Doctor's Note — Clinical Trial Summary

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TRIAL

Phase 2 Combination of Melphalan/HDS Via PHP + Tebentafusp in Treating Metastatic Uveal Melanoma

NCT ID: NCT07276386 Phase: PHASE2 Sponsor: H. Lee Moffitt Cancer Center and Research Institute Status: Recruiting

SUMMARY

This Phase 2 study evaluates the efficacy and safety of sequential treatment with percutaneous hepatic perfusion (PHP) using melphalan/HDS followed by tebentafusp in patients with metastatic uveal melanoma (mUM) with isolated liver metastases. The rationale is that PHP enhances antigen release and immunomodulation, potentially sensitizing tumors to tebentafusp in HLA-A*02:01-positive patients.

KEY ELIGIBILITY CRITERIA

- * Patient is e18 years of age on the day of signing informed consent.
- * ECOG performance status of 0 or 1.
- * Histologically or cytologically confirmed liver metastasis of uveal melanoma.
- * HLA-A*02:01 positive status.
- * Measurable disease by computed tomography (CT) per RECIST 1.1 with at least one target lesion identified in the liver.
- * Patient deemed suitable for PHP and tebentafusp.
- * Female patient of childbearing potential should have a negative urine or serum pregnancy test within 72 hours prior to receiving the first treatment. If the urine test is positive or cannot be confirmed as negative, a serum pregnancy test will be required.
- * Female patients of childbearing potential must be willing to use an adequate method of contraception, for the course of the study through 150 days after the last dose of study medication. Note: Abstinence is acceptable if this is the usual lifestyle and preferred contraception for the subject.
- * Male patients of childbearing potential must agree to use an adequate method of contraception, starting with the first dose of study therapy through 150 days after the last dose of study therapy. Abstinence is acceptable if this is the usual lifestyle and preferred contraception for the subject.
- * Limited extrahepatic disease would be allowed initially, that can be treated with stereotactic body radiation therapy (SBRT) or surgical resection prior to the start of tebentafusp. This concept is similar to the FOCUS trial - definition of "treatable" limited disease at the discretion of the PI.

ENROLLMENT CONTACT

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Total sites: 1 | 1 currently recruiting