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 13, 2021

FATE THERAPEUTICS, INC.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-36076**	**65-1311552**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

12278 Scripps Summit Drive **San Diego, California** **(Address of Principal Executive Offices)**	**92131** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: 858 875-1800

3535 General Atomics Court, Suite 200
San Diego, California 92121
(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:

☐ 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, $.001 par value	**FATE**	**NASDAQ Global Market**

Indicate by check mark whether the registrant is an emerging growth company 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 December 13, 2021, Fate Therapeutics, Inc. (the "Company") issued (i) a press release providing a clinical and regulatory update on the Company's FT516 product candidate and (ii) a press release providing a clinical update on the Company's FT596 product candidate. Copies of the press releases are attached hereto as Exhibits 99.1 and 99.2 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release dated December 13, 2021, entitled "Fate Therapeutics Highlights Positive Durability of Response Data from FT516 Phase 1 Study for B-cell Lymphoma and Announces FDA Regenerative Medicine Advanced Therapy Designation Granted to FT516 for Relapsed / Refractory DLBCL."
99.2	Press release dated December 13, 2021, entitled "Fate Therapeutics Showcases Positive Interim Phase 1 Data from FT596 Off-the-shelf, iPSC-derived CAR NK Cell Program for Relapsed / Refractory B-cell Lymphoma at 2021 ASH Annual Meeting."
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

FATE THERAPEUTICS, INC.

December 14, 2021

By: /s/ J. Scott Wolchko
J. Scott Wolchko
President and Chief Executive Officer

Fate Therapeutics Highlights Positive Durability of Response Data from FT516 Phase 1 Study for B-cell Lymphoma and Announces FDA Regenerative Medicine Advanced Therapy Designation Granted to FT516 for Relapsed / Refractory DLBCL

6 of 10 Patients Naïve to Treatment with Autologous CAR T-cell Therapy Continue in Ongoing Response at Median Follow-up of 9.1 Months, including 4 Patients with >6 Months Follow-up, at ≥90 Million FT516 Cells per Dose

3 of 8 Patients Previously Treated with Autologous CAR T-cell Therapy Achieve Complete Response at ≥90 Million FT516 Cells per Dose; 2 Patients Continue in Complete Response at Median Follow-up of 6.5 Months

Outpatient Treatment Regimen Was Well-tolerated; No Events of Any Grade of Cytokine Release Syndrome, Immune Effector Cell-Associated Neurotoxicity Syndrome, or Graft-vs-Host Disease

Dose-expansion Cohorts Initiated at 900 Million FT516 Cells per Dose, including in Patients with Aggressive B-cell Lymphoma Previously Treated with Autologous CAR T-cell Therapy

San Diego, CA – **December 13, 2021** – Fate Therapeutics, Inc. (NASDAQ: FATE), a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer, today presented positive clinical data from the dose-escalation stage of its ongoing Phase 1 study of FT516 for patients with relapsed / refractory B-cell lymphoma (BCL) at the 63rd American Society of Hematology Annual Meeting and Exposition. FT516 is the Company's universal, off-the-shelf natural killer (NK) cell product candidate derived from a clonal master induced pluripotent stem cell (iPSC) line engineered with a novel high-affinity, non-cleavable CD16 (hnCD16) Fc receptor, which is designed to maximize antibody-dependent cellular cytotoxicity (ADCC), a potent anti-tumor mechanism by which NK cells recognize, bind and kill antibody-coated cancer cells.

In addition, the Company today announced that the U.S. Food and Drug Administration (FDA) granted Regenerative Medicine Advanced Therapy (RMAT) designation to FT516 for the treatment of relapsed / refractory diffuse large B-cell lymphoma (DLBCL). The RMAT program provides all of the benefits of the fast track and breakthrough therapy designation programs such as early interactions with the FDA to discuss potential pathways for accelerated approval.

"We continue to be highly encouraged by the differentiated therapeutic profile of FT516 as an off-the-shelf NK cell therapy administered in the outpatient setting, and its potential to deliver deep and durable responses for patients with advanced B-cell lymphomas, including those that have received prior autologous CAR T-cell therapy," said Wayne Chu, M.D., Senior Vice President of Clinical Development of Fate Therapeutics. "The RMAT designation for the treatment of relapsed / refractory DLBCL reflects the

positive clinical data we have observed with FT516 in the dose-escalation stage of our Phase 1 study, and it is an important milestone for the Company that recognizes the unique potential of off-the-shelf, iPSC-derived, NK cell cancer immunotherapy. We look forward to working closely with the FDA to accelerate the development of FT516 in this area of significant unmet medical need with the goal of expanding the reach of transformative cell therapies."

Phase 1 Dose-escalation Efficacy Data

The Phase 1 clinical trial in relapsed / refractory BCL is assessing FT516 in an off-the-shelf treatment regimen of up to two cycles, with each cycle consisting of three days of conditioning chemotherapy (500 mg/m^2 of cyclophosphamide and 30 mg/m^2 of fludarabine), a single-dose of rituximab (375 mg/m^2), and three weekly doses of FT516 each with IL-2 cytokine support. The FT516 treatment regimen is designed to be administered in the outpatient setting.

Patients in the dose-escalation stage had received a median of 3.5 prior lines of therapy and a median of three prior lines containing CD20-targeted therapy. As of the data cutoff date of October 18, 2021, four patients in the second dose cohort of 90 million cells per dose, seven patients in the third dose cohort of 300 million cells per dose, and seven patients in the fourth dose cohort of 900 million cells per dose were evaluable for assessment of safety and efficacy (n=18). Of these 18 patients, 10 patients were naïve to treatment with autologous CD19-targeted chimeric antigen receptor (CAR) T-cell therapy and eight patients were previously treated with autologous CD19-targeted CAR T-cell therapy, including three patients in the fourth dose cohort that were refractory to CAR T-cell therapy (see Table 1).

Table 1. FT516 Phase 1 Dose Cohorts 2, 3 and 4 in Relapsed / Refractory B-cell Lymphoma [1]

	CAR T Naïve		**Prior CAR T**
	Aggressive BCL [2]	**Indolent BCL [3]**	**Aggressive BCL [4]**
n	5	5	8
Response [5]			
Objective Response (%)	4 (80%)	4 (80%)	3 (38%)
Complete Response (%)	2 (40%)	3 (60%)	3 (38%)
Durability of Response [6]			
Response Rate – 3 Months (%)	4 (80%)	4 (80%)	3 (38%)
Ongoing Responders (%) Median Follow-up (months)	3 (60%) 8.3 (4.6, 9.9)	3 (60%) 9.9 (3.7, 13.2)	2 (25%) 6.5 (4.6, 8.3)

1 As of data cutoff date of October 18, 2021
2 Includes diffuse large B-cell lymphoma (n=2); high-grade B-cell lymphoma (n=1); transformed indolent lymphoma (n=1); and gray zone lymphoma (n=1)
3 Includes follicular lymphoma (n=3); mantle cell lymphoma (n=1); and marginal zone lymphoma (n=1)
4 Includes diffuse large B-cell lymphoma (n=7) and high-grade B-cell lymphoma (n=1); includes 3 patients refractory to prior CAR T-cell therapy
5 Cycle 2 Day 29 protocol-defined response assessment per Lugano 2014 criteria
6 Measured from initiation of therapy

Of the ten patients naïve to treatment with CAR T-cell therapy, eight patients achieved an objective response (80%), including five patients that achieved a complete response (50%). Three of eight patients previously treated with CAR T-cell therapy achieved an objective response (38%), all of whom achieved a complete response. In each relapsed / refractory BCL disease setting (aggressive BCL naïve to CAR T-cell therapy; indolent BCL naïve to CAR T-cell therapy; aggressive BCL previously treated with CAR T-cell therapy), responses were observed in each of the second, third, and fourth dose cohorts.

All 11 responding patients in the second, third, and fourth dose cohorts continued in ongoing response at three months following initiation of treatment (61%). As of the data cutoff date, eight patients continued in ongoing response (44%) at a median follow-up of 8.3 months:

- Three of five patients with aggressive BCL naïve to CAR T-cell therapy continued in ongoing response (60%), with two patients in ongoing response beyond six months (8.3 and 9.9 months) and one patient in ongoing response at 4.6 months;
- Three of five patients with indolent BCL naïve to CAR T-cell therapy continued in ongoing response (60%), with two patients in ongoing response beyond six months (9.9 and 13.2 months) and one patient in ongoing response at 3.7 months; and
- Two of eight patients with aggressive BCL previously treated with CAR T-cell therapy continued in ongoing response (25%), with responses ongoing at 4.6 and 8.3 months.

The median duration of response in each of the relapsed / refractory BCL disease settings for all responding patients had not been reached.

Phase 1 Dose-escalation Safety Data

No dose-limiting toxicities, and no FT516-related serious adverse events, were observed. The FT516 treatment regimen was well tolerated, and no treatment-emergent adverse events (TEAEs) of any grade of cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome, or graft-versus-host disease were reported by investigators (see Table 2). Grade 3 or greater TEAEs related to FT516 were observed in two patients (neutrophil count decreased; and neutropenia and thrombocytopenia). There were no discontinuations due to adverse events. In addition, no evidence of anti-product T- or B-cell mediated host-versus-product alloreactivity was observed, supporting the potential to safely administer up to six doses of FT516 in the outpatient setting without the need for patient matching.

Table 2. FT516 Phase 1 TEAEs of Interest in Relapsed / Refractory B-cell Lymphoma

n(%)	DL2 = 90M / dose (n=4)		DL3 = 300M / dose (n=7)		DL4 = 900M / dose (n=7)		Total [1] (n=20)	
	All Grade	Grade 3+	All Grade	Grade 3+	All Grade	Grade 3+	All Grade	Grade 3+
CRS	---	---	---	---	---	---	---	---
ICANS	---	---	---	---	---	---	---	---
GvHD	---	---	---	---	---	---	---	---
Infections	3 (75%)	2 (50%)	2 (29%)	1 (14%)	1 (14%)	1 (14%)	6 (30%)	4 (20%)

CRS = Cytokine Release Syndrome; **DL** = Dose Level; **GvHD** = Graft vs. Host Disease; **ICANS** = Immune Cell-Associated Neurotoxicity Syndrome; **M** = Million; **TEAE** = Treatment-Emergent Adverse Event

1 Includes two subjects in the first dose cohort of 30M cells / dose

FT516 RMAT Designation & Dose Expansion

RMAT designation is an FDA program designed to expedite the development and review of regenerative medicine therapies, including cell-based cancer immunotherapies, that have demonstrated the potential to address an unmet medical need based on preliminary clinical evidence. The program allows for early and frequent interactions with the FDA, and enables regulatory authority guidance on efficient drug development, pathways for accelerated approval, and approaches to fulfill post-approval requirements.

The Company has initiated enrollment in the dose-expansion stage of its Phase 1 study of FT516 in combination with rituximab for the treatment of relapsed / refractory BCL at 900 million cells per dose. The Company plans to enroll patients in three disease-specific expansion cohorts using cyclophosphamide and fludarabine as conditioning chemotherapy: patients with relapsed / refractory aggressive lymphomas who have previously been treated with CD19-targeted CAR T-cell therapy; patients with relapsed / refractory aggressive lymphomas who are naïve to treatment with CD19-targeted CAR T-cell therapy; and patients with relapsed / refractory follicular lymphoma. In addition, the Company plans to enroll an expansion cohort without conditioning chemotherapy, combining FT516 with rituximab and bendamustine, a standard-of-care treatment regimen for lymphoma.

About Fate Therapeutics' iPSC Product Platform

The Company's proprietary induced pluripotent stem cell (iPSC) product platform enables mass production of off-the-shelf, engineered, homogeneous cell products that are designed to be administered with multiple doses to deliver more effective pharmacologic activity, including in combination with other cancer treatments. Human iPSCs possess the unique dual properties of unlimited self-renewal and differentiation potential into all cell types of the body. The Company's first-of-kind approach involves engineering human iPSCs in a one-time genetic modification event and selecting a single engineered iPSC for maintenance as a clonal master iPSC line. Analogous to master cell lines used to manufacture biopharmaceutical drug products such as monoclonal antibodies, clonal master iPSC lines are a renewable source for manufacturing cell therapy products which are well-defined and uniform in composition, can be mass produced at significant scale in a cost-effective manner, and can be delivered off-the-shelf for patient treatment. As a result, the Company's platform is uniquely designed to overcome numerous limitations associated with the production of cell therapies using patient- or donor-sourced cells, which is logistically complex and expensive and is subject to batch-to-batch and cell-to-cell variability that can affect clinical safety and efficacy. Fate Therapeutics' iPSC product platform is supported by an intellectual property portfolio of over 350 issued patents and 150 pending patent applications.

About FT516

FT516 is an investigational, universal, off-the-shelf natural killer (NK) cell cancer immunotherapy derived from a clonal master induced pluripotent stem cell (iPSC) line engineered to express a novel high-affinity 158V, non-cleavable CD16 (hnCD16) Fc receptor, which has been modified to prevent its down-regulation and to enhance its binding to tumor-targeting antibodies. CD16 mediates antibody-dependent cellular cytotoxicity (ADCC), a potent anti-tumor mechanism by which NK cells recognize, bind and kill antibody-coated cancer cells. ADCC is dependent on NK cells maintaining stable and effective expression of CD16, which has been shown to undergo considerable down-regulation in cancer patients. In addition, CD16

occurs in two variants, 158V or 158F, that elicit high or low binding affinity, respectively, to the Fc domain of IgG1 antibodies. Numerous clinical studies with FDA-approved tumor-targeting antibodies, including rituximab, trastuzumab and cetuximab, have demonstrated that patients homozygous for the 158V variant, which is present in only about 15% of patients, have improved clinical outcomes. FT516 is being investigated in a multi-dose Phase 1 clinical trial as a monotherapy for the treatment of relapsed / refractory acute myeloid leukemia and in combination with CD20-targeted monoclonal antibodies for the treatment of relapsed / refractory B-cell lymphoma (NCT04023071).

About Fate Therapeutics, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development of first-in-class cellular immunotherapies for patients with cancer. The Company has established a leadership position in the clinical development and manufacture of universal, off-the-shelf cell products using its proprietary induced pluripotent stem cell (iPSC) product platform. The Company's immuno-oncology pipeline includes off-the-shelf, iPSC-derived natural killer (NK) cell and T-cell product candidates, which are designed to synergize with well-established cancer therapies, including immune checkpoint inhibitors and monoclonal antibodies, and to target tumor-associated antigens using chimeric antigen receptors (CARs). Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 including statements regarding the safety and therapeutic potential of the Company's iPSC-derived NK cell product candidates, including FT516 and its ongoing and planned clinical studies, its expected clinical development plans and timelines, and its regulatory pathways and strategy. These and any other forward-looking statements in this release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, the risk that results observed in studies of its product candidates, including preclinical studies and clinical trials of any of its product candidates, will not be observed in ongoing or future studies involving these product candidates, the risk that the Company may cease or delay clinical development of any of its product candidates for a variety of reasons (including requirements that may be imposed by regulatory authorities on the initiation or conduct of clinical trials, the amount and type of data to be generated, or otherwise to support regulatory approval, difficulties or delays in subject enrollment and continuation in current and planned clinical trials, difficulties in manufacturing or supplying the Company's product candidates for clinical testing, and any adverse events or other negative results that may be observed during preclinical or clinical development), and the risk that its product candidates may not produce therapeutic benefits or may cause other unanticipated adverse effects. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the risks and uncertainties detailed in the Company's periodic filings with the Securities and Exchange Commission, including but not limited to the Company's most recently filed periodic report, and from time to time in the Company's press releases and other investor communications. Fate Therapeutics is providing the information in this release as of this date and does not undertake any obligation to update any forward-looking statements contained in this release as a result of new information, future events or otherwise.

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Fate Therapeutics Showcases Positive Interim Phase 1 Data from FT596 Off-the-shelf, iPSC-derived CAR NK Cell Program for Relapsed / Refractory B-cell Lymphoma at 2021 ASH Annual Meeting

5 of 6 Patients Achieve Objective Response, including 4 Patients with Complete Response, with Single Dose of FT596 at 900 Million Cells in Combination with Rituximab

13 of 19 Patients Achieve Objective Response with Single Dose of FT596 at 90 Million and 300 Million Cell Dose; 10 of 11 Patients Treated with a Second FT596 Cycle Continue in Ongoing Response, with 3 Patients in Ongoing Complete Response at ³6 Months Follow-up; Additional 2 Patients Reach 6 Months in Complete Response

FT596 Treatment Regimens were Well-tolerated; No Dose-limiting Toxicities, and No Adverse Events of Any Grade of ICANS or GVHD, were Observed; Three Low-grade Adverse Events of CRS Resolved without Intensive Care Treatment

Company to Host Virtual Investor Event Tomorrow at 8:00 AM Eastern Time

San Diego, CA – **December 13, 2021** – Fate Therapeutics, Inc. (NASDAQ: FATE), a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer, today showcased positive interim Phase 1 data from the Company's FT596 program for patients with relapsed / refractory B-cell lymphoma (BCL) at the 63rd American Society of Hematology (ASH) Annual Meeting and Exposition. FT596 is the Company's off-the-shelf, multi-antigen targeted, iPSC-derived natural killer (NK) cell product candidate derived from a clonal master induced pluripotent stem cell (iPSC) line engineered with three anti-tumor functional modalities: a proprietary chimeric antigen receptor (CAR) optimized for NK cell biology that targets B-cell antigen CD19; a novel high-affinity, non-cleavable CD16 (hnCD16) Fc receptor that has been modified to prevent its down-regulation and to enhance its binding to tumor-targeting antibodies; and an IL-15 receptor fusion (IL-15RF) that augments NK cell activity.

"The interim dose-escalation clinical data from our FT596 program in relapsed / refractory B-cell lymphoma demonstrate that off-the-shelf, iPSC-derived CAR NK cells can bring substantial therapeutic benefit to heavily pre-treated patients in urgent need of therapy, with high response rates and meaningful duration of responses," said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. "We are particularly pleased with the therapeutic profile that has emerged with FT596 in combination with rituximab, where over half of the patients treated with a single dose of FT596 at higher dose levels achieved a complete response with a favorable safety profile that is clearly differentiated from CAR T-cell therapy. We look forward to assessing a two-dose treatment schedule for FT596 to further define its potential best-in-class therapeutic profile and ability to reach more patients, including those earlier in care."

The ongoing Phase 1 study in relapsed / refractory BCL is assessing a single dose of FT596 as monotherapy (Monotherapy Arm) and in combination with a single dose of rituximab (375 mg/m^2) (Combination Arm) following three days of conditioning chemotherapy (500 mg/m^2 of cyclophosphamide and 30 mg/m^2 of fludarabine). Certain patients are eligible for re-treatment with a second, single-dose cycle.

The ASH presentation (*Session 704—Cellular Immunotherapies: Expanding Targets and Cellular Sources for Immunotherapies, Abstract 823*) includes clinical data from 25 evaluable patients for safety (n=12 in Monotherapy Arm; n=13 in Combination Arm) in the first, second, and third single-dose cohorts of 30 million, 90 million, and 300 million cells, respectively, of which 24 patients were also evaluable for efficacy (n=12 in Monotherapy Arm; n=12 in Combination Arm), as of the data cutoff date of October 11, 2021. These 25 patients had received a median of four prior lines of therapy and a median of two prior lines containing CD20-targeted therapy. Of the 25 patients, 15 patients (60%) had aggressive B-cell lymphoma, 15 patients (60%) were refractory to most recent prior therapy, and 8 patients (32%) were previously treated with autologous CD19-targeted CAR T-cell therapy. Subsequent to the data cutoff date for the ASH presentation, an additional patient in the third single-dose cohort of the Combination Arm was evaluable for initial anti-tumor response, and seven patients in the fourth single-dose cohort of 900 million cells (n=1 in Monotherapy Arm; n=6 in Combination Arm) were evaluable for safety and initial anti-tumor response.

Single-dose, Single-cycle Response Data

In the second, third, and fourth dose cohorts of the Monotherapy and Combination Arms comprising a total of 26 patients, 18 patients (69%) achieved an objective response, including 12 patients (46%) that achieved a complete response, on Day 29 following a single dose of FT596 (see Table 1). Nine of these 26 patients were previously treated with autologous CD19-targeted CAR T-cell therapy and, of these nine patients, six achieved an objective response (67%) on Day 29 following a single dose of FT596. Notably, in the third and fourth dose cohorts of the Combination Arm comprising a total of 12 patients, nine patients (75%) achieved an objective response, including seven patients (58%) that achieved a complete response, on Day 29 following a single dose of FT596.

Durability of Response Data

The ASH presentation includes durability of response data from 13 responding patients in the second and third single-dose cohorts of 90 million cells and 300 million cells (n=9 in Monotherapy Arm; n=10 in Combination Arm). As of the data cutoff date of October 11, 2021, 10 patients continued in ongoing response, including three patients in ongoing complete response at least six months from initiation of treatment; two patients reached six months in complete response and subsequently had disease progression; and one patient had disease progression prior to six months. Of these 13 responding patients:

- *Monotherapy Arm (n=7 responding patients)*. Five patients, all of whom were treated with a second FT596 single-dose cycle with the consent of the U.S. Food and Drug Administration (FDA), continued in ongoing response at a median follow-up of 4.1 months, including one patient in ongoing complete response at 8.1 months; one patient, who was treated with only one FT596 single-dose cycle, reached six months in complete response and subsequently had disease progression at 6.5 months; and one patient, who was treated with only one FT596 single-dose cycle, had disease progression at 1.7 months.

- *Combination Arm (n=6 responding patients)*. Five patients, all of whom were treated with a second FT596 single-dose cycle with the consent of the FDA, continued in ongoing response at a median follow-up of 4.6 months, including two patients in ongoing complete response at 6.0 and 10.8 months; and one patient, who was treated with a second FT596 single-dose cycle with the consent of the FDA, reached six months in complete response and subsequently had disease progression at 6.7 months.

Table 1. FT596 Interim Phase 1 Data – Day 29 Response Assessment [1]

1 Dose x 1 Cycle	**Monotherapy (n=13)**		**Combination (n=19)**	
Single-dose Level Cohorts (Cells)	**OR**	**CR**	**OR**	**CR**
30M	1/3 (33%)	0	0/3 (0%)	0
90M	3/4 (75%)	2	2/4 (50%)	2
300M [2]	4/5 (80%)	1	4/6 (67%)	3
900M [2]	0/1 (0%)	0	5/6 (83%)	4
aCD19 History (^{3}90M Cells)	n=10		n=16	
Naïve	7/9 (78%)	3	5/8 (63%)	4
Prior	0/1 (0%)	0	6/8 (75%)	5
Disease Histology (^{3}90M Cells)	n=10		n=16	
Aggressive	1/3 (33%)	0	6/11 (55%)	4
Mantle cell	0/1 (0%)	0	2/2 (100%)	2
Indolent	6/6 (100%)	3	3/3 (100%)	3

aCD19 = autologous CD19-targeted CAR T-cell therapy; **Aggressive** = diffuse large B-cell lymphoma, Grade 3b follicular lymphoma, Richter's transformation, and high-grade B-cell lymphoma; **CR** = complete response; **Indolent** = splenic diffuse red pulp small B-cell lymphoma, non-Grade 3b follicular lymphoma, Waldenstrom's macroglobulinemia, and small lymphocytic lymphoma; **M** = million; **OR** = objective response

1 As of data cutoff date of October 11, 2021, unless otherwise noted. Objective response and complete response are based on Cycle 1 Day 29 protocol-defined response assessment per Lugano 2014 criteria. Data subject to source document verification.

2 Cycle 1 Day 29 protocol-defined response assessment completed subsequent to data cutoff date for one patient in the third single-dose cohort of 300 million cells in the Combination Arm and seven patients in the fourth single-dose cohort of 900 million cells (n=1 in Monotherapy Arm; n=6 in Combination Arm).

Safety Data

The FT596 treatment regimens were well tolerated, including in those patients treated with a second, single-dose cycle. No dose-limiting toxicities, and no treatment-emergent adverse events (TEAEs) of any grade of immune effector cell-associated neurotoxicity syndrome (ICANS) or graft-versus-host disease (GvHD) were observed. Three low-grade adverse events (two Grade 1, one Grade 2) of cytokine release syndrome (CRS) were reported, which were of limited duration and resolved without intensive care treatment (see Table 2).

The Company has initiated enrollment of a two-dose treatment schedule in the Combination Arm, with FT596 administered on Day 1 and Day 15 at 900 million cells per dose. Patients with clinical benefit following administration of the first two-dose cycle are eligible for re-treatment with a second two-dose cycle. Additionally, patients with clinical response are eligible for re-treatment following disease progression.

Table 2. FT596 Interim Phase 1 Data – TEAEs of Interest				
	Monotherapy (n=13)		Combination (n=19)	
n (%)	All Grade	Grade 3+	All Grade	Grade 3+
CRS	1 (8%)	---	2 (11%)	---
ICANS	---	---	---	---
GvHD	---	---	---	---
Infections	6 (46%)	3 (23%)	6 (32%)	3 (16%)
FT596-related SAEs	---	---	1 (5%) [a]	---

CRS = Cytokine Release Syndrome; **GvHD** = Graft vs. Host Disease; **ICANS** = Immune Cell-Associated Neurotoxicity Syndrome; **TEAE** = Treatment-Emergent Adverse Event; **SAE** = Severe Adverse Events

[a] Grade 2 CRS

Investor Event Webcast

The Company will host a live audio webcast on Tuesday, December 14, 2021 at 8:00 a.m. ET to highlight interim Phase 1 clinical data from the Company's FT516 and FT596 programs for the treatment of relapsed / refractory B-cell lymphoma. The live webcast can be accessed under "Events & Presentations" in the Investors section of the Company's website at www.fatetherapeutics.com. The archived webcast will be available on the Company's website beginning approximately two hours after the event.

About Fate Therapeutics' iPSC Product Platform

The Company's proprietary induced pluripotent stem cell (iPSC) product platform enables mass production of off-the-shelf, engineered, homogeneous cell products that are designed to be administered with multiple doses to deliver more effective pharmacologic activity, including in combination with other cancer treatments. Human iPSCs possess the unique dual properties of unlimited self-renewal and differentiation potential into all cell types of the body. The Company's first-of-kind approach involves engineering human iPSCs in a one-time genetic modification event and selecting a single engineered iPSC for maintenance as a clonal master iPSC line. Analogous to master cell lines used to manufacture biopharmaceutical drug products such as monoclonal antibodies, clonal master iPSC lines are a renewable source for manufacturing cell therapy products which are well-defined and uniform in composition, can be mass produced at significant scale in a cost-effective manner, and can be delivered off-the-shelf for patient treatment. As a result, the Company's platform is uniquely designed to overcome numerous limitations associated with the production of cell therapies using patient- or donor-sourced cells, which is logistically complex and expensive and is subject to batch-to-batch and cell-to-cell variability that can affect clinical safety and efficacy. Fate Therapeutics' iPSC product platform is supported by an intellectual property portfolio of over 350 issued patents and 150 pending patent applications.

About FT596

FT596 is an investigational, universal, off-the-shelf natural killer (NK) cell cancer immunotherapy derived from a clonal master induced pluripotent stem cell (iPSC) line engineered with three anti-tumor functional modalities: a proprietary chimeric antigen receptor (CAR) optimized for NK cell biology that targets B-cell antigen CD19; a novel high-affinity 158V, non-cleavable CD16 (hnCD16) Fc receptor, which has been modified to prevent its down-regulation and to enhance its binding to tumor-targeting antibodies; and an IL-15 receptor

fusion (IL-15RF) that augments NK cell activity. In preclinical studies of FT596, the Company has demonstrated that dual activation of the CAR19 and hnCD16 targeting receptors enhances cytotoxic activity, indicating that multi-antigen engagement may elicit a deeper and more durable response. Additionally, in a humanized mouse model of lymphoma, FT596 in combination with the anti-CD20 monoclonal antibody rituximab showed enhanced killing of tumor cells *in vivo* as compared to rituximab alone. FT596 is being investigated in a multi-center Phase 1 clinical trial for the treatment of relapsed / refractory B-cell lymphoma as a monotherapy and in combination with rituximab, and for the treatment of relapsed / refractory chronic lymphocytic leukemia (CLL) as a monotherapy and in combination with obinutuzumab (NCT04245722).

About Fate Therapeutics, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development of first-in-class cellular immunotherapies for patients with cancer. The Company has established a leadership position in the clinical development and manufacture of universal, off-the-shelf cell products using its proprietary induced pluripotent stem cell (iPSC) product platform. The Company's immuno-oncology pipeline includes off-the-shelf, iPSC-derived natural killer (NK) cell and T-cell product candidates, which are designed to synergize with well-established cancer therapies, including immune checkpoint inhibitors and monoclonal antibodies, and to target tumor-associated antigens using chimeric antigen receptors (CARs). Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 including statements regarding the safety and therapeutic potential of the Company's iPSC-derived NK cell product candidates, including FT596, its ongoing and planned clinical studies, and the expected clinical development plans for FT596. These and any other forward-looking statements in this release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, the risk that results observed in studies of its product candidates, including preclinical studies and clinical trials of any of its product candidates, will not be observed in ongoing or future studies involving these product candidates, the risk that the Company may cease or delay clinical development of any of its product candidates for a variety of reasons (including requirements that may be imposed by regulatory authorities on the initiation or conduct of clinical trials, the amount and type of data to be generated, or otherwise to support regulatory approval, difficulties or delays in subject enrollment and continuation in current and planned clinical trials, difficulties in manufacturing or supplying the Company's product candidates for clinical testing, and any adverse events or other negative results that may be observed during preclinical or clinical development), and the risk that its product candidates may not produce therapeutic benefits or may cause other unanticipated adverse effects. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the risks and uncertainties detailed in the Company's periodic filings with the Securities and Exchange Commission, including but not limited to the Company's most recently filed periodic report, and from time to time in the Company's press releases and other investor communications. Fate Therapeutics is providing the information in this release as of this date and does not undertake any obligation to update any forward-looking statements contained in this release as a result of new information, future events or otherwise.

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