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

January 8, 2024
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 7.01. Regulation FD Disclosure.

As previously announced, the Marker Therapeutics, Inc. (the "Company") management team led by Chief Executive Officer, Juan Vera, plans to participate in the Biotech Showcase and present at the 19th Annual Non-Dilutive Funding Summit held alongside the 42nd Annual J.P. Morgan Healthcare Conference 2024 (J.P. Morgan Week).

On January 8, 2024, the Company issued a press release announcing Clinical Program Updates and Pipeline Prioritization. A copy of the press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

In addition, on January 8, 2024, the Company updated its corporate presentation for use in meetings with investors, analysts and others during J.P. Morgan Week and thereafter, as well as in connection with the non-dilutive funding summit. The corporate presentation is available through the Company's website and a copy is attached hereto as Exhibit 99.2 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 and 99.2) 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 subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information shall not be deemed incorporated by reference into 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 January 8, 2024.
99.2	Corporate Presentation, dated January 2024.
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: January 8, 2024

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

Exhibit 99.1

Marker Therapeutics Announces Clinical Program Updates and Pipeline Prioritization

Strategic prioritization of clinical programs with focus on MT-601 in patients with lymphoma

MultiTAA-specific T cell therapies demonstrate clinical safety and positive clinical data across multiple indications

Marker provides updates supporting the clinical benefits of MT-401 in patients with measurable residual disease (MRD)

Houston, TX – January 8, 2024 – 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 tumors, today announced a restructuring of its clinical programs and a strategic prioritization of its multi-tumor associated antigen (multiTAA)-specific T cell product pipeline. In addition, the Company reported a clinical update on the Phase 2 ARTEMIS study investigating MT-401, a multiTAA-specific T cell product, for the treatment of patients with acute myeloid leukemia (AML).

Following the non-dilutive transaction with Cell Ready (Press Release, May 1, 2023), Marker has made significant progress on clinical and corporate restructuring with the objective of accelerating the commercial development of our unique multiTAA technology. The Company today announced the prioritization of MT-601 in chimeric antigen receptor (CAR) relapse patients with lymphoma (APOLLO; clinicaltrials.gov identifier: NCT05798897). This strategic decision was made based on 1) the Company's promising non-clinical and clinical data using the multiTAA technology in lymphoma, and 2) the lack of an approved treatment for patients who experience relapse after treatment with CD19 CAR T (up to 60% within a year; Chong EA et al, N Engl J Med, 2021), which is a clear unmet medical need and provides an opportunity for accelerated product development.

Highlights from the Lymphoma Study

Clinical Efficacy in Patients with Lymphoma in Previous Clinical Trial

- The multiTAA-specific T cell product targeting 5 TAAs was investigated in the TACTAL study, a Phase 1 trial conducted at Baylor College of Medicine.
- The TACTAL study enrolled patients with Hodgkin's and non-Hodgkin's lymphoma and demonstrated clinical safety and efficacy with durable clinical responses for 6 years (Vasileiou et al, J Clin Oncol, 2021).

Non-Clinical Proof-of-Concept Data

- Marker developed a long-term *in vitro* killing assay 1) to better understand resistance mechanisms following CAR T cell treatment and 2) to determine if a product that is capable of targeting 6 TAAs (MT-601) will be able to kill CAR-resistant lymphoma cells (Press Release, May 31, 2023).
- After CD19-targeting CAR T cell treatment, 98% of lymphoma cells were eliminated *in vitro*. Long-term follow-up (three weeks) demonstrated outgrowth of CD19-negative tumor cells. Additional anti-CD19 CAR T cell treatment failed to inhibit tumor growth due to the lack of target antigen (CD19) expression on the tumor.

- Treating CAR-resistant lymphoma cells with MT-601 resulted in complete long-term growth inhibition (over three weeks) highlighting that MT-601 has the potential to effectively treat CD19 CAR-resistant tumors (Pre-Clinical Data in Lymphoma, May 31, 2023).

Durable Response in CAR Relapsed Patient with Lymphoma

- The Company-sponsored Phase 1 APOLLO study investigates the safety and efficacy of MT-601 in patients with lymphoma who have failed or are ineligible to receive anti-CD19 CAR T cell therapy.
- The first study participant, a 57-year-old female with diffuse large B cell lymphoma (DLBCL), was enrolled in the Phase 1 dose escalation stage of the trial after failing 4 prior lines of therapy, including anti-CD19 CAR T cell therapy (Press Release, June 12, 2023). The participant relapsed within 90 days of CAR T cell therapy, and was treated with MT-601 without prior lymphodepletion.
- The patient tolerated MT-601 well without treatment-related adverse events and achieved a complete response eight weeks after the second infusion of MT-601 (Press Release, Sep 11, 2023).
- Six months following treatment with MT-601 the study participant has maintained a complete response to treatment suggesting that MT-601 is more durable compared to CAR T cells in this study participant (Press Release, Dec 11, 2023).

CD19-targeting CAR T cell therapies are associated with severe side effects and toxicities, and up to 60% of patients with DLBCL relapse within a year (Chong EA et al, N Engl J Med, 2021). Additionally, the FDA is investigating CAR T therapies for the potential risk of inducing secondary cancers (U.S. Food and Drug Administration, Nov 28, 2023). To date, multiTAA-specific T cell therapies have been well-tolerated in over 200 patients in clinical trials, and Marker believes that, unlike CAR T cells, multiTAA-specific T cells could represent a safer therapeutic option 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.

Promising Clinical Observations and New Directions with MT-401 in Patients with MRD in AML

Today, Marker is providing a clinical update on the Phase 2 ARTEMIS clinical study (clinicaltrials.gov identifier: NCT04511130), and the direction it will pursue. This multicenter study is evaluating the safety and efficacy of MT-401 in patients with AML after allogeneic hematopoietic stem cell transplantation (HSCT).

A total of 8 patients with MRD+ AML after HSCT were enrolled and treated with MT-401. None of the 8 treated patients experienced a drug related adverse event. Of the 8 treated patients, 4 experienced a clinical benefit, with 3 showing a conversion to MRD-negative, and one patient showing a partial response with a logarithmic reduction of MRD levels by PCR. One patient has not yet had the first assessment post treatment. Of the 8 treated patients in the study, only 1 patient had documented disease progression and was taken to a second transplant. The other 3 patients were taken off the study for reasons unrelated to the clinical outcome.

Obtaining timely consent and re-accessing HSCT donors for apheresis for the manufacture of MT-401 caused delayed patient accrual and patient eligibility issues. Consequently, the rapid progression of disease contributed to some patients to withdraw from the study prior to administration of study product. Therefore, to streamline resources and to reduce time to treatment, Marker intends to focus on a ready for use product from commercially available leukapheresis material and will discontinue the patient-specific part (ARTEMIS) of the AML program.

“We are encouraged by the clinical observations in patients with MRD in our AML study,” said Juan Vera, M.D., President and CEO of Marker Therapeutics. “The data demonstrate the safety of MT-401 and provide evidence that MT-401 could benefit patients with MRD+ AML.”

Dr. Vera continued: “Decreasing the time to treatment is critical when it comes to the treatment of patients that suffer from rapidly progressing cancers, such as patients with MRD in AML, which typically advances rapidly into frank relapse with poor outcomes. We believe using commercial leukapheresis material from healthy donors can bypass the bottleneck associated with donor identification and facilitate large-scale manufacturing. This approach is expected to not only reduce manufacturing costs, but also expedite time to treatment to as little as 72 hours. We are currently working to initiate the clinical study and anticipate that the first patient with AML will be treated with MT-401 manufactured from healthy donors in the second half of 2024.”

The Company previously announced that the FDA has cleared the clinical protocol to investigate a ready for use MT-401 product manufactured from healthy donors in patients with AML, and a cellular inventory has been established with continuous efforts to expand this inventory (Press Release, Aug 7, 2023).

Marker has secured non-dilutive funding to support the clinical investigation of a ready for use MT-401 product in patients with AML. Using these allocated funds will allow the Company to proceed with the ready for use program without affecting the ongoing Phase 1 APOLLO study and the capital runway of the Company into the fourth quarter of 2025.

In addition, the Company has an Investigational New Drug (IND) application cleared by the U.S. FDA for a Phase 1 trial to investigate MT-601 in patients with pancreatic cancer in combination with first-line chemotherapy. The clinical advancement of this multicenter study will be pending additional funding from non-dilutive sources, including grant activities.

“The strategic restructure of our multiTAA pipeline reflects our ongoing commitment to innovate and deliver groundbreaking treatments,” said Dr. Vera. “The decision to shift our focus on MT-601 in patients with lymphoma is based on our promising non-clinical and clinical observations. Lymphoma is a highly competitive landscape with numerous companies striving to compete with CAR T cell therapies. However, our approach differs by targeting multiple antigens and focusing on a unique niche: patients who have experienced CAR T cell relapse or are ineligible for CAR T therapy.”

Dr. Vera continued: “We believe that MT-601 could address the unmet medical need in this patient population. Developing a product in this patient population is commercially attractive due to the well understood natural history, the unmet medical need, and the lower number of competing trials. Assuming we continue to see promising results in our APOLLO study, this would allow us to accelerate the development of MT-601 in CAR relapse patients with lymphoma.”

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-401 for the treatment of patients with AML and 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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Exhibit 99.2


MARKER THERAPEUTICS
CORPORATE PRESENTATION
January 2024

Forward Looking Statements

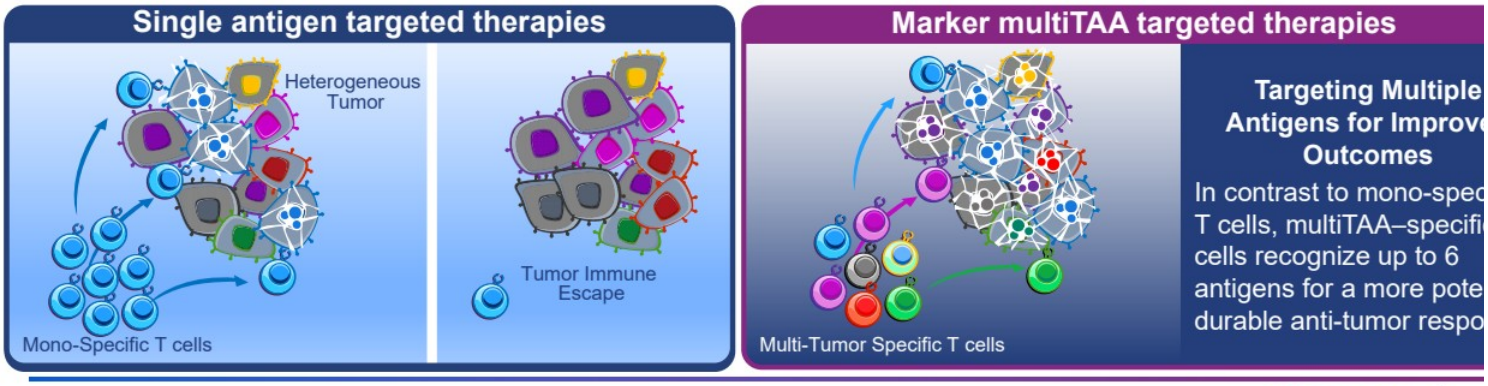
Certain statements contained herein are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1 as amended, and Section 27A of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amen that involve risks and uncertainties. All statements other than statements relating to historical matters including statements to the effect tha "believe", "expect", "anticipate", "plan", "target", "intend" and similar expressions, including without limitation statements regarding Ma Therapeutics, Inc.'s ("Marker" or the "Company") intentions, beliefs, projections, outlook, analyses or current expectations concerning, an other things: the Company's research, development and regulatory activities and expectations relating to its non-engineered multi-tumor ant specific T cell therapies; the effectiveness of these programs or the possible range of application and potential curative effects and safety ir treatment of diseases; the timing, conduct and success of the Company's clinical trials of its product candidates, including MT-401 for treatment of MT-401 for the treatment of patients with Acute Myeloid Leukemia ("AML"), MT-401 Off-the-Shelf ("OTS") for the treatment of pati with AML and MT-601 for the treatment of patients with relapsed non-Hodgkin lymphoma; the Company's long-term stability and cash runway Company's optimized manufacturing process; and the future development of multiTAA therapies. Forward-looking statements are by their na subject to risks, uncertainties and other factors which could cause actual results to differ materially from those stated in such statements. S 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 other SEC filings which are available through EDGAR at WWW.SEC.GOV. No representation or warranty (expressed or implied) is made a and no reliance should be placed on, the fairness, accuracy or completeness of the information contained herein. Accordingly, none of Company, or any of its principals, partners, subsidiaries or affiliates, or any of such person's board members, officers or employees accepts liability whatsoever arising directly or indirectly from the use of this presentation. Certain information set forth herein includes estima projections and targets and involves significant elements of subjective judgement and analysis, which may or may not be correct. representations are made as to the accuracy of such estimates, projections or targets or that all assumptions relating to such estima projections or targets have been considered or stated or that such estimates, projections or targets will be realized. This presentation does purport to contain all of the information that may be required to evaluate the Company and any recipient hereof should conduct its independent analysis of the Company and the data and information contained herein. Any forward-looking statements are not guarantee future performance and actual results may differ materially from estimates in the forward-looking statements. Unless otherwise stated information in this presentation is as of the date of the cover page of this presentation, and the Company undertakes no obligation to revise th forward-looking statements to reflect events or circumstances that arise after the date hereof.

Marker Therapeutics Overview

Marker is a clinical-stage immuno-oncology company focusing on developing next-generation T ce
based immunotherapies for the treatment of hematological malignancies and solid tumor indicatio

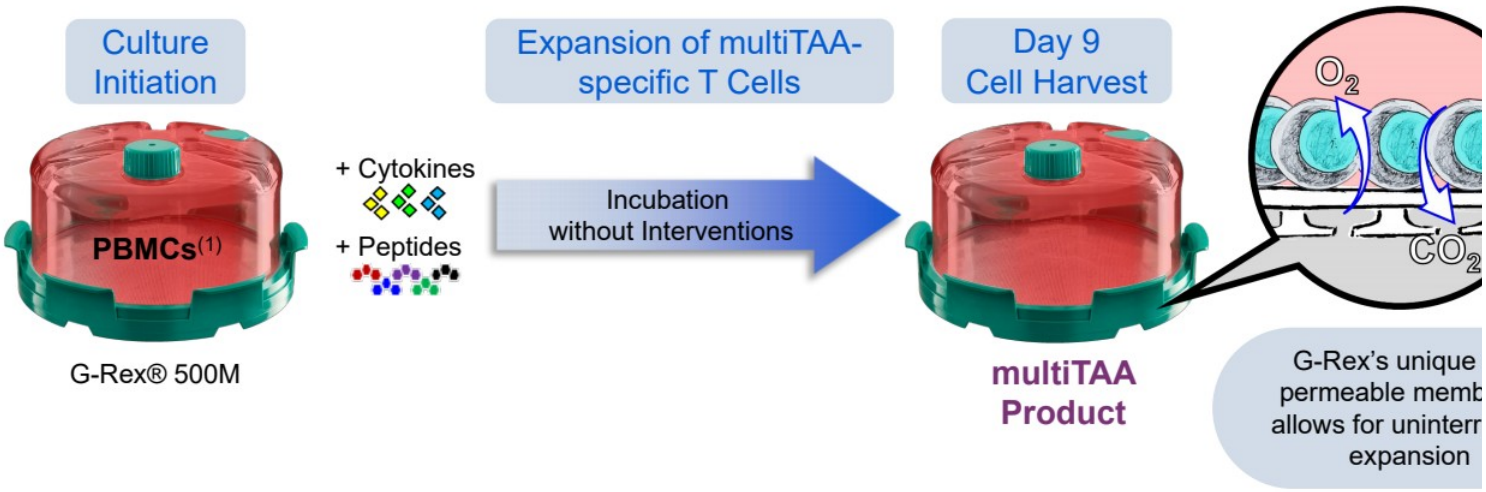
- Multi targeted T cell therapy
- Does not require genetic engineering
- Non-clinical proof-of-concept data
- Clinical data in >200 patients across 7 indicatio in Phase 1/2 trials

Key Advantages of Marker's multiTAA Therapy



MARKER Therapeutics

Simple Manufacturing Process



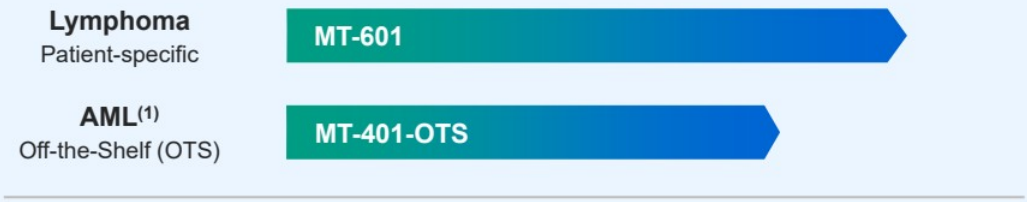
A single G-Rex device can produce enough product for up to 3 infusions (complete course for 1 patient)

(1) PBMCs, peripheral blood mononuclear cells.

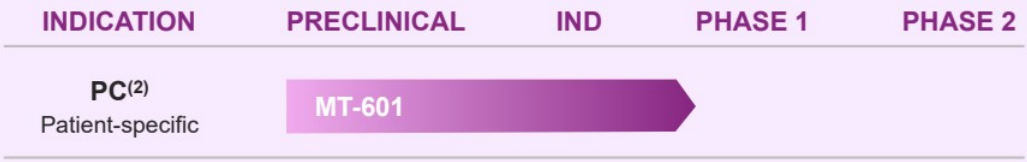
MARKER Therapeutics

Marker's multiTAA-Specific T Cell Pipeline

HEMATOLOGIC MALIGNANCIES



SOLID TUMORS



(1) AML, Acute Myeloid Leukemia (2) PC, Pancreatic Cancer

MARKER Therapeutics

Marker's multiTAA-Specific T Cell Pipeline

HEMATOLOGIC MALIGNANCIES

INDICATION	PRECLINICAL	IND	PHASE 1	PHASE 2
Lymphoma Patient-specific	MT-601			
AML[1] Off-the-Shelf (OTS)	MT-401-OTS			

SOLID TUMORS

INDICATION	PRECLINICAL	IND	PHASE 1	PHASE 2
PC[2] Patient-specific	MT-601			

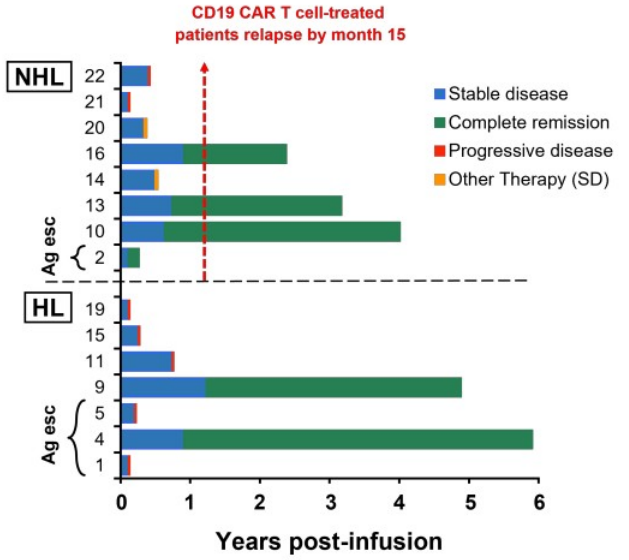
[1] AML, Acute Myeloid Leukemia [2] PC, Pancreatic Cancer

MARKER Therapeutics

Durability of Response of multiTAA-Specific T Cells vs. CAR T Ce in Lymphoma

Durability of Response

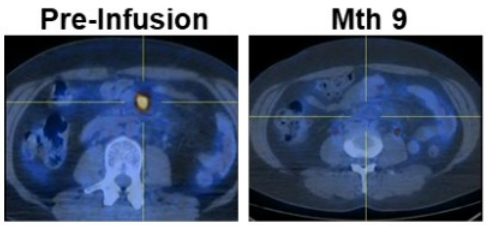
multiTAA-specific Ts (6 years) vs CAR Ts (15 months)

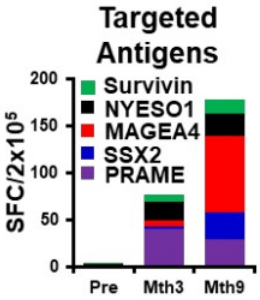


HL: Hodgkin's Lymphoma; NHL: Non-Hodgkin's Lymphoma

Potent and Specific

multiTAA have shown potent and specific anti-tumor activ

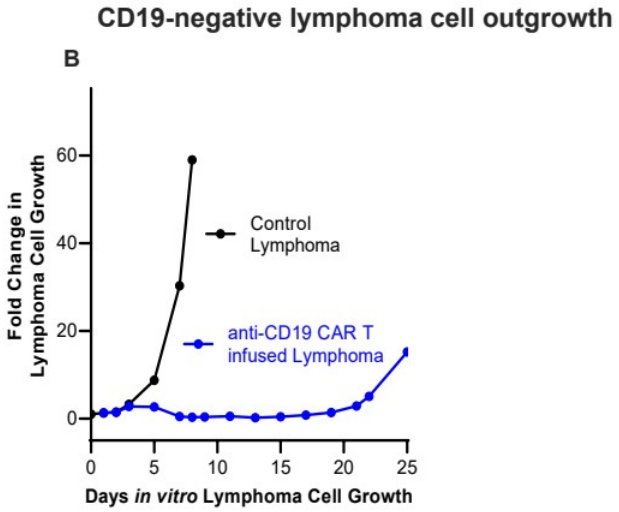




Vasileiou S et al. J Clin Oncol 2021; Locke FL et al. Lancet Oncol 2019; Schuster SJ et al. Lancet Oncol 2021; Locke FL et al. N Engl J Med 2022.

MARKER Therapeutics

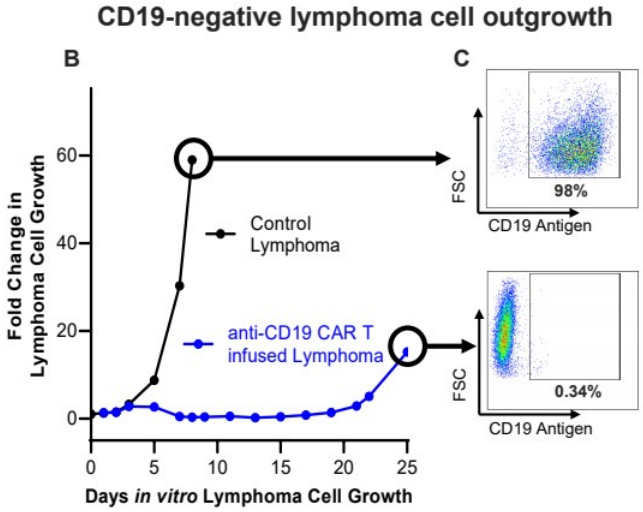
Lymphoma Cells Become Resistant to CD19 CAR T Cells



- Hodgkin's lymphoma cell line engineered to overexpress CD19.
- Lymphoma cells relapse 3 weeks after initial anti-CD19 CAR T cell treatment.

MARKER Therapeutics

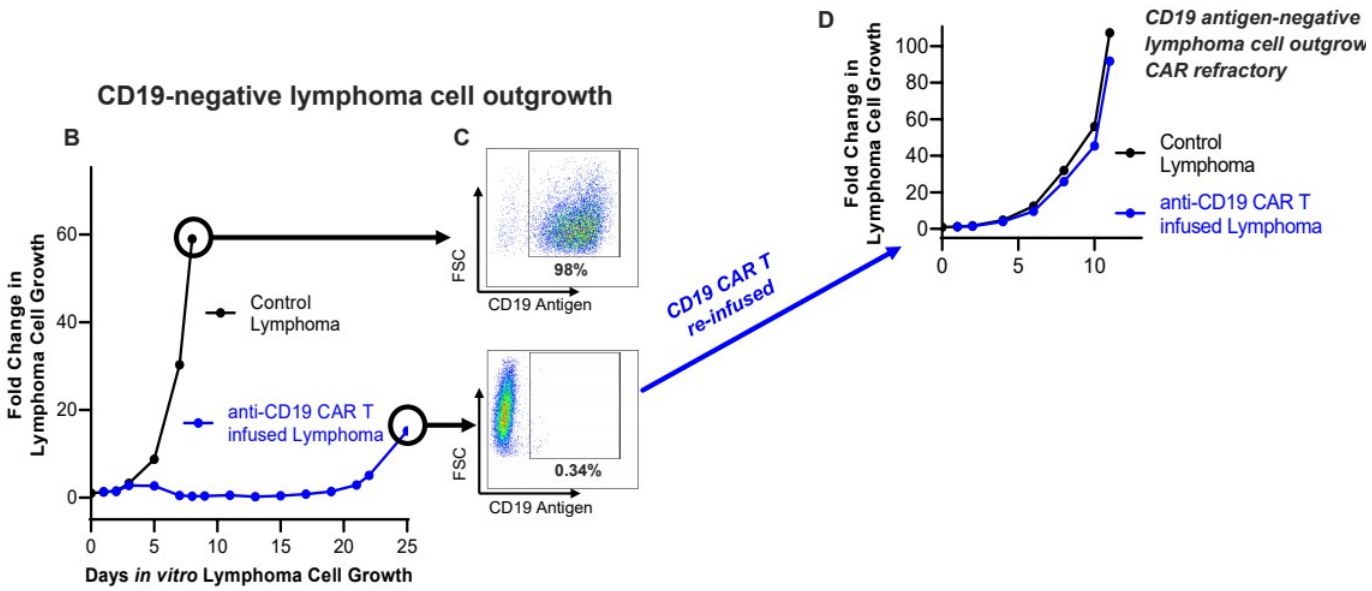
CD19 Antigen Escape Results in CAR Resistant Lymphoma Cells



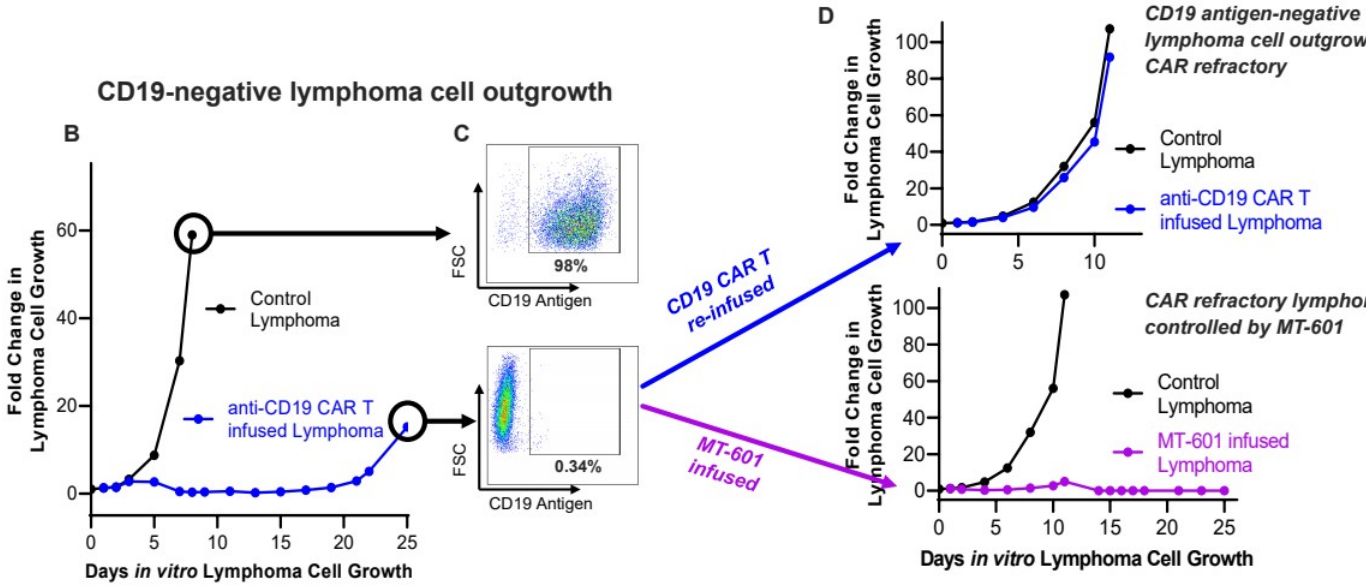
- Hodgkin's lymphoma cell line engineered to overexpress CD19.
- Lymphoma cells relapse 3 weeks after initial anti-CD19 CAR T cell treatment.
- Resistant lymphoma cells are negative for CD19.

MARKER Therapeutics

Antigen-Negative Lymphoma Cells are CD19 CAR Refractory



MT-601 Demonstrates Anti-Tumor Activity in CAR Refractory Lymphoma Cells



Broad antigen targeting of MT-601 resulted in killing of CD19 CAR T refractory lymphoma ce

MARKER Therapeutics

First Study Participant Treated with MT-601 in Phase 1 APOLLO Trial

Demographics

- 57-year-old female
- Diagnosed with DLBCL[1]

Clinical History

- 4 Prior treatment lines, including CD19 CAR T cells
- Relapse within 90 days after CD19 CAR T cell therapy
- Subsequent treatment with 2 doses of MT-601 ($200x10^6$ cell dose)

[1] DLBCL, Diffuse Large B Cell Lymphoma

MARKER Therapeutics

Complete Response in Lymphoma Patient Treated with MT-601 after CAR T Relapse

MT-601 Clinical Safety

- MT-601 treatment was well tolerated
- No > Grade 1 treatment-related adverse events

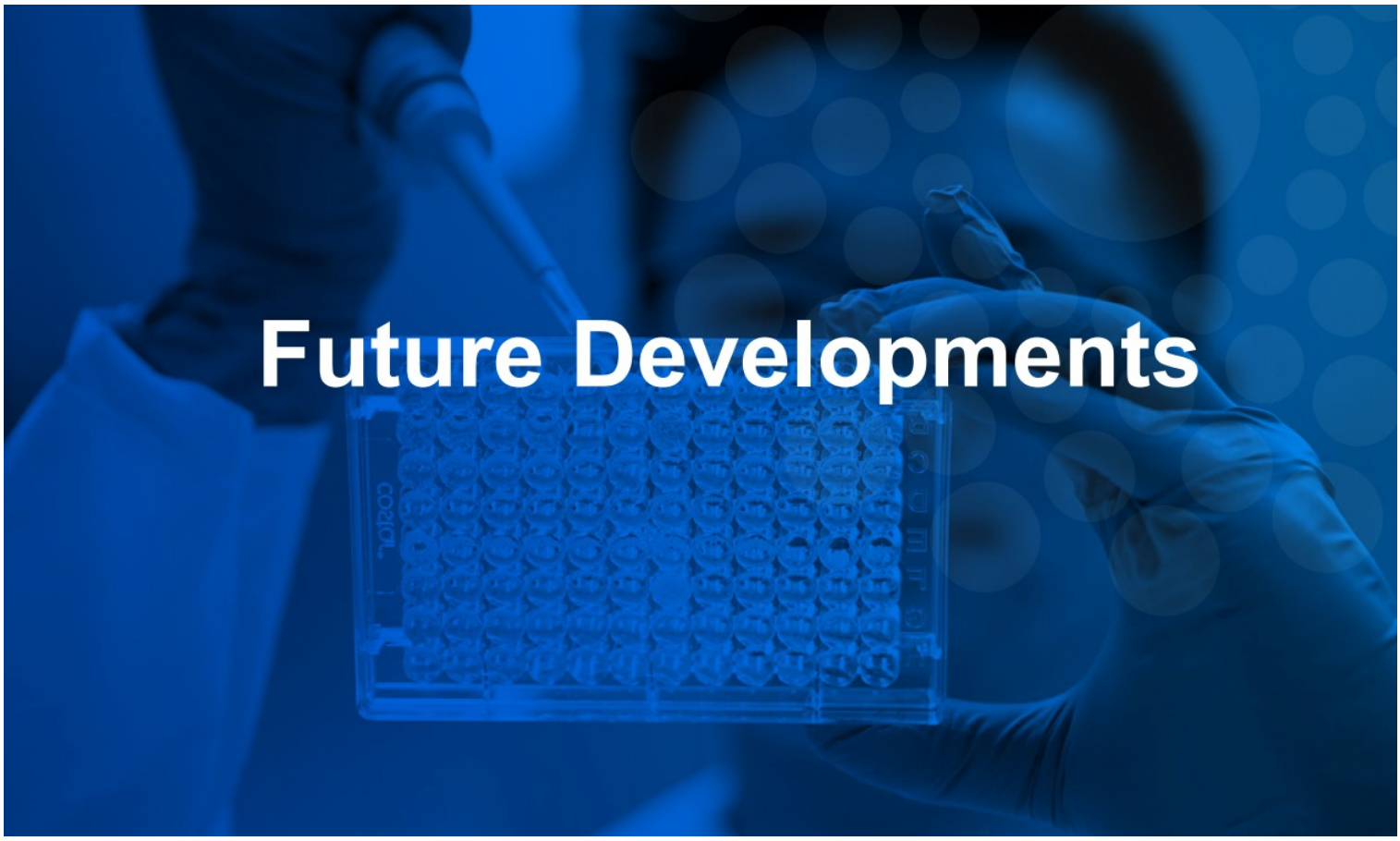
Clinical Response

- Study participant achieved **complete metabolic response** 8 weeks after 2nd infusion of MT-601
- Patient remains in complete response 6 months after MT-601 treatment

MARKER Therapeutics

Clinical Investigation of MT-601 in Marker's APOLLO Trial

APOLLO Trial	Investigate MT-601 in a Phase 1, multicenter, open-label study
Study Participants	Lymphoma patients who relapsed after or are ineligible for anti-CD19 CAR T cell therapy
Primary Objective	Evaluate safety and efficacy of MT-601 in study participants with various lymphoma subtypes
Clinical Sites	9 clinical sites across the United States will cumulatively enroll up to approx. 30 participants during Dose Escalation phase


Future Developments

Marker's multiTAA-Specific T Cell Pipeline

HEMATOLOGIC MALIGNANCIES

INDICATION	PRECLINICAL	IND	PHASE 1	PHASE 2
Lymphoma Patient-specific	MT-601			
AML[1] Off-the-Shelf (OTS)	MT-401-OTS			

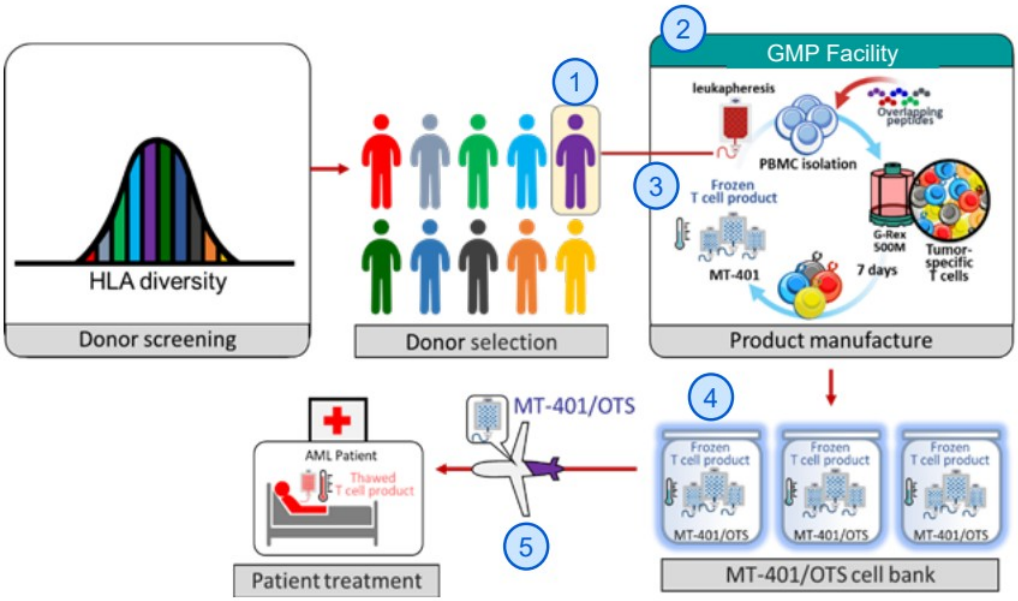
SOLID TUMORS

INDICATION	PRECLINICAL	IND	PHASE 1	PHASE 2
PC[2] Patient-specific	MT-601			

[1] AML, Acute Myeloid Leukemia [2] PC, Pancreatic Cancer

MARKER Therapeutics

Off-the-Shelf (OTS) Production and Treatment Strategy



MARKER Therapeutics

Marker's multiTAA-Specific T Cell Pipeline

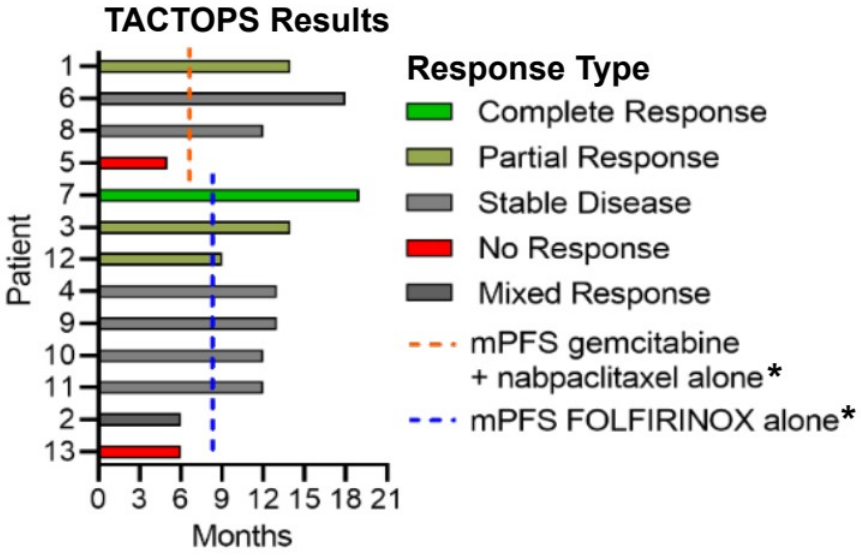
SOLID TUMORS

INDICATION	PRECLINICAL	IND	PHASE 1	PHASE 2
PC[2] Patient-specific	MT-601			

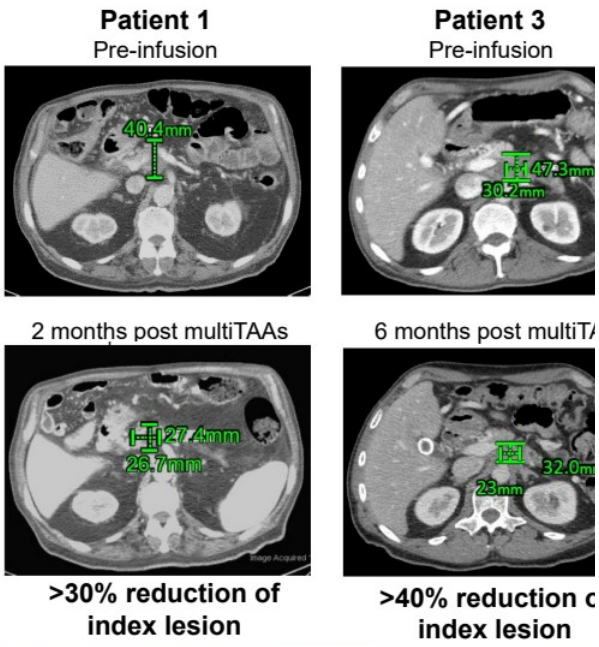
[1] AML, Acute Myeloid Leukemia [2] PC, Pancreatic Cancer

MARKER Therapeutics

MultiTAA-specific T cells Demonstrated Benefit to SOC Chemotherapy in Patients with Pancreatic Cancer



* Combination therapy demonstrates responses beyond historical survival points (orange & blue lines).



Smaglo BG et al. J Clin Oncol 2020. ASCO 2020 Presentation.

MARKER Therapeutics

Corporate & Financial Highlights

- ✓ Demonstrated clinical response in hematological malignancies and solid tumor
- ✓ Favorable safety profile in clinical trials to date
- ✓ 3 FDA-approved INDs
- ✓ Awarded over $17 million non-dilutive funding through grants
- ✓ Cash & Cash Equivalents of $17.5 million[(1)]
- ✓ Current cash runway expected through Q4 2025

[(1)] As of September 30, 2023.

MARKER Therapeutics

MARKER Therapeutics