Doctor's Note — Clinical Trial Summary

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TRIAL

A Phase 1-1b Study to Evaluate the Safety, Efficacy and Dosimetry of Study Drug A9-3408 in Subjects With Metastatic Melanoma

NCT ID: NCT07076550 Phase: PHASE1 Sponsor: Alpha-9 Oncology USA Inc. Status: Terminated

SUMMARY

The goal of this trial is to see if this investigational drug is safe for adult patients with melanoma that has spread to other parts of the body or cannot be removed by surgery. It will also see if this investigational drug can shrink melanoma tumors in the body. The main questions this study aims to answer are:

* What are the side effects of this investigational drug?
* What is the highest dose of this investigational drug that can be given safely?

Participants will:

* Take the investigational drug once every 6 weeks, for up to 6 times in total
* Visit a doctor's office on a regular basis for checkups and tests

KEY ELIGIBILITY CRITERIA

- * Able to provide written informed consent
- * \[68Ga\]Ga-A9T-3202 uptake in at least one measurable lesion (per RECIST v1.1) on PET scan
- * Histologically or cytologically confirmed unresectable or metastatic melanoma with disease progression on prior standard of care therapy
- * Adequate ECOG performance status
- * Adequate baseline organ function within 14 days of first dose of investigational product
- * Recovered from side effects of prior anticancer therapy
- * Women of childbearing potential (WOCBP) must have a negative pregnancy test and follow adequate birth control method(s) during the treatment period and for at least 6 months after last dose of \[225Ac\]Ac-A9-3408. Sexually active males with partners who are WOCBP must agree to adequate birth control method(s) during the treatment period and for at least 3 months after last dose of \[225Ac\]Ac-A9-3408
- * Previous treatment with radioactive nuclides except radioactive imaging tracers
- * Treatment with another investigational product shortly prior to first dose of \[225Ac\]Ac-A9-3408 with exception of anti-PD-1/PD-L1 agents.
- * Concurrent anticancer therapy

Total sites: 4 | 0 currently recruiting

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