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PACT NeoTCR-P1 Clinical Trial for Locally Advanced or Metastatic Solid Tumors

University of California, Irvine | UCLA-UCI Alpha Stem Cell Clinic at UC Irvine, and the Department of Medicine

Study Title: A Phase 1 Study of Gene-Edited Autologous Neoantigen-Targeted TCR-T Cells With or Without Anti–PD-1 in Patients with Solid Tumors

Lead Investigator: Samuel Ejadi, MD

What is the study?

The purpose of this research study is to evaluate if an investigational cellular therapy called Neo-TCR-P1 is safe, well tolerated and effective in patients who have been diagnosed with cancer. Patients with advanced melanoma, bladder cancer, colorectal cancer, ovarian cancer, breast cancer, or prostate cancer will be considered for this trial. The disease should have progressed after at least one available standard therapy, where no additional curative therapies are available.

How long will my participation last?

Study participation may last anywhere from 2 - 15 years.

How can I take part in this trial?

UC Irvine will enroll approximately 25 patients.

Main Inclusion Criteria

- Are at least 18 years of age
- Life expectancy > 90 days
- Willing to remain within 60 miles of treatment site for 28 days following NeoTCR-P1 infusion
- Willing and able to undergo Leukapheresis & biopsies
- Disease has progressed after therapy, or therapy is not an option
- Willing to provide a tumor tissue sample

Main Exclusion Criteria

- Any approved anti-cancer therapy (chemotherapy, hormonal therapy, radiology), within 2 weeks of Leukapheresis
- Use of corticosteroids
- Major surgical procedure within 4 weeks of enrollment

Please note this is not a complete list of eligibility criteria.

How does it work?

The study includes screening assessments such as blood work, tumor tissue collection, and physical assessments. Patients will then have Leukapheresis, Chemotherapy, and an infusion of NeoTCR-P1 requiring a minimum of 7 days as an inpatient in the hospital.

The NeoTCR-P1 treatment will be given to patients through an infusion in their vein. Some patients may receive a combination of NeoTCR-P1 and Nivolumab, which is another cancer treatment.

Patients will have follow up appointments at the study site for 2 - 15 years. The follow up visits may include bloodwork, tests to check on their cancer, ECGs, biopsies, and questions about their health.

Where is the study conducted?

At the University of California, Irvine Medical Center located in Orange, CA.

Will I be compensated?

No compensation is provided.

For more information, please contact:

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