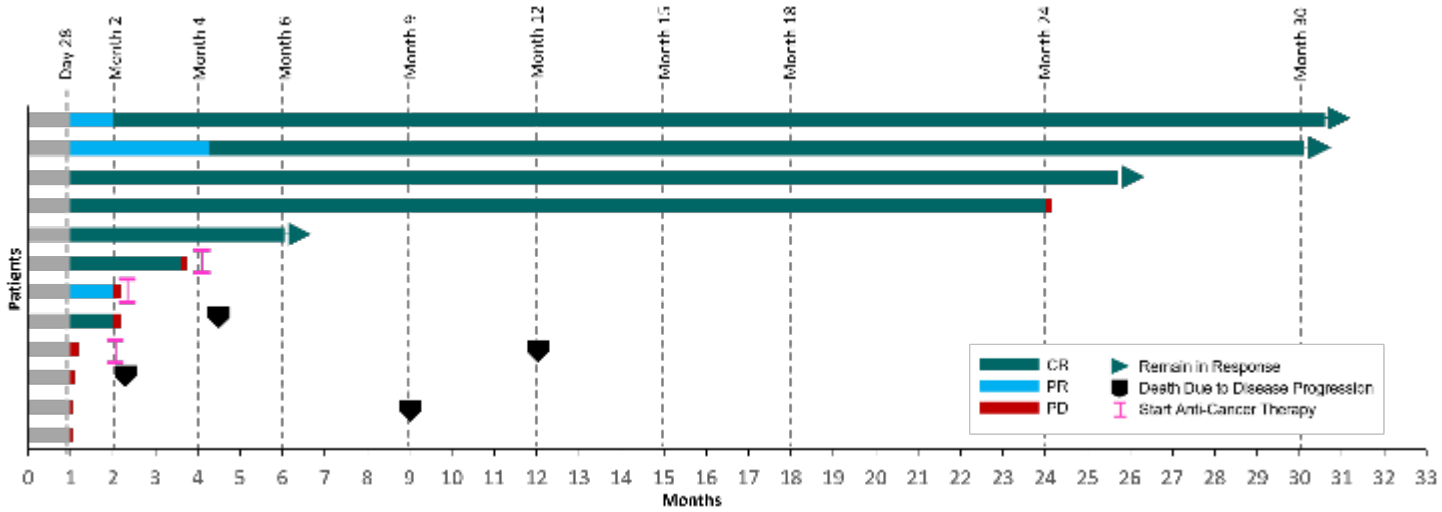
Efficacy Results for Patients Treated With Phase 2 Regimen

Response Rates

	N=12
ORR, n (%)	8 (67)
CR, n (%)	7 (58)
6 months CR[a], n (%)	5 (42)

[a] Analysis of patients who had the opportunity to be followed through Month 6 or experienced disease progression prior to Month 6

Swimmer Plot of Tumor Response



All 12 patients had the opportunity to be followed through Month 6:

- 7 of 12 (58%) patients achieved CR and 5 (42%) patients sustained CR through Month 6
- 4 of 5 (80%) patients who were in CR at 6 months remain in CR
- 3 patients remain in remission at 24+ months, the longest at 31+ months
- Median duration of response is 23.1 months

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Conclusions

1. A single dose of ALLO-501/ALLO-501A following FCA90 provided durable remissions up to 31+ months that compared favorably to outcomes achieved with autologous CAR T cell therapies in patients with r/r LBCL.

2. ALLO-501/ALLO-501A following FCA90 was generally well tolerated with no Gr≥3 CRS, no ICANS, and no GvHD. Cytopenias and infections were manageable and comparable to experience with autologous CAR T cell therapies in r/r LBCL.

3. An off-the-shelf allogeneic CAR T cell product, like ALLO-501A, which eliminates the need for leukapheresis or bridging therapy, may be more accessible to all eligible patients, evidenced by a median time of 3 days from enrollment to initiation of study treatment.

4. These findings support broader evaluation of ALLO-501A in the ongoing, first potentially pivotal Phase 2 trial (ALPHA2) of an allogeneic CAR T cell product.

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