ALL0-501/501A Alpha Studies Targeting CD19 in Relapsed/Refractory (R/R) Non-Hodgkin Lymphoma

Allogene THERAPEUTICS

ALLO-501, an AlloCAR T™ Therapy

The ALPHA Trial: Relapsed or Refractory Non-Hodgkin Lymphoma (NHL)

ALLO-501 is an investigational anti-CD19 allogeneic CAR T (AlloCAR T™) therapy being jointly developed under a clinical development collaboration between Servier and Allogene based on an exclusive license granted by Cellectis to Servier. ALLO-501 utilizes TALEN® gene-editing technology pioneered and owned by Cellectis. Servier grants to Allogene exclusive rights to ALLO-501 in the U.S. while Servier retains exclusive rights for all other countries.

Objectives

Assess safety and tolerability at increasing dose levels of ALLO-501 in the most common Non-Hodgkin Lymphoma (NHL) subtypes of relapsed/refractory diffuse large B-cell lymphoma (DLBCL) or follicular lymphoma (FL).

Study Design

- Up to 24 patients
- Patients with relapsed/refractory large B-cell lymphoma (DLBCL) or follicular lymphoma (FL) and:
  - Failed at least two prior lines of therapy
  - Absence of pre-existing donor (product)-specific anti-HLA antibodies
- Within each dose cohort, enrolled patients will be observed for safety and dose limiting toxicities before evaluating whether the subsequent dose cohort can open for enrollment.
  - Maximum tolerated dose (MTD) will be determined by assessing dose limiting toxicities within each dose cohort.
  - Preliminary tumor response assessments and translational data such as allogeneic CAR T cell expansion will also be considered.

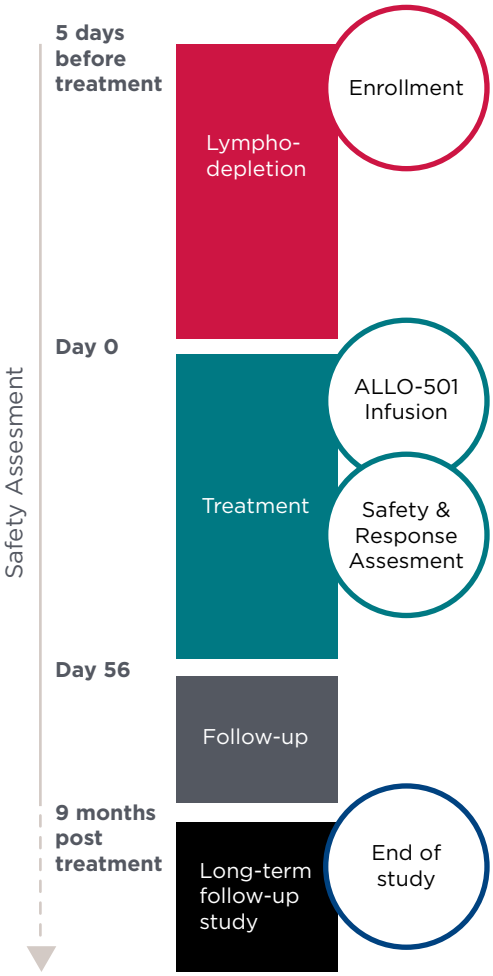
PRIMARY ENDPOINTS

- Safety
- Tolerability

SECONDARY ENDPOINTS

- Anti-tumor activity
- ALLO-501 cellular kinetics
- ALLO-647 pharmacokinetics
- Immunogenicity and host lymphocyte reconstitution

Key Patient Benchmarks



Lymphodepletion

- Lymphodepletion is the process of destroying lymphocytes including T cells before administering immunotherapy.
- Fludarabine/cyclophosphamide (Flu/Cy) and ALLO-647, Allogene's proprietary anti-CD52 antibody, will be administered as part of the lymphodepletion regimen with the intent of reducing the likelihood of the patient's immune system from rejecting AlloCAR T™ cells.

Lymphodepletion

ALLO-647 (starting dose and schedule)	Fludarabine	Cyclophosphamide
13-30mg / day	30mg/m² / day	300mg/m² / day
x3 days	x3 days	x3 days

Treatment

- ALLO-501 will be administered following lymphodepletion.
- Patients were initially treated at a starting dose of 40 million CAR T cells, which roughly equates to 500,000 cells/kg.

Treatment

Starting cell dose	Dose escalation up to	Dose escalation design
40 million CAR+ cells	360 million CAR+ cells	3+3

ALLO-501 Interim Data

ALLO-501 and ALLO-647 Demonstrate Manageable Safety Profile

AE of Interest ‡	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	All grades n (%)
Cytokine Release Syndrome *	2 (9%)	4 (18%)	1 (5%)	-	-	7 (32%)
ICANS *	-	-	-	-	-	-
Graft-versus-Host Disease	-	-	-	-	-	-
Infection	5 (23%)	4 (18%)	2 (9%)†	-	-	11 (50%)
Infusion Reaction #	1 (5%)	9 (41%)	1 (5%)	-	-	11 (50%)
Neutropenia	-	1 (5%)	7 (32%)	7 (32%)	-	15 (68%)

- No DLT, GvHD
- Manageable CRS
- ALLO-501 toxicity not dose-proportional
- Median duration of hospitalization from D0: 7 days

Serious Adverse Events (time to resolution) ‡

- **4 patients (18%):**
  - Gr2 pyrexia (2 days) and Gr2 CMV reactivation (6 days)
  - Gr3 rotavirus infection (15 days) and Gr3 hypokalemia (2 days)
  - Gr3 febrile neutropenia (2 days) and Gr3 hypotension (2 days)
  - Gr3 upper GI hemorrhage (<1 day) and Gr3 CMV reactivation (25 days)

* ASTCT Lee, 2019. ICANS: Immune Effector Cell-Associated Neurotoxicity Syndrome
† CMV reactivations and Rotavirus infection
# attributed to ALLO-647

‡ Number of patients with AE regardless of attribution unless otherwise indicated, occurring from the start of study drug up to subsequent anti-cancer therapy (for patients reporting more than one AE within a preferred term, only one AE with the maximum grade is reported).

Data Cutoff Date: May 11, 2020

Phase 1 ALPHA Best Overall Response

Cell Dose and LD regimen	39mg ALLO-647			ALL 39mg ALLO-647 (N = 11)	90mg ALLO-647		All 90mg ALLO-647 (N=8)	All Patients (N=19) Rate (95%CI)
	40 x 10^6 CAR+ cells (N=4)	120 x 10^6 CAR+ cells (N=4)	360 x 10^6 CAR+ cells (N=3)		120 x 10^6 CAR+ cells (N=6)	360 x 10^6 CAR+ cells (N=2)		
ORR, n (%)	3 (75%)	3 (75%)	1 (33%)	7 (64%)	4 (67%)	1 (50%)	5 (63%)	12/19 (63%) (38%, 84%)
CR , n (%)	1 (25%)	1 (25%)	1 (33%)	3 (27%)	4 (67%)	0 (0%)	4 (50%)	7/19 (37%) (16%, 62%)

Median follow-up time: 3.8 months (range: 0.7 - 6.1)

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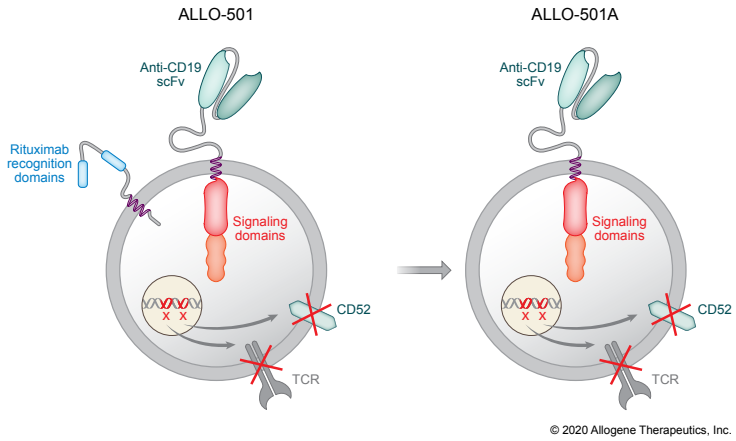
ALLO-501A, a next generation AlloCAR T™ Therapy

The ALPHA2 Trial: Relapsed or Refractory Non-Hodgkin Lymphoma (NHL)

ALLO-501A is a next generation investigational anti-CD19 AlloCAR T™ devoid of the rituximab recognition domains found in ALLO-501. This could allow for use in a broader patient population, including those NHL patients with recent rituximab exposure. ALLO-501A is intended for Phase 2 development, and enrollment has been initiated in the Phase 1 portion of the ALPHA2 trial of ALLO-501A.



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Study Design

- R/R LBCL
- At least 2 prior lines of therapy, including an anthralcycline and anti-CD20 monoclonal antibody
- ECOG 0 or 1
- Prior autologous CAR T allowed if tumor remains CD19+ and patient had a CR ≥ 16 weeks
- Patients with Donor Specific Antibodies are excluded

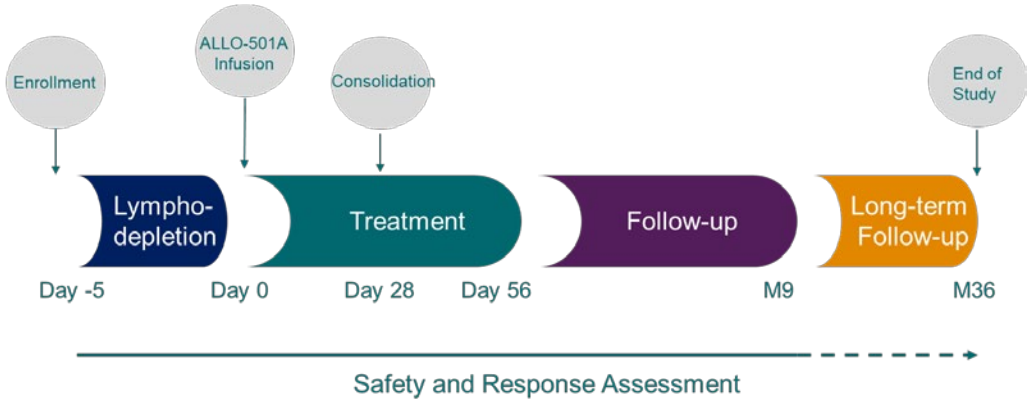
PRIMARY ENDPOINTS

- Safety and dose-limiting toxicity of ALLO-647/Flu/Cy followed by ALLO-501A
- Overall response rate by central imaging review

SECONDARY ENDPOINTS

- Overall response rate by investigator assessment
- ALLO-501A cell kinetics
- ALLO-647 PK

Key Patient Benchmarks



	DL1	DL2	DL2 Consolidation	DL3
Cell Dose	40 x 10^6 CAR^+ T cells	120 x 10^6 CAR^+ T cells	120 x 10^6 CAR^+ T on D0, and D28 for SD or better	360 x 10^6 CAR^+ T cells

- Lymphodepletion Regimen
  - LD: Flu/Cy and ALLO-647 30 mg/d x 2 days (Day -4 and -3 only)

Timing & Results

ALLO-501 and ALLO-501A are investigational products. Safety and efficacy have not been established. There is no guarantee that ALLO-501 or ALLO-501A will receive regulatory approval from the FDA and become commercially available for the uses being investigated.

Forward-Looking Statement

This posting contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The posting may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements include statements regarding intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: the ability to progress the ALLO-501 and ALLO-501A clinical trials, the timing to report clinical data, the ability of an anti-CD52 mAb to contribute to AlloCAR T™ cell expansion, the ability to manufacture AlloCAR T™ therapies, the ability to initiate and progress additional clinical trials of AlloCAR T™ therapies, and the potential benefits of AlloCAR T™ therapy. Various factors may cause differences between Allogene's expectations and actual results as discussed in greater detail in Allogene's filings with the Securities and Exchange Commission (SEC), including without limitation in its Form 10-Q for the quarter ended September 30, 2020. Any forward-looking statements that are made in this posting speak only as of the date of this posting. Allogene assumes no obligation to update the forward-looking statements whether as a result of new information, future events or otherwise, after the date of this posting.

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