

The UNIVERSAL Trial: A Phase 1 Study of ALLO-715 in Relapsed/Refractory Multiple Myeloma



ALLO-715

ALLO-715 is an investigational anti-BCMA allogeneic CAR T (AlloCAR T™) therapy that utilizes the TALEN® gene-editing technology pioneered and owned by Cellectis. Allogene has an exclusive license to the Cellectis technology for allogeneic products directed at the BCMA target. Allogene holds the global development and commercial rights for this investigational candidate.

Objectives

Assess safety and tolerability of increasing dose levels of ALLO-715 and varying lymphodepletion regimens in patients with relapsed/refractory multiple myeloma (MM).

Study Design

- Up to 24 patients expected in dose finding stage
 - Additional patients to be enrolled in cohorts designed to test alternative lymphodepletion strategies
 - Additional patients may be enrolled for further dose expansion
- Patients with relapsed/refractory multiple myeloma and:
 - Failed at least three prior MM regimens
 - Proteasome inhibitor, immunomodulatory agent, anti-CD38 mAb
 - Absence of pre-existing donor (product)-specific anti-HLA antibodies
 - No prior anti-BCMA therapy
- 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.

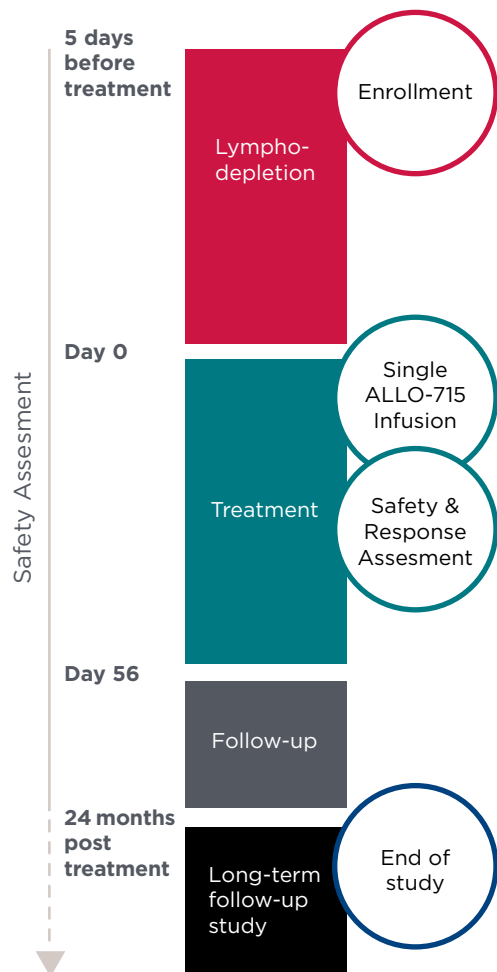
PRIMARY ENDPOINTS

- Safety
- Tolerability

SECONDARY ENDPOINTS

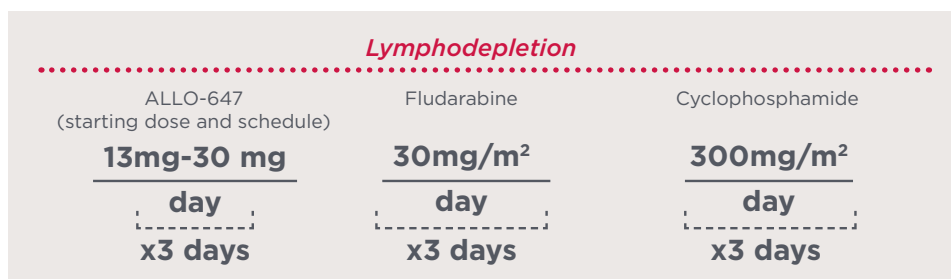
- Anti-tumor activity
- ALLO-715 cellular kinetics
- ALLO-647 pharmacokinetics
- Immunogenicity and host lymphocyte reconstitution

Key Patient Benchmarks



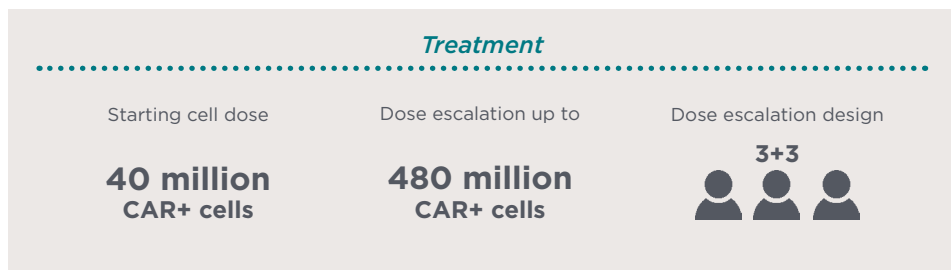
Lymphodepletion

- Lymphodepletion is the process of destroying lymphocytes and 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.

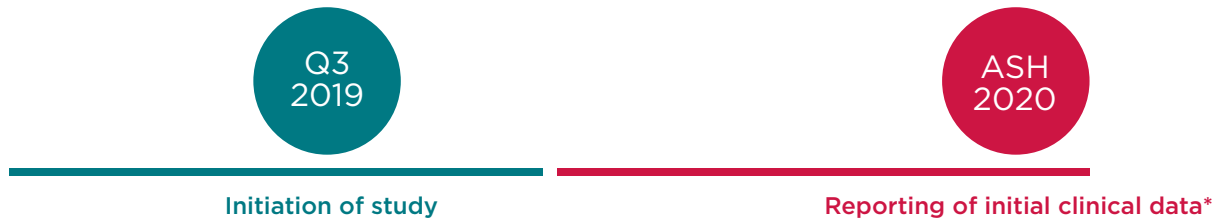


Treatment

- ALLO-715 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.



Timing & Results



* Allogene initiated the Phase 1 UNIVERSAL study of ALLO-715 in Q3 2019. If the study proceeds as planned, initial clinical data is expected by the end of 2020.

ALLO-715 is an investigational product. Its safety and efficacy have not been established. There is no guarantee that ALLO-715 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-715 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, 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.