Doctor's Note — Clinical Trial Summary

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TRIAL

A Study to Investigate the Safety and Efficacy of IOV-3001 in Adults With Advanced Melanoma Who Will Receive Lifileucel

NCT ID: NCT06940739 Phase: PHASE1 / PHASE2 Sponsor: Iovance Biotherapeutics, Inc. Status: Recruiting

SUMMARY

A Phase 1/2, open-label study of a modified interleukin-2 fusion protein (IOV 3001) in participants with previously treated, unresectable or metastatic melanoma who will receive lifileucel.

KEY ELIGIBILITY CRITERIA

- 1. Participant must be e 18 years of age at the time of signing the informed consent.
- 2. Participant has unresectable or metastatic melanoma.
- 3. Participant has melanoma not of uveal/ocular origin and experienced documented radiographic disease progression during systemic therapy with a PD-1/PD-L1 blocking antibody or within 12 weeks after the last dose of the PD-1/PD-L1 blocking antibody. If the tumor is BRAF V600 mutation positive, the participant also received or refused a BRAF inhibitor with or without a MEK inhibitor.
- OR Phase 1, Part 1 only: For participants with uveal melanoma, tebentafusp must have been received if available as standard of care (human leukocyte antigen \[HLA\]-A*02:01 positive participant and approved by local authorities for uveal melanoma) or refused.
- 4. Participant has an ECOG performance status of 0 or 1 and, in the investigator's opinion, an estimated life expectancy of \> 6 months.
- 5. Phase 1, Part 2 only: Following tumor resection for lifileucel generation, the participant will have at least one remaining measurable lesion, as defined by RECIST v1.1.
- 6. Participant has recovered from all prior anticancer treatment-related AEs
- 1. Participant has symptomatic untreated brain metastases.
- 2. Participant is at an increased risk for systemic infections; seizure disorders; coagulation disorders; or other active major medical illnesses of the cardiovascular, respiratory, or immune systems.
- 3. Participant has active uveitis that requires active treatment.

Total sites: 5 | 5 currently recruiting

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