Doctor's Note — Clinical Trial Summary

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TRIAL

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

NCT ID: NCT06627244 Phase: PHASE2 Sponsor: University of Miami Status: Recruiting

SUMMARY

The purpose of this study is to determine the effects (good and bad) that Tebentafusp in combination with Yttrium-90 (Y-90) radioembolization has on patients with metastatic uveal melanoma that has spread to the liver.

KEY ELIGIBILITY CRITERIA

- 1. Metastatic uveal melanoma, confined mainly to the liver, and documented by pathology review
- 2. Serum bilirubin \<2 mg/dl, aspartate aminotransferase (AST) and alanine aminotransferase (ALT) \< 5 x upper limit of normal (ULN)
- 3. Mapping angiogram procedure shows radioembolization is feasible and safe to perform
- 4. Human leukocyte antigen-A*02:01(HLA AU 02:01) positive
- 5. Patient age e 18 years old
- 6. Ability to provide and understand written informed consent
- 7. Eastern Cooperative Oncology Group (ECOG) performance status 0-1
- 8. Patients must have measurable disease or non-measurable disease according to RECIST 1.1 (Eisenhauer et al, 2009).
- 1. Patient with any tumor size \> 8 cm
- 2. Total bilirubin \> 1.5 × ULN, except for patients with Gilbert's syndrome, who are excluded if total bilirubin \> 3.0 × ULN or direct bilirubin \> 1.5 × ULN

ENROLLMENT CONTACT

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Total sites: 1 | 1 currently recruiting

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