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

September 11, 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.)

9350 Kirby Drive, Suite 300 **Houston, Texas**	**77054**
(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 8.01 Other Events.

On September 11, 2023, Marker Therapeutics, Inc. (the "***Company***") issued a press release announcing preliminary results for the first patient treated with MT-601, its multi-tumor associated antigen (multiTAA)-specific T cell product targeting six TAAs, in the Phase 1 multicenter APOLLO clinical trial. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release, dated September 11, 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: September 11, 2023

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

Exhibit 99.1

Marker Therapeutics Announces Complete Response in First Lymphoma Patient Treated with MT-601 after CAR T Relapse

Marker Therapeutics reports clinical updates in APOLLO trial for the treatment of lymphoma patients who have relapsed after anti-CD19 CAR T cell therapy

Patient with Non-Hodgkin's Lymphoma who relapsed after anti-CD19 CAR T cell therapy tolerated initial dose level well and achieved complete response after MT-601 treatment

Houston, TX – September 11, 2023 – Marker Therapeutics, Inc. (Nasdaq: MRKR) is 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 Marker is announcing the preliminary results of the first participant treated with MT-601, its multi-tumor associated antigen (multiTAA)-specific T cell product targeting 6 TAAs, in the Phase 1 multicenter APOLLO clinical trial. The APOLLO trial is investigating the safety and efficacy of MT-601 for the treatment of patients with lymphoma who have either failed or are ineligible to receive anti-CD19 CAR T cell therapy.

This first APOLLO study participant had diffuse large B cell lymphoma (DLBCL) and was enrolled into the Phase 1 dose escalation stage of the trial (Press Release, June 12, 2023) after failing 4 prior lines of therapy, including anti-CD19 CAR T cell therapy.

After relapse following anti-CD19 CAR T cell therapy, the participant was treated with 2 doses of MT-601 at the 200 million cell dose level without prior lymphodepletion. MT-601 treatment was well tolerated with no reports of higher than Grade 1 treatment-related adverse events. The tolerability at this initial dose level is consistent with the favorable clinical safety profile and tolerability previously reported for other multiTAA-specific T cell products. Eight weeks after the 2nd infusion of MT-601, the participant demonstrated complete metabolic response based on PET-CT scans.

Marker previously reported non-clinical proof-of-concept data that showed that MT-601 has the potential to eliminate lymphoma cells that are resistant to anti-CD19 CAR T cells, highlighting the therapeutic potential of MT-601 *in vitro* (Press Release, May 31, 2023).

"We are delighted to announce that the first study participant treated in the APOLLO trial achieved a complete response after treatment with MT-601," said Monic Stuart, M.D., Chief Medical Officer of Marker Therapeutics. "This is a significant initial step forward in our Phase 1 clinical trial and highlights the potential benefit of MT-601 in patients who have relapsed after anti-CD19 CAR T cell therapy. The patient will remain under close observation as we continue to monitor long-term treatment effects and the durability of response."

"The complete response we have observed in this CAR T relapsed patient with lymphoma marks a remarkable milestone for Marker and our technology," said Juan F. Vera, M.D., President and Chief Executive Officer of Marker Therapeutics. "Our APOLLO trial is an important area for MT-601 assessment, as up to 60% of patients treated with anti-CD19 CAR T therapies relapse within one year. While a complete response in our first patient treated with MT-601 is certainly encouraging, the focus of the APOLLO study is to continue to treat and evaluate additional participants in this Phase 1 study."

About MT-601

MT-601 utilizes a novel non-genetically modified approach that specifically targets six different tumor antigens upregulated in lymphoma cells (Survivin, PRAME, WT-1, NY-ESO-1, SSX-2, MAGEA-4). Marker is currently investigating MT-601 in the Company-sponsored Phase 1 APOLLO trial (clinicaltrials.gov identifier: NCT05798897) for the treatment of lymphoma patients who are relapsed/refractory after or ineligible to anti-CD19 CAR T cell therapies.

About APOLLO

The APOLLO trial (clinicaltrials.gov Identifier: NCT05798897) is a Phase 1, multicenter, open-label study designed to evaluate the safety and efficacy of MT-601 in participants with relapsed or refractory lymphoma who either received anti-CD19 chimeric antigen receptor (CAR) T cell therapy or are ineligible for anti-CD19 CAR T cell therapy. The primary objective of this exploratory Phase 1 clinical trial is to evaluate the optimum dose, safety, and preliminary efficacy of MT-601 in participants with various lymphoma subtypes. Under the APOLLO trial, eight clinical sites across the United States will cumulatively enroll up to approximately 30 participants during the dose escalation phase.

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/donor’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 autologous and allogeneic multiTAA-specific T cell products were well tolerated and demonstrated durable clinical responses, and consistent epitope spreading. The latter is typically not observed with other T cell therapies and enables the potential contribution to a lasting anti-tumor effect.

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 T cell therapy technology developed by Marker 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 the T cells, Marker believes that its 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; the timing, conduct and success of our clinical trials of our product candidates, including MT-601 for the treatment of patients with 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 its forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release except as may be required by law.

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