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

June 12, 2023
Date of Report (Date of earliest event reported)

MARKER THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-37939**	**45-4497941**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4551 Kennedy Commerce Dr. **Houston, Texas**	**77032**
(Address of principal executive offices)	(Zip Code)

(713) 400-6400
Registrant's telephone number, including area code

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K 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, par value $0.001 per share	MRKR	The Nasdaq Stock Market LLC

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 7.01 Regulation FD Disclosure.

On June 12, 2023, Marker Therapeutics, Inc. (the "***Company***") issued a press release announcing that the first patient has been treated in the Company sponsored Phase 1 multicenter APOLLO trial investigating MT-601, the Company's multi-tumor-associated antigen (multiTAA)-specific T cell product. A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press release, dated June 12, 2023
104	Inline XBRL for the cover page of this Current Report on Form 8-K

SIGNATURES

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

Marker Therapeutics, Inc.

Dated: June 12, 2023

By: /s/ Juan Vera
Juan Vera
President and Chief Executive Officer

Exhibit 99.1

Marker Therapeutics Announces First Lymphoma Patient Treated with MT-601 in Phase 1 Clinical Trial

Marker Therapeutics initiated APOLLO trial for the treatment of lymphoma patients who have relapsed after anti-CD19 CAR T therapy in the first quarter of 2023

Houston, TX — June 12, 2023 – Marker Therapeutics, Inc. (Nasdaq: MRKR), a clinical-stage immuno-oncology company focusing on developing next-generation T cell-based immunotherapies for the treatment of hematological malignancies and solid tumor indications, today announced that the first patient has been treated in the company sponsored Phase 1 multicenter APOLLO trial investigating MT-601, a multi-tumor-associated antigen (multiTAA)-specific T cell product targeting six antigens, for the treatment of patients with lymphoma who have failed or are ineligible to receive anti-CD19 CAR T cell treatment.

Adoptive T cell transfer, such as genetically modified T cells expressing anti-CD19 chimeric antigen receptors (CARs) targeting CD19 antigens, is a therapeutic modality that has recently demonstrated impressive clinical impact in patients with large B-cell malignancies who have failed more than two lines of treatment. Administration of anti-CD19 CAR T cells to patients with relapsed/refractory B-cell lymphomas have been a transformative treatment paradigm because of their significant benefit relative to the standard of care. However, for various reasons, including low antigen levels and loss of CD19 antigen expression, anti-CD19 CAR T cell therapy is associated with relapse rates of up to 60%, within one year (Chong et al, N Engl J Med, 2021). In addition, a number of patients with relapsed/refractory B-cell lymphomas are ineligible for anti-CD19 CAR T cell therapy due to the associated toxicities.

A recent Phase 1 study conducted by Baylor College of Medicine (TACTAL) investigated the safety and efficacy of a multiTAA-specific T cell product that recognizes five tumor antigens in both Hodgkin's lymphoma and non-Hodgkin's lymphoma (Vasileiou et al, J Clin Oncol, 2021). Treatment with this multiTAA-specific T cell product resulted in positive patient outcomes with some patients remaining in complete remission at the 72 months follow-up.

Marker is developing MT-601, an autologous T cell product that is directed against six tumor associated antigens for the treatment of patients with relapsed/refractory lymphoma who are either ineligible to receive or have failed anti-CD19 CAR T cell therapy. Given the positive TACTAL trial results, which targeted five tumor associated antigens, Marker believes broadening its multiTAA-specific T cell product to target six antigens could result in better and more durable responses due to its ability to overcome antigen loss by targeting more than one antigen.

The recent press release issued by Marker on May 31, 2023, referenced *in vitro* nonclinical data indicating that MT-601 prevented growth of lymphoma cells regardless of CD19 expression and prevented growth of CD19 expressing lymphoma cells that had become resistant to CAR T infusion. These data demonstrate the therapeutic potential of MT-601.

The APOLLO trial (clinicaltrials.gov Identifier: NCT05798897) sponsored by Marker is assessing MT-601 in patients with lymphoma who have either relapsed after anti-CD19 CAR T cell therapy or were ineligible to receive it. The primary objective of this exploratory Phase 1 clinical trial is to evaluate the optimum dose, safety, and preliminary efficacy of MT-601 in patients with various lymphoma subtypes. Data from the APOLLO trial will guide Marker Therapeutics on the future development of MT-601.

The first patient in the APOLLO trial recently received MT-601 at the 200 million cell dose level. This patient was monitored for 18 days after being dosed and showed no treatment-related adverse events, indicating that the therapy was well tolerated. This observation is consistent with the favorable safety profile and tolerability previously reported for lymphoma patients in the TACTAL study. Under the APOLLO trial, eight clinical sites across the United States will cumulatively enroll up to 30 patients during the dose escalation phase.

"The initiation of clinical treatment under the APOLLO trial represents not just a major achievement for our team at Marker, but a beacon of hope for countless individuals with lymphoma who are confronting the reality of disease progression," said Monic Stuart, M.D., Chief Medical Officer of Marker Therapeutics. "Our vision with MT-601 is to fundamentally change the treatment landscape of lymphoma, providing a solution that could drastically enhance the lives of patients."

"Phase 1 of the clinical trial is a critical period," continued Dr. Stuart. "This stage will provide us with key insights into the safety, optimal dosage range, and initial efficacy of MT-601. The collected data will serve as a foundation for refining our understanding of the performance of MT-601 and its potential outcomes in patients with lymphoma who have relapsed after anti-CD19 CAR T therapy."

"We are grateful to our dedicated team of scientists, clinicians, and trial participants who have made this significant step possible," said Juan F. Vera, M.D., Chief Executive Officer of Marker Therapeutics. "Behind this milestone is an extensive body of research and a rigorous development process. The initiation of this clinical trial is rooted in a set of scientific data, which has shown compelling signs of potential clinical impact of MT-601 in attacking anti-CD19 CAR T refractory lymphoma cells. These promising nonclinical results, together with previous clinical observations from the TACTAL study, have given us confidence in the potential for multiTAA-specific T cell therapies to target lymphoma cells."

"The initiation of clinical treatment under the Phase 1 trial of MT-601 is a major step in our mission to bring forward transformative advancements in lymphoma treatment, with the goal of significantly improving patient outcomes. We are committed to diligently monitoring and analyzing the data from this Phase 1 clinical trial to ensure we continue making informed decisions that prioritize patient safety and therapeutic effectiveness," concluded Dr. Vera.

About multiTAA-specific T cells

The multi-tumor associated antigen (multiTAA)-specific T cell platform is a novel, non-genetically modified cell therapy approach that selectively expands tumor-specific T cells from a patient's blood capable of recognizing a broad range of tumor antigens. Clinical trials that enrolled more than 180 patients with various hematological malignancies and solid tumors showed that the multiTAA-specific T cell product was well tolerated, demonstrated durable clinical responses, and consistent epitope spreading. The latter is typically not observed with other T cell therapies and enables the patient's own T cells to expand, potentially contributing to a lasting anti-tumor effect. Unlike other cell therapies which require hospitalization and close monitoring, multiTAA-specific T cells are designed to be administered in an outpatient setting.

About Marker Therapeutics, Inc.
Marker Therapeutics, Inc. is a clinical-stage immuno-oncology company specializing in the development of next-generation T cell-based immunotherapies for the treatment of hematological malignancies and solid tumor indications. The cell therapy technology Marker has is based on the selective expansion of non-engineered, tumor-specific T cells that recognize tumor associated antigens (i.e., tumor targets) and kill tumor cells expressing those targets. This population of T cells is designed to attack multiple tumor targets following infusion into patients and to activate the patient's immune system to produce broad spectrum anti-tumor activity. Because Marker does not genetically engineer its T cell therapies, we believe that our product candidates will be easier and less expensive to manufacture, with reduced toxicities, compared to current engineered CAR-T and TCR-based approaches, and may provide patients with meaningful clinical benefit. As a result, Marker believes its portfolio of T cell therapies has a compelling product profile, as compared to current gene-modified CAR-T and TCR-based therapies.

To receive future press releases via email, please visit: https://www.markertherapeutics.com/email-alerts.

Forward-Looking Statements
This release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Statements in this news release concerning the Company's expectations, plans, business outlook or future performance, and any other statements concerning assumptions made or expectations as to any future events, conditions, performance or other matters, are "forward-looking statements." Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: our research, development and regulatory activities and expectations relating to our non-engineered multi-tumor antigen specific T cell therapies; the effectiveness of these programs or the possible range of application and potential curative effects and safety in the treatment of diseases; and the timing, conduct and success of our clinical trials of our product candidates, including MT-601 for the treatment of patients with relapsed non-Hodgkin lymphoma. Forward-looking statements are by their nature subject to risks, uncertainties and other factors which could cause actual results to differ materially from those stated in such statements. Such risks, uncertainties and factors include, but are not limited to the risks set forth in the Company's most recent Form 10-K, 10-Q and other SEC filings which are available through EDGAR at WWW.SEC.GOV. The Company assumes no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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