Doctor's Note — Clinical Trial Summary

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TRIAL

Tebentafusp in HLA-A*0201 Positive Previously Untreated Metastatic Uveal Melanoma

NCT ID: NCT06070012 Phase: PHASE2 Sponsor: Diwakar Davar Status: Recruiting

SUMMARY

This is a phase II open-label, single-arm, multi-center study of tebentafusp in HLA- A*0201 positive previously untreated (1L) untreated metastatic uveal melanoma (mUM) with an integrated circulating tumor DNA (ctDNA) biomarker.

KEY ELIGIBILITY CRITERIA

- Histologically or cytologically confirmed untreated metastatic uveal melanoma (mUM).
- HLA-A*0201 genotype positive as assessed using a CLIA-certified blood typing method and confirmed by central review.
- * If HLA-A status is not known, blood for HLA-A testing must be submitted during Screening, and HLA-A*0201 positive status confirmed prior to enrollment using a CLIA- certified blood typing method.
- * If the patient is known to be HLA-A*0201 positive, this information must be provided in the Screening packet and centrally reviewed by treating PI and Sponsor-Investigator prior to enrollment.
- * The following HLA testing methodologies are suitable to determine HLA-A*0201 positivity:
- * Multiplex real-time PCR based testing performed by entities including but not limited to Labcorp, and American Red Cross.
- * HLA testing as part of peripheral blood molecular profiling technology including but not limited to Caris Life Sciences Molecular Profiling Technology.
- * Patients be willing to undergo ctDNA assessment using Signatera assay.
- * Have provided newly obtained core biopsy of a tumor lesion not previously irradiated.
- * Adequate organ function on screening labs obtained within 4 weeks of Week 1 day 1

ENROLLMENT CONTACT

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Total sites: 3 | 3 currently recruiting