Doctor's Note — Clinical Trial Summary

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TRIAL

Tebentafusp-tebn With LDT in Metastatic UM

NCT ID: NCT06626516 Phase: PHASE1 / PHASE2 Sponsor: Thomas Jefferson University Status: Recruiting

SUMMARY

This study is a multicenter, open label phase I/ II trial to assess the safety and clinical efficacy of tebentafusp-tebn in combination with liver-directed therapies in HLA-A*0201 positive patients with metastatic uveal melanoma. In Part 1 of the study, the Prinicipal Investigator will investigate the safety and efficacy of tebentafusp-tebn in combination with hepatic IE in patients with a low to moderate hepatic disease burden. In Part 2, the study will investigate the efficacy of tebentafusp-tebn in combination with TACE in patients with bulky hepatic disease.

KEY ELIGIBILITY CRITERIA

• 1\. Age e18 years of age 2. Histologically or cytologically confirmed metastatic uveal melanoma in the liver. Patients must have at least one measurable liver metastasis that is e 10 mm in longest diameter by CT scan or MRI. Extra-hepatic disease is allowed. 3. Tumor Size Criteria: i. Part 1: Total volume of tumor must be \< 50% of the liver involvement by CT or MRI; M1a or M1b disease with largest tumor d 5 cm ii. Part 2: M1b disease with largest tumor \> 5 cm, M1c disease, or e 50% liver involvement by CT or MRI 4. No prior systemic treatment with tebentafusp-tebn 5. Prior therapy: i. Part 1: Patients must be treatment naïve in the metastatic setting.

• 1. Prior surgery or ablation for oligometastatic disease is allowable.

• 2. Palliative radiation of non-target lesions also allowable. ii. Part 2: Patients may have had prior systemic therapy with chemotherapy, immunotherapy, or targeted therapy. They can also have had prior liver directed therapy including surgery, ablation, immunoembolization, or radioembolization. However cannot have had more than two prior lines of treatment total.

• 6\. HLA-A*0201 positive 7. ECOG performance status or 0 or 1 at the time of screening 8. Life expectancy of greater than 3 months as assessed by the investigator 9. Patients must have normal organ and bone marrow function as defined below:

• 1. Platelet count e 100,000/mm³

• 2. Hemoglobin \> 8.0g/dL

• 3. ANC e 1500

• 4. AST and/or ALT \< 3x upper limited of normal (ULN)

• 5. Total bilirubin d 2.0 mg/ml

• 6. Note: Patients with hyperbilirubinemia clinically consistent with an inherited disorder of bilirubin metabolism (e.g., Gilbert syndrome) will be eligible at the discretion of the treating physician and/or the principal investigator.

ENROLLMENT CONTACT

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Total sites: 1 | 1 currently recruiting