Doctor's Note — Clinical Trial Summary

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TRIAL

Targeted Alpha Particle Radiotherapy for Metastatic Uveal Melanoma

NCT ID: NCT05496686 Phase: PHASE1 Sponsor: Modulation Therapeutics, Inc. Status: Active Not Recruiting

SUMMARY

The primary aim of the study is to establish the maximum-tolerated dose (MTD) of 225Ac-MTI-201 in participants with metastatic uveal melanoma. The secondary aims are to describe the pharmacokinetics of 225Ac-MTI-201 and the toxic effects of 225Ac-MTI-201 in participants with metastatic uveal melanoma.

KEY ELIGIBILITY CRITERIA

- * Histologically confirmed metastatic uveal melanoma.
- * Progression after at least one prior line of therapy for metastatic uveal melanoma. Liver directed therapy (e.g., hepatic arterial embolization, isolated hepatic perfusion) will count as one line of therapy. Should any additional treatment(s) receive regulatory approval for metastatic uveal melanoma during the conduct of this trial, participants (if eligible for the newly approved treatment) would need to demonstrate disease progression on the additional treatment(s) before being eligible to participate in the current study. There is no limit to the number of previous treatments for metastatic disease.
- * Participants must have measurable disease per RECIST 1.1.
- * Adults, age 18 or over, with no upper age limit.
- * ECOG (Eastern Cooperative Oncology Group) performance status of 0-1 (Karnofsky e 70 percent).
- * Acceptable organ and marrow function as defined below:
- * Leucocytes e 3,000¼
- * Absolute neutrophil count e 1,500¼
- * Platelets e 100,000¼
- * Aspartate aminotransferase (AST)/ Alanine aminotransferase (ALT) d 2.5x institutional upper limit of normal (ULN)

Total sites: 1 | 0 currently recruiting

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