

# The PALL and CALM Trials: Phase 1 studies of UCART19 in Relapsed/Refractory Acute Lymphoblastic Leukemia (ALL) (Servier Sponsored)



## UCART-19

UCART19 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. UCART19 utilizes TALEN® gene-editing technology pioneered and owned by Cellectis. Servier grants to Allogene exclusive rights to UCART19 in the U.S. while Servier retains exclusive rights for all other countries.

## Objectives

Assess safety and tolerability of increasing dose levels of UCART19 in patients with relapsed/refractory acute lymphoblastic leukemia (ALL).

## Study Design

- Eligible patients with CD19 positive relapsed/refractory acute lymphoblastic leukemia and:
  - Morphological or MRD+
  - Failed previous treatment options
- PALL Study: UCART19 ALL Pediatric Study, for patients under 16 years of age.
- CALM Study: UCART19 ALL Adults Study, for patients over 16 years of age.
- Within each dose cohort, enrolled patients will be observed for safety and dose limiting toxicities for at least 28 days 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

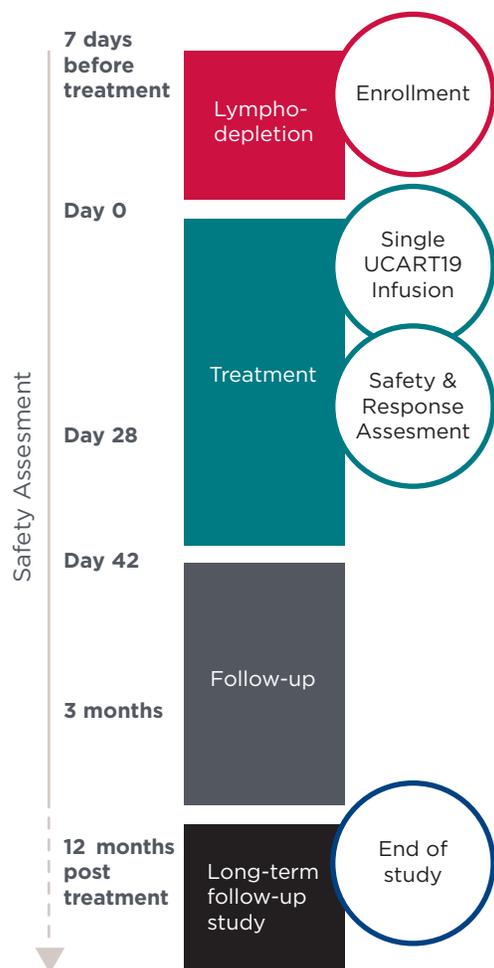
### SECONDARY ENDPOINTS

- Anti-tumor activity

### EXPLORATORY ENDPOINTS

- UCART19 expansion and persistence

## Key Patient Benchmarks



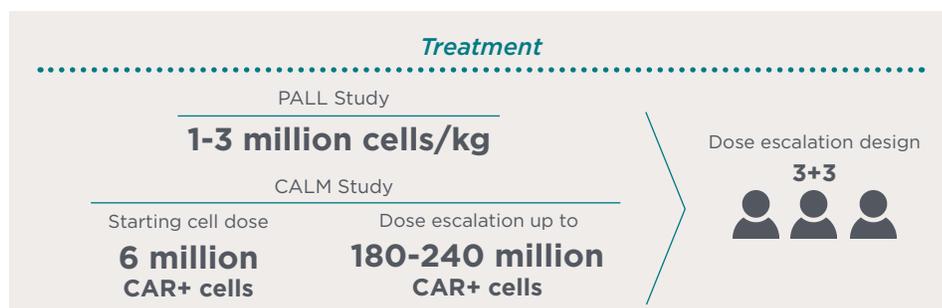
## Lymphodepletion

- Lymphodepletion is the process of destroying lymphocytes including T cells before administering immunotherapy.
- Fludarabine/cyclophosphamide (Flu/Cy) and an 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		
Fludarabine	Cyclophosphamide	Anti-CD52 mAb
<b>90mg/m<sup>2</sup> for adults</b>	<b>1,500mg/m<sup>2</sup> for adults</b>	<b>40mg for adults</b>
<b>150mg/m<sup>2</sup> for pediatrics</b>	<b>120mg/kg for pediatrics</b>	<b>1mg/kg capped to 40mg for pediatrics</b>

## Treatment

- UCART19 will be administered following lymphodepletion.
- Patients in the PALL study are treated at a dose of approximately 1-3 million CAR T cells/kg.
- Six patients in the CALM study were treated at the starting dose of 6 million CAR T cells. Six patients were then treated at the second dose level of 60-80 million CAR T cells. Treatment in the third cohort is ongoing at a dose level of 180-240 million CAR T cells.



UCART19 is an investigational product. Its safety and efficacy have not been established. There is no guarantee that UCART19 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 UCART-19 clinical trials, the ability of an anti-CD52 mAb to contribute to AlloCAR T™ cell expansion, the ability to complete the build-out of the manufacturing facility, 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.

