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 29, 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

Phase 1 Results from the ALPHA Trial

On May 29, 2020, 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 initial results from the dose escalation Phase 1 ALPHA study of ALLO-501 in relapsed/refractory non-Hodgkin lymphoma ("NHL") at the American Society of Clinical Oncology annual meeting.

As of the May 2020 data cutoff, 23 patients were enrolled and 22 patients received ALLO-501. One patient was removed from the study prior to lymphodepletion due to acute renal failure from urinary obstruction. The median time from enrollment to the start of therapy was five days.

For the efficacy analysis, 19 out of 22 patients reached at least one month assessment as of the May 2020 data cutoff. Responses were observed across all cell doses and tumor histologies (diffuse large B-cell lymphoma and follicular lymphoma) with an overall response rate ("ORR") of 63% and complete response ("CR") rate of 37%. Higher dose ALLO-647 was associated with a higher CR rate of 50%, deeper lymphodepletion and delayed host T cell recovery. With a median follow-up of 3.8 months, nine of the 12 responding patients (75%) remained in response as of the data cutoff.

Cell Dose and LD regimen	**39mg ALLO-647**				**90mg ALLO-647**			**All Patients (N=19) (95% CI)**
	40 x 10^6 CAR^+ cells (N=4)	120 x 10^6 CAR^+ cells (N=4)	360 x 10^6 CAR^+ cells (N=3)	**All 39mg ALLO-647 (N=11)**	120 x 10^6 CAR^+ cells (N=6)	360 x 10^6 CAR^+ cells (N=2)	**All 90mg ALLO-647 (N=8)**	
ORR, n (%)	3 (75%)	3 (75%)	1 (33%)	**7 (64%)**	4 (67%)	1(50%)	5 (63%)	**12/19 (63%)** (38%, 84%)
CR, n (%)	1 (25%)	1 (25%)	1 (33%)	**3 (27%)**	4 (67%)	0 (0%)	4 (50%)	**7/19 (37%)** (16%, 62%)

One of the ongoing responders is a patient with an initial partial response ("PR") who progressed by month two. This patient achieved a CR after re-treatment with the same dose of ALLO-501 and a higher dose (90mg) of ALLO-647. This patient is reflected as a PR in the table above and not as a CR.

Included in the overall efficacy analysis are three patients who were refractory to prior autologous CAR T therapy (the best response of progressive disease or disease progression within three months). These patients were also refractory to allogeneic CAR T therapy. In CAR T naïve patients, the ORR was 75% and the CR rate was 44%.

	All Cell Doses + 39mg ALLO-647 (N10)	120 x 10^6 and 360 x 10^6 CAR^+ cells + 90mg ALLO-647 (N=6)	**All CAR T Naïve Patients (N=16)**
ORR, n (%)	7 (70%)	5 (83%)	**12/16 (75%)** (48%, 93%)
CR, n (%)	3 (30%)	4 (67%)	**7/16 (44%)** (20%, 70%)

No dose limiting toxicities, graft-vs-host disease, or Immune Effector Cell-Associated Neurotoxicity Syndrome ("ICANS") was observed.

Adverse Events of Interest	Grade 1 N (%)	Grade 2 N (%)	Grade 3 N (%)	Grade 4 N (%)	Grade 5 N (%)
Cytokine Release Syndrome	2 (9%)	4 (18%)	1 (5%)	—	—
ICANS	—	—	—	—	—
Graft-versus-Host Disease	—	—	—	—	—
Infection	5 (23%)	4 (18%)	2 (9%)	—	—
Infusion Reaction	1 (5%)	9 (41%)	1 (5%)	—	—
Neutropenia	—	1 (5%)	7 (32%)	7 (32%)	—

Cytokine release syndrome occurred in 32% of the patients, was mainly mild to moderate in severity, manageable with standard recommendations, and all events resolved within a maximum of seven days. Patients treated with 90mg ALLO-647 did not experience an increase in infection as compared to those treated with 39mg ALLO-647.

Four patients (18%) experienced serious adverse events (“SAEs”). One patient had Grade 2 pyrexia and Grade 2 cytomegalovirus (“CMV”) reactivation which resolved in two days and six days, respectively. One patient had Grade 3 rotavirus infection and Grade 3 hypokalemia which resolved in 15 days and two days, respectively. One patient had Grade 3 febrile neutropenia and Grade 3 hypotension which each resolved in two days. One patient had a Grade 3 upper GI hemorrhage which resolved in one day and Grade 3 CMV reactivation which resolved in 25 days.

Adverse events were observed across all dose levels of ALLO-501 and ALLO-647. SAEs were observed at ALLO-501 cell dose level 40 x 10^6 and 120 x 10^6 and at both dose levels of ALLO-647.

The Company is the sponsor of the Phase 1 ALPHA trial which is designed to assess the safety and tolerability at increasing dose levels of ALLO-501 and ALLO-647 in the most common NHL subtypes of relapsed/refractory diffuse large B-cell lymphoma or follicular lymphoma. The Company plans to continue the ALPHA trial to further explore and optimize treatment.

ALLO-501A is a next generation anti-CD19 allogeneic CAR T therapy devoid of the rituximab recognition domains found in ALLO-501. This could allow for use in a broader patient population, including those NHL patients with recent rituximab exposure. ALLO-501A is intended for Phase 2 development and enrollment has been initiated in the Phase 1 portion of the ALPHA2 trial of ALLO-501A.

ALLO-501 and ALLO-501A are being jointly developed under a collaboration agreement between Servier and the Company based on an exclusive license granted by Cellectis S.A. (“Cellectis”) to Servier. ALLO-501 and ALLO-501A use Cellectis technologies. Servier grants to the Company exclusive rights to ALLO-501 and ALLO-501A in the United States while Servier retains exclusive rights for all other countries

General Updates

Due to the exceptional circumstances related to the COVID-19 pandemic, Servier halted recruitment in the CALM and PALL clinical trials earlier this year. Servier has recently resumed recruitment in the CALM and PALL clinical trials in an effort to complete previously planned cohorts. The Company is continuing to enroll patients in the ALPHA trial, ALPHA2 trial and UNIVERSAL trial, however, enrollment of new patients and the ability to conduct patient follow-up will be impacted by the COVID-19 pandemic. The Company has also closed its headquarters with administrative employees continuing their work outside of the Company’s offices and limited the number of staff working onsite. Construction of the Company’s manufacturing facility in Newark, California, was interrupted for a period of time and may in the future be interrupted due to the COVID-19 pandemic. The exact timing of delays and overall impact of the COVID-19 pandemic to the Company’s business, preclinical studies and clinical trials is currently unknown, and the Company is monitoring the pandemic as it continues to rapidly evolve.

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 29, 2020