Novel RNA-lipid Particle (RNA-LP) Vaccine for Anti-PD-1 Antibody Therapy Sensitization

NCT05264974

Status	RECRUITING
Phase	Phase 1
Sponsor	University of Florida
Enrollment	18 participants

Plain Language Summary

This early-phase study is testing a personalized RNA vaccine made from a patient's own tumor — combined with an anti-PD-1 immunotherapy drug — to see if it can help the immune system better fight cancer. Each vaccine is custom-made using genetic material extracted from the patient's own tumor cells.

You may be eligible if...
- You are 18 years or older
- You are in generally good health (ECOG 0–2)
- You have a solid tumor that can be surgically sampled to extract RNA
- You have only one active cancer at the time of enrollment
- Your blood counts and organ function are within acceptable ranges

You may NOT be eligible if...
- Your tumor cannot be safely sampled for RNA extraction
- You have active autoimmune disease requiring treatment
- You have recently received chemotherapy, immunotherapy, or radiation therapy (within defined washout periods)
- You are pregnant or breastfeeding

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (28)

- Adults e 18 years old
- ECOG performance d 2
- Lab values within the specified ranges:
- Hemoglobin e 8G/DL
- Platelets e 150 thou/cumm

... and 23 more (see full listing online)

Exclusion (24)

- Subjects that have an active second malignancy, however, previously treated early stage malignancies with no evidence of disease recurrence after 3 years of follow-up will be allowed
- Subjects with a history of immune-mediated treatment-related adverse reactions leading to discontinuation of prior aPD1 therapy or severe hypersensitivity reaction to any monoclonal antibody or any other baseline risk in the opinion of the investigator that precludes continued use of aPD1 therapy
- Patients with active and symptomatic brain metastases or leptomeningeal metastases at time of inclusion. Patients with isolated brain lesions that have been treated with stereotactic radiosurgery or surgical resection as part of oligometastatic initial management prior to start of immunotherapy may be eligible as long as they have no new disease and are asymptomatic at time of inclusion

• If patients develop new brain metastases during the time between tumor sampling and vaccine generation and administration, patients may remain on study as long as they can receive definitive stereotactic radiosurgery or surgery to brain metastases and be able to resume systemic therapy within 6 weeks of discovery of new brain metastases.

• Subjects who received an investigational drug in another clinical trial must wait 28 days or at least 5 half-lives of the study drug, whichever is shorter, prior to enrollment in this study

... and 19 more (see full listing online)

Locations (1 total)

University of Florida, Gainesville, Florida, United States