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

Date of Report (Date of earliest event reported): April 8, 2024

Poseida Therapeutics, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39376**	**47-2846548**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

9390 Towne Centre Drive, Suite 200	
San Diego, California	**92121**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (858) 779-3100

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing 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 $0.0001 per share	PSTX	Nasdaq Global Select Market

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 April 8, 2024, Poseida Therapeutics, Inc. (the "Company") issued a press release announcing that members of its scientific research team and external advisors are providing an update on the Company's research and development programs, including the Company's Phase 1 study of P-BCMA-ALLO1 and Phase 1 study of P-MUC1C-ALLO1. The Company presented two posters at the American Association for Cancer Research (AACR) Annual Meeting, taking place in San Diego, California from April 5-10, 2024. A copy of the press release and the posters that were presented are attached as Exhibit 99.1, Exhibit 99.2 and Exhibit 99.3, respectively, to this report.

The information in this Item 7.01 of this report (including Exhibit 99.1, Exhibit 99.2 and Exhibit 99.3) 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.

Exhibit No.	Description
99.1	Press Release of Poseida Therapeutics, Inc., dated April 8, 2024.
99.2	Poster: Clinical Activity of P-BCMA-ALLO1, a B-cell Maturation Antigen (BCMA) Targeted Allogeneic Chimeric Antigen Receptor T-cell (CAR-T) Therapy, in Relapsed Refractory Multiple Myeloma (RRMM) Patients Following Progression on Prior BCMA Targeting Therapy.
99.3	Poster: Solid Tumor Patients Require Higher Cyclophosphamide Dose than Multiple Myeloma Patients to Achieve Adequate Lymphodepletion Necessary to Enable Allogeneic CAR-T Expansion.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

Poseida Therapeutics, Inc.

Date: April 8, 2024

By: /s/ Harry J. Leonhardt, Esq.
Name: Harry J. Leonhardt, Esq.
Title: General Counsel, Chief Compliance Officer & Corporate Secretary

Exhibit 99.1

Poseida Therapeutics Presents New Phase 1 Data at AACR 2024 Supporting Potential of P-BCMA-ALLO1 Allogeneic CAR-T Therapy to Benefit Broad Range of Patients with Multiple Myeloma

– Promising early data suggest patients with relapsed/refractory multiple myeloma who progressed after prior BCMA-targeted therapy achieved clinical responses with P-BCMA-ALLO1, which was well tolerated

– Following efforts to optimize allogeneic CAR-T therapy, Poseida is presenting a new data analysis underscoring the need for higher lymphodepletion chemotherapy doses when treating solid tumors vs. multiple myeloma

SAN DIEGO, April 8, 2024 – Poseida Therapeutics, Inc. (Nasdaq: PSTX), a clinical-stage cell and gene therapy company advancing a new class of treatments for patients with cancer and rare diseases, today announced new data from a subset of patients in an ongoing Phase 1 study of its lead program, P-BCMA-ALLO1. Results showed that three of the five (60%) patients with relapsed/refractory multiple myeloma who had progressed following BCMA-targeted therapy achieved clinical responses with P-BCMA-ALLO1. In addition, this investigational treatment was well-tolerated.

P-BCMA-ALLO1 is a novel investigational B-cell maturation antigen (BCMA)-targeted allogeneic, T stem cell memory (T_{SCM})-rich chimeric antigen receptor T-cell (CAR-T) therapy manufactured from healthy donor T-cells and available off-the-shelf. These new Phase 1 study subgroup data and a new data analysis of different lymphodepletion regimens in patients treated with P-BCMA-ALLO1 for multiple myeloma or P-MUC1C-ALLO1 for solid tumors are being presented today in a poster session at the American Association for Cancer Research (AACR) Annual Meeting 2024 in San Diego.

“Multiple myeloma remains incurable, and patients often relapse, despite initial high response rates with BCMA-targeted immunotherapies, including autologous CAR-T therapies,” said Bhagirathbhai Dholaria, M.D., Associate Professor of Medicine (Hematology/Oncology) at the Vanderbilt-Ingram Cancer Center in Nashville, Tenn. “New treatment options are urgently needed for these patients, which is why I’m encouraged by these impressive Phase 1 subgroup results, which may be the first report of an allogeneic CAR-T therapy showing clinical activity in heavily pretreated patients whose myeloma has progressed after multiple BCMA-targeted immunotherapies.”

“These new data build on the P-BCMA-ALLO1 data presented at ASH 2023, which demonstrated a 100% overall response rate in patients who had not been previously treated with a BCMA-targeted therapy. The new findings also provide additional evidence that our investigational, off-the-shelf allogeneic CAR-T therapy could be an appropriate treatment for a broader range of patients with multiple myeloma, including those with relapsed/refractory disease whose cancer progressed following prior BCMA-targeted therapy, representing the highest unmet need in this setting,” said Syed Rizvi, M.D., Chief Medical Officer at Poseida. “In addition, we continue to explore the optimal lymphodepletion regimen for CAR-T in solid tumors and are directly applying these learnings to our P-MUC1C-ALLO1 trial with the goal of delivering the same benefits in solid tumors as we have seen in myeloma. We look forward to sharing more fulsome datasets on both our BCMA and MUC1-C programs in the second half of 2024.”

New Phase 1 P-BCMA-ALLO1 Study Subgroup Data

The open-label, multicenter Phase 1 dose-escalation study in patients with relapsed/refractory multiple myeloma is assessing the safety and maximum tolerated dose of P-BCMA-ALLO1 (primary objective) and its anti-myeloma activity (secondary objective). Study participants were required to have received a prior proteasome inhibitor, immunomodulatory drug and anti-CD38 monoclonal antibody. Five study participants who had progressed on or following prior BCMA-targeting autologous CAR-T, T-cell engagers or both, and with ninety days post-P-BCMA-ALLO1 treatment follow-up, are presented in this poster.

Key findings from the subgroup analysis showed that P-BCMA-ALLO1 was well tolerated with no dose-limiting toxicities, graft vs. host disease, or Grade 3 or greater cytokine release syndrome (CRS) or immune effector cell neurotoxicity syndrome (ICANS). The overall response rate in patients receiving P-BCMA-ALLO1 was 60%, with all three patients who achieved a clinical response experiencing a very good partial response (VGPR). This included one patient who had previously received both teclistamab and an autologous CAR-T therapy and has maintained a response for more than four months.

New Data on Optimizing Lymphodepletion (LD) Regimen for Patients with Solid Tumors Treated with Investigational Allogeneic CAR-T Therapy

As patients with multiple myeloma receive more bone marrow suppressive treatments than those with solid tumors during their treatment journeys, this analysis evaluated the effect of increasing amounts of cyclophosphamide in LD regimens to optimize CAR-T pharmacokinetics.

The analysis compared various LD regimens in two early Phase 1 trials of Poseida's investigational allogeneic CAR-T cell therapies in patients with multiple myeloma and solid tumors. Results showed that patients with solid tumors may require higher cyclophosphamide doses to achieve adequate LD, which would provide a sufficient niche to support allogeneic CAR-T expansion.

Poster Presentation Details

Title	Poster #	Presenting Author	Session Title	Session Date/Time	Location
Clinical Activity of P-BCMA-ALLO1, a B-cell Maturation Antigen (BCMA) Targeted Allogeneic Chimeric Antigen Receptor T-cell (CAR-T) Therapy, in Relapsed Refractory Multiple Myeloma (RRMM) Patients Following Progression on Prior BCMA Targeting Therapy	CT071	Rajesh Belani, M.D., Clinical Development, Poseida Therapeutics	Phase I Clinical Trials 1	Monday, April 8, 9:00 a.m.-12:30 p.m. PT	Poster section 48, Poster board 21
Solid Tumor Patients Require Higher Cyclophosphamide Dose than Multiple Myeloma Patients to Achieve Adequate Lymphodepletion Necessary to Enable Allogeneic CAR-T Expansion	CT070	Sabrina Haag, Ph.D., Translational Medicine, Poseida Therapeutics	Phase I Clinical Trials 1	Monday, April 8, 9:00 a.m.-12:30 p.m. PT	Poster section 48, Poster board 20

About P-BCMA-ALLO1

P-BCMA-ALLO1 is an investigational allogeneic CAR-T therapy licensed to Roche that targets B-cell maturation antigen (BCMA) and is in Phase 1 clinical development for the treatment of patients with relapsed/refractory multiple myeloma. This allogeneic program includes a VH-based binder that targets BCMA. Phase 1 clinical data presented at ASH 2023 supports the Company's belief that T_{SCM}-rich allogeneic CAR-Ts have the potential to offer effective, safe and reliable treatment addressing unmet needs in multiple myeloma. The U.S. Food and Drug Administration granted Orphan Drug Designation to P-BCMA-ALLO1 for the treatment of multiple myeloma. Additional information about the Phase 1 study is available at www.clinicaltrials.gov (NCT04960579).

About P-MUC1C-ALLO1

P-MUC1C-ALLO1 is an investigational allogeneic CAR-T therapy in Phase 1 clinical development for multiple solid tumor indications. Poseida believes P-MUC1C-ALLO1 has the potential to treat a wide range of solid tumors derived from epithelial cells, such as breast, ovarian, colorectal, lung, pancreatic and renal cancers, as well as other cancers expressing a cancer-specific form of the Mucin 1 protein (MUC1-C). P-MUC1C-ALLO1 is designed to be fully allogeneic, with genetic edits to eliminate or reduce both host-vs-graft and graft-vs-host alloreactivity. Poseida has demonstrated the elimination of tumor cells to undetectable levels in preclinical models of both breast and ovarian cancer. Additional information about the Phase 1 study is available at www.clinicaltrials.gov (NCT05239143).

About Poseida Therapeutics, Inc.

Poseida Therapeutics is a clinical-stage biopharmaceutical company advancing differentiated cell and gene therapies with the capacity to cure certain cancers and rare diseases. The Company's pipeline includes allogeneic CAR-T cell therapy product candidates for both solid and liquid tumors as well as in vivo gene therapy product candidates that address patient populations with high unmet medical need. The Company's approach to cell and gene therapies is based on its proprietary genetic editing platforms, including its non-viral piggyBac® DNA Delivery System, Cas-CLOVER™ Site-Specific Gene Editing System, Booster Molecule, and nanoparticle and hybrid gene delivery technologies as well as in-house GMP cell therapy manufacturing. The Company has formed a global strategic collaboration with Roche to unlock the promise of cell therapies for patients with hematological malignancies. Learn more at www.poseida.com and connect with Poseida on X and LinkedIn.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding, among other things, expected plans with respect to clinical trials, including timing of regulatory submissions and approvals and clinical data updates; anticipated timelines and milestones with respect to the Company's development programs and manufacturing activities and capabilities; the potential capabilities and benefits of the Company's technology platforms and product candidates, including the efficacy, safety and reliability profile of such product candidates; the quotes from Drs. Dholaria and Rizvi; and the Company's plans and strategy with respect to developing its technologies and product candidates. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon the Company's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, the Company's reliance on third parties for various aspects of its business; risks and uncertainties associated with development and regulatory approval of novel product candidates in the biopharmaceutical industry; the Company's ability to retain key scientific or management personnel; the fact that interim data from the Company's clinical trials may change as more patient data become available and remain subject to audit and verification procedures that could result in material differences from the final data; the fact that subgroup data may differ from future results of the same study once additional data has been received; and the other risks described in the Company's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

# # #

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CT071

Clinical Activity of P-BCMA-ALLO1, a B-cell Maturation Antigen (BCMA) Targeted Allogeneic Chimeric Antigen Receptor T-cell (CAR-T) Therapy, in Relapsed Refractory Multiple Myeloma (RRMM) Patients Following Progression on Prior BCMA Targeting Therapy

Bhagirathbhai Dholaria[1], Leyla Shune[2], Andrew Kin[3], Katherine McArthur[4], Jeff D. Eskew[4], Christopher E. Martin[4], Sabrina Haag[4], Joanne McCaigue[4], Hamid Namini[4], Samuel DePrimo[4], Stacey Cranert[4], Julia Coronella[4], Devon Shedlock[4], Rajesh Belani[4]

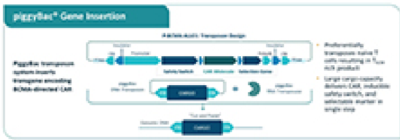
[1]Vanderbilt University Medical Center, Nashville, TN; [2]Division of Hematological Malignancies and Cellular Therapeutics, University of Kansas Medical Center, Westwood, KS; [3]Karmanos Cancer Institute, Wayne State University, Detroit, MI; [4]Poseida Therapeutics, San Diego, CA

BACKGROUND

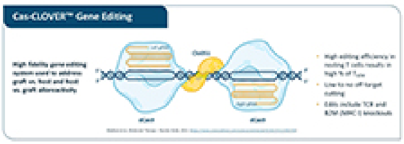
[illegible]

Proprietary, non-viral approach to produce T_{SCM}-rich, fully allogeneic P-BCMA-ALLO1 CAR-T from healthy donors

piggyBac® Gene Insertion

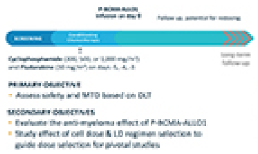


Cas-CLOVER™ Gene Editing



High-yield Clinical Manufacturing

Study P-BCMA-ALLO1-001: open-label, multicenter, phase 1 study to assess the safety of P-BCMA-ALLO1 in patients with RRMM



Key Inclusion Criteria:
- RRMM as defined by the IMWG
- Must have received PI, IMiDs & CD38 mAb or triple refractory
- ECOG 0 or 1

PRIMARY OBJECTIVE
- Assess safety and MTD based on DLT

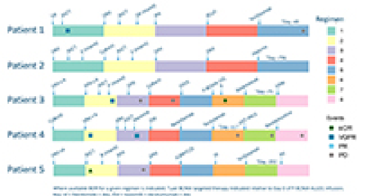
SECONDARY OBJECTIVES
- Evaluate the anti-myeloma effect of P-BCMA-ALLO1
- Study effect of cell dose & LD regimen selection to guide dose selection for pivotal studies

Presented are patients that have received and progressed on BCMA targeted therapies

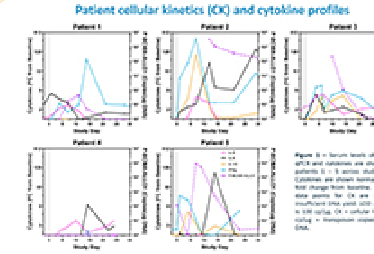
Patient characteristics

Characteristics	Patient 1	2	3	4	5
Demographics	57-year-old white Male	62-year-old white female	64-year-old white female	45-year-old African American male	71-year-old white female
Year Dx / # prior regimens	2015, 5 priors	2014, 5 priors	2015, 8 priors	2018, 6 priors	2013, 8 priors
Myeloma Diagnosis Subtype	IgG Kappa free light chain	IgG Lambda free light chain	IgG Kappa free light chain	IgG Kappa free light chain	IgG Kappa free light chain
Target or Measurable Plasmacytoma	Extramedullary disease present	Absent	Absent	Absent	Absent
Cytogenetics	Standard risk	Standard risk	Standard risk	High-risk [illegible]	Standard risk
Prior anti-BCMA CAR-T and anti-BCMA therapy	Teclistamab	Abecma	P-BCMA-101 (AUTO), Belantamab	Belantamab, Teclistamab	[illegible], Teclistamab
BCMA MFI/ BCMA % +	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
P-BCMA-ALLO1 Response (BOR)	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
P-BCMA-ALLO1 Related SAEs	None	[illegible]	[illegible]	[illegible]	Febrile neutropenia [illegible]

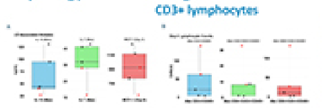
Heavily pretreated patients with prior PD on BCMA targeted agents



Patient cellular kinetics (CK) and cytokine profiles



Responding patients showed higher max IL-15 and IL-7 and lower day 4 CD3+ lymphocytes



Preliminary clinical activity in heavily pre-treated and previously BCMA exposed patients

CONCLUSIONS

- P-BCMA-ALLO1 is a T_{SCM}-rich allogeneic CAR-T manufactured from healthy donor cells that is rapidly available for dosing without the need for bridging chemotherapy.
- We have previously reported that P-BCMA-ALLO1 demonstrates high response rates in multiple myeloma patients who have received PI, IMiDs and CD38 mAb (Dholaria et al. ASH 2023, abstract [illegible]). Here we demonstrate that P-BCMA-ALLO1 has promising clinical activity in patients who have received all currently available BCMA directed therapies including antibody drug conjugates, CAR-T and TCE.
- P-BCMA-ALLO1 was well tolerated with no cases of DLTs or GvHD, and no instances of >Gr2 CRS or ICANS.
- These early promising results suggest that P-BCMA-ALLO1 can fulfil the unmet medical need in a wide variety of multiple myeloma patients.
- Further enrollment in the study is ongoing, with extensive biomarkers and correlative analysis to understand drivers of response and mechanisms of resistance.

[illegible]

Exhibit 99.3

CT070

Solid Tumor Patients Require Higher Cyclophosphamide Dose than Multiple Myeloma Patients to Achieve Adequate Lymphodepletion Necessary to Enable Allogeneic CAR-T Expansion

Sabrina Haag, Jeff D. Eskew, Katherine McArthur, Joanne McCaigue, Sepideh Vaziri, Samuel DePrimo, Christopher E. Martin, Catherine Gregovics, Ann Murphy, Ellen Christie, Marcela Martinez-Prieto, Rajesh Belani, Stacey Cranert, Julia Coronella, Devon J. Shedlock

Poseida Therapeutics Inc., San Diego CA

BACKGROUND

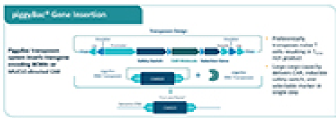
Poseida Therapeutics is developing innovative allogeneic T stem cell memory-rich CAR-T therapeutics for both hematologic malignancies and solid tumors. These include P-BCMA-ALLO1 which targets BCMA for multiple myeloma, and P-MUC1C-ALLO1 targeting MUC1-C for epithelial-derived solid tumors.

Optimal lymphodepletion for allogeneic cell therapies remains to be established. Most allogeneic CAR-T clinical trials have focused on hematologic malignancies, where patients have likely undergone hematopoietic stem cell transplantation and are, therefore, lymphodepletion experienced in contrast to solid tumor patients. Consequently, solid tumor patients treated with allogeneic CAR-T may require higher doses of conditioning chemotherapy to achieve lymphodepletion depth comparable to patients with hematologic malignancies.

This retrospective analysis sought to compare lymphodepletion characteristics and CAR-T cellular kinetics with multiple cyclophosphamide doses across our two phase 1 trials (NCT05239143/NCT04960579) which are enrolling solid tumor and multiple myeloma patients, respectively.

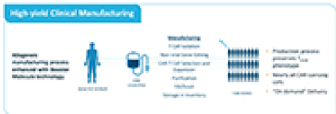
Proprietary, non-viral approach to produce T_{SCM}-rich, fully allogeneic CAR-T from healthy donors

piggyBac® Gene Insertion



Cas-CLOVER™ Gene Editing

High-yield Clinical Manufacturing



Design of two phase 1 studies evaluating the safety of Poseida's T_{SCM}-rich allogeneic CAR-T cells

P-BCMA-ALLO1

KEY INCLUSION CRITERIA:
- RRMM as defined by the IMWG
- Must have received PI, IMiDs & CD38 mAb or be triple refractory
- ECOG 0 or 1

PRIMARY ENDPOINTS
- Assess safety and MTD based on DLT

SECONDARY OBJECTIVES
- Evaluate the anti-myeloma effect of P-BCMA-ALLO1
- Study effect of cell dose & LD regimen to guide dose selection for pivotal studies

LD arms and number of dosed subjects:
- Arm S (CY 300 mg/m²): n=23
- Arm P1 (CY 500 mg/m²): n=10
- Arm P2 (CY 1000 mg/m²): n=7

Data cutoff: Jan 4th, 2024

P-MUC1C-ALLO1

KEY INCLUSION CRITERIA:
- Advanced or metastatic epithelial-derived solid tumor with measurable disease per RECIST v1.1
- Refractory to standard of care treatment or ineligible/refused other existing treatment options

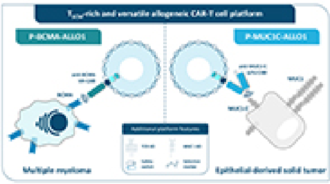
PRIMARY ENDPOINTS
- Assess safety and MTD based on DLT

SECONDARY OBJECTIVES
- Evaluate the anti-tumor effect of P-MUC1C-ALLO1
- Study effect of cell dose & LD regimen to guide dose selection for pivotal studies

LD arms and number of dosed subjects:
- Arm A/B (CY 300 mg/m²): n=20
- Arm P1 (CY 500 mg/m²): n=11
- Arm P2 (CY 1000 mg/m²): n=3

Data cutoff: Feb 21st, 2024

T_{SCM}-rich and versatile allogeneic CAR-T cell platform



P-MUC1C-ALLO1 patients presented with higher baseline WBC counts & achieved comparable lymphodepletion to P-BCMA-ALLO1 patients only at CY1000

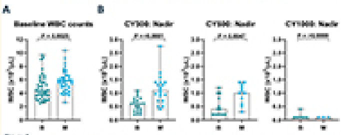


Figure 1
A. Baseline WBC counts prior to conditioning chemotherapy and CAR-T infusion are higher for solid tumor patients (n=33) receiving P-MUC1C-ALLO1 compared to multiple myeloma patients (n=42) receiving P-BCMA-ALLO1. **B.** Post-lymphodepletion median WBC nadir was lower at CY300 and CY500 doses for P-BCMA-ALLO1 patients compared to P-MUC1C-ALLO1 patients. Both groups achieved similar deep WBC nadir when receiving CY1000. All patients received the same fludarabine dose. B = P-BCMA-ALLO1, M = P-MUC1C-ALLO1.

CY1000 improves depth of lymphodepletion in multiple myeloma & solid tumor patients

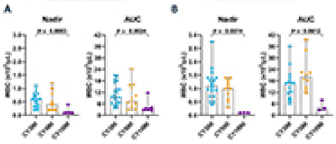
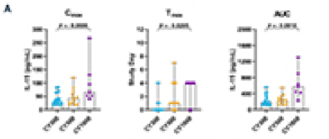


Figure 2
CY1000 produces deeper lymphodepletion compared to CY300 for P-BCMA-ALLO1 (A) and P-MUC1C-ALLO1 (B) patients as demonstrated by lower WBC nadir. **A.** WBC nadir and AUC for the treatment window from day 0 to the day 10 visit were trending lower for P-BCMA-ALLO1 patients treated with CY500 compared to CY300. **B.** No reduction of WBC nadir and AUC was observed for P-MUC1C-ALLO1 patients treated with CY500 compared to CY300. This indicates that CY1000 is required to produce comparable lymphodepletion between solid tumor patients and multiple myeloma patients. All patients received the same fludarabine dose.

Peak IL-15 was increased & C_{max} delayed in both solid tumor and multiple myeloma patients with CY1000

P-BCMA-ALLO1



P-MUC1C-ALLO1

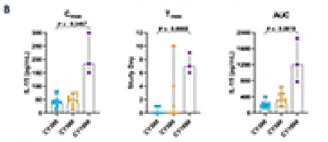
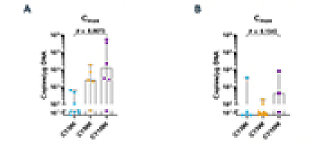


Figure 3
P-BCMA-ALLO1 (A) and P-MUC1C-ALLO1 (B) patients treated with CY1000 compared to CY300 showed increased IL-15 levels as demonstrated by increased C_{max} and AUC in the window between Day 0 to Day 10. The IL-15 C_{max} was also delayed in patients receiving CY1000 as compared to the lower CY groups. All patients received the same fludarabine dose.

Lymphodepletion with CY500 did not improve CAR-T cell expansion in P-MUC1C-ALLO1 patients



	CY300	CY500	CY1000
Number of subjects	8	5	6
Mean	171	6,090	152,554
Std. Deviation	246	7,569	234,264

	CY300	CY500	CY1000
Number of subjects	5	11	3
Mean	692	31	2,940
Std. Deviation	1,531	58	4,717

Figure 4
Cellular kinetics in P-BCMA-ALLO1 (A) or P-MUC1C-ALLO1 (B) patients presented by cyclophosphamide dose level. Peak expansion (C_{max}) is shown for patients infused with a single cell dose of ~2 x 10^6 cells/kg. 500 mg/m² cyclophosphamide as part of lymphodepletion regimen did not improve P-MUC1C-ALLO1 expansion in solid tumor patients. Cellular kinetics have been assessed by qPCR measuring transposon copies per µg DNA. All patients received the same fludarabine dose.

CONCLUSIONS

- Solid tumor patients had numerically higher WBC counts prior to conditioning chemotherapy than multiple myeloma patients.
- Increasing CY dose from 300 mg/m² to 500 mg/m² or 1,000 mg/m² for P-BCMA-ALLO1 patients enhanced lymphodepletion depth leading to improved CAR-T cell expansion.
- In contrast, for P-MUC1C-ALLO1 patients, increasing CY from 300 mg/m² to 500 mg/m² did not improve LD depth and there was no improvement in CAR-T cell expansion for patients treated with CY 500 mg/m² compared to those treated with CY 300 mg/m².
- P-MUC1C-ALLO1 patients treated with CY 1000 mg/m² demonstrated improved lymphodepletion compared to those treated with CY 300 mg/m². There was a trend towards improved P-MUC1C-ALLO1 expansion in patients receiving CY 1000 mg/m² compared to those who received CY 300 mg/m².
- CAR-T cell product attributes are unlikely responsible for the distinct LD requirement for the two patient populations because P-BCMA-ALLO1 cells and P-MUC1C-ALLO1 cells utilize the same transposon, gene editing and manufacturing techniques and both products are produced using the same screened, healthy donor pool.
- A major difference between these two patient populations is the prior exposure of multiple myeloma patients to lymphodepleting chemotherapy associated with prior CAR-T therapy or hematopoietic stem cell transplantation.
- Preliminary data suggest that solid tumor patients may require higher CY doses to achieve adequate LD to enable allogeneic CAR-T expansion.
- Continued evaluation of LD regimen is needed as part of developing investigational allogeneic CAR-T in solid tumors.

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