Doctor's Note — Clinical Trial Summary

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TRIAL

Adoptive Transfer of Tumor Infiltrating Lymphocytes for Metastatic Uveal Melanoma

NCT ID: NCT03467516 Phase: PHASE2 Sponsor: Udai Kammula Status: Recruiting

SUMMARY

This is a Phase 2 study in which the efficacy of a non-myeloablative lymphodepleting preparative regimen followed by infusion of autologous TIL and high-dose aldesleukin in patients with metastatic uveal melanoma will be evaluated.

Metastatic uveal melanoma (UM) carries a poor prognosis with estimated survival of 4-6 months. There are no known effective systemic therapies. Metastatic UM is classified as an "orphan" disease and there are currently few clinical trial options for these patients. Thus, novel systemic approaches are desperately needed.

A recent pilot study has found that administration of autologous tumor infiltrating lymphocytes (TIL) generated from resected metastases can induce objective tumor response and durable complete response in metastatic uveal melanoma patients. These encouraging results require confirmation to determine if this immunotherapy is of future benefit in treating this disease.

KEY ELIGIBILITY CRITERIA

- * Measurable metastatic uveal melanoma.
- * Patients must be co-enrolled on the companion protocol HCC 17-220 (Cell Harvest and Preparation to Support Adoptive Cell Therapy Clinical Protocols and Pre-Clinical Studies) and have available TIL cultures for therapy.
- * Patients with 3 or fewer brain metastases that are less than 1 cm in diameter and asymptomatic are eligible. Lesions that have been treated with stereotactic radiosurgery must be clinically stable for 1 month after treatment for the patient to be eligible. Patients with surgically resected brain metastases are eligible.
- * Greater than or equal to 18 years of age and less than or equal to age 75
- * Able to understand and sign the Informed Consent Document
- * Clinical performance status of ECOG 0 or 1
- * Life expectancy of greater than three months
- * Patients of both genders must be willing to practice birth control from the time of enrollment on this study and for up to four months after receiving the treatment.
- * Serology:
- * Seronegative for HIV antibody. (The experimental treatment being evaluated in this protocol depends on an intact immune system. Patients who are HIV seropositive can have decreased immune-competence and thus be less responsive to the experimental treatment and more susceptible to its toxicities.)

ENROLLMENT CONTACT

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Total sites: 1 | 1 currently recruiting