UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 5, 2020

Allogene Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38693**	**82-3562771**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

210 East Grand Avenue, South San Francisco, California 94080
(Address of principal executive offices including zip code)

Registrant's telephone number, including area code: (650) 457-2700
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**ALLO**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b–2 of the Securities Exchange Act of 1934 (§ 240.12b–2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events

Initial Phase 1 Results from the UNIVERSAL Trial

On December 5, 2020, Allogene Therapeutics, Inc. (the "Company") announced initial results from the dose escalation Phase 1 UNIVERSAL trial of ALLO-715, an allogeneic chimeric antigen receptor ("CAR") T cell therapy targeting B-cell maturation antigen ("BCMA"), in relapsed/refractory multiple myeloma at the American Society of Hematology annual meeting.

As of the October 30, 2020 data cutoff, 35 patients were enrolled with 31 patients evaluable for safety and 26 patients evaluable for efficacy. Patients were refractory to their last line of myeloma therapy, had a median of five prior lines of therapy, and 94% were penta-exposed. Four patients became ineligible for treatment due to rapidly progressing disease. The median time from enrollment to the start of therapy was five days.

In the initial dose escalation phase of the UNIVERSAL trial, patients received lymphodepletion ("LD") followed by ALLO-715 at one of three dose levels (DL1 = 40M cells, DL2 = 160M cells, DL3 = 320M cells) in a 3+3 dose escalation design. DL4 (480M cells) was added in a subsequent cohort. Two LD regimens were evaluated, with the trial enrollment primarily focused on the FCA lymphodepletion regimen:

- FCA: **F**ludarabine 90 mg/m^2, **C**yclophosphamide 900 mg/m^2, and **A**LLO-647 from 39 to 90mg divided over three days; and
- CA: **C**yclophosphamide 900 mg/m^2 and **A**LLO-647 39mg divided over three days.

Higher CAR T cell doses were associated with an increased response rate and greater cell expansion. In the DL3 cohort (320M CAR T+ cells), the overall response rate ("ORR") was 60% with 40% of patients achieving a very good partial response (VGPR) or better (VGPR+). VGPR+ is defined as a stringent complete response, complete response or VGPR. Across all cohorts and lymphodepletion regimens, six patients achieved VGPR+, five of whom were in the FCA lymphodepletion regimen. Minimal residual disease (MRD) assessment was completed in five of the six patients with a VGPR+ response and all achieved an MRD negative status.

As of the data cutoff, the overall median follow-up for efficacy was 3.2 months and six out of the nine patients treated with DL3 or DL4 with a response remain in response. The longest response was ongoing at six months from the DL3 cohort with FCA lymphodepletion.

Cell Dose and LD regimen	**FCA**						**CA**	
	DL1 40 x 10^6 CAR+ cells	DL2 160 x 10^6 CAR+ cells	**DL3 320 x 10^6 CAR+ cells**			DL4 480 x 10^6 CAR+ cells	**DL2 160 x 10^6 CAR+ cells**	DL3 320 x 10^6 CAR+ cells
	Low ALLO-647 (N=3)	Low ALLO-647 (N=4)	Low ALLO-647 (N=6)	High ALLO-647 (N=4)	**ALL ALLO-647 (N=10)**	Low ALLO-647 (N=3)	Low ALLO-647 (N=3)	Low ALLO-647 (N=3)
ORR*, n (%)	—	2 (50%)	3 (50%)	3 (75%)	**6 (60%)**	1 (33%)	—	2 (67%)
VGPR+ Rate*, n (%)	—	1 (25%)	3 (50%)	1 (25%)	**4 (40%)**	—	—	1 (33%)

*Responses included two subjects with only day 14 assessment and one subject who converted from a confirmed PR to VGPR (pending confirmation). All first responses as of the data-cutoff date have converted to confirmed responses.

Of the 31 patients evaluable for safety, there was no graft-vs-host disease or Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) observed. Grade 1 and Grade 2 cytokine release syndrome was reported in 14 patients (45%) and was manageable with standard therapies. Infection events ≥ Grade 3 in the trial was similar to what has been reported in other advanced multiple myeloma studies. Adverse events ≥ Grade 3 reported as serious adverse events occurred in 19% of patients. As previously reported, a single Grade 5 event related to progressive myeloma and conditioning regimen occurred in the CA cohort.

Adverse Events of Interest	Grade 1 N (%)	Grade 2 N (%)	Grade 3 N (%)	Grade 4 N (%)	Grade 5 N (%)	All Grades N (%)
Cytokine Release Syndrome	5 (16%)	9 (29%)	—	—	—	14 (45%)
ICANS	—	—	—	—	—	—
Graft-versus-Host Disease	—	—	—	—	—	—
Infection	2 (7%)	6 (19%)	4 (13%)	—	1 (3%)	13 (42%)
Infusion Reaction to ALLO-647	4 (13%)	3 (10%)	—	—	—	7 (23%)

Clinical Development Updates

As part of the Company's three-pronged anti-BCMA strategy, the Phase 1 UNIVERSAL trial continues to enroll patients at higher doses of ALLO-715 and ALLO-647 in an effort to optimize the therapy. The UNIVERSAL trial is expected to begin enrolling patients in the first half of 2021 to evaluate ALLO-715 in combination with SpringWorks Therapeutics, Inc.'s investigational gamma secretase inhibitor, nirogacestat. An investigational new drug application ("IND") is expected to be submitted in the first half of 2021 for the Company's first TurboCAR™ candidate, ALLO-605, an investigational BCMA-directed allogeneic CAR T cell therapy for multiple myeloma. TurboCAR technology allows cytokine activation signaling to be engineered selectively into CAR T cells and has shown the ability to improve the potency and persistence of allogeneic cells in preclinical models.

The U.S. Food and Drug Administration has recently cleared an IND for a Phase 1 trial of ALLO-316, an allogeneic CAR T cell therapy targeting CD70, for patients with advanced or metastatic clear cell renal cell carcinoma. The Company's Phase 1 ALLO-316 trial is expected to begin enrolling patients in 2021.

ALLO-715, ALLO-605 and ALLO-316 utilize TALEN® gene-editing technology pioneered and owned by Cellectis S.A. Allogene has an exclusive license to the Cellectis technology for allogeneic products directed at BCMA and CD70 and holds all global development and commercial rights for these investigational candidates.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ALLOGENE THERAPEUTICS, INC.

By: /s/ David Chang, M.D., Ph.D.
David Chang, M.D., Ph.D.
President, Chief Executive Officer

Dated: December 7, 2020