Doctor's Note — Clinical Trial Summary

Generated by FindMyCure.ai on November 25, 2026 | For discussion with your oncologist

TRIAL

Proof of Concept of TBio-4101, Lymphodepleting Chemo, IL-2 for Relapsed/Refractory Melanoma

NCT ID: NCT05628883 Phase: PHASE1 Sponsor: H. Lee Moffitt Cancer Center and Research Institute Status: Completed

SUMMARY

The purpose of this first in human study is to evaluate the feasibility, safety, and efficacy of administering TBio-4101 (tumor infiltrating lymphocytes \[TIL\]) after receiving a lymphodepleting chemotherapy regimen and before receiving interleukin-2 (IL-2) in participants with unresectable or metastatic melanoma.

KEY ELIGIBILITY CRITERIA

- * Participants must have histologically confirmed, unresectable 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 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 inhibitor, a CTLA-4 inhibitor, and if BRAF V600 activating mutation positive, a BRAF ± MEK inhibitor.
- Note: if treatment failure occurs during adjuvant therapy or within 6 months of adjuvant therapy completion, this will count as a failure of the applicable regimen as noted above.
- * Any systemic therapy, including anti-cancer monoclonal antibodies, must have been completed at least 4 weeks from the start of lymphodepleting therapy (except for bridging therapy as defined below), and any prior therapy-related AEs must have resolved to Grade d 1 except for alopecia and vitiligo. Neuropathy must have resolved to Grade d 2.
- * Participants must be between the ages of 18 and 75 years old. Additionally, participants who are e 60 years of age must undergo a cardiology evaluation including a cardiac stress test after which they must be deemed to be low/acceptable risk.
- * ECOG performance status of 0 or 1

Total sites: 1 | 0 currently recruiting

This document is for informational purposes only and does not constitute medical advice. Always discuss clinical trial decisions with your oncologist. Data sourced from ClinicalTrials.gov (NCT05628883) and public sources. Generated by FindMyCure.ai.