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): May 19, 2021

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 Stock Market LLC**

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.

On May 19, 2021, Allogene Therapeutics, Inc. (the "Company"), in collaboration with Les Laboratoires Servier SAS and Institut de Recherches Internationales Servier SAS, an independent international pharmaceutical company (together, "Servier"), announced results from the Phase 1 ALPHA trial of ALLO-501 and from the Phase 1 ALPHA2 trial of ALLO-501A in relapsed/refractory non-Hodgkin lymphoma ("NHL"). In addition, the Company reported on safety, pharmacokinetic ("PK") and pharmacodynamic ("PD") data from ALLO-647.

Phase 1 ALLO-501 ALPHA Trial

As of the April 19, 2021 data cutoff, 42 patients were enrolled and 41 received ALLO-501, including nine who had previously received autologous chimeric antigen receptor ("CAR") T cell therapy. The one patient not treated was enrolled but removed from the study prior to lymphodepletion due to lymphoma related obstructive kidney disease. In the trial, 98% of patients received ALLO-501 and the median and mean time from enrollment to the start of therapy was five days.

Responses were observed across all cell doses and tumor histologies (large B-cell lymphoma ("LBCL") and follicular lymphoma ("FL")). In CAR T naïve patients, response rates were similar to those seen in autologous CAR T therapy trials:

	LBCL (N=11)	FL (N=21)	**All Patients** (N=32)
Overall Response Rate ("ORR") (95% CI)	7 (64%) (31, 89)	17 (81%) (58, 95)	**24 (75%)** **(57, 89)**
Complete Response ("CR") (95% CI)	5 (46%) (17, 77)	11 (52%) (30, 74)	**16 (50%)** **(32, 68)**

The percent of these patients remaining in CR at six months following a single infusion was 29%, including 36% of patients with LBCL and 24% of patients with FL. Data reported following the data cutoff to May 12, 2021 indicate three LBCL patients remain in CR and eight FL patients remain in CR, with the longest ongoing CRs at 15 months.

ALLO-647 was used in lymphodepletion with fludarabine ("Flu")/cyclophosphamide ("Cy") at doses ranging from 39mg to 90mg.

	ALLO-647 39 mg (N=11)		**ALLO-647 60 mg (N=6)**		**ALLO-647 90 mg (N=24)**		**All Patients (N=41)**	
Adverse Events of Interest	**All Gr**	**Gr 3+**	**All Gr**	**Gr 3+**	**All Gr**	**Gr 3+**	**All Gr**	**Gr 3+**
Infusion Related Reaction ("IRR")	5 (46%)	—	3 (50%)	—	18 (75%)	1 (4)	26 (63%)	1 (2%)
CRS	2 (18%)	—	1 (17%)	—	8 (33%)	—	11 (27%)	—
ICANS	—	—	—	—	1 (4%)	1 (4%)	1 (2%)	1 (2%)
GvHD	—	—	—	—	—	—	—	—
Infection	7 (64%)	1 (9%)	1 (17%)	1 (17%)	17 (71%)	8 (33%)	25 (61%)	10 (24%)

Grade 1 represents mild toxicity, Grade 2 represents moderate toxicity, Grade 3 represents severe toxicity and Grade 4 represents life threatening toxicity. Grade 5 toxicity represents toxicity resulting in death. No dose limiting toxicities or graft-vs-host disease ("GvHD") were observed and one (2%) case of Grade 3 Immune Effector Cell-Associated Neurotoxicity Syndrome ("ICANS") was reported. Cytokine release syndrome ("CRS") occurred in 27% of patients, was limited to Grade 1 or 2, and was manageable with standard protocols. Infection rates were similar to those observed in autologous CAR T trials. During this study, there were five treatment-emergent deaths in the absence of disease progression, one each from fungal pneumonia, arrythmia, and stroke, and two instances of COVID-19 acquired in the community setting. Three of these patients were in ongoing CR at the time of death.

Phase 1 ALLO-501A ALPHA2 Trial

ALLO-501A is a next generation anti-CD19 AlloCAR T™ candidate intended for Phase 2 development and is engineered without the rituximab recognition domains found in ALLO-501. The Phase 1 dose escalation portion of the ALPHA2 trial was

designed to confirm that the profile of ALLO-501A is similar to ALLO-501 prior to advancing ALLO-501A into Phase 2. This trial is only enrolling patients with relapsed/refractory LBCL.

Following promising efficacy data from patients (N=4) treated at dose level 2 (120 x 10^6 CAR+ cells; "DL2"), patient enrollment in ALPHA2 focused on exploration of a consolidated dosing strategy that enabled patients who did not progress following an initial dose of ALLO-501A to receive a second, scheduled dose of cells. In consolidation dosing, 60mg ALLO-647 was provided with Flu/Cy for lymphodepletion before the first cell administration at DL2, and 30mg ALLO-647 with no Flu/Cy was provided for lymphodepletion before the second cell infusion at DL2 to patients with selective hematologic criteria.

As of the April 19, 2021 data cutoff, 13 patients were enrolled and 12 patients were treated with ALLO-501A. One patient was treated with ALLO-647 but not ALLO-501A and deemed unable to proceed to cell infusion. Nine patients treated at the targeted 120M cell dose evaluable for efficacy were CAR T naïve patients, except for one patient who received autologous CAR T therapy and previously achieved a 16-week CR followed by relapse. Interim data reported following the data cutoff to May 12, 2021 from these nine patients demonstrate efficacy and safety for ALLO-501A consistent with that observed for ALLO-501 in the ALPHA trial:

	DL2 (N=4)	Consolidation (N=5)	**All Patients** (N=9)
ORR (95% CI)	2 (50%) (7, 93)	3 (60%) (15, 95)	**5 (56%)** **(21, 86)**
CR (95% CI)	2 (50%) (7, 93)	3 (60%) (15, 95)	**5 (56%)** **(21, 86)**

As of May 12, 2021, all of the CRs remain ongoing, with a median follow-up of 2.3 months. Of the eight patients treated in the consolidation cohorts across both ALPHA studies, the ORR was 75% and CR rate was 63%, with four patients converting from a partial response at day 28 to a CR at day 56.

No dose limiting toxicities, GvHD or ICANS were observed in ALPHA2.

	DL 1 40 x 106 (40M) (N=1)		**DL2 120 x 106 (120M) CAR+ cells (N=5)**		**Consolidation (120M + 120M) (N=6)**		**All Patients (N=13)***	
Adverse Events of Interest	**All Gr**	**Gr 3+**	**All Gr**	**Gr 3+**	**All Gr**	**Gr 3+**	**All Gr**	**Gr 3+**
Infusion Related Reaction ("IRR")	1 (100%)	—	2 (40%)	—	2 (33%)	—	5 (39%)	—
CRS	1 (100%)	1 (100%)	1 (20%)	—	—	—	2 (15%)	1 (8%)
ICANS	—	—	—	—	—	—	—	—
GvHD	—	—	—	—	—	—	—	—
Infection	1 (100%)	—	4 (80%)	1 (20%)	2 (33%)	—	7 (54%)	1 (8%)

* One patient was treated with ALLO-647 but not ALLO-501A and deemed unable to proceed to cell infusion.

The Company plans to collect additional data from the consolidation arms of the ALPHA and ALPHA2 studies, finalize a dose and schedule of ALLO-501A and lymphodepletion for a potential Phase 2 trial, and discuss the Phase 2 trial design with regulatory authorities. Pending the collection of data and regulatory feedback, the Company plans to move to the Phase 2 portion of ALPHA2 by the end of 2021.

ALLO-647 Consolidated Safety and PK/PD Analysis

The safety and PK/PD profile of ALLO-647 was evaluated as part of a proprietary lymphodepletion regimen that also deploys Flu/Cy. Patients treated as part of the ALPHA trial, ALPHA2 trial and UNIVERSAL trial (Phase 1 trial of anti-BCMA candidate, ALLO-715, in relapsed/refractory multiple myeloma) were included in the analyses.

The data show that ALLO-647, when used in combination with Flu/Cy, induced deep, durable exposure-dependent lymphodepletion. Lymphodepletion is designed to provide a window for allogeneic CAR T cell persistence, and exposure to

ALLO-647 correlated with lymphocyte depletion, CAR T cell expansion and greater clinical response. ALLO-647 in combination with Flu/Cy had a manageable safety profile with rates of Grade 3 infection similar to autologous CAR T therapies.

TRIAL	**Multiple Myeloma UNIVERSAL (N=34)**			**Non-Hodgkin Lymphoma ALPHA (N=41) & ALPHA2 (N=13)**			
ALLO-647 Dose	**39 mg (N=22)**	**60 mg (N=9)**	**90 mg (N=3)**	**39 mg (=11)**	**60 mg (N=14)**		**90 mg (N=29)**
					FCA60 & Consolidation (N=14)	**Consolidation (N=9)**	**Gr 3+**
ALL TEAES*	22 (100%)	9 (100%)	3 (100%)	11 (100%)	13 (93%)	8 (89%)	29 (100%)
Grade ≥3 AEs	2 (9%)	3 (33%)	—	—	2 (14%)	1 (11%)	7 (24%)
All Infection++	12 (55%)	6 (67%)	1 (33%)	7 (64%)	4 (29%)	3 (33%)	21 (72%)
Grade ≥3 Infection	5 (23%)	4 (44%)	—	1 (9%)	2 (14%)	1 (11%)	8 (28%)
Infusion Related Reaction to ALLO-647 (All Grades)	6 (27%)	2 (22%)	1 (33%)	5 (45%)	6 (43%)	4 (44%)	20 (69%)
Grade ≥3 Hematologic AEs							
Anemia	7 (32%)	2 (22%)	—	2 (18%)	3 (21%)	—	12 (41%)
Thrombocytopenia	6 (27%)	3 (33%)	1 (33%)	3 (27%)	5 (36%)	2 (22%)	14 (48%)
Neutropenia	11 (50%)	6 (67%)	2 (67%)	9 (82%)	8 (57%)	4 (44%)	21 (72%)

*Treatment emergent adverse events (“TEAES”). Number of patients with adverse event (“AE”) 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.
++All infections (bacterial, fungal, and viral) included.

The UNIVERSAL trial, which enrolled heavily pre-treated myeloma patients, including those with rapidly progressing disease, included two Grade 5 events. One previously disclosed event was attributed to progressive myeloma and lymphodepletion with cyclophosphamide and ALLO-647. The second was a 78-year-old male, heavily pretreated and with ongoing lymphopenia prior to therapy, who had adenovirus reactivation.

ALLO-715 was recently granted Regenerative Medicine Advanced Therapy designation by the FDA for the treatment of relapsed refractory multiple myeloma.

Cautionary Note on Forward-Looking Statements and Other Information

This Form 8-K contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. This Form 8-K 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 timing and ability to progress the ALPHA and ALPHA2 trials, including progressing to the Phase 2 portion of the ALPHA2 trial; clinical outcomes, which may materially change as patient enrollment continues and more patient data become available; and the potential benefits of AlloCAR T™ therapy and the Company’s lymphodepletion strategy. Various factors may cause differences between the Company’s expectations and actual results as discussed in greater detail in the Company’s filings with the Securities and Exchange Commission, including without limitation in its Form 10-Q for the quarter ended March 31, 2021. Any forward-looking statements that are made in this Form 8-K speak only as of the date hereof. The Company assumes no obligation to update the forward-looking statements whether as a result of new information, future events or otherwise, after the date hereof.

Statements regarding autologous CAR T data are based on review of Kymriah United States product insert (USPI), Schuster S et al NEJM 2019; Yescarta USPI, Locke, AACR 2017; and Breyanzi USPI. Caution should be exercised when interpreting results from separate trials involving separate product candidates. There are differences in the clinical trial design, patient populations, published data, and the product candidates themselves, and the results from the clinical trials of autologous products may have no interpretative value on our existing or future results.

The Company’s AlloCAR T programs utilize Cellectis, S.A. (“Cellectis”) technologies. ALLO-501 and ALLO-501A are anti-CD19 allogeneic CAR T therapies being jointly developed under a collaboration agreement between Servier and Allogene based on an exclusive license granted by Cellectis to Servier. Servier grants to Allogene exclusive rights to ALLO-501 and ALLO-501A in the U.S. while Servier retains exclusive rights for all other countries.

Allogene has an exclusive license to the Cellectis technology for allogeneic products directed at BCMA 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: May 19, 2021