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 phase II trial tests how well tebentafusp works to shrink tumors prior to primary treatment with surgery or radiation in patients with uveal (eye) melanoma that has spread to nearby tissue or lymph nodes (locally advanced) or that cannot be removed by surgery (unresectable). Tebentafusp is a drug that binds to melanoma tumor cells as well as immune cells called T-cells. This binding causes an immune response against the melanoma cells, which leads to tumor cell death. Tebentafusp has been approved for the treatment of locally advanced and unresectable uveal melanoma. Giving tebentafusp before primary treatment with surgery or radiation may help shrink the tumor, prevent the disease from spreading, or reduce the likelihood that patients will require total eye removal (called enucleation).

KEY ELIGIBILITY CRITERIA

- 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.
- 10. All other relevant medical conditions must be well-managed and stable, in the opinion of the investigator, for at least 28 days prior to first administration of study drug.

ENROLLMENT CONTACT

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Total sites: 2 | 1 currently recruiting