Doctor's Note — Clinical Trial Summary

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TRIAL

Tebentafusp and Roginolisib in Uveal Melanoma to Prolong T-cell Homeostasis

NCT ID: NCT07203391 Phase: PHASE1 Sponsor: St Vincent's Hospital, Sydney Status: Recruiting

SUMMARY

This is a combination study of Tebentafusp and the PI3Kdelta inhibitor, Roginolisib

KEY ELIGIBILITY CRITERIA

- 1. Male or female participants must be aged 18 years or over at the time, to be eligible to participate in this study.
- 2. Histologically or cytologically confirmed metastatic UM or unresectable UM patients
- 3. HLA-A*02:01 positive
- 4. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- 5. Currently undergoing first-line treatment for mUM with tebentafusp
- 6. Tebentafusp related toxicity, including cytokine release syndrome that has resolved to grade d 1 as per CTCAE v5.0.
- 7. Male and female participants of childbearing potential who are sexually active with a non-sterilized partner must agree to use highly effective methods of birth control (eg double barrier) from the trial screening date until 6 months after the final dose of the program intervention; cessation of birth control after this point shall be discussed with a responsible physician.
- 8. Pregnant or lactating women are prohibited from enrolling on this program.
- 9. Male participants are not allowed to donate sperm from the time of enrolment until 6 months post- administration of program interventions.
- 1. Presence of untreated or symptomatic central nervous system (CNS) metastases, leptomeningeal disease, or cord compression. NOTE: Participants with treated CNS lesions may enroll provided all of the following apply:

ENROLLMENT CONTACT

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Total sites: 2 | 1 currently recruiting

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