Doctor's Note — Clinical Trial Summary

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TRIAL

Neoadjuvant Tebentafusp for Uveal Melanoma

NCT ID: NCT06414590 Phase: PHASE2 Sponsor: Thomas Jefferson University Status: Recruiting

SUMMARY

This is a prospective, single arm, phase II clinical trial of neoadjuvant Tebentafusp (KIMMTRAK®) in patients with locally advanced primary uveal melanoma. Patients must be HLA-A*02:01 with large, surgically unresectable (other than complete enucleation of the eye) primary uveal melanoma. The efficacy of this treatment will be assessed with the Simon's two stage design. The choice of design is guided by a desire to stop the trial early if the actual regression rate of primary uveal melanoma is 1% or lower.

KEY ELIGIBILITY CRITERIA

- Individuals must meet all of the following inclusion criteria in order to be eligible to participate in the study:
- 1. Male or female patient age e 18 years of age at the time of informed consent.
- 2. Ability to provide and understand written informed consent prior to any study procedures.
- 3. Willingness to undergo tumor biopsies at baseline and post-Tebentafusp treatment.
- 4. Treatment naïve primary uveal melanoma with T3 or T4 category tumor size that are surgically unresectable (other than complete enucleation of eye).
- 5. No surgical indication to completely remove the tumor without enucleation.
- 6. Clinically or cytologically confirmed primary uveal melanoma.
- 7. Participants must be HLA-A*02:01 positive.
- 8. Predicted life expectancy of at least 12 weeks as estimated by investigator
- 9. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 at screening.

ENROLLMENT CONTACT

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Total sites: 2 | 1 currently recruiting