

Study of Tebentafusp and Radioembolization in the Treatment of Metastatic Uveal Melanoma

NCT06627244

Status	RECRUITING
Phase	Phase 2
Sponsor	University of Miami
Enrollment	30 participants

Plain Language Summary

This trial tests combining tebentafusp-tebn (an immune-activating cancer drug) with radioembolization (a targeted liver radiation treatment using radioactive beads called Y-90) in patients with uveal melanoma — a rare eye cancer — that has spread to the liver.

****You may be eligible if...****

- You are 18 or older with metastatic uveal melanoma confirmed by pathology, mainly in the liver
- Your liver function tests are within acceptable limits
- A pre-study mapping procedure shows the liver treatment is safe and feasible
- You carry a specific immune marker (HLA-A*02:01)
- Your disease is measurable or evaluable on scans

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

- Any single tumor is larger than 8 cm
- Your bilirubin or liver enzymes are significantly elevated
- You have had prior treatment with tebentafusp-tebn

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

Key Eligibility Criteria

Inclusion (8)

- Metastatic uveal melanoma, confined mainly to the liver, and documented by pathology review
- Serum bilirubin ≤ 2 mg/dl, aspartate aminotransferase (AST) and alanine aminotransferase (ALT) ≤ 5 x upper limit of normal (ULN)
- Mapping angiogram procedure shows radioembolization is feasible and safe to perform
- Human leukocyte antigen-A*02:01 (HLA AU 02:01) positive
- Patient age ≥ 18 years old

... and 3 more (see full listing online)

Exclusion (53)

- Patient with any tumor size > 8 cm
- Total bilirubin $> 1.5 \times$ ULN, except for patients with Gilbert's syndrome, who are excluded if total bilirubin $> 3.0 \times$ ULN or direct bilirubin $> 1.5 \times$ ULN
- Clinical laboratory measurements that meet any of the following criteria:
 - Alanine aminotransferase (ALT) $> 3 \times$ ULN
 - Aspartate aminotransferase (AST) $> 3 \times$ ULN

... and 48 more (see full listing online)

<https://clinicaltrials.gov/study/NCT06627244>

Locations (1 total)

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