

# Doctor's Note — Clinical Trial Summary

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## 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

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