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

December 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 December 11, 2023, Marker Therapeutics, Inc. (the "**Company**") issued a press release announcing Sustained Complete Response in First Lymphoma Patient Treated with MT-601 following CAR T Relapse.

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 December 11, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: December 11, 2023

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

Exhibit 99.1

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

Study participant with Non-Hodgkin's Lymphoma who relapsed after anti-CD19 CAR T cell therapy tolerated initial dose level well and remains in complete response six months after MT-601 treatment

Houston, TX – December 11, 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 reported a clinical update on the APOLLO study. The Phase 1 APOLLO study is investigating MT-601, a multi-tumor associated antigen (multiTAA)-specific T cell product, for the treatment of patients with lymphoma who have failed or are ineligible to receive anti-CD19 CAR T cell therapy.

The Company previously reported first enrollment in the dose escalation stage of the Phase 1 trial (Press Release, June 12, 2023). The patient had diffuse large B cell lymphoma (DLBCL) and failed four prior lines of therapy, including anti-CD19 CAR T cell therapy. Marker reported in September that the study participant tolerated the treatment well without treatment-related adverse events and achieved a complete metabolic response eight weeks after the second infusion of MT-601 (Press Release, September 11, 2023). Marker reports today that six months following the initial treatment with MT-601 the study participant has maintained complete response to treatment.

These clinical results are reinforced by non-clinical proof-of-concept data demonstrating that MT-601 has the potential to eradicate lymphoma cells resistant to anti-CD19 CAR T cells, highlighting the therapeutic potential of MT-601 *in vitro* (Press Release, May 31, 2023).

Although CD19-targeting CAR T cell therapies have gained acceptance as treatment for patients with lymphoma, up to 60% of patients treated with CAR T therapies relapse within one year (Chong EA et al, N Engl J Med, 2021). This APOLLO study participant relapsed within 90 days after CAR T cell therapy, yet maintained a complete response for at least six months after treatment with MT-601, suggesting that MT-601 is more durable compared to CAR T cells in this study participant.

CAR T cell therapies, which have known severe side effects such as neurotoxicity, are also currently being investigated by the FDA for the risk of potential induction of secondary cancers (U.S. Food and Drug Administration, November 28, 2023), adding another layer of concern for patients and clinicians. Notably, multiTAA-specific T cell therapies have been well-tolerated in clinical trials, and Marker believes that multiTAA-specific T cells are a safe alternative to CAR T cells due to their non-genetically engineered approach that selectively expands tumor-specific T cells from a patient's/donor's blood without the risk of mutagenesis.

"Witnessing the sustained complete response in our first patient treated with MT-601 over six months has been an encouraging and rewarding experience," commented Dr. Geoffrey Shouse, the Principal Investigator at City of Hope National Medical Center in Duarte California. "This is a remarkable achievement, demonstrating the potential impact of MT-601 in patients with lymphoma who have relapsed after anti-CD19 CAR T cell therapy. We are encouraged by the benefit this therapy has provided for one our patient's life, the newfound hope it brings, and the potential impact MT-601 could have as a novel treatment option for patients with lymphoma."

“Relapse rates following CAR T cell therapy are high,” said Juan F. Vera, M.D., President and Chief Executive Officer of Marker Therapeutics. “The ongoing complete response observed after MT-601 infusion in a CAR relapsed patient with lymphoma suggests superior durability of our therapy over CAR T cells in this patient. To further validate these observations, we have already enrolled additional patients in this study to replicate and reinforce these promising results."

Dr. Vera continued: “The sustained complete response is a significant milestone in our Phase 1 study and highlights the potential benefit of MT-601 in patients who relapse after anti-CD19 CAR T cell therapy. We will continue to monitor long-term treatment effects and durability of response and look forward to treating 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 failed 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, nine 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 200 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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