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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)

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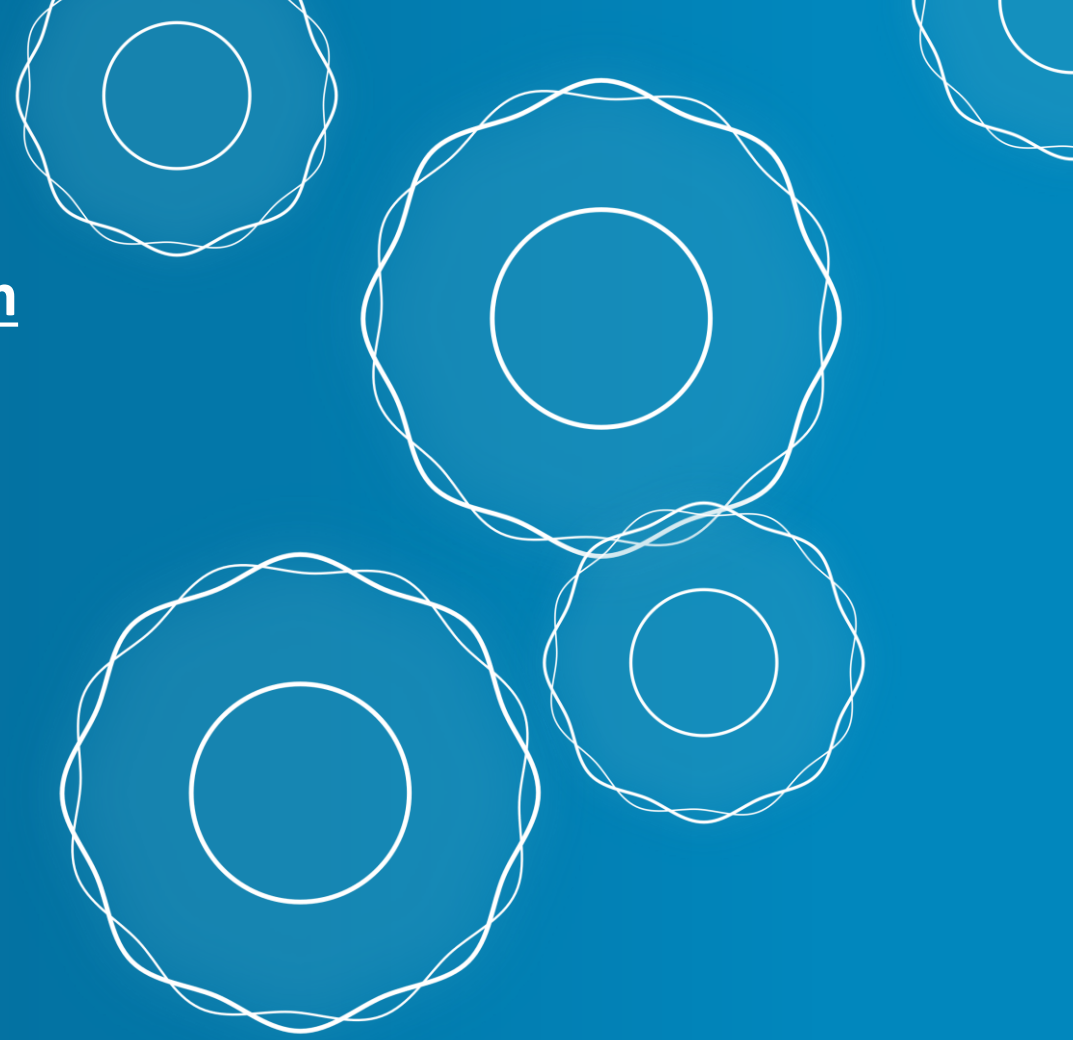
Overview

- 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**



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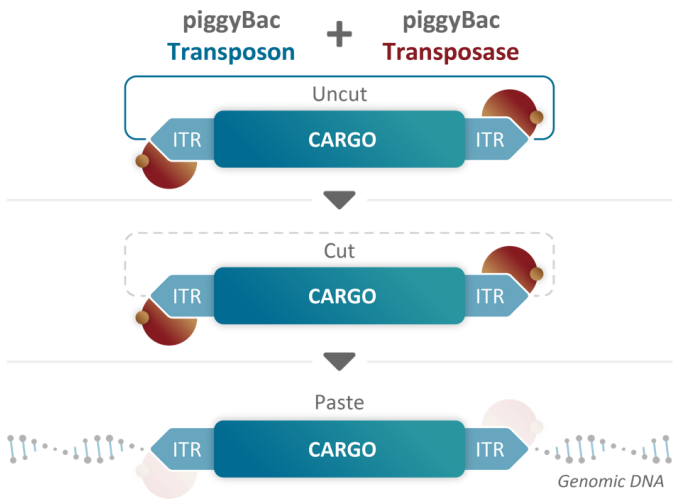
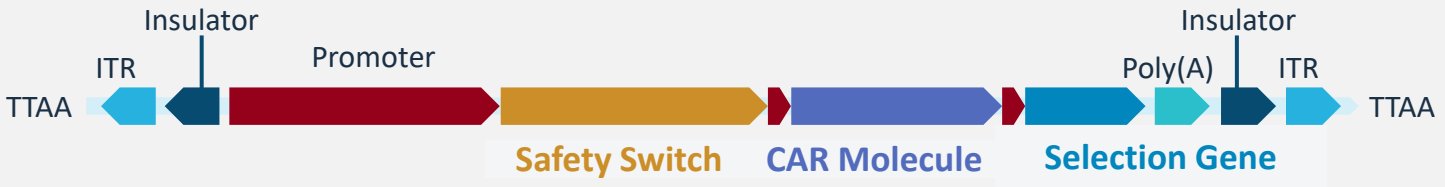
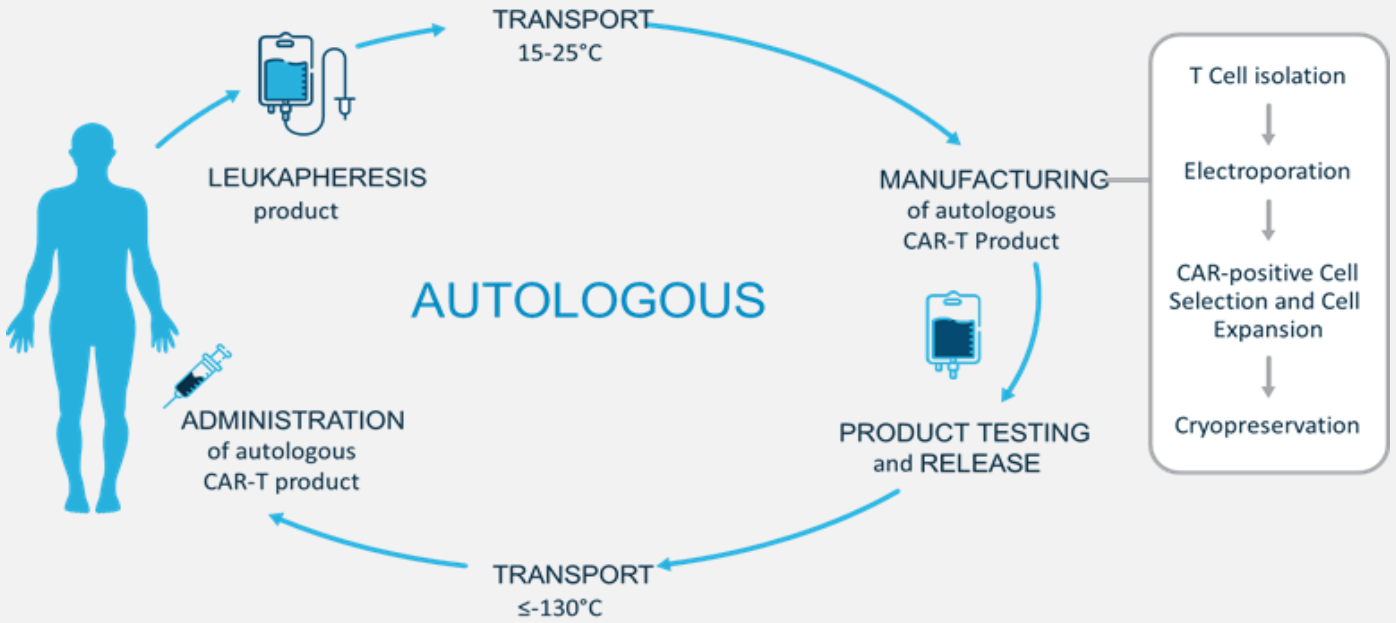
piggyBac®: A Non-viral DNA Delivery System That Creates High-T_{SCM} CAR-T Products



- 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

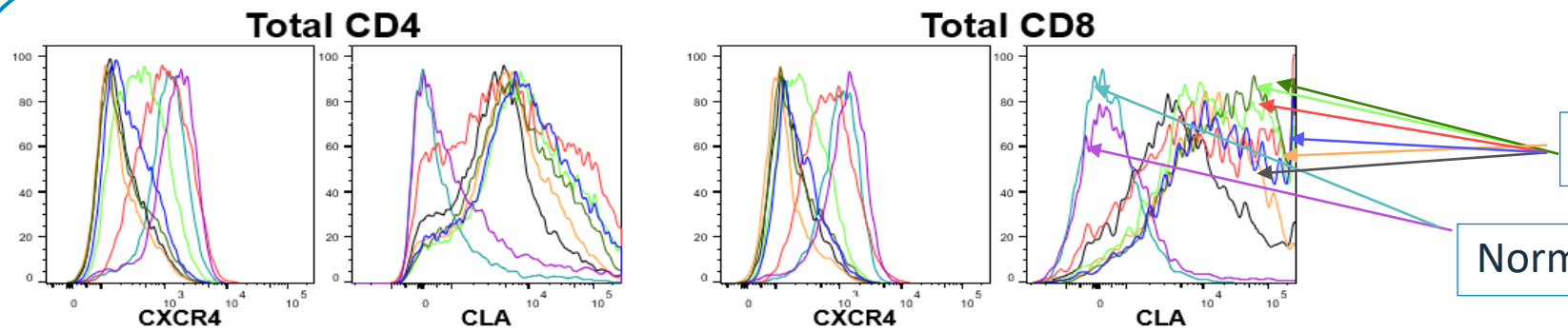
T_{EFF} Cell

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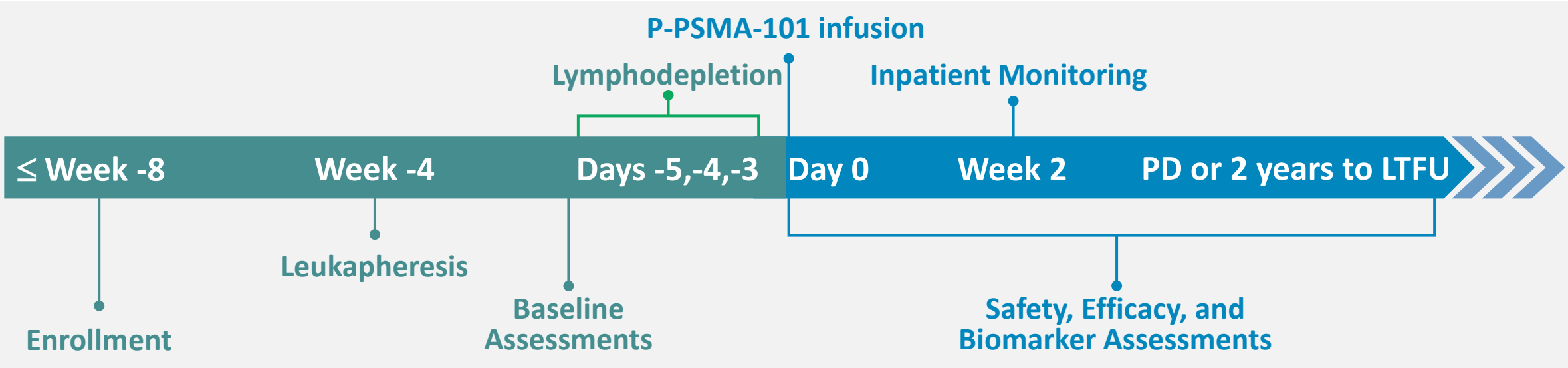
Phase 1 mCRPC Clinical Trial: P-PSMA-101-001

- 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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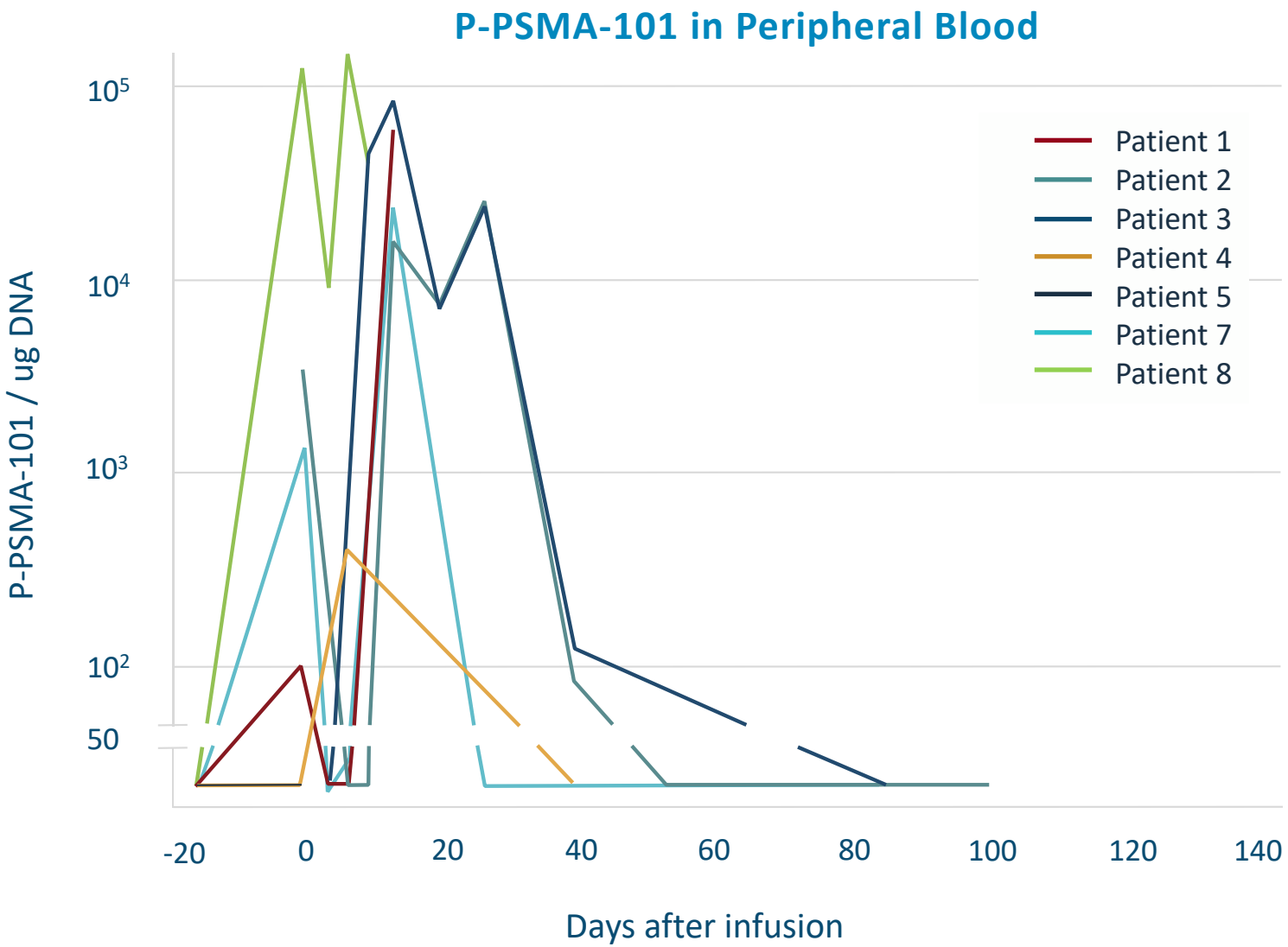
Demographics & Characteristics (Heavily Pretreated mCRPC Patients)

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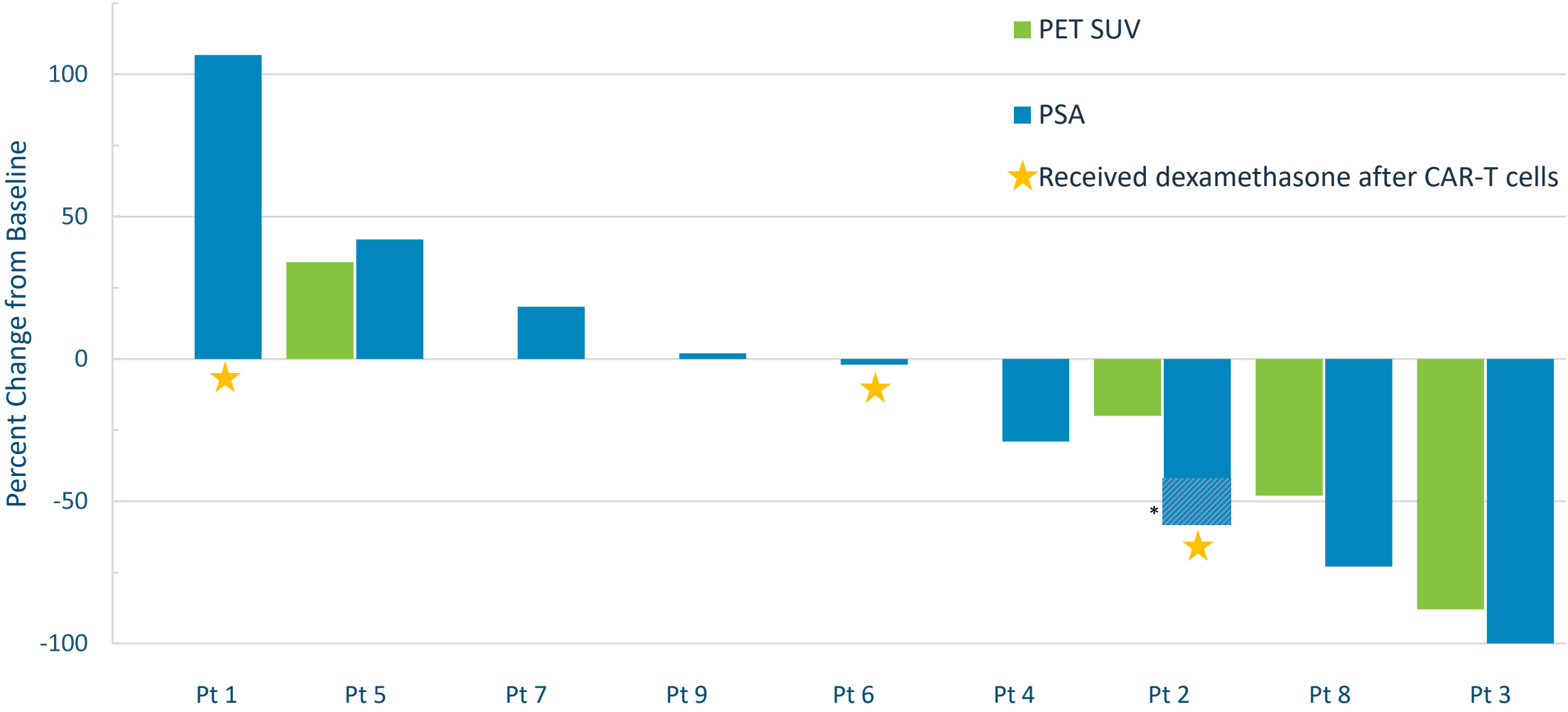
Efficacy: Exceptional Anti-Tumor Responses at the Lowest Dose Levels

Marked decreases in PSA and PSMA-PET SUVs



*central / local results

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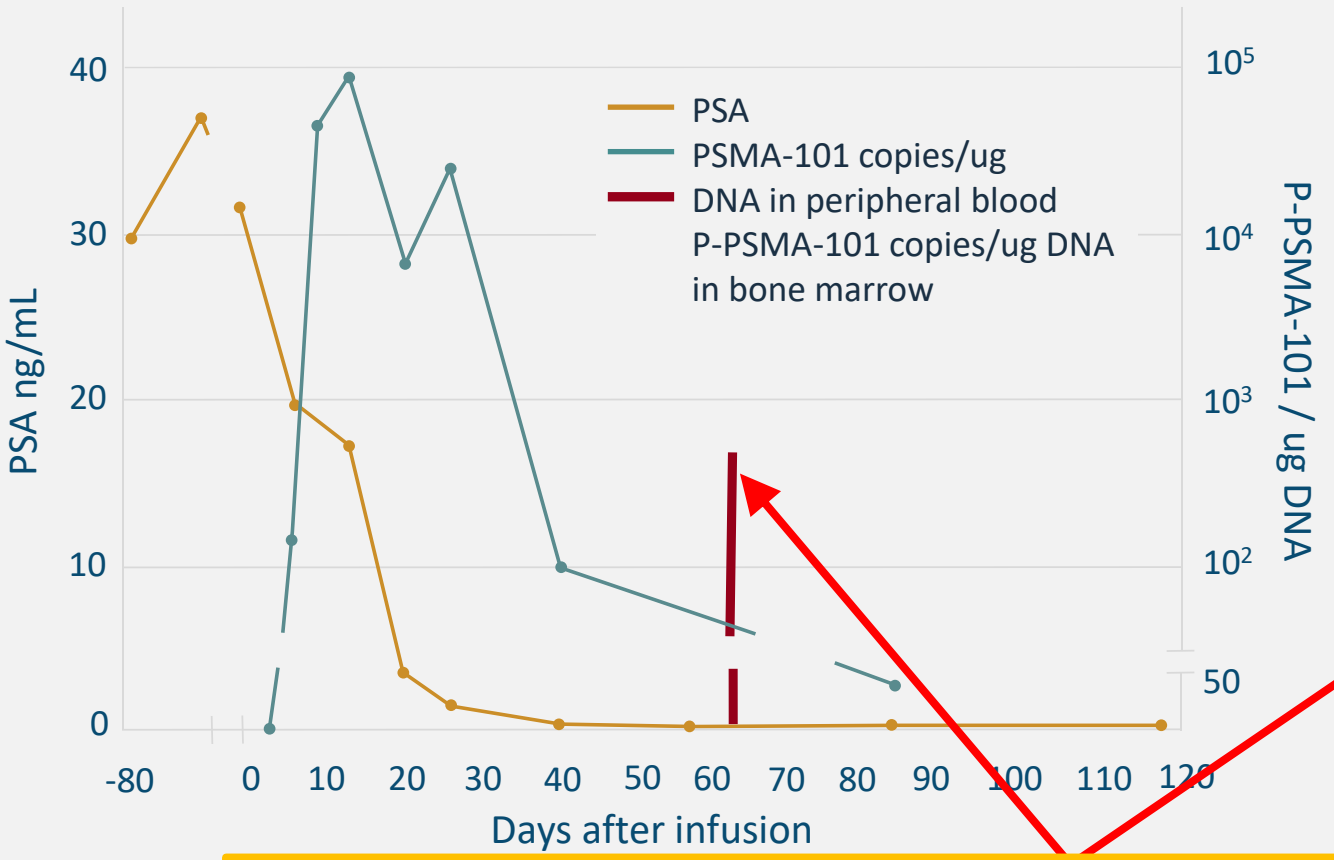
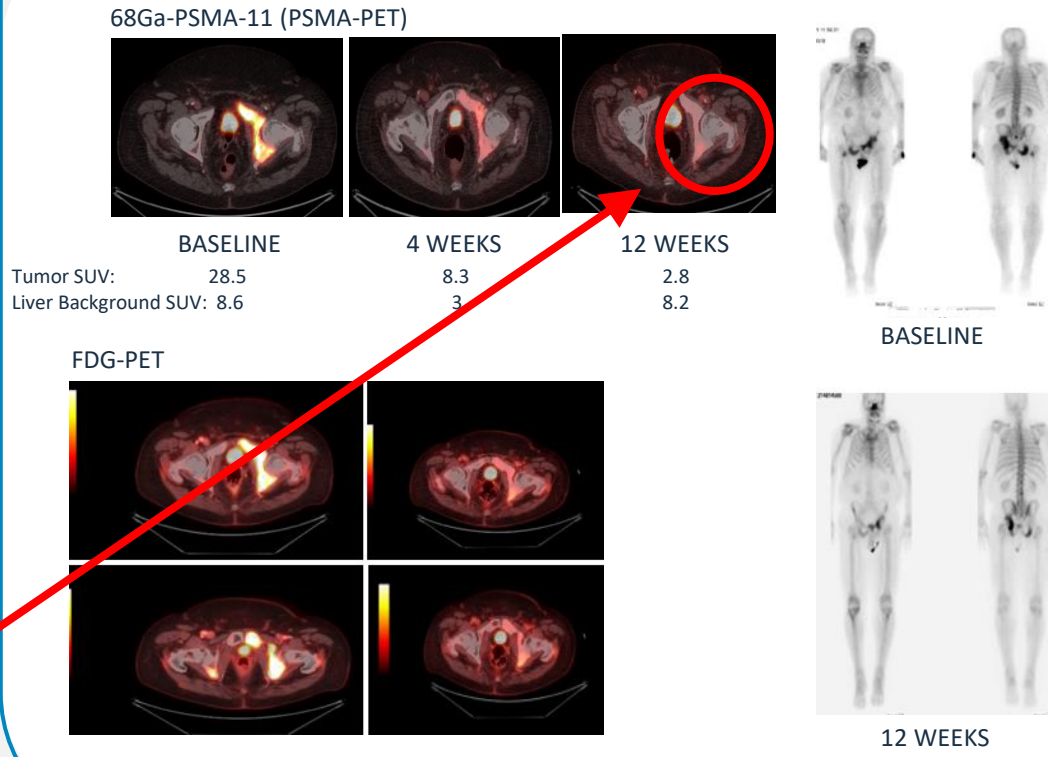
Patient 3: Evidence of Complete Tumor Elimination

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

PSA & PK



PSMA-PET & FDG-PET Images, BS



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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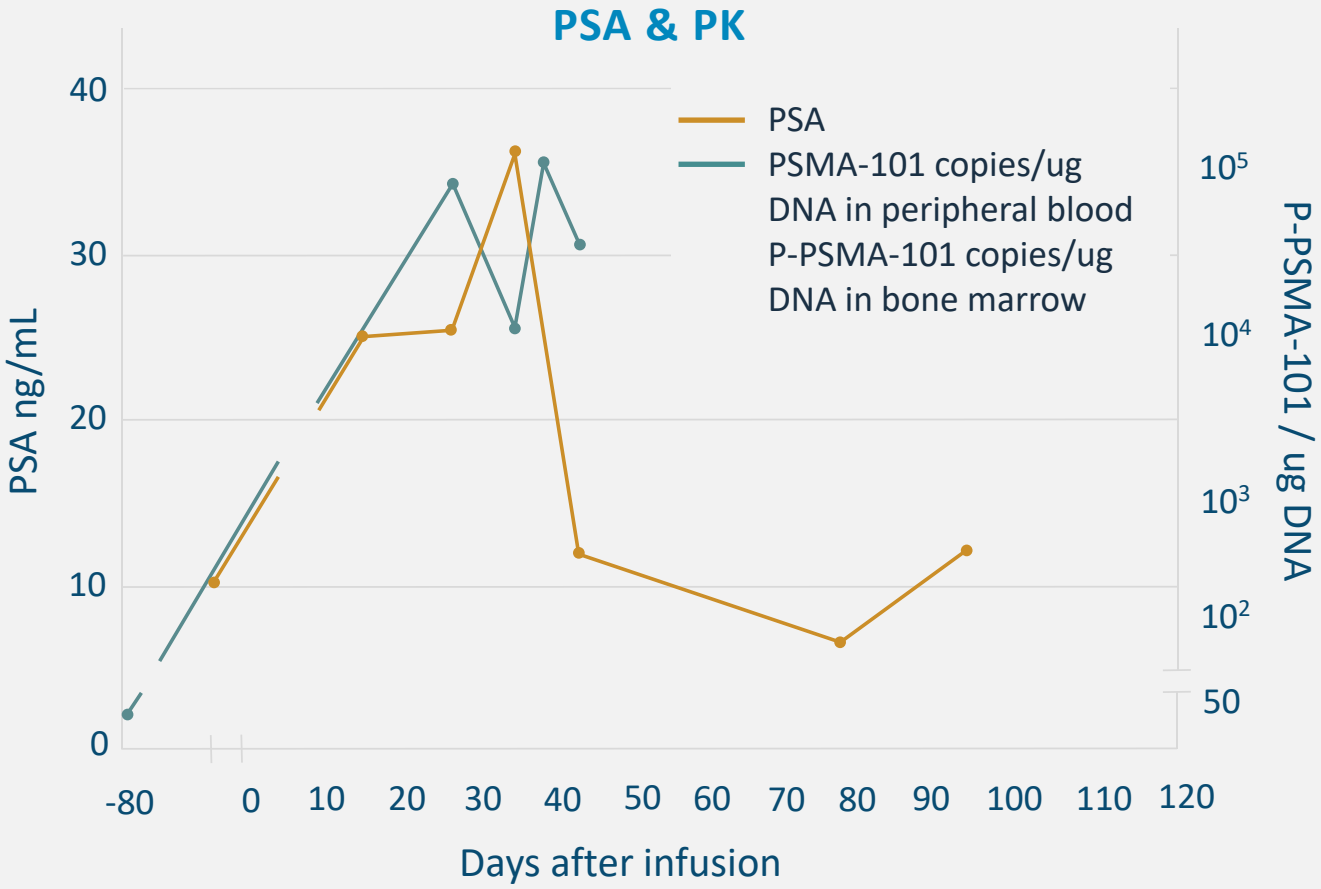
Patient 3: Summary

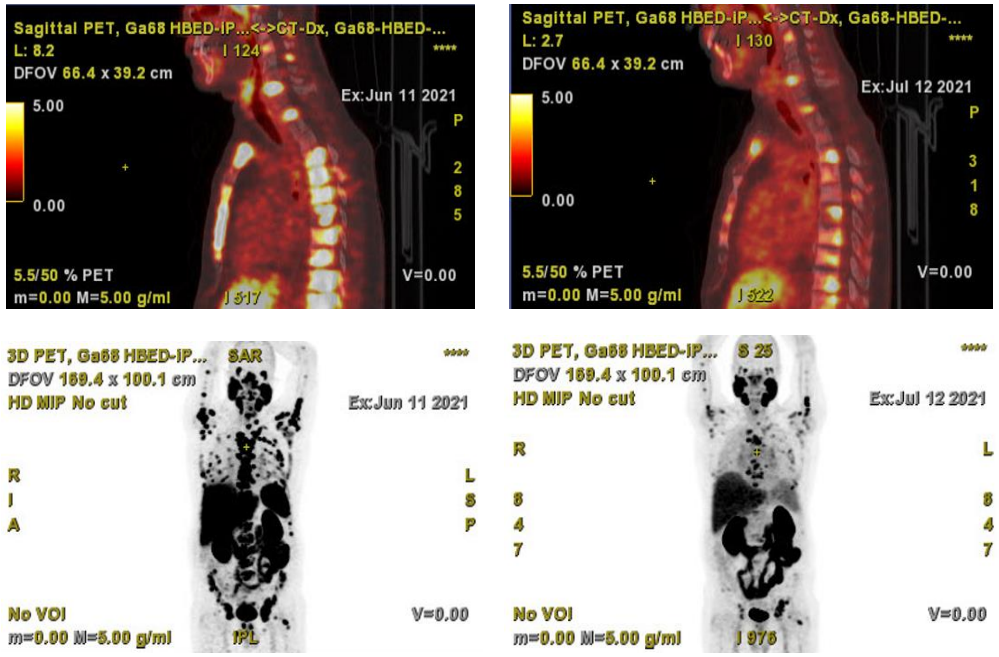
- 71 year-old male with mCRPC after 4 prior regimens, treated with 22 x 10^6 (0.25 X 10^6/kg) P-PSMA-101 CAR-T cells
- **Evidence of potential complete tumor elimination**
  - >99% PSA decline with multiple values below 0.2 ng/mL over multiple months = possible PSA complete response
  - Concordant PSMA-PET 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



PSMA-PET Images



BASELINE

4 WEEKS

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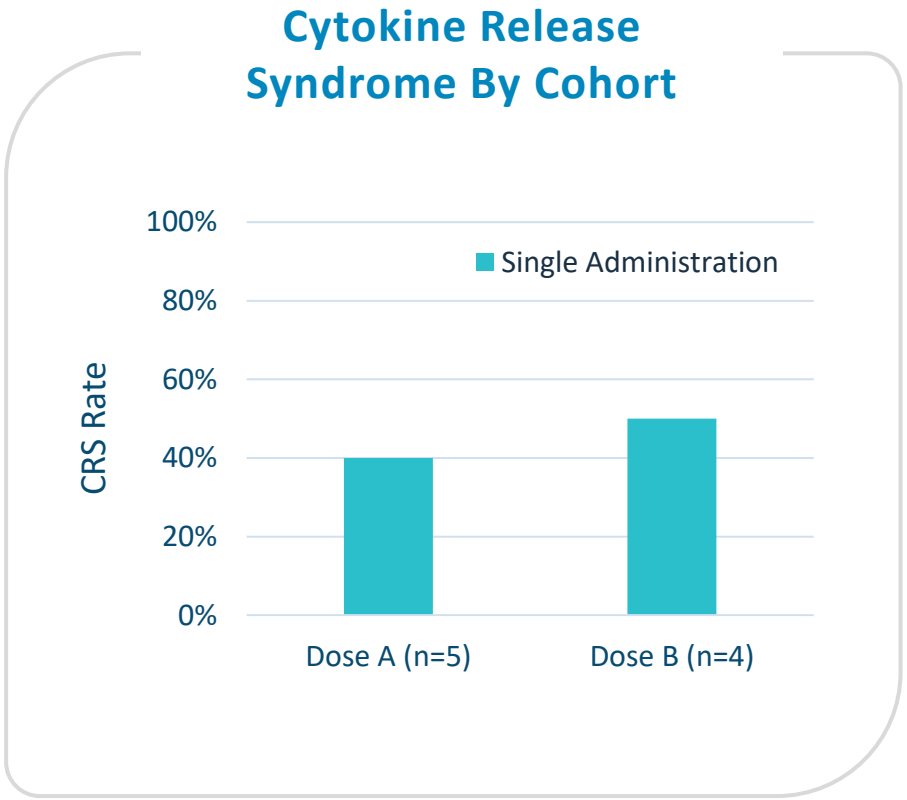
Adverse Events of Interest: Low Rate of Significant AEs

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



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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**

Acknowledgements

With the greatest appreciation to the patients

P-PSMA-101-001 Investigators

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Thank You

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