**Phase 1 Study of P-MUC1C-ALLO1 Allogeneic CAR-T Cells in Patients With Epithelial-Derived Cancers**

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**BACKGROUND**

- There is high clinical and research interest in solid tumors, as advances in immunologic techniques have improved outcomes in metastatic melanoma.
- Most solid tumors are of epithelial origin and express mucin 1 (MUC1) and mucin 1C (MUC1C).
- Expression profile was consistent with what has been previously reported for MUC1 and MUC1C.

**PRECLINICAL RATIONALE**

- Tumor tissue arrays: percentage positive samples
- Representation of UC using MUC1C cells

**CLINICAL STUDY METHODS AND DESIGN**

- **Study Information:** This is a Phase 1 dose escalation, single cohort study of P-MUC1C-ALLO1 in patients with advanced or metastatic solid tumors.
- **Study Design:** 4 cohorts with dose escalation is planned with dose expansion in cohorts 3 and 4.
- **Major Inclusion Criteria:**
  - Adults with confirmed unresectable, locally advanced or metastatic epithelial-derived solid tumors
  - MUC1C expression ≥ 10% in tumor tissue
  - No prior treatment with a mucoepithelial-directed CAR-T product

**CLINICAL END POINTS**

- **Safety assessments:**
  - Cytokine release syndrome
  - Graft-versus-host disease
  - Other safety endpoints

- **Efficacy endpoints:**
  - Disease control of advanced, metastatic, or recurrent tumors
  - Pharmacokinetics

**PARTICIPATING STUDY CENTERS**

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  - University of California, San Francisco
  - Poseida Therapeutics, Inc., San Diego, CA
  - Saradon Cancer Center, Pittsburgh, PA
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**SUMMARY**

- P-MUC1C-CAR is highly expressed across common epithelial cancers and is actively restricted in normal tissues.
- Primary tumor activity was seen in triple-negative breast cancer and ovarian serous tumors.
- The Phase 2 study for P-MUC1C-CAR is scheduled to begin in 2022 with the first patient treated in May 2022 and is estimated to treat up to 100 patients.
- An accrual data cut off is set for Phase 3 dose escalation and is currently enrolling in cohort 2 at dose level 2 x 10^6.