Doctor's Note — Clinical Trial Summary

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TRIAL

Adding IL-2 to Tebentafusp to Eradicate Cancer Progression

NCT ID: NCT07063875 Phase: PHASE1 / PHASE2 Sponsor: St Vincent's Hospital, Sydney Status: Recruiting

SUMMARY

A recent clinical trial found that after 36 months, patients taking tebentafusp had a median survival of 21.6 months, compared to 16.9 months for those in the control group. Since recruitment for tebentafusp in metastatic uveal melanoma (mUM) has ended, a new trial is starting to test whether adding IL-2 can help overcome resistance to tebentafusp and improve its effectiveness.

This study aims to answer:

1. Can combining tebentafusp with IL-2 improve tumor response and overall survival?
2. What are the benefits and side effects of this combination therapy?

All participants will receive both IL-2 and tebentafusp in a 28-day treatment cycle. The dosing schedule is as follows:

Cycle1:

Day1-3 IL-2 Day4 Tebentafusp Day 10 IL-2 Day 11 Tebentafusp Day 17 IL-2 Day 18 Tebentafusp Day 24 IL-2 Day 25 Tebentafusp

Cycle 2 \& thereafter Day 1 IL-2 Day 2 Tebentafusp Day 8 IL-2 Day 9 Tebentafusp Day 15 IL-2 Day 16 Tebentafusp Day 22 IL-2 Day 23 Tebentafusp

KEY ELIGIBILITY CRITERIA

- 1. Histologically or cytologically confirmed metastatic UM or unresectable UM patients
- 2. HLA-A*02:01 positive
- 3. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- 4. RECIST 1.1 defined progression on single-agent Tebentafusp, with no other intervening systemic therapies
- 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: Treated CNS lesions must be radiographically stable for e 4 weeks after intervention (surgery and/or radiation). Participants must be neurologically stable off systemic corticosteroids for at least 2 weeks prior to trial entry, AND Greater than 14 days elapsed between the last dose of previous Tebentafusp and first dose of IL-2 on trial)
- 2. Systemic treatment with steroids or any other immunosuppressive drug use within 2 weeks of the planned first dose of program intervention, with the following exceptions: Treatment for well-controlled and asymptomatic adrenal insufficiency is permitted, but

replacement dosing is limited to prednisone d 10 mg daily or the equivalent; Local steroid therapies (eg, optic, ophthalmic, intra- articular, or inhaled medications) are acceptable.

• 3. Any relevant medical condition, which in the opinion of the treating physician, would prevent the participant enrolling into the Program due to concerns related to safety, compliance with procedures, or interpretation of program results.

• 4. Chronic viral infections as indicated below. NOTE: Testing for human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) status prior to enrollment is not necessary unless clinically indicated.

ENROLLMENT CONTACT

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Total sites: 2 | 1 currently recruiting