

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 24, 2019

Date of Report (Date of earliest event reported)

MARKER THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-37939

(Commission File Number)

45-4497941

(IRS Employer Identification No.)

**3200 Southwest Freeway
Suite 2240**

Houston, Texas

(Address of principal executive offices)

77027

(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.

A copy of an investor presentation that the Company intends to use in investor meetings beginning on September 24, 2019 is attached to this Current Report on Form 8-K as Exhibit 99.1 and incorporated herein by reference.

The information in this Item 7.01 of this Current Report on 8-K (including Exhibit 99.1) is furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, 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 other filing with the Securities and Exchange Commission made by the Company, whether made before or after today’s date, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific references in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Investor Presentation.</u>

SIGNATURES

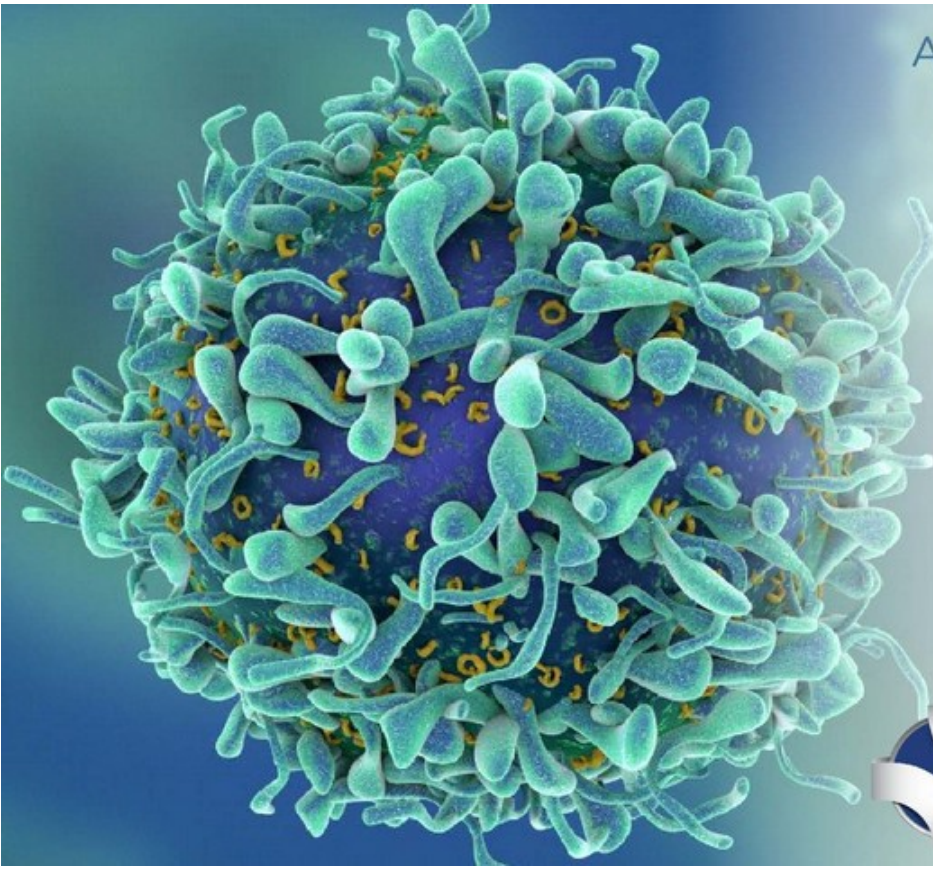
Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Marker Therapeutics, Inc.

Dated: September 24, 2019

By: /s/ Anthony Kim
Anthony Kim
Chief Financial Officer

A MAJOR LEAP FORWARD
IN CELL THERAPY



MARKER
THERAPEUTICS

FORWARD LOOKING STATEMENT

Certain statements contained herein are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, that involve risks and uncertainties. All statements other than statements relating to historical matters including statements to the effect that we "believe", "expect", "anticipate", "plan", "target", "intend" and similar expressions, including without limitation statements relating to long-term stability, Marker Therapeutics Inc.'s ("Marker" or the "Company") plan of operations and finances, and the potential for the Company's vaccines and proposed clinical trials, should be considered forward-looking statements. Our actual results could differ materially from those discussed in the forward-looking statements as a result of a number of important factors, including factors discussed under the heading "Risk Factors" in the Company's periodic reports on Form 10-Q and 10-K. No representation or warranty (expressed or implied) is made as to, and no reliance should be placed on, the fairness, accuracy or completeness of the information contained herein. Accordingly, none of the Company, or any of its principals, partners, subsidiaries or affiliates, or any of such person's board members, officers or employees accepts any liability whatsoever arising directly or indirectly from the use of this presentation. Certain information set forth herein includes estimates, projections and targets and involves significant elements of subjective judgment and analysis, which may or may not be correct. No representations are made as to the accuracy of such estimates, projections or targets or that all assumptions relating to such estimates, projections or targets have been considered or stated or that such estimates, projections or targets will be realized. This presentation does not purport to contain all of the information that may be required to evaluate the Company and any recipient hereof should conduct its own independent analysis of the Company and the data and information contained herein. Any forward-looking statements are not guarantees of future performance and actual results may differ materially from estimates in the forward-looking statements. Unless otherwise stated, all information in this presentation is as of the date on the cover page of this presentation, and the Company undertakes no obligation to revise these forward-looking statements to reflect events or circumstances that arise after the date hereof.

This presentation is being distributed for information purposes only and is not intended to, and does not, constitute an offer, invitation or solicitation for the sale or purchase



INVESTMENT HIGHLIGHTS

TRANSFORMATIONAL T CELL THERAPIES

Unique and highly differentiated approach that addresses the major challenges faced by CAR and TCR approaches

MULTI-ANTIGEN APPROACH DRIVES ENHANCED EFFICACY

Durable responses with clear evidence of epitope spreading targeting multiple tumor associated antigens safely

REQUIRES NO GENE MODIFICATION OF T CELLS

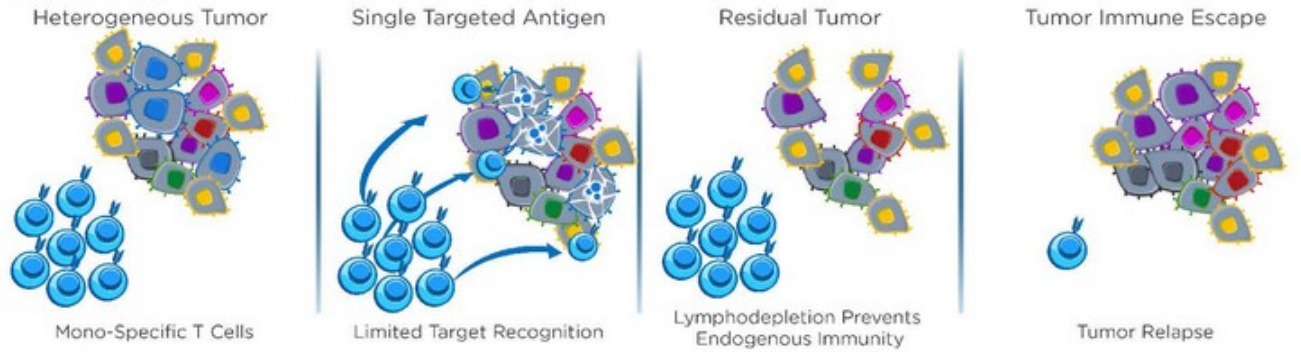
Significantly reduced cost and complexity of manufacturing as compared to conventional CAR-T and TCR approaches

ROBUST CLINICAL RESPONSE WITH MINIMAL TOXICITY

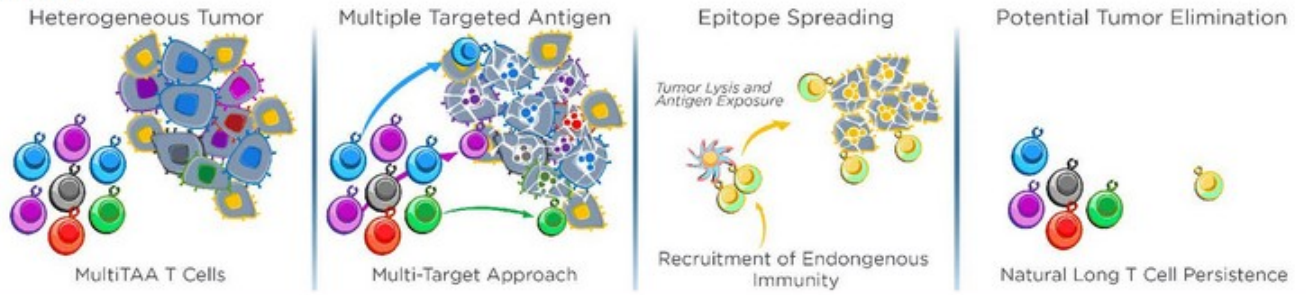
Strong clinical responses in approximately 100 patients with no CRS/neurotoxicity and opportunity for commercialization



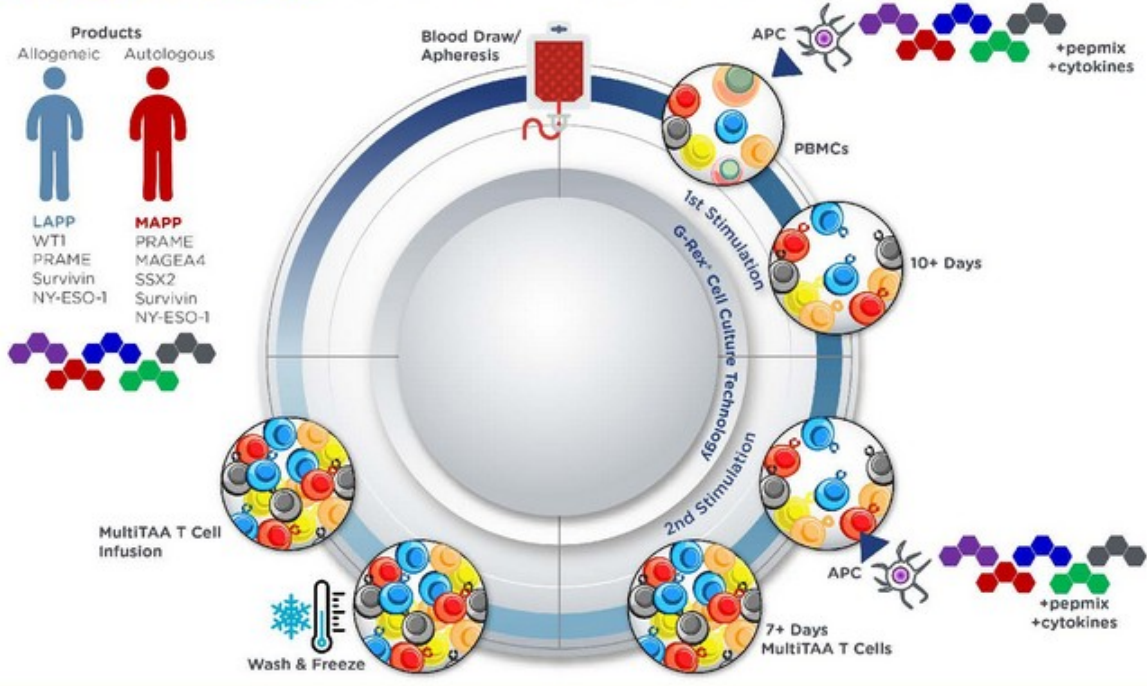
CAR T Cell Therapy



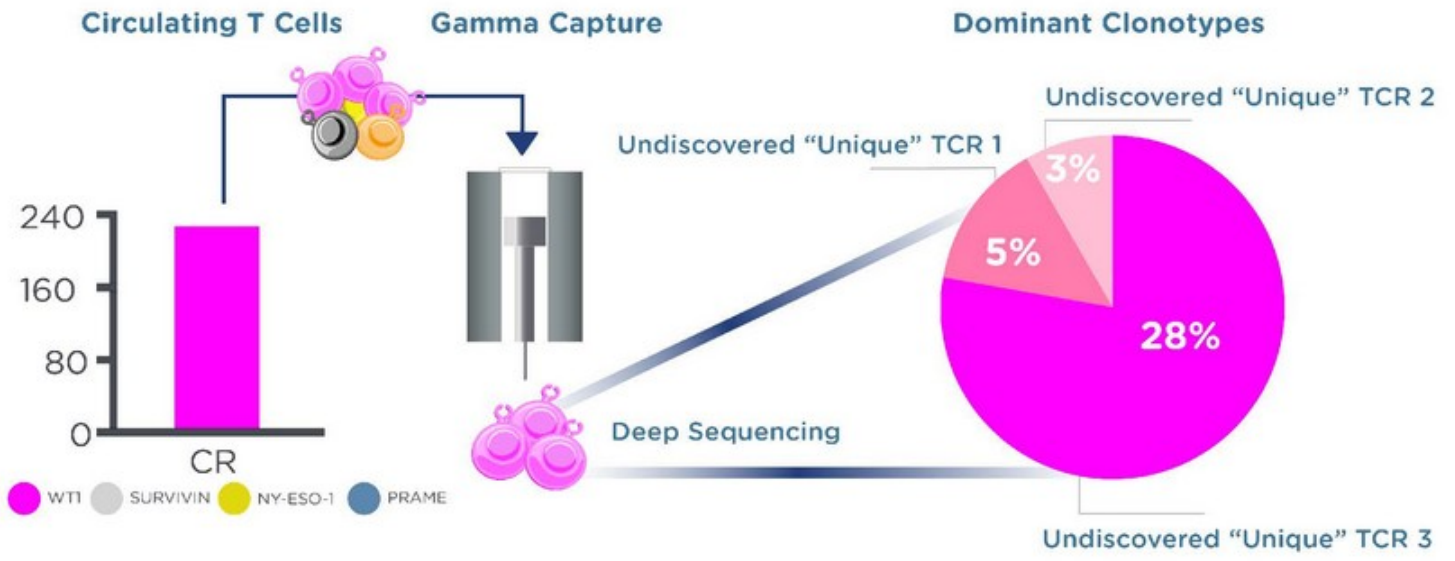
Marker T Cells



MULTITAA T CELL MANUFACTURING PROCESS

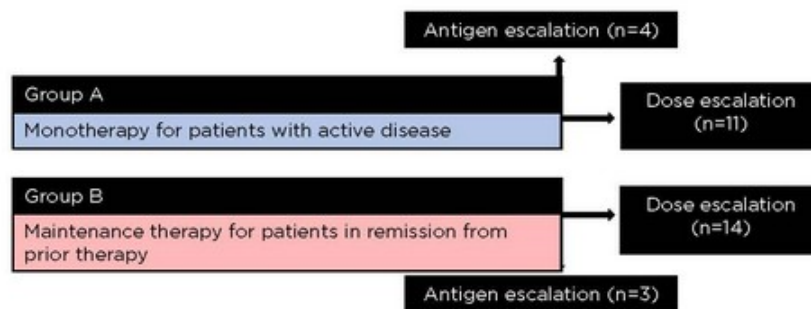


TCR PROFILE - WT1 REACTIVE CELLS



LYMPHOMA PHASE I TRIAL (TACTAL)

Autologous MultiTAA T cells for adult patients with lymphoma



Group A: Active disease (15 patients)

- 7 complete responses (CR)
 - Durable for 4 months -->5 years
 - No patient achieving a CR has subsequently relapsed
- 8 stable disease (SD)
 - Durable for 4 -->12 months)
 - 2 patients subsequently achieved CR with confounding factors

Group B: Adjuvant (17 patients*)

- 14/17 currently remain in remission
 - Range 9 months -->4 years
 - Mean time in CCR is 29 months
- 3 relapses occurred between 8-33 months

*1 patient treated twice after initial relapse

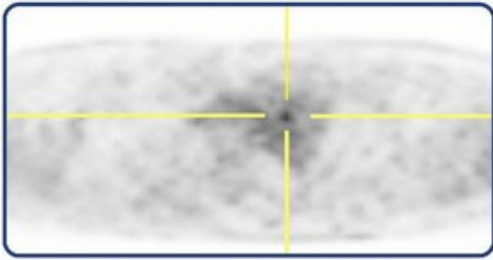


Presented at Society of Hematology Oncology (SOHO) Sept 2019

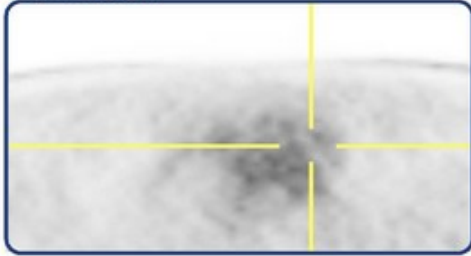
RESPONSE IN LYMPHOMA TRIAL OF PATIENT 5

Data demonstrates clinical benefit as post-infusion T cells exhibit antigen spreading

Pre-Infusion

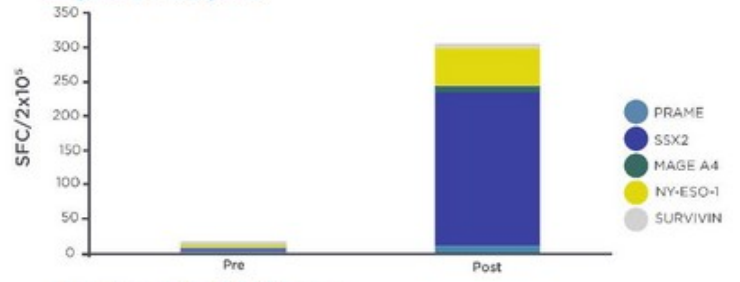


Post-Infusion

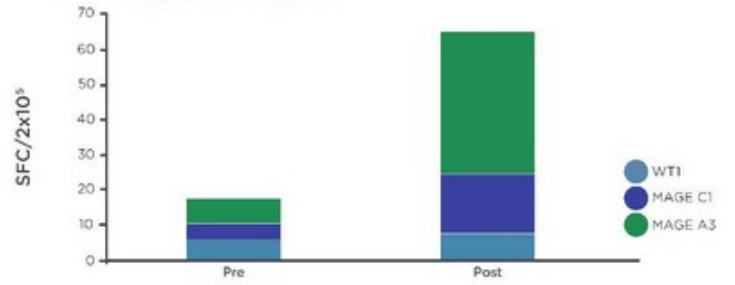


SUVmax: Decreases 5.7 to 1.8

Targeted Antigens

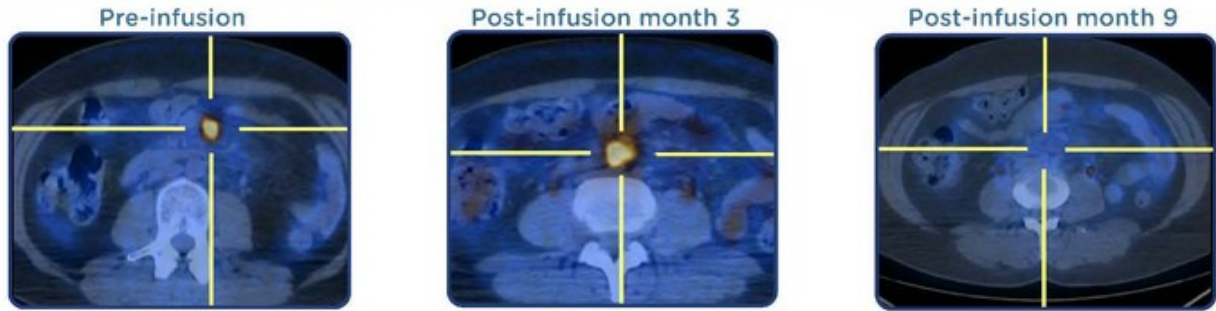


Non-Targeted Antigens

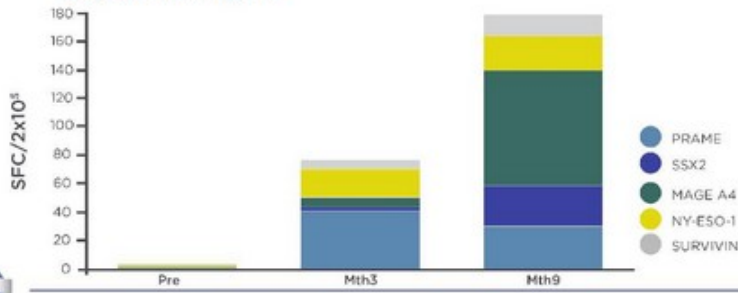


RESPONSE IN LYMPHOMA TRIAL OF PATIENT 6

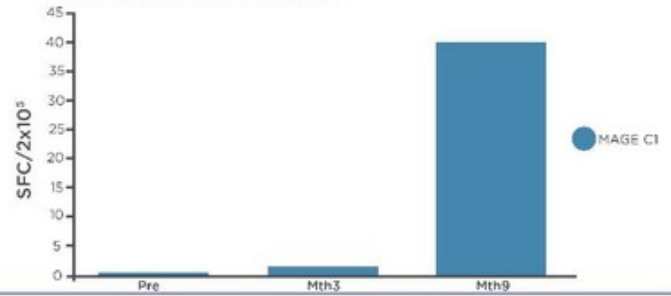
Marker T cell expansion changes over time to match antigen expression on tumor



Targeted Antigens



Non-Targeted Antigens



AML & MDS PHASE I TRIAL (ADSPAM)

Allogeneic MultiTAA T cells ≥ 30 days post allo-HSCT

Group A
Maintenance therapy for AML/MDS patients who are disease-free after transplant
Group B
Monotherapy for patients with relapsed/refractory AML/MDS post-transplant

Dose Escalation

DL1	5×10^6 cells/m ²
DL2	1×10^7 cells/m ²
DL3	2×10^7 cells/m ²
DL4*	5×10^7 cells/m ²
DL5*	1×10^8 cells/m ²

Group A: Adjuvant (11 AML, 2 MDS) (13 patients)

- 11/13 patients remain alive (range 6 weeks to 2.5 years post-infusion)
 - 9 never relapsed and remain in CR (durable for 6 weeks to 2.5 years)
 - 2 patients had relapse in CNS treated with local therapy, 1 patient had extramedullary relapse treated in Group B with CR for 13 months

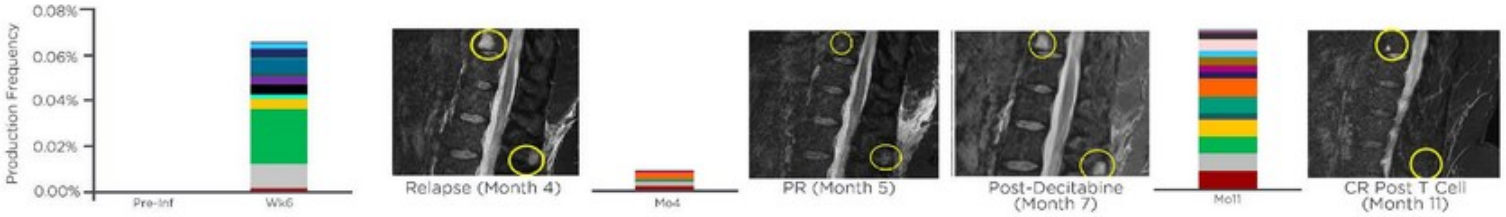
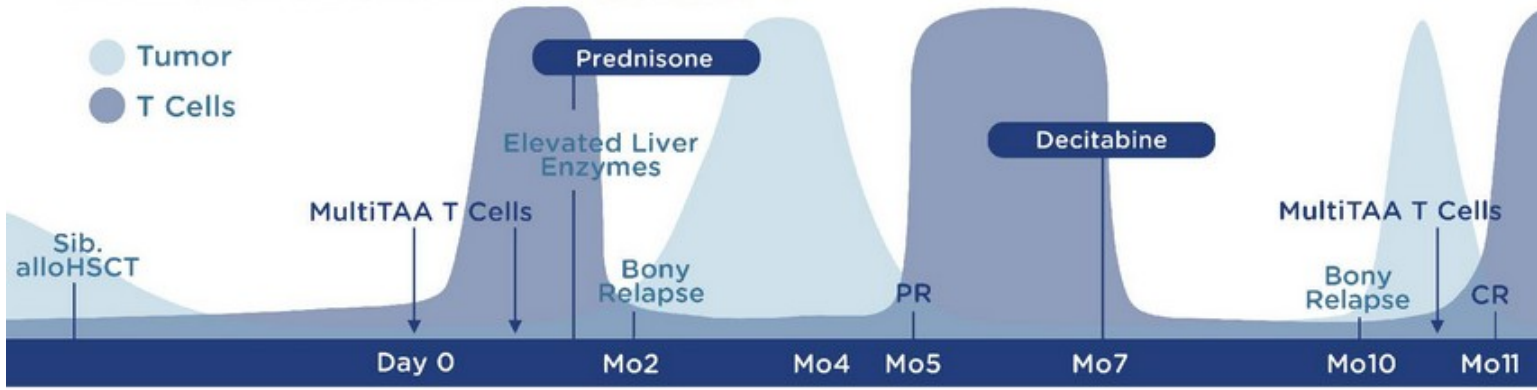
Group B: Active Disease (All AML) (6 patients †)

- 1 CR: Duration 13 months
 - Survived 2.5 years; died of heart attack
- 1 partial response (PR): Duration 4 months
- Significant reduction in circulating tumor blasts
 - Tumor reduction from 50% to 15% and 70% to 40%
- 3 patients responded sufficiently to qualify for a subsequent therapy for which they were previously ineligible
- Overall survival ranged from 4 months to 30 months

*DL4 and DL5 added during amendment, currently ongoing
†1 patient treated twice



CLINICAL COURSE OF PATIENT I



57yo female with AML post multiple courses of chemoRx and allo-HSCT. First Rx with MultiTAA T cells during remission. Elevated AST was Rx'd with prednisone, causing relapse that resolved once prednisone was DC'd. Rx with decitabine led to a relapse. Rx with MultiTAA T cells led to CR.



OUTCOMES OF AML/MDS PATIENTS POST ALLO-HSCT



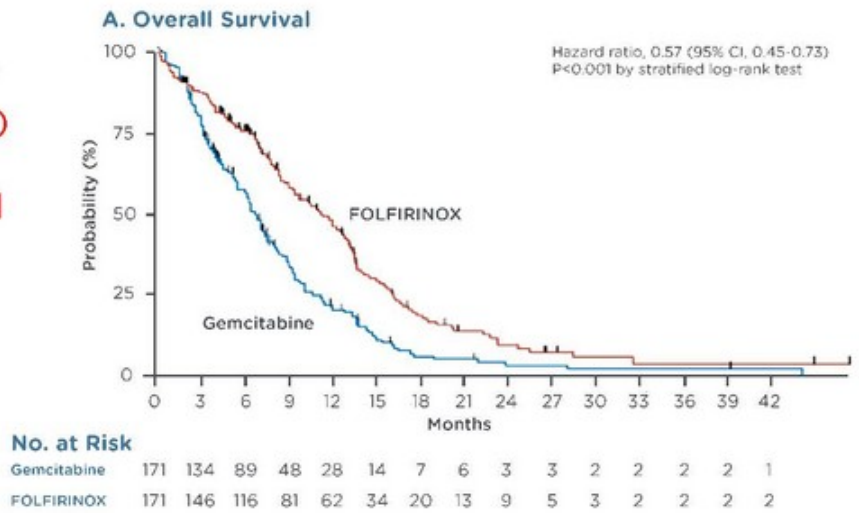
POST-TRANSPLANT AML

- Once an AML patient progresses to transplant, treatment options are very limited
- Other AML therapies, such as FLT3/IDH inhibitors, are currently approved for **pre-transplant** use
- CAR-T candidates, such as CD123 and CD33, target antigens which are prevalent on hematopoietic stem cells
 - Depletion of hematopoietic stem cells will cause fatal neutropenia for a patient; Thus CD123/CD33 CARs must be used prior to treatment
- Currently, the only therapeutic alternative for an AML patient post-transplant is a Donor Lymphocyte Infusion
 - DLIs generally yield 5%-10% ORR, but carry a 30%-50% risk of severe and debilitating GvHD (Grade 3 or higher)



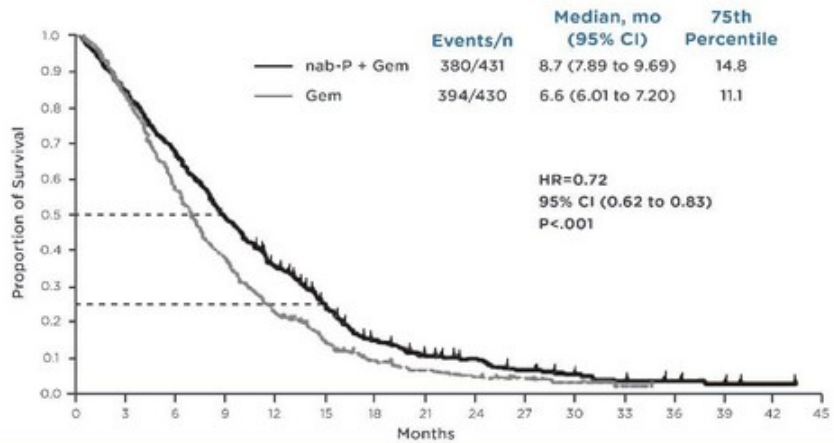
ACCORD-11: FOLFIRINOX GENERATES LONGEST OVERALL SURVIVAL BUT IS HIGHLY TOXIC

- All patients with metastatic pancreatic cancer
- FOLFIRINOX vs. gemcitabine
- FOLFIRINOX option for first line
- Median OS 11.1 months (vs. 6.8m) and ORR is 31.6% (vs. 9.4%)
- Median progression-free survival is 6.4 months

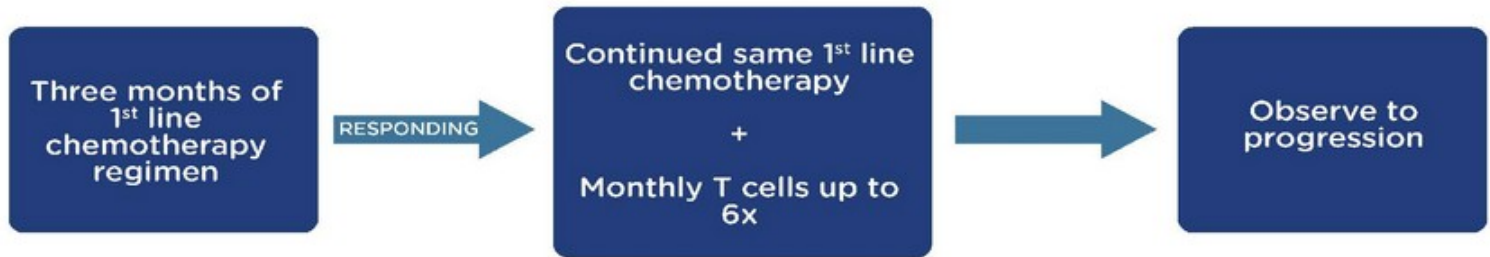


MPACT: GEM-ABRAXANE GENERATES SHORTER OVERALL SURVIVAL BUT IS BETTER TOLERATED

- All patients with metastatic pancreatic cancer
- Gemcitabine/nab-paclitaxel vs. gemcitabine
- Gemcitabine/nab-paclitaxel option for first line
- **Median OS 8.5 months (vs. 6.7m) and ORR of 23% (vs. 7%)**
- **Median progression-free survival is 5.5 months**



PANCREATIC PHASE I/II TRIAL (TACTOPS ARM A)



Notable observations:

- Tumor biopsies showed significant T cell infiltration within the tumor
- Significant T cell expansion and epitope spreading was observed in patients responding to therapy
- Limited or no significant T cell expansion and epitope spreading was seen amongst non-responders

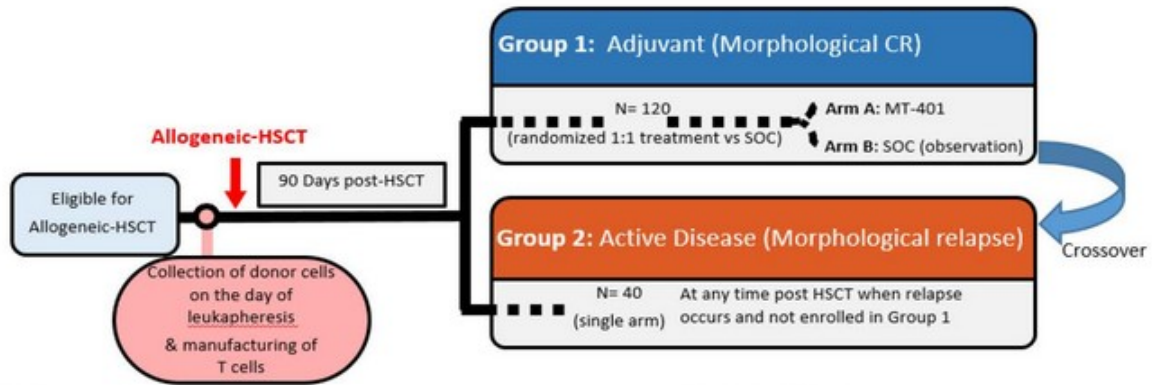


PANCREATIC PHASE I/II TRIAL (TACTOPS) ARM A HIGHLIGHTS

- 10 patients: 9 evaluable, 1 too early
- **3 confirmed objective responses** (OR), out of 9 evaluable patients:
1 complete response (CR) and **2 partial responses** (PR) after receiving MultiTAA cells
- 4 stable disease (SD): Notably, **2 patients** within stable disease boundaries (+20%/-30%) **saw reversal of tumor growth** - tumors previously growing after chemotherapy alone showed shrinkage following administration of MultiTAA cells
- 1 mixed response: Some lesions increased and others decreased for a net zero change in size of tumor lesions
- **Aggregate tumor volume shrinkage** observed in **6 out of 8** evaluable patients with measured lesions after use of MultiTAA cells in combination with standard of care chemotherapy



PHASE 2 STUDY DESIGN FOR AML



Primary objectives are to evaluate:

- Relapse-free survival (RFS) (Group 1)
- The best overall response rate (BOR), duration of response (DOR) (Group 2)

Additional objectives include:

- The safety of multiple tumor associate antigen (multiTAA)-specific T cell therapy
- OS
- Graft-versus-host disease RFS (GRFS)
- PFS (Group 2)
- Study the expansion, persistence, and anti-tumor immune effects of the adoptively-transferred, donor-derived, multiTAA-specific T cells, as well as the presence of epitope spreading

Main Entry Criteria:

- Patients with AML after allogeneic HSCT (HLA-matched related donor, matched unrelated donor, or haploidentical)
- Karnofsky/Lansky score of ≥ 60
- Age ≥ 18
- Life expectancy ≥ 8 weeks
- Adequate organ function

Immune Monitoring

- Analyzed for immunological parameters at multiple timepoints



A LEADING ONCOLOGY PIPELINE

