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):
August 31, 2021

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)**	**(I.R.S. 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

N/A
(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 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 August 31, 2021, Poseida Therapeutics, Inc. (the "Company") issued a press release reporting preliminary results on the first nine patients at low dose cohorts in an ongoing Phase 1 clinical trial of P-PSMA-101, an autologous chimeric antigen receptor T-cell (CAR-T) product candidate in metastatic castrate-resistant prostate cancer (mCRPC). The results were also presented at the 6th Annual CAR-TCR Summit virtual meeting on August 31, 2021.

Efficacy:

As of the cutoff date in August 2021, the study had enrolled a total of nine patients with mCRPC: five patients at Dose A who each received a single treatment of 0.25X10E6 cells/kg (an average of about 20M cells), and four patients at Dose B, who each received a single treatment of 0.75X10E6 cells/kg (an average of about 60M cells). All patients received a lymphodepletion regimen consisting of 30 mg/m2 fludarabine + 300 mg/m2 cyclophosphamide. Patients were heavily pre-treated, having received an average of six prior lines of therapy with a median time since diagnosis of 6.4 years.

Key findings included:

- Five patients dosed showed measurable declines in prostate-specific antigen (PSA) levels
- Three patients treated showed a greater than 50% decline in PSA levels and had concordant improvements in PSMA-PET imaging
- One patient demonstrated evidence of complete tumor elimination at 12 weeks and remained in a durable response of greater than five months at the time of the presentation.

Safety and Tolerability:

As of the data cutoff date, P-PSMA-101 showed a favorable safety and tolerability profile. After a previously reported case of macrophage activation syndrome (MAS) exacerbated by patient non-compliance, only three cases of possible CRS were observed, which were all low grade (1/2) and were managed well with early treatment. No cases of neurotoxicity (CRES/ICANS) were observed as of the cutoff date. Other grade 3 or greater treatment-emergent adverse events observed as of the data cutoff date were neutropenia (n=3), thrombocytopenia (n=2), anemia (n=1) and infection (n=1). As of the data cutoff date, peak expansion of P-PSMA-101 CAR-T cells occurred between 14 and 28 days.

The Phase 1 trial is an open label, multi-center, 3+3 dose-escalating study designed to assess the safety of P-PSMA-101 in up to 40 adult subjects with mCRPC. The primary objectives of this study are to determine the safety, efficacy, and maximum tolerated dose of P-PSMA-101.

A copy of the press release and the slides presented by the Company at the 6th Annual CAR-TCR Summit virtual meeting are attached hereto as Exhibits 99.1 and 99.2, respectively.

Forward-Looking Statements

Statements contained in this report 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, the potential benefits of the Company's technology platforms and product candidates, the Company's plans and strategy with respect to developing its technologies and product candidates, and anticipated timelines and milestones with respect to the Company's development programs. 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, risks and uncertainties associated with development and regulatory approval of novel product candidates in the biopharmaceutical industry and the other risks described in the Company's filings with the Securities and Exchange Commission. All forward-looking statements contained in this report 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Exhibit Description
99.1	Press Release of Poseida Therapeutics, Inc., dated August 31, 2021.
99.2	Presentation of Poseida Therapeutics, Inc., dated August 31, 2021.
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: August 31, 2021

By: /s/ Harry J. Leonhardt
Harry J. Leonhardt
General Counsel and Chief Compliance Officer

Exhibit 99.1

Poseida Therapeutics Presents Preliminary Results from Phase 1 Trial of P-PSMA-101 at the 6th Annual CAR-TCR Summit

Encouraging data confirming activity in a solid tumor indication presented on first nine patients at low dose cohorts in ongoing autologous CAR-T trial in metastatic castrate-resistant prostate cancer

Three patients showed a greater than 50% decline in prostate-specific antigen (PSA) and concordant PSMA-PET imaging results, including one patient at lowest dose with evidence of complete tumor elimination

Favorable safety profile with modest overall rates of CRS and no neurotoxicity observed

Company to host webcast today to further review results at 11:00am ET

SAN DIEGO, Aug. 31, 2021 – Poseida Therapeutics, Inc. (Nasdaq: PSTX), a clinical-stage biopharmaceutical company utilizing proprietary genetic engineering platform technologies to create cell and gene therapeutics with the capacity to cure, today announced preliminary results from its Phase 1 clinical trial of P-PSMA-101, the Company's solid tumor autologous CAR-T product candidate to treat patients with metastatic castrate-resistant prostate cancer (mCRPC). These data will be presented at the 6th Annual CAR-TCR Summit virtual meeting at 10:00am ET today in a presentation entitled, "P-PSMA-101 is a High-Tscm Autologous CAR-T Targeting PSMA Producing Exceptionally Deep and Durable Responses in Castration-Resistant Metastatic Prostate Cancer."

"We are excited about the preliminary data from our Phase 1 trial of P-PSMA-101, which provides further evidence of the effectiveness of our CAR-T platform for solid tumor cancers," said Eric Ostertag, M.D., Ph.D., Chief Executive Officer of Poseida, who will present at the CAR-TCR Summit. "To date, other CAR-T therapeutics have not had much success outside of hematologic malignancies. The deep and durable responses in our trial demonstrate that CAR-T products have the potential to work well against solid tumors, even at low doses, when using the appropriate technology platform."

Efficacy:

As of the cutoff date, the study had enrolled a total of nine patients with mCRPC: five patients at Dose A who each received a single treatment of 0.25X10E6 cells/kg (an average of about 20M cells), and four patients at Dose B, who each received a single treatment of 0.75X10E6 cells/kg (an average of about 60M cells). All patients received a lymphodepletion regimen consisting of 30 mg/m2 fludarabine + 300 mg/m2 cyclophosphamide. Patients were heavily pre-treated, having received an average of six prior lines of therapy with a median time since diagnosis of 6.4 years.

Key findings included:

- *Five patients dosed showed measurable declines in PSA levels*
- *Three patients treated showed a greater than 50% decline in PSA levels and had concordant improvements in PSMA-PET imaging*
- *One patient demonstrated evidence of complete tumor elimination and remains in a durable response of greater than five months at the time of this presentation*

"This innovative Poseida PSMA-directed CAR T cell platform has demonstrated a robust anti-tumor response in patients with metastatic castration resistant prostate cancer," commented Susan F. Slovin, M.D., Ph.D., Associate Vice Chair of Academic Administration at Memorial Sloan Kettering Cancer Center and investigator on the trial. "This is the first time that I have seen such impressive responses with an immunotherapy product. The responses of my patients in the trial are far beyond my expectations."

Safety and Tolerability:

P-PSMA-101 demonstrated a favorable safety and tolerability profile. After a previously reported case of Macrophage Activation Syndrome (MAS) exacerbated by patient non-compliance, only three cases of possible Cytokine Release Syndrome (CRS) were observed, which were all low grade (1/2) and were managed well with early treatment. No cases of neurotoxicity (CRES/ICANS) were observed as of the cutoff date.

The Phase 1 trial is an open label, multi-center, 3+3 dose-escalating study designed to assess the safety of P-PSMA-101 in up to 40 adult subjects with mCRPC. The primary objectives of this study are to determine the safety, efficacy, and maximum tolerated dose of P-PSMA-101. Additional information about the study is available at www.clinicaltrials.gov using identifier: NCT04249947.

"We believe the key to success in solid tumors is a product with a high percentage of desirable stem cell memory T cells (Tscm)," said Matthew Spear, M.D., Chief Medical Officer of Poseida. "In this study, we have demonstrated that a high-percentage Tscm CAR-T product can home to the bone marrow and, in at least one case, completely eliminate tumor. This bone marrow homing property may be particularly important for bone avid diseases such as prostate adenocarcinoma. Importantly, the favorable tolerability associated with our Tscm CAR-T products has carried over to prostate cancer where we have so far seen manageable cytokine release syndrome and no neurotoxicity."

Company-Hosted Conference Call and Webcast Information

Poseida's management team will host a conference call and webcast today, August 31, 2021 at 11:00am ET. The dial-in conference call numbers for domestic and international callers are (866) 939-3921 and (678) 302-3550, respectively. The conference ID number for the call is 50220147. Participants may access the live webcast and the accompanying presentation materials on Poseida's website at www.poseida.com in the Investors section under Events and Presentations. An archived replay of the webcast will be available for 30 days following the event.

Additional CAR-TCR Summit Highlights

Presentation: "Developing CAR-T Cells for Multiple Myeloma: From Autologous to Allogeneic"

Session Date/Time: Wednesday, September 1, 2021, 4:00pm ET

Presenter: Matthew Spear, M.D., CMO, Poseida Therapeutics

This presentation will outline Phase 1 and 2 development of the Company's lead autologous P-BCMA-101 CAR-T therapy and insights that were used to develop a fully allogeneic version, P-BCMA-ALLO1 that is expected to enter the clinic soon. The presentation will be part of the afternoon session on the Clinical Management Track.

Presentation: "Advancing Nonviral Manufacturing for Multi-Product Allogeneic T-Cell Therapies"

Session Date/Time: Wednesday, September 1, 2021, 4:30pm ET

Presenter: Devon Shedlock, Ph.D., SVP Research & Development, Poseida Therapeutics

This presentation will discuss how Poseida's piggyBac® DNA Delivery System, Cas-CLOVER™ Site-specific Gene Editing System and Booster Molecule are used to manufacture multi-product, fully allogeneic T-cell therapies. The Company will also discuss how efficient multiplexed Cas-CLOVER gene editing exhibits low to no off-target editing or translocations as determined by next-generation sequencing, and how the Company's Booster Molecule helps to protect against the "allo tax," maintaining a favorable high-stem cell memory T cell (Tscm) product and enabling up to hundreds of doses in a single manufacturing run. This presentation will be part of the afternoon session on the Manufacturing Track.

Presentation: "Developing 'Off-the-Shelf' CAR-T Cells for Bone Marrow Transplant Conditioning"

Session Date/Time: Thursday, September 2, 2021, 9:00am ET

Presenter: Nina Timberlake, Ph.D., Associate Director, Research (Gene Therapy), Poseida Therapeutics

This presentation will discuss leveraging the piggyBac DNA Delivery System and Cas-CLOVER Site-specific Gene Editing System to generate off-the-shelf fully allogeneic CAR-T cells to specifically target hematopoietic cells in the bone marrow. This potential therapeutic could be used as a non-myeloablative conditioning regimen for hematopoietic stem cell transplant or as a therapeutic for the treatment of acute myeloid leukemia (AML). The presentation will occur as part of the conference's Focus Day, "CAR-TCR Beyond Oncology: Fundamental Biology & Mechanisms of Action Beyond Oncology."

The full presentations at the CAR-TCR Summit will be made available on Poseida's website at their respective session times.

About Poseida Therapeutics, Inc.

Poseida Therapeutics is a clinical-stage biopharmaceutical company dedicated to utilizing our proprietary genetic engineering platform technologies to create next generation cell and gene therapeutics with the capacity to cure. We have discovered and are developing a broad portfolio of product candidates in a variety of indications based on our core proprietary platforms, including our non-viral piggyBac DNA Delivery System, Cas-CLOVER Site-specific Gene Editing System and nanoparticle- and AAV-based gene delivery technologies. Our core platform technologies have utility, either alone or in combination, across many cell and gene therapeutic modalities and enable us to engineer our wholly-owned portfolio of product candidates that are designed to overcome the primary limitations of current generation cell and gene therapeutics. To learn more, visit www.poseida.com to connect with us on Twitter 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, the potential benefits of Poseida’s technology platforms and product candidates, Poseida’s plans and strategy with respect to developing its technologies and product candidates, and anticipated timelines and milestones with respect to Poseida’s development programs. 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 Poseida’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, risks and uncertainties associated with development and regulatory approval of novel product candidates in the biopharmaceutical industry and the other risks described in Poseida’s filings with the Securities and Exchange Commission. All forward-looking statement contained in this press release speak only as of the date on which they were made. Poseida 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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Exhibit 99.2

POSEIDA THERAPEUTICS

P-PSMA-101 is a High-T_{scm} Autologous CAR-T Targeting PSMA Producing Exceptionally Deep and Durable Responses in Castration-Resistant Metastatic Prostate Cancer (mCRPC)

Eric Ostertag, MD, PhD

CEO, Poseida Therapeutics

August 31, 2021

Disclaimer

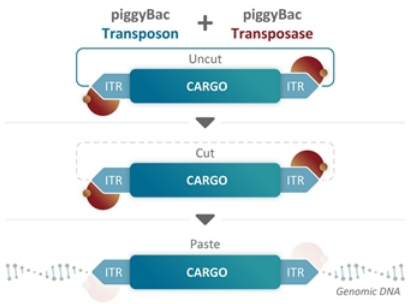
This presentation and any accompanying oral commentary contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts and include, without limitation, statements related to future events; our future financial performance or condition; business strategy; expected timing and plans with respect to development milestones, clinical trials, and regulatory activities; estimated market opportunities for product candidates; and future results of anticipated development efforts. Words such as "expect(s)," "feel(s)," "believe(s)," "will," "may," "anticipate(s)", “potentially” or negative of these terms or similar expressions are intended to identify forward-looking statements. These forward-looking statements are based on management's current expectations of future events only as of the date of this presentation and are subject to a number of important risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: risks associated with conducting clinical trials; whether any of our product candidates will be shown to be safe and effective; our ability to finance continued operations; our reliance on third parties for various aspects of our business; competition in our target markets; our ability to protect our intellectual property; our ability to retain key scientific or management personnel; and other risks and uncertainties described in our filings with the Securities and Exchange Commission, including under the heading “Risk Factors”. Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons why actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

Overview

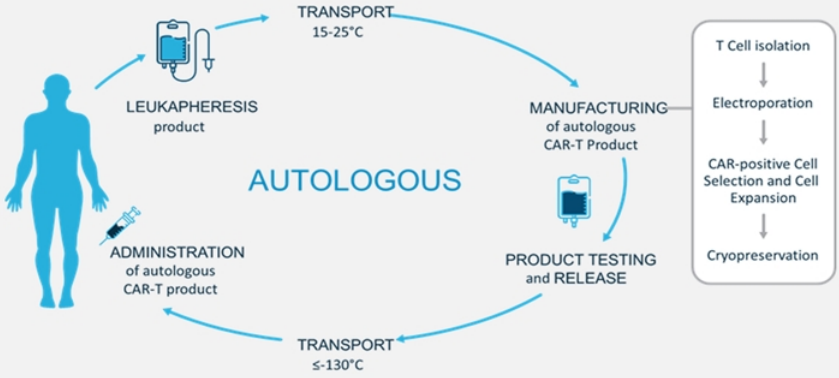
- P-PSMA-101 is made using a **unique CAR-T platform** that results in a product comprised of a high percentage of **T stem cell memory (T_{SCM}) cells**
- **T_{SCM} cells have bone marrow homing capability that may be particularly relevant to specific solid tumors, such as prostate adenocarcinoma**
- At very low doses, **P-PSMA-101 induces deep and durable responses** in heavily pretreated mCRPC patients
- P-PSMA-101 demonstrates a **good safety profile** with manageable rates of CRS and **no neurotoxicity**

POSEIDA THERAPEUTICS

piggyBac®: A Non-viral DNA Delivery System That Creates High-T_{SCM} CAR-T Products



- Non-viral gene insertion technology
- Enables efficient DNA integration & stable expression
- Multiple safety, timeline and cost benefits
- Very large cargo capacity (>20X viral systems)
- Works in a wide variety of cell types (Tscm cells)



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Not All T Cells Are Created Equally

The Importance of Stem Cell Memory T Cells (T_{SCM})

LESS DIFFERENTIATED

T_{SCM} Cell
Stem Cell Memory

- Self renewing
- Long lived
- Multipotent

T_{CM} Cell
Central Memory

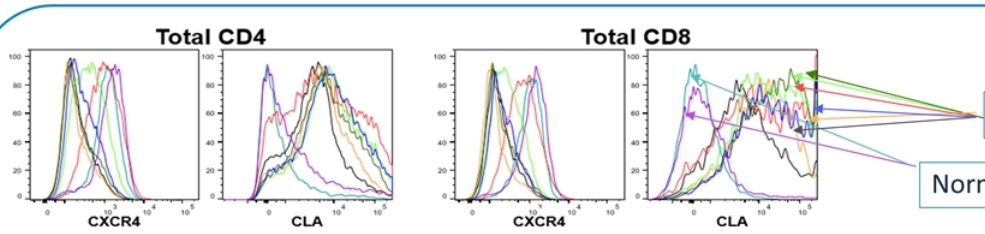
T_{EM} Cell
Effector Memory

MORE DIFFERENTIATED

T_{EFF} Cell
Effector T Cell

STEMNESS MATTERS
Products with High % of T_{SCM} Cells

- Strong correlation with best responses in the clinic
- More gradual tumor killing with less toxicity
- Better duration of response and potential for re-response
- **T_{SCM} engrafts in bone marrow – key to CAR-T success in solid tumors**



P-PSMA-101 clinical products (N=6)

Normal PBMC controls (N=2)

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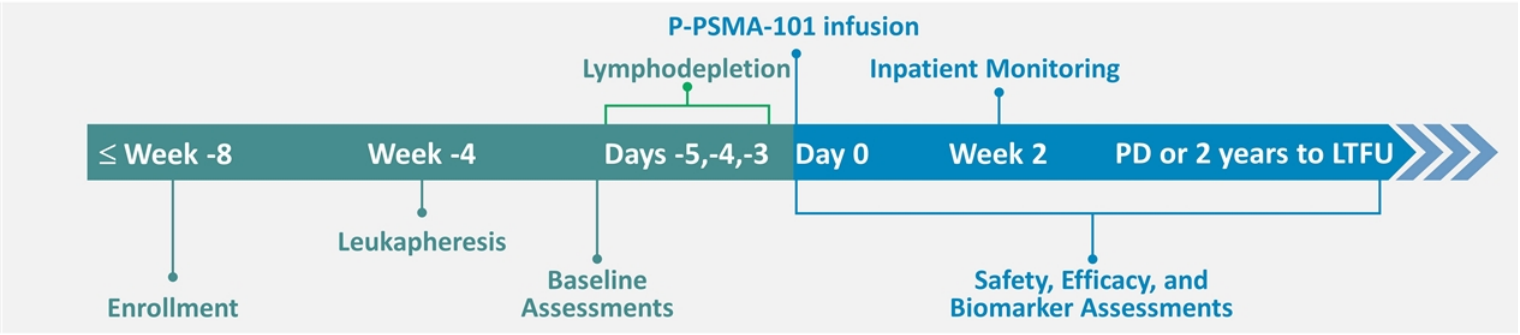
Phase 1 mCRPC Clinical Trial: P-PSMA-101-001

- Open Label, 3+3 Design, Dose Escalation + RP2D expansion, 40 patients
- Standard 3d lymphodepletion regimen: fludarabine 30 mg/m2 – CTX 300 mg/m2
- Standard response criteria as per PCWG3: PSA, bone scans (BS)/CT, as well as exploratory biomarkers and novel tumor-targeted PET imaging (i.e., PSMA-PET, FDG)
- Key Inclusion Criteria: mCRPC, measurable disease, received a CYP17 inhibitor or second-generation antiandrogen therapy and a taxane, and adequate organ function
- Key Exclusion Criteria: 2nd malignancy, active infection, significant autoimmune, CNS, cardiac, ocular, or liver disease



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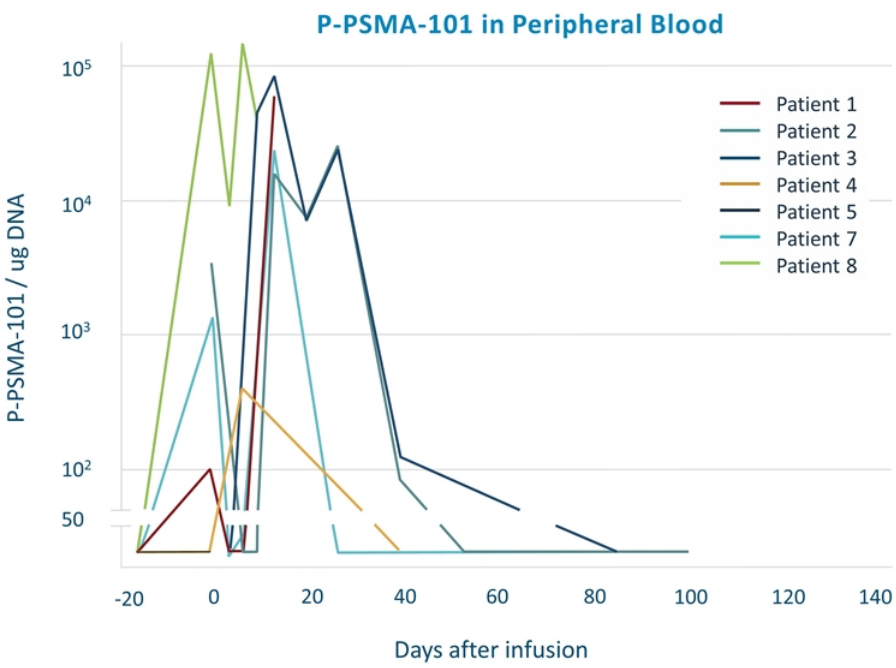
Demographics & Characteristics (Heavily Pretreated mCRPC Patients)

CAR-T cells administered: Cells/kg	Mean (Min/Max) x 10^6	Patients (#)
Dose A: 0.25 x 10^6	21.4 (19/24)	5
Dose B: 0.75 x 10^6	59.0 (37/73)	4

Parameter (n=9)	
Median (min, max) age, y	71 (57, 79)
Median (min, max) time since diagnosis, y	6.4 (1, 23)
ECOG (Baseline) PS, n (%), 0/1	6(67) / 3 (33)
Median (min, max) prior regimens	**6 (3, 15)**
LHRH agonist/antagonist	9 (100)
bicalutamid / flutamide	5 (56)
enzalutamide	6 (67)
abiraterone	8 (89)
taxane	6 (67)
PSMA bispecific	**3 (3, 33)**
PSMA radioimmunotherapy	0

Pharmacokinetics: Consistently High Expansion



- Most patients have **significant CAR-T cell** expansion in peripheral blood
- Many CAR-T products show **peak expansion between 5-14 days**
- **Peak expansion of CAR-Ts often associated with CRS**
- P-PSMA-101 shows **peak expansion between 14-28 days**
- P-PSMA-101 reaches peak expansion gradually **with little CRS**

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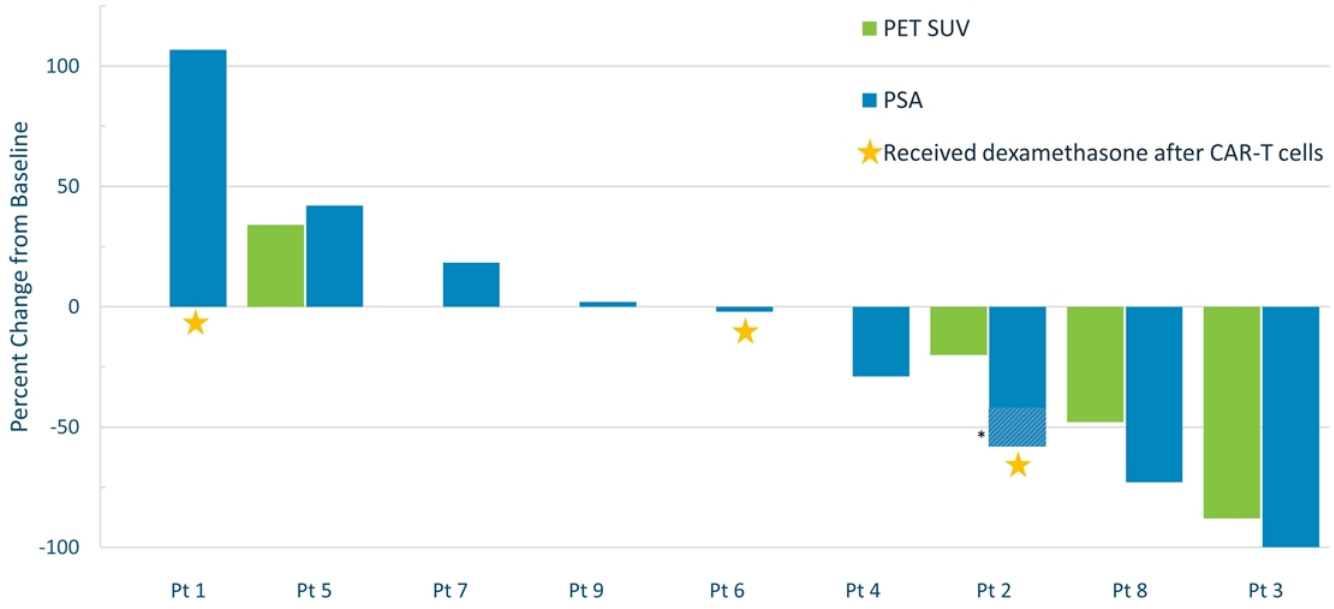
Efficacy: Exceptional Anti-Tumor Responses at the Lowest Dose Levels

Marked decreases in PSA and PSMA-PET SUVs



*central / local results

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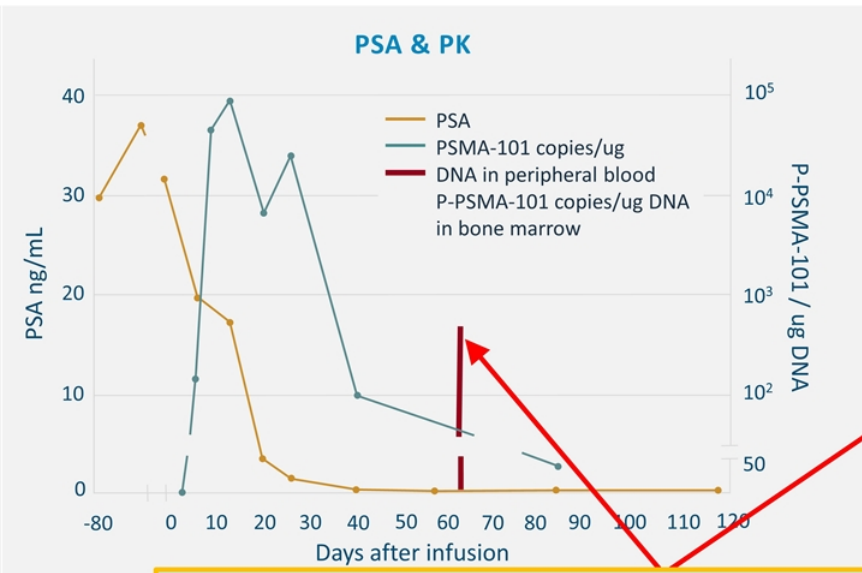
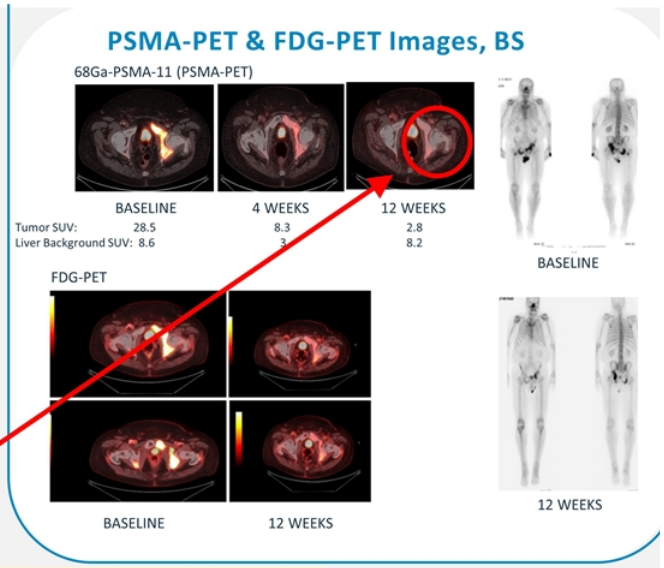
Patient 3: Evidence of Complete Tumor Elimination

PK, PSA, PSMA-PET, FDG-PET, Bone Scan (BS) & Pathology Correlate in Response





Biopsy of prior bone metastasis: CAR-T cells, bone remodeling and bone marrow, but no tumor cells – presence of CD4+ and CD8+ T cells

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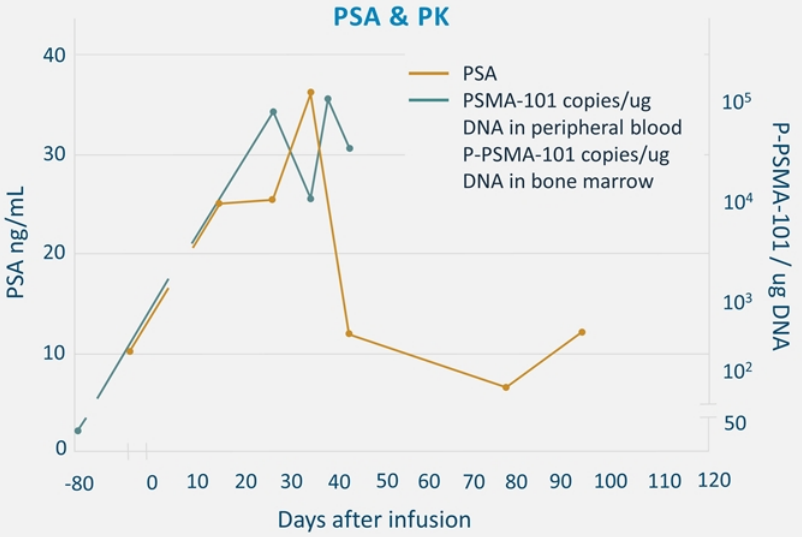
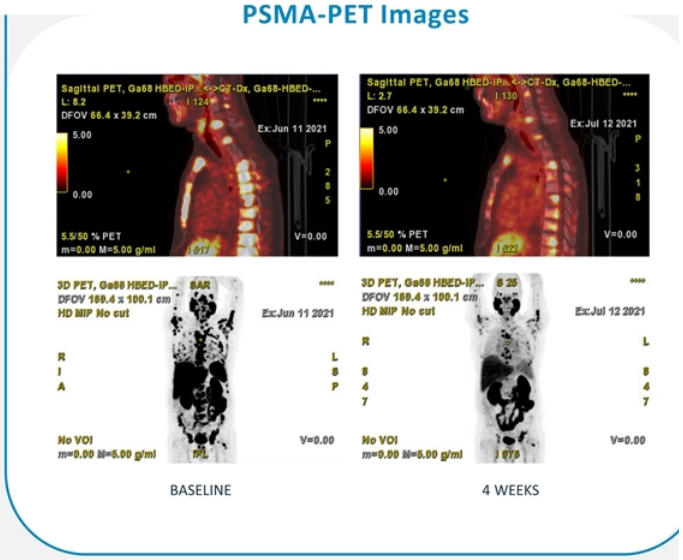
Patient 3: Summary

- 71 year-old male with mCRPC after 4 prior regimens, treated with 22 x 10^6 (0.25 X 10^6/kg) P-PSMA-101 CAR-T cells
- **Evidence of potential complete tumor elimination**
  - >99% PSA decline with multiple values below 0.2 ng/mL over multiple months = possible PSA complete response
  - Concordant PSMA-PET with SUV for all tumors declining below liver background SUV
  - No evidence of tumor via bone marrow biopsy at site of prior tumor involvement
- **Durable response**
  - Patient continues to do exceptionally well clinically more than 5 months post-CAR-T infusion

Patient 8: Rapid Marked Response

Early in the clinical course, with multiple response indicators correlating





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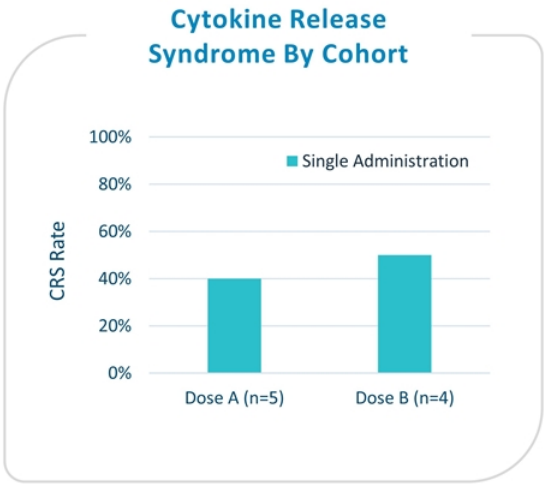
Adverse Events of Interest: Low Rate of Significant AEs

Treatment-Emergent Adverse Events (n=9)

TEAE, n (%)	Overall	≥ Grade 3
Dose Limiting Toxicity (DLT)	1 (11%)	1 (11%)
Cytokine Release Syndrome (CRS)/transaminitis[a]	**4 (44%)**	**1 (11%)**
CAR-T Related Encephalopathy Syndrome (CRES)	**0**	**0**
Neutropenia/Neutrophil count decreased[b]	3 (33%)	3 (33%)
Thrombocytopenia/Platelet count decreased[b]	3 (33%)	2 (22%)
Anemia	2 (22%)	1 (11%)
Infection		
Overall	2 (22%)	1 (11%)
First month	2 (22%)	1 (11%)

[a] ≥ Grade 3 event was one case of macrophage activation syndrome (MAS) (Grade 4/5)
[b] subject counted once for either term



POSEIDA THERAPEUTICS

Summary

Exceptional Early Efficacy with Novel Anti-PSMA CAR-T Cell Product

- **P-PSMA-101 at very low doses induces deep and durable responses in heavily pretreated mCRPC patients**
  - Several patients with responses among the best ever described by a CAR-T product in a solid tumor indication
  - Tscm cells have elevated bone homing markers - highly relevant in a bone predominant cancer
- **Good safety profile**
  - Only 4 cases of possible CRS observed
    - 3 cases Grade 1/2 managed well with early treatment
    - Only one case of MAS, likely related to non-compliance delaying diagnosis and treatment (Grade 4/5)
  - No cases of neurotoxicity (ICANS/CRES)
- **Poseida's portfolio includes fully allogeneic CAR-T cells for PSMA and other targets**

POSEIDA THERAPEUTICS

Acknowledgements

With the greatest appreciation to the patients

P-PSMA-101-001 Investigators

Memorial Sloan-Kettering Cancer Center
Susan F. Slovin, M.D., Ph.D.

City of Hope
Tanya Dorff, M.D.

Sarah Cannon Research Institute - HealthOne Denver
Gerald Falchook, M.D.

Dana-Farber Cancer Institute
Xiao Wei, M.D.

Massachusetts General Hospital
Xin Gao, M.D.

University of California at San Francisco (UCSF)
David Oh, M.D.

University of California at San Diego (UCSD)
Rana Mckay, M.D.

We would particularly like to recognize the commitment and dedication of the scientists and professionals at Poseida who made this possible.

POSEIDA THERAPEUTICS

Thank You

The Next Wave of Cell & Gene Therapies with the Capacity to Cure