

# Targeted Alpha Particle Radiotherapy for Metastatic Uveal Melanoma

NCT05496686

Status	RECRUITING
Phase	Phase 1
Sponsor	Modulation Therapeutics, Inc.
Enrollment	16 participants

## Plain Language Summary

This study is testing a targeted alpha particle radiotherapy — a type of precision radiation that delivers intense, short-range radiation directly to cancer cells — in patients with metastatic uveal melanoma (a rare cancer that starts in the eye and commonly spreads to the liver). This cancer has very limited effective treatment options, and this approach aims to target cancer cells while sparing surrounding healthy tissue.

### \*\*You may be eligible if...\*\*

- You are 18 or older with confirmed metastatic uveal melanoma
- Your cancer has progressed after at least one prior treatment
- You have measurable cancer on scans (per RECIST 1.1)
- You are in good general health (ECOG 0–1)
- Your blood counts and organ function meet the required levels

### \*\*You may NOT be eligible if...\*\*

- You have not tried any prior treatment for metastatic uveal melanoma
- Your blood counts, liver, or kidney function are below required thresholds
- You have uncontrolled infections or serious medical conditions
- You are pregnant or breastfeeding

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

## Key Eligibility Criteria

### Inclusion (14)

- Histologically confirmed metastatic uveal melanoma.
  - Progression after at least one prior line of therapy for metastatic uveal melanoma. Liver directed therapy (e.g., hepatic arterial embolization, isolated hepatic perfusion) will count as one line of therapy. Should any additional treatment(s) receive regulatory approval for metastatic uveal melanoma during the conduct of this trial, participants (if eligible for the newly approved treatment) would need to demonstrate disease progression on the additional treatment(s) before being eligible to participate in the current study. There is no limit to the number of previous treatments for metastatic disease.
  - Participants must have measurable disease per RECIST 1.1.
  - Adults, age 18 or over, with no upper age limit.
  - ECOG (Eastern Cooperative Oncology Group) performance status of 0-1 (Karnofsky e 70 percent).
- ... and 9 more (see full listing online)

### Exclusion (7)

- Prior alpha-particle therapy.
- Has known symptomatic central nervous system (CNS) metastases and/or carcinomatous meningitis. Participants with previously treated brain metastases may participate provided they are stable without evidence of progression by imaging for at least four weeks after definitive intervention and using no more than the equivalent of dexamethasone 2 mg/d for the management of vasogenic edema, if necessary. This exception does not include carcinomatous meningitis, which is excluded regardless of clinical stability.

<https://clinicaltrials.gov/study/NCT05496686>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).

- Participants with an active malignancy requiring anticancer treatment at the time of study entry that, in the judgment of the investigator could impact the results of treatment of metastatic uveal melanoma.
  - Pregnant or nursing women. Women of childbearing potential (defined as having had a menstrual cycle within the past 12 months, and not having had a surgical procedure for sterilization) must have a negative pregnancy test (urine or serum) within 7 days of treatment with 225Ac-MTI-201.
  - Participants with uncontrolled inter-current illness including, but not limited to, ongoing or active bacterial infection, active hepatitis B/C infection requiring antiviral therapy, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements.
- ... and 2 more (see full listing online)

## Locations (1 total)

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H. Lee Moffitt Cancer Center and Research Institute, Tampa, Florida, United States