Doctor's Note — Clinical Trial Summary

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TRIAL

Clinical Trial of CD40L-augmented TIL for Patients With Advanced Melanoma

NCT ID: NCT06961357 Phase: PHASE1 / PHASE2 Sponsor: H. Lee Moffitt Cancer Center and Research InstituteStatus: Recruiting

SUMMARY

This is a phase I/II clinical trial of a single dose of CD40L-augmented TIL administered in patients with advanced melanoma (Cohort 1: Cutaneous acral melanoma, cutaneous non-acral melanoma, (n=26); Cohort 2: Mucosal melanoma, uveal melanoma, (n=10)). Patients will undergo an excision of a readily accessible tumor for preparation of TIL. Eligible patients with progressive disease after standard of care therapy will undergo lymphodepletion with cyclophosphamide and fludarabine followed by CD40L-augmented TIL and standard of care bolus dose interleukin-2 (short-course IL-2).

KEY ELIGIBILITY CRITERIA

- * Participants must have histologically confirmed, unresectable (Stage III/IV) or metastatic melanoma as follows: Cutaneous, non-acral, melanoma (including melanoma of unknown primary); Cutaneous acral melanoma; Mucosal melanoma; Ocular melanoma (including uveal, iris, conjunctival melanoma).
- * Participants must have failed, be refractory to, or unable to tolerate at least one line of standard of care in the opinion of the Investigator. For participants with cutaneous non-acral melanoma, standard of care therapy includes a PD-1/L1 or combination therapy with anti-PD1 and anti-CTLA4 or combination therapy of anti-PD1 and anti-LAG3 or if BRAF V600 activating mutation positive, a BRAF ± MEK inhibitor. Participants are allowed to be enrolled in this trial if they failed one line of any of those standards of care therapy regimens.
- * Any systemic therapy, including anti-cancer monoclonal antibodies, must have been completed at least 4 weeks from the start of lymphodepleting therapy, and any prior therapy-related AEs must have resolved to Grade d 1 except for alopecia and vitiligo.
- * Participants must be ages e18. Additionally, participants who are e 65 years of age may need to undergo a cardiology evaluation including a cardiac stress test or coronary computed tomography after which they must be deemed to be low/acceptable risk. This cardiac evaluation may be omitted for patients who underwent testing within 6 months and have no interval change in cardiopulmonary clinical status. Note 1: Cardiac stress test may be omitted for patients e65 years old (y/o) who are fully functional with no relevant medical comorbidities and are able to carry e4 METS activities at baseline. For patients who demonstrate abnormal cardiac stress test cardiac evaluation by cardiologist will be done and if deemed low acceptable risk, will be allowed to participate in this trial per PI discretion. Cardiac stress test may be indicated for any patient \<65 y/o who have relevant medical comorbidities or demonstrate clinically worrisome symptoms. Note 2: While age preference will be between 18-75 years, this study allows age \>75 years if the patient meets eligibility criteria and demonstrates no significant medical comorbidities per PI.
- * ECOG performance status of 0 or 1.
- * Participants must have adequate organ and marrow function as defined within the protocol.
- * Seronegative for Human immunodeficiency virus (HIV) antibody, hepatitis B surface antigen, and hepatitis C (HCV) antibody (if HCV antibody positive, must be tested for HCV RNA, which must be negative to be eligible).
- * Participants with brain metastases are eligible provided that the brain metastases have been successfully treated with stereotactic radiosurgery or resection and clinically stable for at least 4 weeks (±14 days). Note: Participants who develop brain metastases after tumor harvest and/or lymphodepleting therapy will be allowed to remain on study and may proceed with cell therapy after undergoing

definitive radiation therapy and/or surgery. For those participants who develop brain metastases during lymphodepleting therapy and undergo definitive radiation therapy and/or surgery careful decision will be made to proceed with TIL infusion after discussion with treating physician, neurosurgeon, radiation oncologist and PI.

• * Women of child-bearing potential must have a negative pregnancy test.

• * The effects of CD40L-augmented TIL on the developing human fetus are unknown. For this reason and because TIL agents, as well as other therapeutic agents used in this trial including IL-2 are known to be teratogenic, both males and females of childbearing potential must be willing to practice birth control starting with screening through 1 year after the last study drug is administered for females or 6 months for males.

ENROLLMENT CONTACT

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Total sites: 1 | 1 currently recruiting