Doctor's Note — Clinical Trial Summary

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TRIAL

Gene Modified Immune Cells After Conditioning Regimen for the Treatment of Stage IIIC or IV Melanoma or Metastatic Solid Tumors

NCT ID: NCT04119024 Phase: PHASE1 Sponsor: Anusha Kalbasi Status: Recruiting

SUMMARY

This phase I trial studies the side effects and best dose of modified immune cells (IL13Ralpha2 CAR T cells) after a chemotherapy conditioning regimen for the treatment of patients with stage IIIC or IV melanoma or solid tumors that have spread to other places in the body (metastatic). The study agent is called IL13Ralpha2 CAR T cells. T cells are a special type of white blood cell (immune cells) that have the ability to kill tumor cells. The T cells are obtained from the patient's own blood, grown in a laboratory, and modified by adding the IL13Ralpha2 CAR gene. The IL13Ralpha2 CAR gene is inserted into T cells with a virus called a lentivirus. The lentivirus allows cells to make the IL13Ralpha2 CAR protein. This CAR has been designed to bind to a protein on the surface of tumor cells called IL13Ralpha2. This study is being done to determine the dose at which the gene-modified immune cells are safe, how long the cells stay in the body, and if the cells are able to attack the cancer.

KEY ELIGIBILITY CRITERIA

- * Histologically confirmed malignancy that is considered surgically incurable with either:
- * Stage IIIC melanoma including locally relapsed, satellite, in-transit lesions or bulky draining node metastasis
- * Stage IV melanoma including patients with known brain metastases
- * Other metastatic, non-central nervous system (CNS) solid tumor relapsed or refractory after all standard-of-care systemic therapies for which the patient is eligible
- * Confirmed IL13Ralpha2 tumor expression by immunohistochemistry (immunohistochemical assay \[IHA\] H-Score \>= 50 in at least 10% of the total tumor specimen and in at least two high-power fields)
- * Age greater than or equal to 18 years old and less than 75 years old
- * Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1
- * A minimum of one measurable lesion defined as:
- * Meeting the criteria for measurable disease according to Response Evaluation Criteria in Solid Tumors (RECIST), OR
- * Skin lesion(s) selected as non-completely biopsied target lesion(s) that can be accurately measured and recorded by color photography with a ruler to document the size of the target lesion(s)

ENROLLMENT CONTACT

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Total sites: 3 | 3 currently recruiting