

The ALPHA Trial: A Phase 1 Study of ALLO-501 in Relapsed/Refractory Non-Hodgkin Lymphoma



ALLO-501, an AlloCAR T™ Therapy

ALLO-501 is an 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) to establish RP2D of 501 and 647.

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

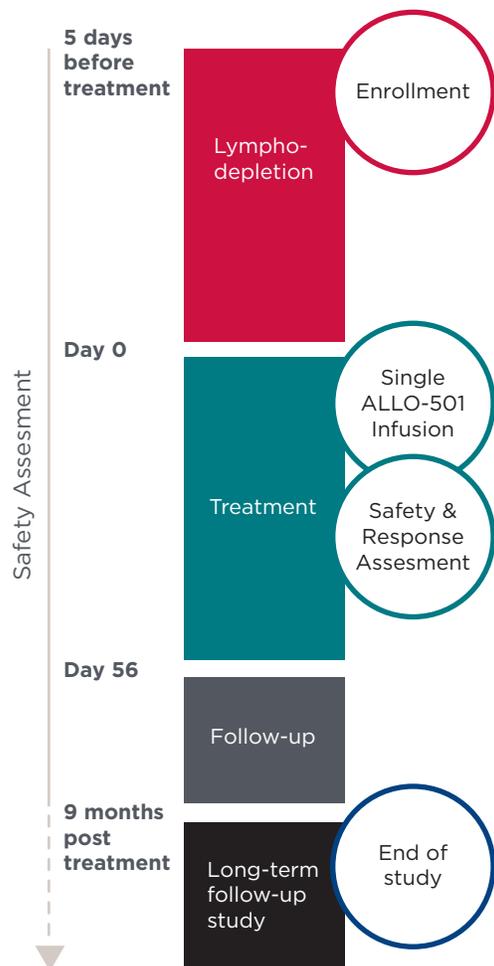
- Lymphodepletion is the process of destroying lymphocytes including T cells before administering immunotherapy.
- Fludarabine/cyclophosphamide (Flu/Cy) and ALLO-647, Allogene's proprietary anti-CD52 antibody, will be administered as part of the lymphodepletion regimen with the intent of reducing the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

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



Enrolling at 7 Clinical Trial Sites Across the U.S.



Timing & Results



* Allogene initiated the Phase 1 ALPHA study of ALLO-501 in Q2 2019. If the study proceeds as planned, initial clinical data is expected in the first half of 2020.

ALLO-501 is an investigational product. Its safety and efficacy have not been established. There is no guarantee that ALLO-501 will receive regulatory approval from the FDA and become commercially available for the uses being investigated.

Cautionary Note on Forward-Looking Statements

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 clinical trials, the timing to report initial 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, 2019. 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.